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February 14th, 2019

Dear Dr. Ukwatta,

The issue of injuries within sports is a recent issue that has come to our attention. Sports injuries can come from several different circumstances; however, self-induced injuries have the most potential for possible prevention. In addition to this, ACL related injuries are often career ending injuries for high caliber athletes. Our team is dedicated to developing a brace-like system to detect high-risk movements in athletes.

The main goal of our design is to keep players from being injured. To do this, we hope to detect the potential for an injury moments before and after it happens. The ACL has the potential to stretch and tear partially or fully. Detecting excessive force on the ACL allows the athlete to be aware of the stresses placed on their own bodies to prevent irreversible damage. In addition, we hope to make the design non-invasive and as lightweight as possible with seamless integration between the current knee braces athletes wear. As such we are not creating a system to replace the current technology availed for knee ligament protection rather our design intends to add new features and give more data to the medical professionals working with these athletes.

We plan to do this with a flexible and thin material utilizing sensors and a small microcontroller monitoring input. The device will detect dangerous movements or accelerations in the knee within the medial and lateral direction. We know this device will help countless athletes and look forward to hearing back.

Warm regards,

Bilal Ayyache
Devin Catt
Monica Malek
Daniel Sherman
Trevor Smith

Design 3 Interim Report

University of Guelph, School of Engineering
ENGG 3100, Group Mon1-08
Dr. Ukwatta

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In signing this report and providing my PEO SMP (Student Membership Program) number, I certify that I have been an active member of the team and provided approximately equal contribution to the work. I take shared credit and responsibility for the content of this report. I understand that taking credit for work that is not my own is a form of academic misconduct and will be treated as such.

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1 Executive Summary

An ACL tear can be an extremely painful injury, which can have lifelong effects to a person's ability to move. Many players who tear their ACLs do not return to their sport, which can be a life altering trauma, especially for an athlete who is trying to play professional sports. Around 350,000 ACL reconstruction surgeries are performed in the United States and Canada annually, making this injury a fairly common one. Being able to detect the forces on the knee that can tear an ACL is important to solve, because the knowledge gained can lead to a future solution of some kind of device that can actually intervene when an athlete may tear their ACL, allowing them to continue to play their sport and avoid a life altering injury. The scope of this project is to create a non-invasive device that can be worn during sport that will be able to detect potentially dangerous ACL movements, and will be able to wirelessly communicate this data to a person such as a coach, trainer, or physiotherapist who may be on the sidelines who could pull the player out of the game for medical attention. The most high risk sports for an ACL tear are Volleyball, Basketball, and American Football, so those sports (and therefore equipment necessary for said sports) will be studied in depth to ensure that the design solution is compatible with any equipment necessary for those sports. Creating a device to physically intervene with an ACL tear is beyond the scope of this project, and can be explored with later research, outside of ENGG*3100.

Most ACL tears are the result of non-contact injuries, making the problem a little easier to solve. The most reported actions for an ACL to tear are when an athlete lands from a jump lock-kneed or when they suddenly change their acceleration, a motion akin to pivoting extremely quickly. Anatomically, the ACL tears when the Tibia shifts anterior to the Femur, causing a great deal of stress and strain to the ligament, which can cause failure.

Currently, most solutions to support the knee and the ACL are some kind of knee brace. The knee braces can be a cloth sleeve, a bulky metal frame, or even kinesiology tape, but all solutions involve supporting the knee, and not gathering any data about the forces on the knee to try and intervene with the actual motions. It is an unfortunate side effect of these solutions that the athlete's natural range of motion is effected, even the best knee braces limit the range of motion while this protects the athlete it also effects athletic performance.

Independently, each member of the design team began to generate ideas in a number of different methods, and each person's best idea was fleshed out and brought back to the group. Together, each of the solutions were built upon and critiqued until they were all ready to be ranked and the best idea was thought of. The alternatives that were not the best at meeting the determined criteria were similar to Kinesiology tape, a cloth brace, a metal frame brace, and tension bands.

The best solution determined was a combination of a cloth brace with a flex sensor in it and an addition to keep in the shoe (similar to Nike's Nike+ Sensor). Both of these devices will allow the tracking of the knee's angle and the forces that are on the knee. They will be able to wirelessly communicate with each other to process the desired data, and send findings to a person on the sidelines who is monitoring player health. This solution came to the forefront mainly by being the lightest and most multisport applicable, Through our derivation and fleshing out of the design it quickly became apparent that by separating the two components the system would maintain these benefits but remove many issues the design team was running into. Because this revelation and subsequent design changes the system being further detailed in these report is offering a new alternative to the current marketable tech this creates a unique opportunity to create a system that can be how following systems are measured.

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2 Problem Description

2.1 Technical Problem

The trauma of tearing the anterior cruciate ligament (ACL) to an athlete is a major disruption within an athlete's life as not only is their athletic performance affected, but every aspect of daily life has now changed. Specifically, within high caliber sports where athletes turn their performance into a career, an ACL tear can cause an athlete's life to change drastically through irreversible damage. A current protective solution for high performance athletes is to wear stabilizing braces during all events. These braces not only restrict movement but the added weight can negatively impact the athlete's performance. Creating a device that implements sensors to track knee movement allows training staff and coaches to have more information about an athlete during performance, allowing coaches to remove players from dangerous play. Training staff will then be able to quickly and accurately determine the correct course of action to return the athlete to the field of play as soon as possible.

Many individual components of the overall design must be considered starting with where the ACL lies. The ACL originates at the tibial plateau of the femur and inserts onto the lateral femoral condyle of the tibia preventing anterior movements of the tibia. As such, direct muscle engagement of the quadriceps and hamstrings as well as the positioning of the femur relative to the tibia has a massive impact on the amount of stress the ACL is put under. Due to this, the device's design must account for muscle engagement of the upper leg, the valgus movement of the knee, the positioning of the tiba relative to the femur as well as the bending angle of the knee. While the device will have many components to measure all of these criteria, the overall system will have to factor and weigh them appropriately in order to build an accurate model for the forces the ACL experiences.

Working alongside coaches and athletes to provide a product meeting all constraints and criteria is a necessary step. This integrated approach improves upon current preventative athletic devices used within similar applications. By identifying and assessing ACL injuries in high caliber athletes, coaches will have access to more player data allowing them to understand the force and trauma the player just experienced. As such the athletes can focus on the game without the concern of a high medical issue as the coaches are receiving active electronic monitoring of the stresses directly placed on the ACL

2.2 Economic Impact

The anterior cruciate ligament injury is definitely a very common knee injury especially among young and active individuals, however the economical impact plays a big part in understanding why a solution to such issue is required [8]. The MultiCenter Orthopaedic Outcomes Network released a report in 2013 which claims that a mean lifetime cost from a typical patient undergoing ACL treatment was $38,121 compared to $88,538 for rehabilitation. This shows that treatment to such injury is very expensive creating an economical impact in society. The graph in figure one demonstrates an increase in rehab cost from start to completion. Rehab starts at almost $40,000 and increases to $160,000. An average player in the MLS league makes an approximate of $148,693.26 per year. Assuming that an MLS player undergoes an ACL injury, a year worth earnings will be spent to get the player back on the field [8]. If player is financially restricted, recovery may take longer than 1 year which drastically affects his career in sports. When recovery cost is that high, such economical impact leads to other societal impact in the community.

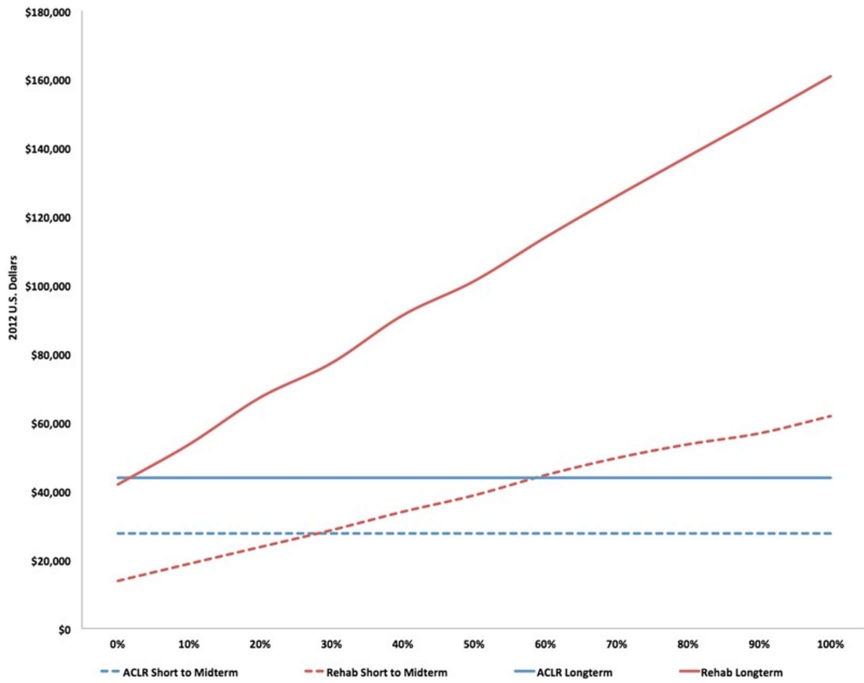

Figure 1: Sensitivity of total cost to the rate of instability after rehabilitation. [8]

2.3 Societal Impact

The high cost of treatment introduces a new problem as 20-30% of injured patients are left untreated due to financial challenges [8]. An untreated ACL injury would leave the patient unable to trust the stability of the knee and prevent them from resuming their career in sports. An untreated knee injury acts as a barrier that prevents the patient from performing daily tasks or activities which leads to depression in some cases [8]. The cost of a torn ACL treatment is substantial, and the results of an untreated ACL can lead to disorders, loss of motivation, and unemployment. Such results introduce societal problems in the community. The graph below shows the increase in cost of rehab as instability increase [8].

2.4 Environmental Impact

As with any manufacturing endeavour, the materials needed in typical ACL braces have an impact on the environment. To minimize a negative impact on the environment, the life cycle of the product needs to be considered. There is little environmental impact from the act of a person tearing their ACL, but the materials used to create ACL braces need to be considered when creating a brace. Most braces in today's market is made with cotton which is not environment friendly due to the pesticides used when producing. Cotton will be replaced with a nylon fabric due to the added stretch and durability within this product application. Nylon provides an added source of compression and protection an athlete requires. Nylon is a slightly recyclable material but has an alternative that can be further looked into. Econyl is derived from recycled plastics and shows similar properties while being more environmentally friendly[23].

3 Literature Review

There are several aspects to understand about the problem at hand before even attempting to design a solution to the problem. As with all sports injuries, it is important to consider important biomechanics, anatomy, and pathology of injury. The impact to the person who was injured, and the impact to the health care industry must also be considered.

It is important to understand the biomechanics behind the problem at hand. There are several ways to reduce loading on the knee, which fall under one of two methods: reducing the adduction moment around the knee or reduce muscle activity [2]. To reduce loading on the knee, one can change their stride, use a stride altering device, or surgically alter their limb [2]. Obviously for sports applications, altering stride is not ideal. Unloading the knee can help reduce fatigue and wear on it [2]. However, unloading the knee can also lead to issues, if unloaded a large amount. To reduce muscular activity of the knee, a player can adopt altered stride kinematics, or use a restrictive brace, both solutions are less than ideal [2]. The main forces that act of the knee in a day to day situation are due to the adduction movement of walking, and laterally stabilizing the knee [2]. Having a firm grasp on the biomechanics of the ACL can help give insight on what could go wrong in an injury and lead to ways to prevent injury.

