Design 3 Design Proposal

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Executive Summary

The trauma of tearing an 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 slowed down. 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 are also heavy and 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's performance, allowing them to remove players from dangerous play. Then, training staff will 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 positioning of the ALC originates at the tibial plateau and inserts onto the lateral femoral condyle 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 weight them appropriately in order to get an accurate model of the forces the ACL is experiencing.

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 preventing 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 athlete can play the game without having to worry about their ACL unless if they are put at risk, which then the device will protect their vital ligament while also warning the training staff.

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1.1 Problem Description

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].

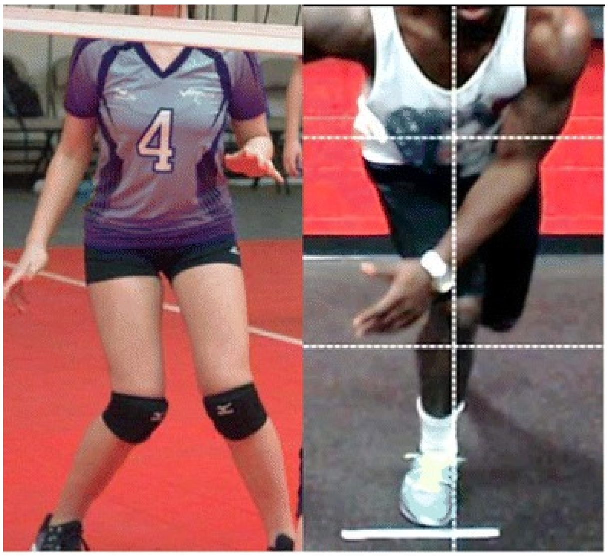

Figure 1: Landing with knee extended and adduction moment causing stress to the ACL [9]

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.

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. 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. Exercise modes such as strength training, neuromuscular training, and plyometric can help in addressing these faulty movements' patterns [8]. 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 2: 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].

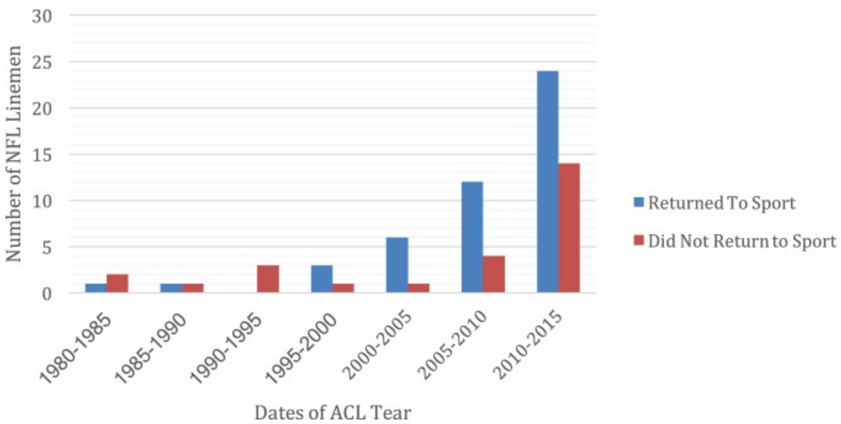

Figure 3: ACL tears in NFL Linemen since 1980. ACL, anterior cruciate ligament; NFL, National Football League. [9]

The Anterior cruciate ligament injury is definitely a very common knee injury especially among young and active individuals, however the societal impacts in terms of social and economical perspective plays a big part in understanding how important such problem is [8]. The MultiCenter Orthopaedic Outcomes Network released a report in 2013 which claims that a mean lifetime cost to society 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 and not every athlete can afford such costs [8]. 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 leads to economic problem in the community. The graph below shows how the cost of rehab increases as instability increase [8].

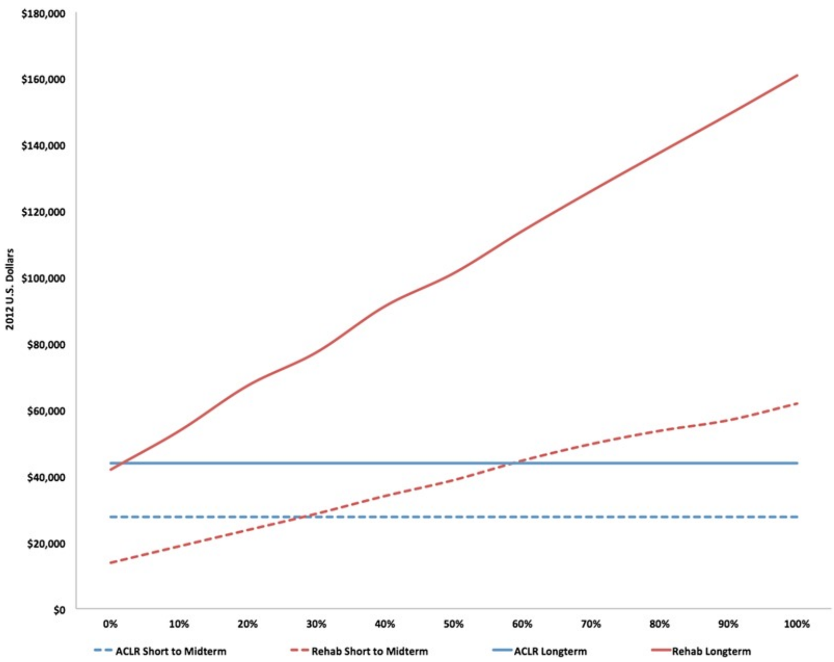

Figure 4: Sensitivity of total cost to the rate of instability after rehabilitation. [8]

1.2 Literature Review

There are many aspects to understand about the problem at hand before even attempting to design a solution to the problem. As with all sports injuries, there are important biomechanics, anatomy, pathology of injury, the impact to the person who was injured, and the impact to the health care industry.