Furthermore, it is necessary to understand the anatomy and its limitations. The ACL can extend to approximately 40mm, when the knee joint is fully extended [3]. The ACL provides a majority of the resistance for movements of the tibia and the femur [4]. The Quadriceps and Hamstring muscles results in translational forces directed in the anterior and posterior directions [4]. The forces exerted on the ligament vary from angles of 0 and 60 degrees [4]. During typical squatting and lunging exercises, it was found that the peak strain in the ACL was around 2.8% to 4% (around 100N to 150N) at angles between 0 and 30 degrees [4]. The Ultimate Tensile Strength of the ACL found in a normal human adult was around 2000N [4].

To understand why ACL injuries are an important problem to be considered, it is important to consider that injuries are not just a mechanical problem, and that actual people are affected with every injury. It is more common for an ACL injury to happen during high-impact activities like sports than low-impact activities such as squatting or walking [5]. An ACL injury was 7 times more likely to occur in competitive game/environment than during practice, as athletes try to push their bodies to the limits where their ligament cannot handle the high stress applied [7]. Women's soccer had the highest injury rate, followed by men's football, whereas a sport like ice hockey is relatively low on the list [1] [7]. In sex-comparable sports, women in sport had a higher rate of tearing their ACL compared to men [7]. In addition, women are 6 times more likely to tear their ACL than men, as their femoral notch is smaller, causing a smaller area for pressure to be applied [1]. Children are more likely to participate in high risk activities for ACL tears, so they have a higher risk for injuring themselves [1].

When designing some kind of device to restrict ACL tearing, the athletic motions that happen when injury occurs is important to study. Interestingly enough, two-thirds of ACL injuries are due to non-contact injuries [1]. The most frequent motions where an ACL is torn are when an athlete lands from a jump "lock-kneed" on one foot or when they decelerate and accelerate extremely quickly in a motion akin to pivoting [1].

Knee injury anatomy is significant to understand if a method of prevention is to be found. Anatomically, an ACL tear can happen when the tibia is translated forward relative to the femur [1]. Combined with rotation of the tibia, a lot of tensile and shearing forces can be placed on the ACL, causing damage [1]. The multiple planes of motion can be a large contributing cause to the large forces exerted on the ligament during injury [6]. It is more common to injure the ACL when the knee is hyper extended, in fact when the knee is near full extension, the highest amount of forces are felt [6].

It has been found that wearing a knee brace can reduce external knee adduction movement, which can alleviate pain in people suffering with pain in their knees [14]. Wearing a knee brace can help restrict knee adduction movement [14], which can be a risk factor for tearing an ACL.

3.1 Problem Overview

Research estimates that nearly 350,000 ACL reconstruction surgeries are performed in Canada and the United States annually. The Anterior cruciate ligament is considered to be among the most economically costly sport injury, frequently requiring expensive surgery and rehabilitation. 76% of these injuries occur during dynamic movements when playing sports that primarily involve pivoting such as basketball, football, soccer, and in sports such as volleyball when landing after a jump [9].

Figure 2: Landing with knee extended and adduction moment causing stress to the ACL [9]

A faulty mechanic during a dynamic movement is identified as the main cause of an anterior cruciate ligament injury [8]. Such movement causes an excessive force to be exerted on the joint in the knee. Faulty mechanics can be prevented by using a knee brace. An unequal limb loading, a lateral displacement of the trunk, or switching in movement direction frequently can be great examples of faulty mechanics. An individual in a fatigued state is more prone to damaging their ACL as they perform more frequent faulty movement patterns [8]. Addressing and preventing these faulty movement patterns can help minimize the risks of injury. This project will be able to address these faulty movement patterns, and notify the coach of the danger before a tear occurs. Exercise modes such as strength training, neuromuscular training, and plyometric can also help in addressing these faulty movements' patterns [8]. A list of exercises will be supplied to the user through the user interface. Such exercises help strengthen connective tissues in the joint by improving resistance to stress and strain during rotation, flexion, and adduction. The table below describes the relationship between the maximum strain and angle applied on the connective tissue. Such data can be used to design a medical device that can alert or notify user when connective tissues is susceptible to failure.

Maximum strain of connective tissue bundles

Connective tissue	Bundle	Maximum strain		
		Flexion (@angle)	Rotation (@angle)	Adduction (@angle)
ACL	aACL	0.128 (120°)	0.041 (30°)	0.051 (15°)
	pACL	−0.004 (0°)	0.010 (30°)	0.144 (15°)
PCL	aPCL	0.120 (100°)	−0.044 (30°)	−0.040 (−15°)
	pPCL	0.030 (0°)	0.216 (30°)	0.228 (−15°)
LCL	LCL	0.036 (0°)	0.139 (−40°)	0.202 (15°)
PL	PL	0.073 (110°)	0.188 (−40°)	0.208 (15°)
MCL	aMCL	0.046 (0°)	0.138 (−40°)	0.184 (−15°)
	iMCL	0.061 (0°)	0.148 (−40°)	0.195 (−15°)
	pMCL	0.037 (0°)	0.099 (−40°)	0.141 (−15°)
	aDMCL	0.037 (0°)	0.357 (−40°)	0.309 (−15°)
	pDMCL	0.001 (0°)	0.275 (−40°)	0.240 (−15°)

Figure 3: Maximum strain of connective tissue bundles [8]

A dysfunctional ACL leads to knee instability as the ACL is considered to be one of the four major knee ligaments [9]. Knee instability makes participation in sports difficult and sometimes impossible depending on the damage caused. Such injury forces semi-professional and professional athletes to undergo an ACL reconstruction surgery to help them get back on the field [9]. A standard ACL rehabilitation treatment takes many athletes 7 to 9 months to complete, not only does this mean the end of their athletic season, but also will interfere with them keeping up with the competition in the sport they play [9]. The figure below describes the increasing amount of NFL linemen that went through ACL reconstruction surgery and did not return to play afterwards over time [9].

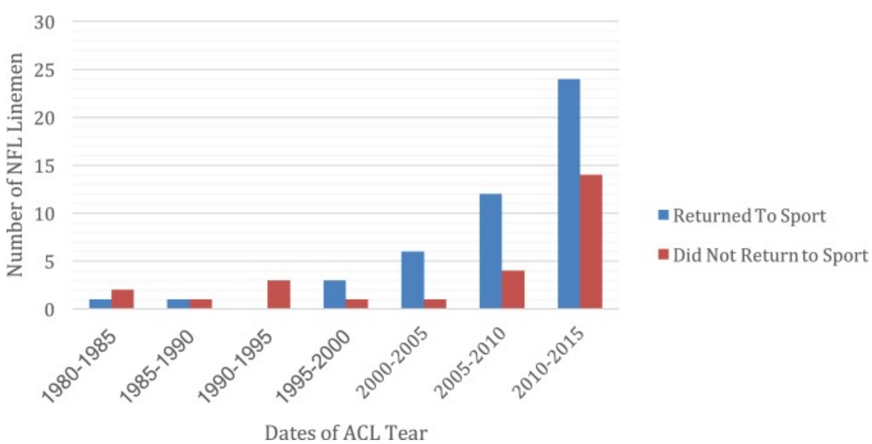

Figure 4: ACL tears in NFL Linemen since 1980. ACL, anterior cruciate ligament; NFL, National Football League. [9]

3.2 Current Technology

The current available technology for knee braces can be very similar. A typical knee brace is made of cloth, has some sort of strong framing woven with the frame, and can be put on like a sock [17]. Knee braces can very a lot in price range, and can be as cheap as approximately $20 and on the pricier end, can exceed $2000 [10] [19]. Current products available commonly utilize a sleeve-like structure around the knee to support the athlete during activity [10]. Some products use straps to achieve a tight fit to support an athlete [12]. Some of the more heavy-duty knee braces on the market utilize a solid frame and hinges to create structural supports for the knee during activity [13]. Some knee braces can resemble an exoskeleton to support the knee using extremely tough metals and frames [11].
One unique product available is Kinesiology Tape (brand name KT Tape). KT tape works by applying a piece of elasticized tape at varying levels of tension on the desired limb [16]. According to KT Health, LLC, KT tape supports joints by reducing pressure on the joints, alleviating pain, and aids muscle contracting which should help prevent over extension [16]. It was found that there is no significant reduction in muscle activity, as found by an EMG, however there was a statistically significant reduction in postural sway when Kinesiotape (general name for KT Tape) was applied (Figure 5).

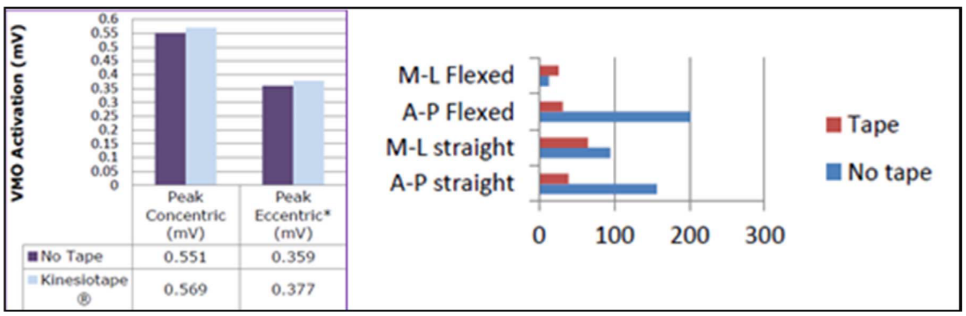

Figure 5: EMG (mV) readings (left) and Postural Sway (mm) Values Before and after Kinesiotape Application (right) [15]

3.3 Mechanical Analysis of the Knee as a 2 Member System

In order to create a accurate model of a human knee the Tibia and Femur were considered as members as the structure of a bone will transmit forces that will cause the ACL to break. The ACL is modeled as a soild body connecting the two members at a ridged angle. With spring connections (defined to only effect the system in tension) in the position of the PCL and MCL. The angle of the members is then systematical changed along with the soild model of the ACL in correlation with the research provided by

By using the process to create a model we are able to accurately determine the effects on outside forces on the knee joint while in different positions. The forces applied were to the Anterior, posture, medial and lateral sides of the Tibia in turn. A torsion moment was then applied both Clockwise and counter clockwise to the tibia. All forces were applied 100 mm below the knee joint in correlation to where our senors will be in our design would end. In particular we were interested in how the bend angle of the knee, the valgas angle and the anterior distance/displacement of the Tibia from the Femur affected the rupture forces of the ACL

Through this modeling we are able to conclude that there are multiple almost linear relations between bend angle of the knee and the rupture force of the ACL. The Medial and Lateral forces needed for ACL rupture during knee bend testing showed that damage would be done to the LCL or MCL while before the ACL is affected. When a torsion force is applied to the tibia it is also the LCL and MCL that will be damaged before the ACL, although if enough torsional force is applied to rupture the LCL and/or the

MCL the ACL will be put at risk. If the LCL or and/or the MCL rupture from such a force our device has no way of detecting this damage and by extent protecting the ACL at this time.

See Table 11 for the complete data set of the anterior/posture forces that caused our model to rupture. It is these values with a factor of safety that our device will be designed to protect against through detection.

4 Scope and Objective of Project

To create a device that can detect when an athlete is performing a movement that is placing their ACL at risk, when such a movement is detected a coach or training staff will be notified as while as receiving quantifiable data to help in risk assessment. This device will not be used as a preventative brace, the device will only be used for detecting dangerous movements and forces on the ACL. Acting on the data collected from this device to restrict knee movement to hopefully prevent an ACL tear can be explored in a further design project or research.

This device is not intended to be used as a rehabilitation tool, by measuring the angle of movement this device is designed to detect or prevent movement outside of a safe range of motion in rehabilitation a slight pushing of boundaries is needed to continue to make progress as such out device will not be a suitable tool to use.

This device is also not a diagnostic device as such a medical professional should still be the final decision on an athletes ability to remain in the game. The intention is to provide more information to the medical professionals about the trauma but while remaining as minimally invasive as possible.

This device will not be able to mitigate risk involved with compression injuries to areas like the meniscus. To remain as minimally invasive as possible there is no way to support a separation between the femur and Tibia, as such a injury to the meniscus might cause irregular data and be detected but this device will not be speciously report such anomalies.

5 Project Constraints

Table 1: Table of Constraints

Constraints	**Explanation**
The design solution must not restrict knee motion from 185° to 10° of bending during athletic activity.	The specified range of motion covers the range of angles that a knee can bend at, without allowing hyperextension of the knee, which can be a risk factor for tearing an ACL.
The design solution must only restrict 3 degrees of freedom of knee movement. The degrees of freedom of interest are posterior-anterior translation, lateral-medial translation, and external-internal rotation.	The degrees of freedom of interest will restrict the translational movement of the Tibia relative to the Femur, which is one of the largest hazards which can lead to the tearing of the ACL. A visual depiction of the degrees of freedom for knee movement can be visually seen in Figure 18.
The design solution must be able to detect anterior-posterior stress of the ACL equivalent to 52N/mm^2 at a rate of 100 readings per second (Figure 10).	The design must be able to detect a force deemed dangerous (gotten through mechanical analysis) and must be able to check if such a force is exerted at a sufficient rate.
The design solution must be able to wirelessly transmit data to a person outside of athletic activity that the athlete's knee has accelerated above the target threshold.	The design solution cannot feasibly have long wires connected to a terminal, as that would inhibit athletic activity, so for the design solution to be able to transmit data wirelessly to a person monitoring the health of the athletes is a necessity.
Any electrical components part of the design solution must either be removable or be water resistant enough such that a user will be able to wash the device in a household washing machine.	Hygiene is a necessity for wearable devices, the build up of bacteria on the surface of the device would be detrimental to the athlete. As a result, the device must be able to be washed. To protect the integrity of the electrical components, the device must be able to safeguard the components and circuitry, or be able to detach from the device.
The design solution must be compatible to be worn with knee pads for basketball, volleyball, and football, so that if necessary, an athlete can wear the design solution with to any protective equipment.	To be able to wear the device, the athlete must not be put in a hazardous situation, therefore, the device must be able to be worn with other protective equipment necessary for sports.
The design solution must be at maximum 200g.	A typical athletic knee brace weighs around 150g, without any electrical components or sensors. Even with the extra functionality of the sensors, the proposed solution should feel as similar as possible to the athlete as a typical knee brace available on the market.

6 Design Criteria

Table 2: Table of Criteria

Criterion	Explanation
The design should be as lightweight a possible.	To allow the athlete to play at their peak ability while wearing the device, the device should be as light as possible so the athlete will hardly notice they are wearing the brace.
The design solution should have the maximum possible useful life cycle.	To be environmentally friendly and viable, the useful life cycle of the device should be as long as possible.
The design solution should minimize end cost to the user.	To be commercially viable, the device should not be financially cumbersome on the athlete.
The design solution should be made out of biocompatible materials and does not cause any lesions of the skin of the athlete.	To ensure comfort, the device should not irritate the skin of the athlete wearing it.
Through manufacturing, transporting, and after the useful life cycle becoming waste, the design solution should minimize its detrimental effects on the environment.	As the impact on the environment should always be a consideration, the environmental impact should be minimized.

7 Design Process

7.1 Design Approach and Strategies

Prior to any solutions the problem definition was clearly identified along with the specific part of the problem that could be solved with a device. Within this solution the main focus was on the detection of movement in the medial and lateral axis of the tibia relative to the femur. Identifying this constraint allowed for each design to detect this important movement at a different approach. Information gathering from literature about the length of movement in the medial and lateral direction along with the understanding of regulations on medical devices allowed for the development of a viable solution and alternatives.

7.1.1 Idea Generation

Multiple approaches of idea generations were discussed to obtain unique solutions to the current problem. The first approach was to have every group member individually come up with a solution after the lab. This allowed every group member to have enough time to think of a creative solution without being influenced by other group members. After the individual solutions were generated a group meeting was scheduled to discuss all of the potential options and try to integrate the best parts of each design into one shown to be the most effective in solving the current problem at hand.

Table 3: Decision Matrix

Criteria	Criteria Score	KT Tape with Sensors	Tension Bands	Lower Body Leggings	Metal Frame Gear Lock	Cloth Brace	Knee and Foot Sensor
Lightweight	20	9	8	7	4	8	8
Durability	20	3	2	8	10	6	7
Cost Effectiveness	5	4	4	3	3	4	3
Comfort	15	7	6	7	5	7	8
Ease of Application	15	5	4	6	6	7	8
Water Resistance	10	6.5	5	5	8	4	6
Multisport Applicable	10	8	5	8	3	8	10
Enviromental Impact	5	3	2	3	2	4	3
Total Scores	*100*	*6*	*4.8*	*6.55*	*5.8*	*6.5*	*7.3*

7.2 Decision Matrix Weighting Justification

Being lightweight is extremely important for this design, as an athlete will be unable to perform properly while wearing the proposed device. As a result of this, the lightweight criterion is heavily weighted in the decision matrix. Furthermore, in sports such as football, players can be subjected to large forces, or be put under repetitive stresses. Because of this, the design's durability is of high importance, and is reflected as such in the design weighting.

Athlete comfort is important because if a person is unwilling to wear an extra garment during sport, they will not wear it. Due to this, athlete comfort is weighed heavily in the decision matrix. Due to the same reasons, ease of application is also weighted heavily.

The design's versatility in other sports is another important factor to be considered, but not nearly as important as the criteria listed above, and thus is weighted at half of the weighting of durability and lightweight.

As the sports that this brace will be used for are most likely not aquatic sports, the ability for the design to resist water damage is not as important as other factors. However, the ability to withstand some water is important to ensure that sweat does not damage the components. This is reflected with a lower weighting in the decision matrix.

As the environmental sustainability is not a component of the problem being tackled, the impact on the environment of the product's life cycle does not need to be heavily considered. As a result, a low weighting is given.

Finally, the product will be marketed to professional and semi professional athletes who can spare money to ensure their health, so the cost effectiveness does not need to be weighted heavily. A low score is given in the decision matrix.

8 Alternative Solutions

8.1 KT Tape with Sensors

The general idea behind this design is to use disposable, elasticized, kinesiology tape where the sensors to detect knee movements are able to snap in place in the tape, once applied to the knee (Figure 14). Once snapped in, the sensors will be connected to wires that extend to a microprossessor housing that can be worn on the hip, that will transmit data to a person monitoring athletes on the sidelines.

8.1.1 Design Merits

The usage of Kinesiology Tape has been proven to help reduce knee sway, which in turn will help provide the athlete with stability [15]. It has has also been shown that knee angle deviation had a significant difference from before to after applying Kinesiology Tape [18]. Both of these features will be taken advantage of in the proposed design. Furthermore, athletes can apply the Kinesiology Tape to their comfort and preference, getting the desired fit every time, and will not have to worry about finding the right size out of a few options. They will be able to customize the size and fit of their knee support every time. Within the scope of the determined criteria, the design has many strengths. The scores of all the criteria can be seen in Table 3. Firstly, the use of only Kinesiology Tape will make the design extremely lightweight. Furthermore, the fact that an athlete can customize the fit of the athletic device can ensure that comfort for the athletes is as high as it possibly be. In addition, due to the customized fit that athletes can choose, this design solution can be used for many different sports.

8.1.2 Design Limitations

For all the conveniences and merits this proposed design solution has, there are some shortcomings. Due to the nature of the setup for the sensors, wires will need to be run down the legs of athletes. These wires have the potential of getting tangled, or caught on something during play, which can be a major inconvenience for the player. Furthermore, the microprocessor housing can be uncomfortable for players to wear. For a sport such as football, if a player falls on the microprocessor unit, there is a possibility that it could break. It is also possible the housing of the microprocessor could hurt the player's side by falling on it.
Inside the scope of the criteria, there are a few key shortcomings of this design. Due to the nature of using disposable tape strips for athletic activity, the durability of this design is quite low. Also, because new tape will be used for each activity, the environmental impact of the design will be quite high, which is not ideal. Again due to the disposable nature, the cost to the user of this design could be high because athletes will need to refill their supply of Kinesiology tape. A full ranking of all the criteria can be found in Table 3.

8.2 Tension Band

This design is based on the is to use a regular small knee brace that conforms tightly to athletes lower legs while it provides support on the lateral and medial side of the leg. Tension bands will be added to the design running poster and anterior to the knee (Figure 15). These tension bands will have sensors incorporated to detect how much the tension bands are in tension or compression. This detection method will allow the sensors to detect exactly when the knee has shifted too far medially or laterally as it runs over top the athletes knee.

8.2.1 Design Merits

With the tension bands running over top and behind the knee this will give the sensors a quick and constant flow of information. With this design, the tension bands can be incorporated into many knee braces. Cost of tension bands is very low and can be easily replaced.

8.2.2 Design Limitations

As the tension bands will be on the outside of the brace it has the potential to come in contact with other players and hook onto something. This will pull the band fully out of place providing highly inaccurate results. Tension bands are also prone to overstretching and must be replaced often.

8.3 Full length Supportive Leggings

Full length leggings similar to athletic pants worn by athletes will incorporate sensors on the quadriceps, a tension knee brace for support along with 2 sensors on the knee brace detection motion and movement of the athletes femur and tibia. An image of the proposed design can be seen in Figure 17.

8.3.1 Design Merits

This design ensures exact placement of sensors on the athlete without inaccuracies due to a knee brace or sensor slipping out of place. This provides an all in one solution to detect quadriceps activation during play while analyzing the location of both bones attached to the ACL. Quadriceps activation is greatest during landing, and understanding the force of activation of the quadriceps along with the sensors analyzing knee movements allows for the collection of athletes data.

8.3.2 Design Limitations

As this device is a full lower body suit, ensuring a perfect fit from athlete to athlete may prove difficult. Every athlete has a different body ratio of leg width to leg length to knee placement. Optimizing sensor location to every individual athlete on a team will prove to be tedious. Comfort to athletes needs may be unsuccessful therefore the overall product may not be used. This product may be undesirable to those wearing additional layers of team uniforms. During summer sports additional thick layers, such as under soccer chin pads or football uniforms, can be undesirable.

8.4 Metal Frame

This design is based off of current high performance knee braces, it would involve sensors placed throughout the aluminum frame of such bracing systems with the circuity and power being sealed in. A gear lock system would also be implemented to hold the knee in place should the system be triggered.

8.4.1 Design Merits

The design would be very robust and durable being made of study material, with a constant sensor placement as they would be in a soiled body little to no calibration would be required. It would be consistent with current levels of protection to knee ligaments but given more information to coaches.

8.4.2 Design Limitations

This system could easily become to heavy to be comfortably worn especially on the knee as the method of attachment is a tension system. It would also be limited to sports and activities that large metal knee braces are currently involved in, as its bulk could be limiting in different sports.

8.5 Automated Cloth Brace

The general idea behind this design is to connect data from sensors and send to a micro controller where data is collected and shared with the coach wirelessly. This system will consist of 5 sensors, 2 flex sensors, 2 pressure sensors, and an accelerometer. a flex sensor and an accelerometer will be placed by the knee. This will give the acceleration in the x y and z and the flex angle. a flex sensor and 2 pressure sensors will be placed by the ankle. These sensors will provide the shank flex angle, and the pressure applied. A user interface will be created to provide user's height and mass. These variables will be used to calculate the total force applied to the knee.

8.5.1 Design Merits

The hardware design will be embedded into a cloth brace. The cloth brace will provide protection to the knee and help in preventing the ACL from getting insured. This feature will be taken advantage of in the proposed design. The design will be lightweight and comfortable keeping the athlete performance high. Hardware includes tiny IC chips that will prevent a bulky brace. The durability of the design should last for at least one year as the IC Chips consume low power allowing the battery life to last for 1 year. This design is simple and easy to implement making it cost effective. Brace will be easy to use and install as all the player has to do is wear the brace. The brace will calibrate itself as the user inputs his height and mass. Water resistance is still one of the criteria that is weak for such design and still needs to be thought of. This design includes two modules that act as a slave-master which gets rid of the wired connection that affects the players comfortably when using the device.

8.5.2 Design Limitations

Some of the design limitation includes waterproof ability. This comes in play when athletes play under rainy conditions where water may come in contact with the hardware pieces. Another limitation is the microcontroller housing and where the housing should be places. This may affect the comfortably criteria of the device. Another limitation is pairing the two modules. This limitation comes in play when an athlete uses a different slave from the one that is already connected to the master.

9 Design Evaluation

9.1 Proposed Preliminary Design Solution

Based off several of the alternative solutions, the group designed our preliminary design. The device is a variation off of the automated cloth brace alternative design, however, is split into two sub-systems. Instead of having just a cloth knee brace, some of the electronics will be embedded into the shoe of the user. The cloth sleeve will still contain a micro-controller with an accelerometer and a flex sensor to find the acceleration in the x, y, and z directions, as well as flex angle. Embedded in the user's shoe will be another micro-controller connected with two pressure sensors and another flex sensor. These will be used to find the shank flex angle and pressure applied through the foot.

9.1.1 Design Merits

The first subsystem is similar to a cloth sleeve knee brace. Embedded in the cloth sleeve will be an ESP8266 WiFi-enabled micro-controller connected to a multiplexer. The multiplexer is required as ESP8266 micro-controllers only have one pin for analog input. To solve this problem, multiplexers are used with each controller to rapidly change the sensor being read from. By sampling at a fast rate, all sensors can be read from in a reasonable amount of time.

The second system embedded in the shoe is connected to the first ESP8266 micro-controller in a slave-master configuration, where the controller built-in the shoe is the slave and the controller embedded in the sleeve is the master. This avoids the potential issue of connecting the sensors on the foot to the micro-controller on the sleeve with wires, as there would be potential strain on the wire connections.

To power these two sub-systems, rechargeable batteries will be connected to the devices. The cloth brace will be connected with a USB adapter so it can be easily recharged. The system in the shoes, however, will be charged using a magnetic induction charging system. This will allow for the system to be fully embedded into the shoe without having to worry about making it removable. The batteries will be designed to last at least 3 hours on a full charge, however, the system can be easily recharged when the athlete is on the sidelines during a break, or during storage after a game.

9.1.2 Design Limitations that Must be Considered

The team must consider several design limitations, include:

- Limitations in the battery capacity based off of physical size restrictions
- Potential impact and pressure on electronic components of device
- Size limitations to reduce restrictions to athlete
- Noise reduction and elimination

These limitations will be considered when finalizing our design to accomplish the project goals while not impacting the athletes performance or comfort.

9.1.3 Additional Details about Selected Solution

The device will connect to a companion device for the coach to alert them in case of potential injury to the player. This will be a standalone device to receive data from the players in real time, process the data for any potential anomalies in the players movement, and prompt the coach to act if there is a detection. This will be done with a simple tablet device connected to the wifi-signal of the master ESP8266 modules.

10 Updated Required Information and Tools

The anticipated resources that will be needed from design conception to design production are as follows:

1. Vicon Motion Capture
    - Real data collection and analysis will be conducted to get a proper understanding on the range of knee movements during several different sports to asses regular knee kinetics. This data will be used as a reference point for regular gait cycles to know what normal knee movements in athletes look like.
2. MATLAB and Visual 3D
    - The data obtain from the Vicon motion capture system will have to be analyzed with Visual 3D software to obtain the moments and angles around the knee joints. This data will then be used within MATLAB to analyze a regular knee cycles as well as analyzing internal loading at the knee to understand how much force the knees can handle and when movement could be restricted within a movement.
3. SolidWorks and AutoCAD
    - These systems will provide visual representations of the solution throughout the prototyping and design process. Finite Element analysis will be done on the AutoCAD designs to identify areas of additional wear and tear.
4. EAGLE
    - Circuit schematics as well as circuit designs will be created within this software
5. Cost Analysis Software
    - This software will allow the tracking of costs and estimations fees that will arise throughout the designing process, with the designing fees also the costs associated with manufacturing and production.

10.0.1 Regulations

The overall design of an external knee joint brace must follow various rules and standards as this will be considered a medical device and will be in contact with individuals at all times during use [20].

- Food and Drug Administration (FDA) Class 2 medical device.
  This device provides an electronic transfer of data, storage of data, conversion of data, display of obtained data. With a class 2 device, the product will allow for active patient monitoring. This will include electronic and electrical hardware intended to be used in connection with active monitoring [22].
- Acceptance of Electrical Equipment in Canadian Provincial and Territorial Jurisdictions through the Electrical Safety Authority
  As this is an electronic device actively monitoring individuals, proper information, warning and labelling must be present for the safety of everyone in contact
- ISO 14971
  Risk management standard for medical devices
- (IEC-60601-1-1, Section 8, p 135-269) Medical Electrical Equipment
  International standard of general requirements for basic safety and performance of medical equipment.

- CISPR 11:2015
  Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement. As this device will transmit wireless signals, any disturbances this device may create or may interfere will the device must be analyzed.

- IEC 61000-4-3
  Asses the stability of the device against radio frequency noise mimicking those from cell phone transmissions

- Applications for Medical Device Investigational Testing Authorizations Guidance Document
  Testing this device prior to production must be approved by the ethics board to allow for certification. Material information, quality, uses and advantages must all be provided to asses the products safety and effectiveness as a product overall [21].

10.1 Updated Required Information from the Client

Having a standard design capable of being integrated with most knee braces, information from coaches about most common knee braces and shoes worn by the athletes is very important. This device will be worn under the regular knee brace and must seamlessly integrate with those worn during a game. Knowing approximate sizing, thickness of braces will allow for optimal sensor location on the sleeve of the device to not inhibit athletic performance. Shoe information is essential for the placement of pressure and flex sensors. Pressure detection from inside the shoes must be undetectable to the athlete wearing the device. Approximate shoe types and brands are essential to analyze sole thickness, shoe flexibility as well as pressure distributions throughout the shoe. Understating highest pressure spots in the shoes wither on the ball of the foot, or evenly distributed throughout will allow for ideal sensor placement. Understanding athletes movement patterns as well as the devices currently worn will allow for a very accurate detection device.

11 Schedule and Fees

11.1 Updated Schedule of Work

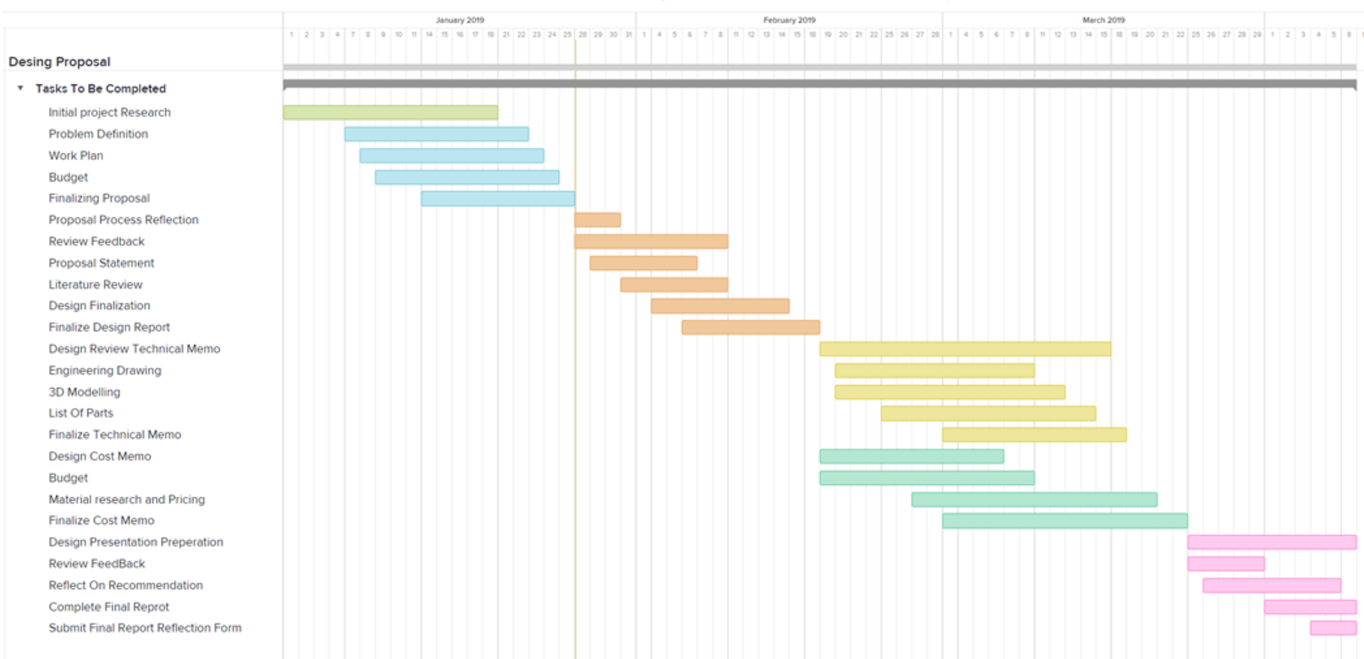

Figure 6: Project GANTT Chart

11.1.1 Initial Project Research (Jan 1st - 18th)

A total of 45 man hours were invested into the research of this project this ranged from looking into relevant Patents, Technical Articles and Trade Journals as well as spending considerable time using the Internet resources and Consultants that were available. All members of the design team were asked to complete their own research and bring the relevant information that they found to the first meeting outside of in-lab. As such each member was able to contribute to the discussion of how to approach this problem.

11.1.2 Problem Definition (Jan 7th - 22nd)

A total of 5 hours were invested into creating a detailed problem definition and by extent problem statement. By defining a solid and detailed problem statement to refer to later, ideas and concepts considered beyond the scope of this project were eliminated before too much time was invested in them.

11.1.3 Work Plan (Jan 8th - 23rd)

No defined amount of time was spent of defining a work plan as it is a continuously evolving entity as team members are able to take and give suggestions as needed to complete the project in a quality and on time manner.

11.1.4 Budget (Jan 9th- 24th)

Due to the nature of this problem and the corresponding design the cost of the design is not as significant. Being marketed to high performance athletes and leagues means that the final cost of the product may be high to the lay person but relatively low to these individuals, especially if it is to protect their physical assets. As such, creating this product as a start up companies first product is not feasible to bring this design to market.

11.1.5 Finalizing Proposal (Jan 14th- 25th)

In order to produce a quality proposal many different concepts of solutions were created with 40 hours spent both in group meetings and individually. After concept generation, the workload for completing the proposal was then split among the design team. In order to complete some of the larger task members worked in smaller subgroups, specifically almost perfectly breaking off into groups by major.

11.1.6 Proposal Process Reflection (Jan 28th- 30th)

Looking back upon the completion of the design proposal the design team should have allotted more time for the entire team to read through the report and make the necessary edits and additions to each others part. As the completion of the report was rushed this time was extremely limited and the cross editing was lacking. As such this was brought up in the next design team meeting as a priority for the inter min report.

11.1.7 Review Feedback (Jan 28th- Feb 8th)

After taking into consideration the feedback given by our TA, the main focus for the next report being the interim report was to create a very specific and easy to read report. As such the use of the software Latex was implemented to create a very detailed and organized report that all members could edit simultaneously.

11.1.8 Proposal Statement (Jan 28th- Feb 6th)

The proposal statement was used as a claim that outlines the problem addressed by this report. The statement of the problem addresses ACL injuries and how to prevent them.

11.1.9 Literature Review (Jan 31th- Feb 8th)

the literature review summarizes and explains the complete and current state of knowledge on "The prevention of ACL injuries" that was found in academic books and journal articles.

11.1.10 Design Finalization (Feb 4th- Feb 14th)

Over 34 hours were put into the finalization of the design, with both a decision matrix and sensitivity analysis being implemented to give quantifiable data to the selection process the design of having two independent parts (one on the knee the other in the shoe) working together in one system became the clear front runner. As such more time was spent in fleshing out the details and working through potential issues than for other designs.

11.1.11 Finalize Design Report (Feb 6th- Feb 18th)

Completing this report ahead of time was extremely important to the design team as avoiding the stress and pressure associated with last minute time frames cause. By meeting frequently in the weeks leading to the due date of the report self imposed soft due dates were created and held too. Through this process the creation of a more accurate and detailed report was created and it is a process that the team is likely to implement moving forward.

11.1.12 Design Report Technical Memo (Feb 19th- Mar 15th)

The technical memo is designed to effectively review project and experimental details of the solution proposed in this report.

11.1.13 Engineering Drawing (Feb 20th- Mar 8th)

The engineering drawing present a visual representation of the solution proposed in this report.

11.1.14 3D Modelling (Feb 20th- Mar 12th)

3D modeling was used throughout the design process, in the beginning Soildworks FEA was used to determine what forces are acceptable for an ACL to experience before our design should intervene. After which modeling a rough idea of the final design was used to help to keep the team on the same page. By adding more details were added and problems were solved the 3d model was updated creating a accurate model of the expected design.

11.1.15 List of Parts (Feb 25th- Mar 14th)

The list of part report will highlight the parts used in this project. The main parts used will include a micro-controller, an accelerometer, 2 flex sensors, and 2 pressure sensors. This report will include the cost of overall system.

11.1.16 Finalize Technical Memo (Mar 1st- Mar 8th)

The team will finalize the technical memo report and make sure any new update in terms of designing the solution is reported .

11.1.17 Design Cost Memo (Feb 19th - March 6th)

The design cost memo report will include the cost of all components used to design the system described in the report. This report will go in depth into why components were used and cost clarification.

11.1.18 Budget (Feb 19th - March 8th)

The budget will be reviewed and edited to make sure report is accurate after design changes committed. New updates and costs will be reported depending on the changes made after finalizing the design report. The main goal of this report is to address the costs of implementing and designing the proposed solution to the problem statement.

11.1.19 Material Research and Pricing (Feb 27th - March 20th)

The main goal of the material research and pricing report is to provide a clear explanation of why the hardware components, materials, and tools were used. This will include the price of all components of the system described in the report. This report will be updated depending on any changes made later on throughout the project timeline.

11.1.20 Design Presentation Preparation (Mar 25th - Apr 8th)

During this phase, the team will get ready to present the solution provided in the report to the School Of Engineering. Preparation includes going over the report and ensuring all information is accurate and presentable.

11.1.21 Review Feedback (Mar 25th - Mar 29th)

Feedback provided will be reviewed and improvements to report will be implemented depending on the comments from the feedback. The feedback provided will help in perfecting the final report.

11.1.22 Reflect on Recommendation (Mar 26th - Apr 5th)

After reviewing feedback, the team will reflect on the improvements implemented into the report. All sections will be updated individually to make sure all sections correlate and accurately describes the solution presented.

11.1.23 Complete Final Report (Apr 1st - Apr 8th)

The team will proof read the final report and connect the final dots together making sure all sections connect in a professional manner. Any chances implemented into the design will be updated to make sure all information is reported in the final report. After team finalizes the report, the team will present the report to teacher assistants to collect minor recommendation to improve the final report.

11.1.24 Submit Final Report Reflection Report (Apr 4th - Apr 8th)

After proof reading and reviewing, The final report will be submitted.

11.2 Updated Resources Required to Create Design

The material of the knee brace must be made from a very lightweight and thin material.
A neoprene material for the material will be favoured due to its toughness and durability. This will allow for a lightweight, durable material. Anti slip silicone coating around the perimeter of the device ensures no slip during exercise while ensuring minimum error from a moving device measuring incorrect movements @ flex sensors will be incorporated to measure the angel of the knee and the flexion/ extension angle of the ankle. 2 pressure sensors incorporated into the soles of the athletes shoes to detect the ground reaction of the athletes either distributed on the heel or ball of the foot. 1 accelerometer will be added to the knee brace to continuously detect changes in motion.

11.3 Updated Summary of Costs

11.3.1 Define Problem

Table 4: Breakdown of Problem Definition

Activity	**Summary of Activity**	**Time Invested**	**Cost**
Problem Statement	What issue does this project solve	5 (H)	375 ($)
Bench marking	How a successful project is determined	5 (H)	375 ($)
Product Dissection	What are the important components needed for this project	15 (H)	1,125 ($)

11.3.2 Gather Information

Table 5: Gather Information

Activity	Summary of Activity	Time Invested	Cost
Internet	Used as a resource to determine our projects validity and comparability to existing models	23 (H)	1,725 (\$)
Patents	Used as a resource to determine our projects validity and comparability to existing models	2 (H)	150 (\$)
Technical Articles	Used as a resource to determine our projects validity and comparability to existing models	10 (H)	750 (\$)
Trade Journals	Used as a resource to determine our projects validity and comparability to existing models	3 (H)	225 (\$)
Consultants	Used as a resource to determine our projects validity and comparability to existing models	7 (H)	525 (\$)

11.3.3 Concept Generation

Table 6: Concept Generation

Activity	Summary of Activity	Time Invested	Cost
Creativity Methods	Using techniques to create unique solutions	3 (H)	225 (\$)
Brainstorming	Using teammates to create possible solutions	16 (H)	1,200(\$)
Functional Models	Creating quick models to describe a design detail	1 (H)	75 (\$)
Decomposition	Creating a system to interface important components	20 (H)	1,500 (\$)

11.3.4 Evaluation of Concepts

Table 7: Evaluation of Concepts

Activity	Summary of Activity	Time Invested	Cost
Decision Making	Team meetings to discuss options for next steps	12 (H)	900(\$)
Selection Criteria	Team meetings to discuss options for project evaluation	20 (H)	1,500 (\$)
Decision Matrix	Used to give analytic value to subjective traits for project evaluation	2 (H)	150 (\$)

11.3.5 Configuration Design

Table 8: Configuration Design

Activity	**Summary of Activity**	**Time Invested**	**Cost**
Preliminary Selection of Materials	Sourcing and evaluating possible materials	11 (H)	825 ($)
Modeling	Creating a detailed/working CAD model of design	25 (H)	1,875 ($)

11.3.6 Parametric Design

Table 9: Parametric Design

Activity	**Summary of Activity**	**Time Invested**	**Cost**
Robust Design/Setting Tolerances	Developing the production end of our design	7 (H)	525 ($)

11.3.7 Detailed Design

Table 10: Breakdown of Problem Definition

Activity	**Summary of Activity**	**Time Invested**	**Cost**
Engineering Drawings	Using CAD model to produce accurate drawings	12 (H)	900 ($)
Finalize PDS		35 (H)	2,625 ($)

Therefore the total amount of time being invested in the project is projected to be 180 Hours. With an average cost for a junior engineer in training of $75 per hour, an approximate cost of design is $13,500. This is not including all resources and tools used for design, so the final cost of design will be a slightly higher amount.

12 Anticipated Challenges

12.1 Technical Challenges

There are several technical challenges that the team will face when creating the final solution. This includes:

- CAD MODEL: One difficult task will be creating 3D CAD models of the design, as there are several different components made of very different materials. Modelling rigid, elastic, and flexible components in the same model is often a complicated procedure, so this will be a time consuming task. In addition to this, circuit modelling software such as EAGLE and AutoCAD Electrical require very different skills than that of other CAD software like SolidWorks.

- MECHANICAL FORCES ANALYSIS: A detailed force analysis of the maximum stress and strain the ACL can endure will also be a difficult task. The human body has many complex structures making an analysis extremely difficult. The model must also be extremely accurate, as an incorrect model will defeat the purpose of the entire device.
- CIRCUITRY COMPONENT CONSTRAINTS: Circuit related challenges include choosing hardware that can read from several sensors in real time, and communicate with other computers with very little latency. In addition to this, finding a small microcontroller with enough analog inputs for all the sensors will be a challenge.
- INTEGRATING COMPONENTS: The last expected technical challenge will be creating an effective method of embedding the bottom sub-system with the two pressure sensors and flex sensor. It is essential they are embedded in a way that will not obstruct the performance of the player, is comfortable for the player, and will protect the electronics.

12.2 Methods for Handling Potential Technical Challenges

To effectively deal with the distribution of the CAD modelling, the team will distribute each segment to those team members with experience in the specific software. Several team members have prior use experience in SolidWorks, AutoCAD Electrical, and EAGLE, so tasks will be distributed to the team members what are most advanced in the specific software.

The mechanical force analysis will be done with accurate approximations and finite element analysis. Research papers have been consulted to gain a thorough understanding in the structure of the the components that make up the knee, and exactly what leads to ACL damage. By using this knowledge, approximations have been made to maintain the integrity of the model, while also making calculations simplified in order to verify the results of the finite element analysis.

To deal with the challenges of interfacing all signals with a small micro-controller, multiplexers will be used to interface several analog sensors to one port. By sampling rapidly and changing the sensor being read from, all sensors can be read from in real time. In addition, the ESP8266 module that will be used has WiFi-capabilities, so the two circuits can be wirelessly connected to one another and the main hub on the sideline.

Integrating of the physical circuit into the shoe of the user will be done in collaboration with the manufacturer of the shoe. In addition, the location of the chips in the shoe will not be located in areas of high stress to support the longevity of the circuit.

As surprise issues will arise, we have allotted time to ensure the everything will be resolved in a timely manner.

12.3 Scheduling Challenges

The one of the largest scheduling challenges that will be anticipated to handle is the busy schedules of the group members. Each member of the design team is taking at least five courses this semester, and some members are taking six courses. Being able to balance design work with the rest of the expectations that coursework has will be a large challenge for this group. Furthermore, on top of schoolwork, the team will have to balance employment commitments, RLS commitments, and research commitments for other Professors. Balancing these commitments will make allotting time for the design project more challenging. Furthermore, another time pressure that the team needs to deal with is job searching for summer employment. With the competitive market for engineering students for summer jobs, searching for a job has become almost like a full time job in itself. It is anticipated that group members will need to allot time to search for jobs, apply for jobs, and interview for jobs. Due to all of the reasons listed above, it is anticipated that at times, finding time for the five group members to meet together in the same place may become extremely difficult.

12.4 Methods for Handling Potential Scheduling Challenges

Further scheduling issues are being avoided by scheduling weekly meetings at a time that works with the entire teams schedule, as well as regular check-ins to ensure progress is being made. Another method for tackling scheduling issues is reallocating tasks when team members need extra time. If someone is struggling to finish a task by a date, or committed to more than expected, other team members assist them to accomplish the task. This allows for everyone to contribute to the project, however, not be overloaded with work. This strategy has been successful from when it was implemented and will likely continue until completion.

12.5 Teamwork Challenges

A challenge that will need to be tackled is interdisciplinary work. This project will need heavy mechanical knowledge to understand forces in the knee during activity, computer knowledge to sense forces, integrate and process the collected data, and biomedical knowledge to understand the anatomy of the knee and to be a common ground between all the disciplines at work.

As a result of this, dividing work will become a challenge. It will be required to have team members with specific expertise working on different aspects of the design. Once each sub project has been completed, another challenge will be to integrate all the sub-solutions to an acceptable main solution.

Furthermore, bolstering spirits may become a problem. Working long days, and tackling difficult problems can become frustrating for team members, and keeping morale high should be thought of when collaborating. Arguments may surface between team members, which should be handled in a respectful, dignified way.

12.6 Methods for Handling Potential Teamwork Challenges

Interdisciplinary work has been approached by each team member by discussing the issues together, and then splitting the tasks based off of existing background knowledge. As everyone is completing their tasks, the group comes together regularly to make sure everyone is converging to the same goal. This makes integration of everyone's work easier at the end of the project. If there are any miscommunications, the group will clarify the goal and scope of the sub task during the regular meetings.

Morale is an important consideration, so the team has also implemented team activities to de-stress from demanding projects and school activities. This will maintain high quality work and create a more enjoyable and positive work environment.

12.7 Methods for Handling Unforeseen Challenges

Due to the nature of unpredictable tasks, it is difficult to plan a response. The most effective method encountered so far to deal with such scenarios has been planning for buffer room. This allows for extra tasks to be completed while still meeting deadlines for the project. In addition, constant communication between team members helps to alert everyone as soon as a challenge arises.

12.8 Challenges that Have Arisen Thus Far

The biggest areas that have been a struggle thus far all regards scheduling. Starting deliverable early, scheduling meetings, and gathering together to do work have all been difficult.

Due to the hectic timetables this semester, projects for design have been delayed to a time that is not ideal for the group members to begin work in a timely manner. This has caused unnecessary stress to finish reports as soon as possible. For example, work began on the design proposal at a time such that all the group members felt distressed to get it done.

Another difficulty regarding busy schedules is scheduling meetings. Design group members often have many things to do, sometimes those take priority over design meetings. Job interviews, studying for other

courses, and other projects may sometimes be more important than a weekly design meeting to update group members of progress made.
Unrelated to scheduling, a final challenge that has arisen so far is interpreting directions for deliverables. Several of the tasks for this project are new and unfamiliar. As a result, tasks must be figured out as they are done. This can lead to confusion. Sometimes, a task that the group believes should be done one way, is expected of the Professors and TAs to be done in a different way.

12.9 Methods for Handling Challenges that Have Arisen Thus Far

As previously started above, communication has been key to mitigating schedule challenges that arise.

Deliverable clarification has been solved by utilizing TAs and professors as resources. Instead of waiting until completing tasks, the team has been proactive and asked for clarification to understand exactly what needs to be done and by when.

13 Next Step

The next steps involved in this project will be to create CAD models of the final chosen design. Knowing the size specifications for the products and how the device is to work with athletes provides a base design that must be followed. Finite element analysis, along with the forces acting on the brace from human movements. Exact sensors that will be used will have to be determined for accurate sensor arrangement with accompanying circuit schematics. A list of materials used within the device will be generated. This list will allow for an estimation of the cost analysis. Life cycle analysis will be carried out for the environmental impact. Planning for the technical memo and cost memo will begin along with a proof of concept to ensure all steps are met.

Appendix A Response to Feedback

A.1 Specificity with Criteria and Constraints

One of the biggest pieces of feedback given from the design proposal was that the listed constraints and criteria were too general. It was heavily recommended to add concrete numbers for constraints and criteria. Having accepted this feedback, the constraints and criteria were revised to include concrete values to achieve. Where possible, numerical values for forces, angles, sampling rates, and stresses. With constraints that were not possible to include numerical values (such as constraints 2, 4, 5, and 6) as much specificity as possible was included by utilizing anatomical descriptions, clearly stating requirements, and conditions that must be met.

A.2 Jargon

Another piece of feedback included was to include more jargon in the description of the problem. Changing from the proposal to the interrim report, descriptions were refined by including medical and anatomical descriptions of the knee anatomy and relative body directions.

A.3 Scheduling Section

An aspect of the proposal that needed to be changed was the Work Scheduling section. The descriptions were not satisfactory and in-depth enough. To fix this for the interrim report, the supplied Gantt chart was updated to be more visually appealing, each individual task was described with words in more detail. Furthermore, at the bottom of the section, a summary table was included to briefly summarize every task that will need completion in a concise area.

A.4 Executive Summary

The executive summary in the design proposal was insufficient in providing details about the contents of the report. To respond to that, more facts and information was provided in the Interrim report.

A.5 Problem Description

An aspect that was unsatisfactory in the design proposal was the included information about the problem description. While the information that was researched was satisfactory, the amount of calculations and information gathered by the group members themselves was not enough. For the interim report, free body diagrams were created to understand the mechanics of the knee including the ACL. Numbers from the mechanical analysis and the research gathered, numbers for an acceptable stress and force on the ACL were able to be discovered, which can be used for educated design decisions. Furthermore, a rudimentary SolidWorks Finite Element Analysis was performed to better understand the fracture mechanics of the knee and the ACL.

Appendix B Calculations, Code, and CAD Modelling

B.1 Mechanical Analysis

To create a mechanical analysis the stress placed on the ACL due to anterior forces were considered as the main force causing an ACL to tear. The dimensions of an average ACL were taken [3] along with the force needed to rupture an average ACL. Using the length and radius the ACL was approximated as a cylinder with a constant volume, this was used to create a fixed variable when the length changed to determine the radius of the ACL through its range of motion. A cross sectional area for each of these different radii was then created for use in the stress derivation. A maximum stress value was determined using 2000N at anatomical position 0°of knee bend. Using this maximum stress value the maximum anterior force may be applied before rupture.

$$\begin{aligned} Volume(mm^3) &= \pi * Radius^2(mm^2) * Length(mm) \\ V &= \pi * 3.5^2 * 37.5 \\ V &= 1443.17(mm^3) \end{aligned} \tag{1}$$

$$\begin{aligned} Radius(mm) &= \sqrt{\frac{Volume(mm^3)}{\pi * Length(mm^2)}} \\ R &= \sqrt{\frac{51.97}{\pi * 36.5}} \\ R &= 3.55(mm) \end{aligned} \tag{2}$$

$$\begin{aligned} CrossSectionalArea(mm^2) &= \pi * Radius^2(mm) \\ Ca &= \pi * 3.55^2 \\ Ca &= 39.54.(mm^2) \end{aligned} \tag{3}$$

$$\begin{aligned} MaxStress(N/mm^2) &= \frac{RuptureForce(N)}{CrossSectionArea(mm^2)} \\ Ms &= \frac{2000}{38.48} \\ Ms &= 51.97(N/mm^2) \end{aligned} \tag{4}$$

$$\begin{aligned} MaxAnteriorForce(N) &= MaxStress(N/mm^2) * CrossSectionalArea(mm^2) \\ MF &= 51.97 * 39.54 \\ MF &= 1541.10(N) \end{aligned} \tag{5}$$

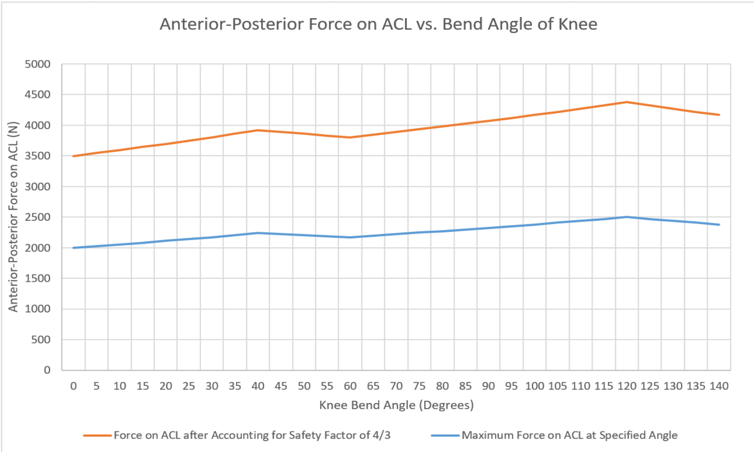

Figure 7: Movement Degrees of Freedom for the Human Knee

Table 11: Raw Data of Anterior-Posterior Force on ACL vs. Knee Bending Angle with a Safety Factor of 4/3

Flexion Angle (θ)	Length of ACL (mm)	Radius of ACL (mm)	Cross Sectional Area of ACL (mm^2)	Maximum Force at Specified Angle (N)	Force Accounting for Safety Factor (N)
0	37.5	3.5	38.48	2000	1500
5	37	3.52	39.00	2027.02	1520.27
10	36.5	3.54	39.53	2054.79	1541.09
15	36	3.57	40.08	2083.33	1562.50
20	35.5	3.59	40.65	2112.67	1584.50
25	35	3.62	41.23	2142.85	1607.14
30	34.5	3.64	41.83	2173.91	1630.43
35	34	3.67	42.44	2205.88	1654.41
40	33.5	3.70	43.07	2238.80	1679.10
45	33.75	3.68	42.76	2222.22	1666.66
50	34	3.67	42.44	2205.88	1654.41
55	34.25	3.66	42.13	2189.78	1642.33
60	34.5	3.64	41.83	2173.91	1630.43
65	34.125	3.66	42.29	2197.80	1648.35
70	33.75	3.68	42.76	2222.22	1666.66
75	33.375	3.70	43.24	2247.19	1685.39
80	33	3.73	43.73	2272.72	1704.54
85	32.625	3.75	44.23	2298.85	1724.13
90	32.25	3.77	44.74	2325.58	1744.18
95	31.875	3.79	45.27	2352.94	1764.70
100	31.50	3.81	45.81	2380.95	1785.71
105	31.12	3.84	46.36	2409.63	1807.22
110	30.75	3.86	46.93	2439.02	1829.26
115	30.37	3.88	47.51	2469.13	1851.85
120	30	3.91	48.10	2500.42	1875.85
125	30.37	3.88	47.51	2469.13	1851.85
130	30.75	3.86	46.93	2439.02	1829.26
135	31.12	3.84	46.36	2409.63	1807.22
140	31.5	3.81	45.81	2380.95	1785.71

B.2 Preliminary Arduino Code

```
/*
 * Code as sample of reading from sensors
 * Functions for reading and converting sensor values
 */

int analogPin = A0;
int val;
int timeValue = 0;

void setup() {
  // put your setup code here, to run once:
  Serial.begin(9600);
  Serial.println("Sensor Analog Output:");
}

void loop() {
  Serial.print("Value is: ");
  val = analogRead(analogPin);     // read the input pin
  Serial.println(val);
}

//FUNCTION FOR READING ANALOG VALUE FROM SENSOR

int readPin(int pinNumber) {
  return analogRead(pinNumber);
}

//FUNCTIONS ASSUME SENSORS HAVE LINEAR OUTPUT AND ARE CALIBRATED
//FUNCTIONS FOR CONVERTING ANALOG VALUE

double analogToDegrees(int analogValue) {
  //180 is max degrees
  //1024 is max analog output
  double scaled = (analogValue + 1)/1024.0 * 180);
  return scaled;
}

double analogToVoltage(int analogValue) {
  return ((analogValue + 1)/1024 * 5);
}

double analogToPressure(int analogValue) {
  //output pressure value in a range of 0 to 100
  return ((analogValue + 1)/1024 * 100);
}

double analogToAcceleration(int analogValue) {
  //output pressure value in a range of 0 to 50
  return ((analogValue + 1)/1024 * 50);
}

//FUNCTIONS FOR READING EACH SENSOR
double readDegrees(int pin) {
  return analogToDegrees(readPin(pin))
}

double readVoltage(int pin) {
  return analogToVoltage(readPin(pin))
}

double readPressure(int pin) {
  return analogToPressure(readPin(pin))
}

double readAcceleration(int pin) {
  return analogToAcceleration(readPin(pin))
}
```

Figure 8: Arduino Code

B.3 CAD Model of the Human Knee

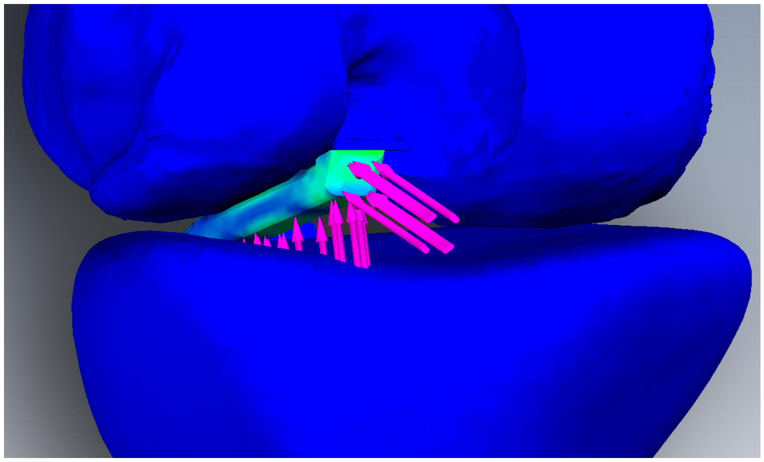

Figure 9: ACL Soild Model under FEA

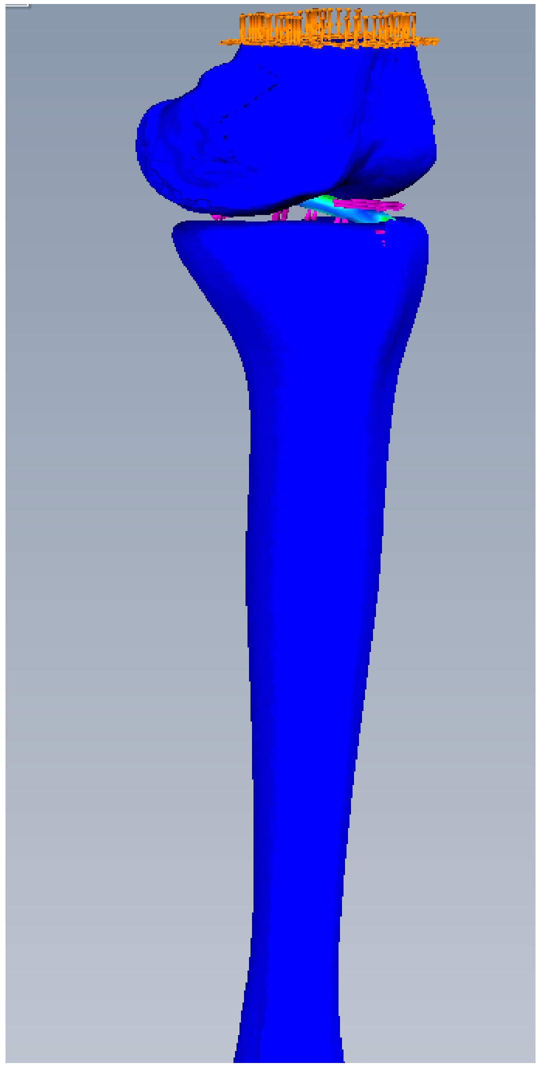

Figure 10: Entire Model used of FEA

B.4 Preliminary Circuit Diagrams

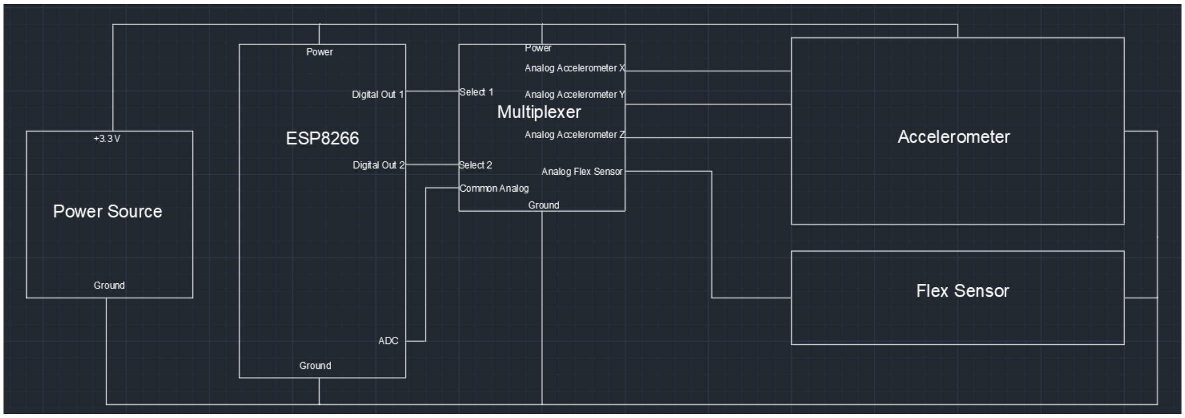

Figure 11: Circuit for knee sub-system

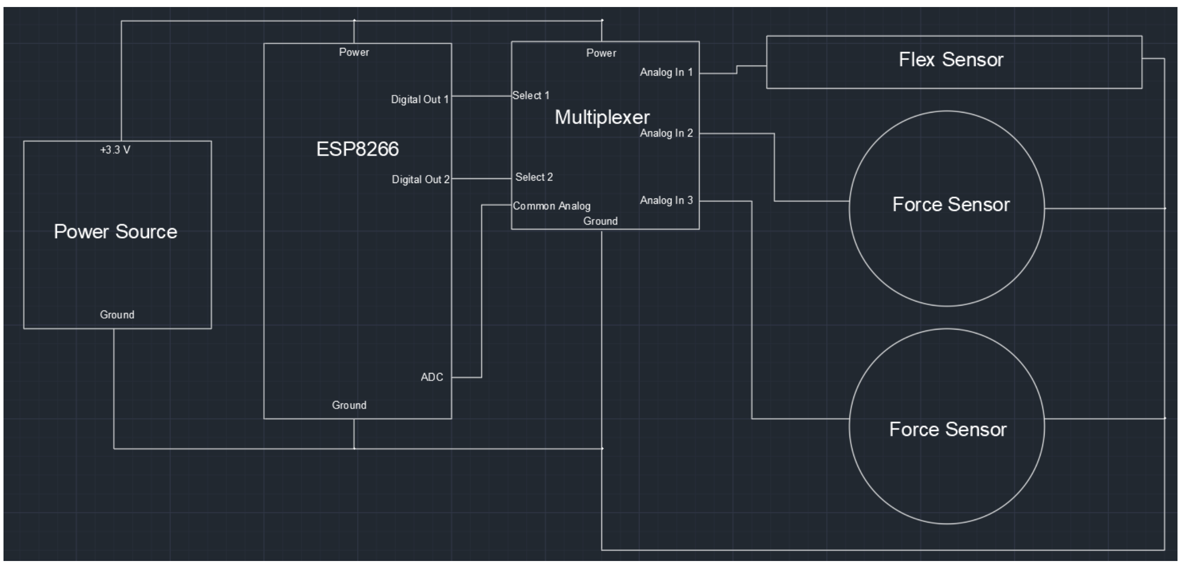

Figure 12: Circuit for shoe sub-system

Appendix C Large Drawings

C.1 Log Book Pages for Alternative Designs

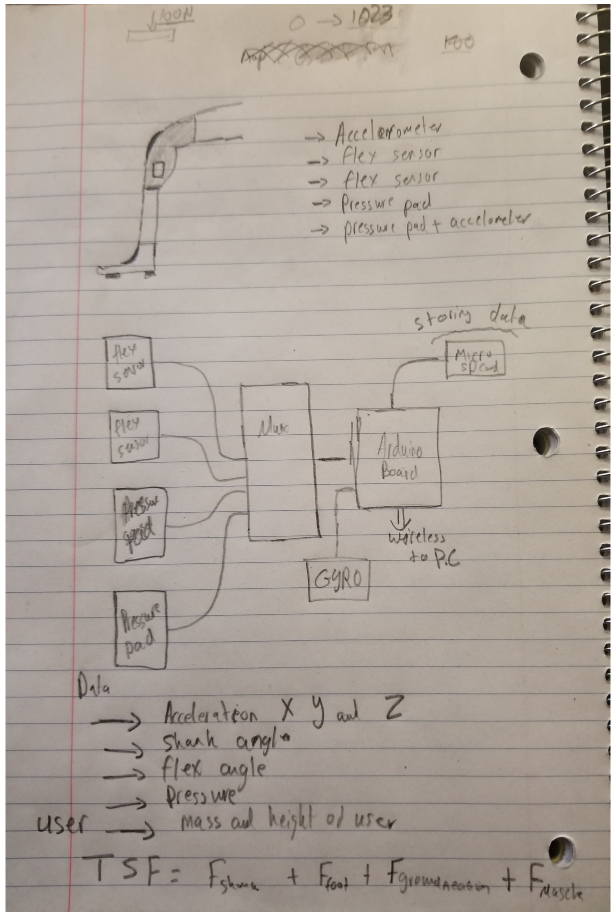

Figure 13: Log book entry for the alternative design "Cloth Brace". Designed by Bilal Ayyache

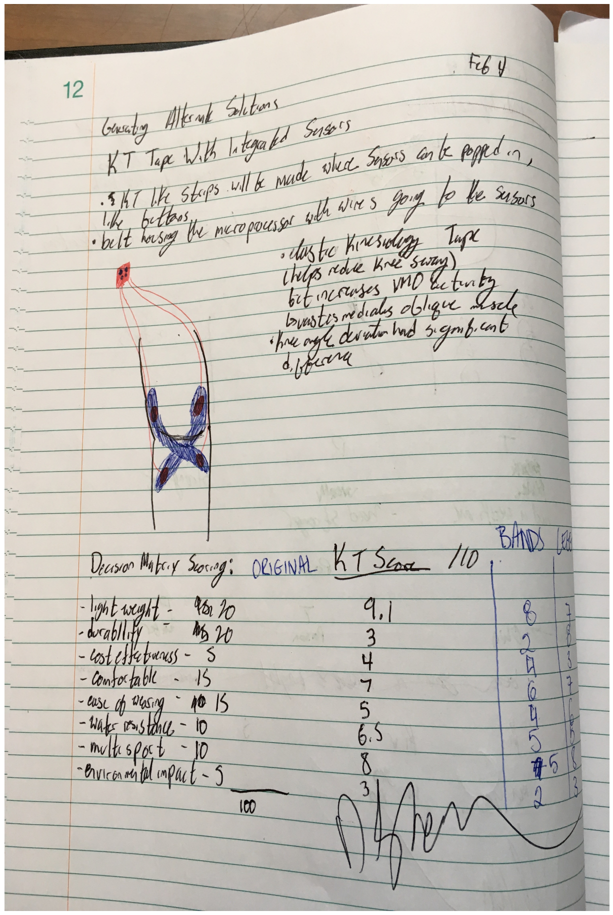

Figure 14: Log book entry for the alternative design "KT Tape with Sensors". Designed by Daniel Sherman

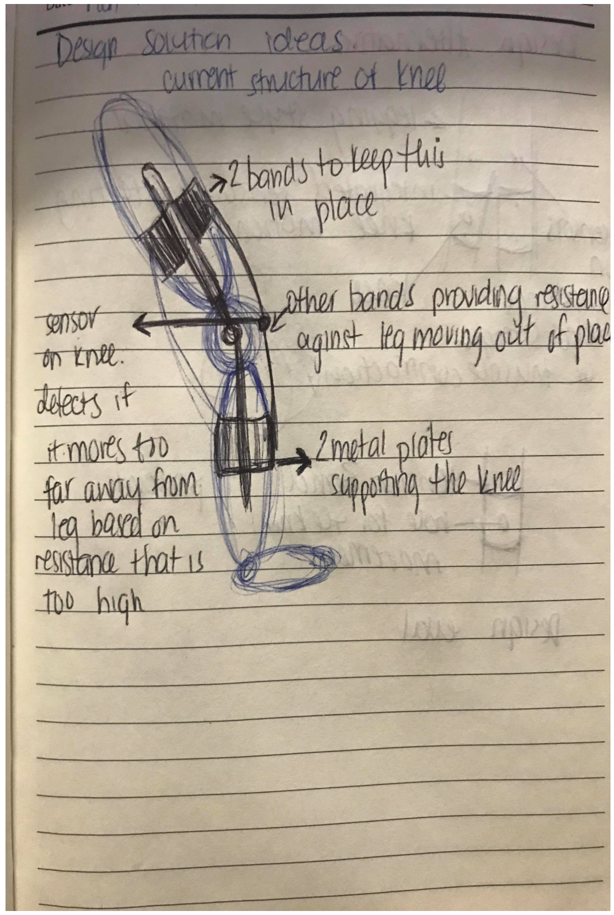

Figure 15: Log book entry for the alternative design "Tension Band". Designed by Monica Malek

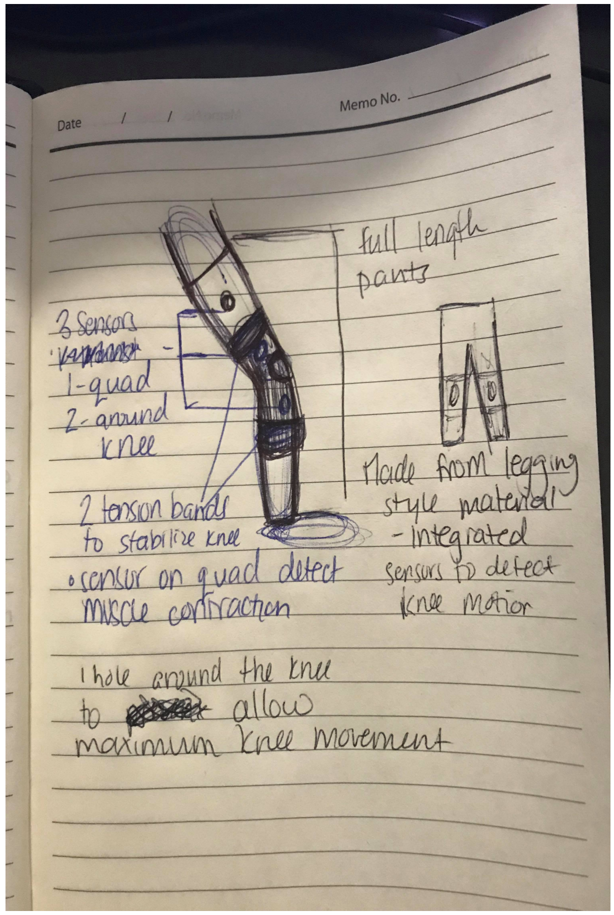

Figure 16: Log book entry for the alternative design "Supportive Leggings". Designed by Monica Malek

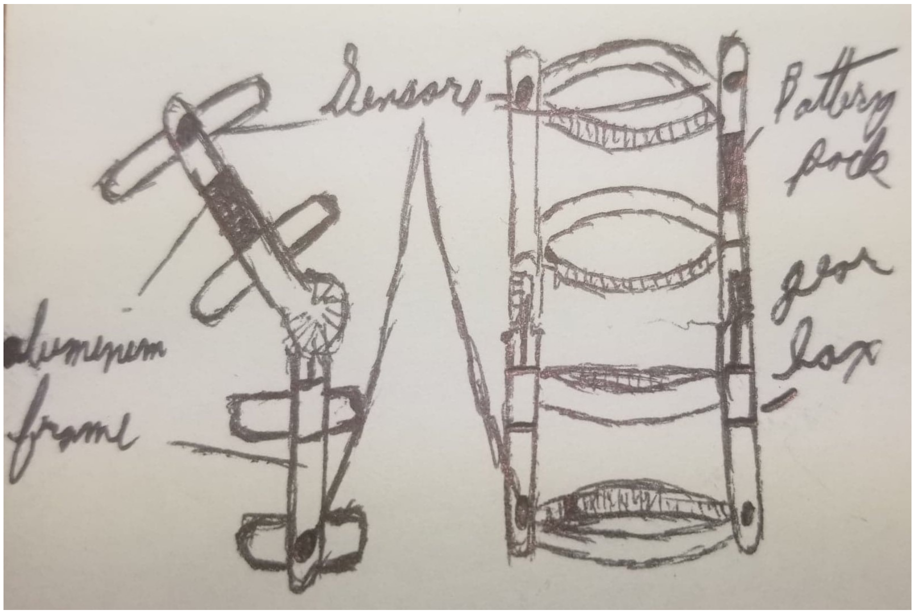

Figure 17: Log book entry for the alternative design "Metal Frame Gear Lock". Designed by Devin Catt

Appendix D Additional Information

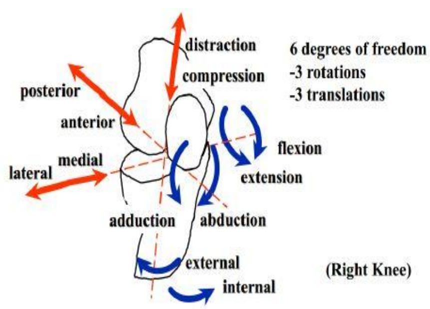

Figure 18: Movement Degrees of Freedom for the Human Knee

References

[1] R.G. Marx and G. Myklebust *The ACL Solution: Prevention and Recovery for Sports' Most Devastating Knee Injury* Demos Health, 2012.

[2] S. Brandon *Brace Yourself: Reducing Medial Knee Loading for Treatment of Osteoarthritis* Queen's University, 2015.

[3] J.W. Mitchell, M.R. Mahfouz, and N. Battaglia *Accurate Length Measurements of ACL and PCL of a Healthy Patient During Weight Bearing Deep Knee Band* University of Tennessee, Knoxville, 2012.

[4] R.F. Escamilla et al. *Anterior Cruciate Ligament Strain and Tensile Forces for Weight-Bearing and Non-Weight-Bearing Exercises: A Guide to Exercise Selection* Journal of Orthopaedic and Sports Physical Therapy, 42(3), 2012.

[5] K. Oberhofer et al. *The Influence of Muscle-Tendon Forces on ACL Loading During Jump Landing: a Systematic Review* Muscle, Ligaments and Tendons Journal, 7(1), 2017.

[6] Y. Shimokochi *Mechanisms of Noncontact Anterior Cruciate Ligament Injury* Journal of Athletic Training, 43(4), 2008.

[7] D.R. Clifton *The First Decode of Web-Based Sports Injury Surveillance* Journal of Athletic Training, 53(11), 2018.

[8] R.C. Mather III et al. *Societal and Economic Impact of Anterior Cruciate Ligament Tears* Journal of Bone Surgery American, 95(19), 2013.

[9] T. Nessler *ACL Injury Prevention: What does Research Tell Us?* Current Reviews of Musculoskeletal Medicine

[10] CAMBIVO *Cambivo Knee Support Brace, Knee Compression Sleeve for Running, Arthritis, ACL, Meniscus Tear, Sports, Joint Pain Relief and Injury Recovery (FDA Approved) - 2 Pack* Amazon.com Inc., 2017.

[11] Brand-Z *BRACEIT K.2 COMFORTLINE KNEE BRACE (SIZE:S16 (THIGH=23-24.5"//CALF=15-16.5") ORANGE)* Amazon.com Inc., 2016.

[12] Arespark *Knee Brace Support, Arespark Breathable Knee Stabilizer and Elastic Compression for Knee Stability and Recovery Aid, Neoprene Open Patellar Dual Stabilizers with Adjustable Veclro - Best for Strains Sprains Pain Relief Rehab Arthritis ACL Meniscus Running Basketball Workout - Black* Amazon.com Inc., 2017.

[13] DISUPPO *DISUPPO Hinged Knee Brace Support Women Men, Adjustable Open Patella Stabilizer Sports Trauma, Sprains, Arthritis, ACL, Meniscus Tears, Ligament Injuries (Black, 3X-Large)* Amazon.com Inc. 2019.

[14] R. Moyer, T. Birmingham, C. Dombroski, R. Walsh, J.R. Giffin *Combined Versus Indivicual Effects of Valgus Knee Brace and Lateral Wedge Foot Orthodic During Stair Use in Patients with Knee Osteoarthritis* Gait & Posture, 54, 2017.

[15] S. Lehane, S. O'Gormann, K. Splink, I. Agoulis *Effects of Kinesiology Tape (KT) on VMO Activation and on Proprioception at the Knee in Adults with Anterior Knee Pain* Gait & Posture, 57, 2017.

[16] KT Health, LLC. *What is KT Tape?* 2008.

[17] Kusmirek et al. *US D745, 176 S* 2015.

[18] S. Hosp, G. Bottoni, D. Heinrich, P. Kofler, M. Hasler, W. Nachbauer *A Pilot Study of the Effect of Kinesiology Tape on Knee Proprioception after Physical Activity in Healthy Women* Journal of Science and Medecine in Sport, 18, 2015.

[19] Clinic Supplies Canada *Bauerfeind MOS-Genu® Knee Brace* Clinic Supplies Canada, 2019.

[20] J. Twomey *Know Your Regulations Before You Design Medical Electronics* Informa USA, 2019

[21] Government of Canada *Applications for Medical Device Investigational Testing Authorizations Guidance Document* Government of Canada, 2018

[22] *Medical Device Classification* U.S. Food and Drug Administration, 2018

[23] *Material Guide How sustainable is Nylon* Good on You, 22 June 2016