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].
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 in creating a brace.

1.3 Scope and Objective of Project

To create a device that can detect when an athlete is performing a movement that is placing their knee ligaments at risk, when such a movement is detected a coach or training staff will be notified and the device will mitigate potential damage to the knee by restricting movement in the joint.
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 be detected but this device will have no way of further protecting the player.

1.4 Project Constraints

1. The design solution must not restrict normal motion of knee during play.

   An athlete will not want to wear the athletic device if it restricts the gate of a player. As a result, the design solution must be non invasive for play.

2. The design solution must be as effective as other wearable assistive athletic device for knees.

   If the design solution created is not as effective as other solutions available to the general public, there will be no interest in the design solution that will be implemented.

3. The design solution must be able to detect dangerous movements of the knee in an appropriate amount of time.

The design goal is to create a wearable athletic device that is able to detect movements that have potential to tear the ACL, so if the proposed design solution cannot do so, it is not a valid design solution.

4. The design solution must be able to wirelessly communicate with an observer that the athlete has done a movement that potentially could injure their ACL.

   It is possible for an athlete to ignore pains they have while playing a game, as they feel a duty to perform and support their team. As a result of this, they may choose to stay and play, and as a result, hurt their ACL more than they would have if they had just left play when they started to feel a little bit of pain. For an observer (such as a coach or trainer) to be notified when a player may be in potential danger of hurting themselves, they can use that information to call a player off the field, to protect them from hurting themselves and be able to play in the future instead of needing to heal.

5. The design solution must be hygienic.

   An athlete will not want to wear a device that is unhygienic and smells fowl due to accumulated sweat. Therefore, the design solution must have some method of cleaning, be it in a washing machine or otherwise.

6. The design solution must be compatible to be worn with any equipment necessary for the intended sports.

   The design solution must fit with any protective equipment required for safety when playing sports.

1.5 Design Criteria

1. The design solution must be as lightweight as possible.

   To ensure comfort when playing, the design solution should not be cumbersome to wear.

2. The design solution should be durable.

   It is financially cumbersome for an athlete to purchase many protective devices, so the proposed design solution should last as long as possible.

3. The design solution should minimize end cost to the user.

4. The design solution should be made out of biocompatible materials and does not cause any lesions of the skin of the athlete.

5. The design solution should be easy to remove and put on.

6. The design solution should be as water resistant as possible.

   Electrical components tend to malfunction when wet or exposed to water. Therefore, to protect them from an athlete's sweat, the design solution should be water resistant.

7. The design solution should be applicable to as many sports as possible.

   To reach as wide as a market as possible, the design solution should be useful and complementary to as many sports as possible.

8. The design solution should minimize the detrimental effect on the environment A life cycle analysis will be done and the effect that production has on the environment will be weighted for the chosen solution.

Plan for Information Gathering and Approach to Design

The design approach will take on an interdisciplinary perspective to the problem, involving strong communication skills between all group members for a seamless integration of all disciplines. Below is an outline of the proposed approach to solve the problem along with all the required information and tools necessary.

1.6 Proposed Approach

The current problem addressed is based on preventing the severity and amount of injuries athletes sustain during sports, specifically around the anterior cruciate ligament (ACL). The proposed solution is seen as a more effective alternative to the current simple knee brace. With a defined problem as in the first step, the next milestone to accomplish is to collect research about simple knee braces, it's current effectiveness and current design flaws - potential improvements - along with more information on precisely what movements most frequently cause ACL injuries in athletes. With extensive research conducted, the next important task is to collaborate with one another and analyze ideas from various research papers and how they can be effectively implemented in the teams solution.

It is also important to factor in other important design factors, such as the list of criteria and constraints previously developed by the team. The next step is to then develop several different prototype models through computer aided design software and see what implementations and desired features are possible. Creating multiple models allows for a better comparison of the potential choices as specific constraints and criteria can be more directly judged between one another. Once one has been chosen, improvements to the model can be made and initial visual representation of the idea will come to life. There will then be the recurring cycle of analyzing potential improvements, updating the proposed model, and reevaluating it once again.

1.7 Required Information and Tools

To ensure a high quality design various tools will be necessary in modelling and creating an optimal design. Various specifications and guidelines must follow federal and provincial safety regulations

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

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

The overall design of an external knee joint brace must follow the Food and Drug Administration (FDA) Class 1 medical device regulations as well as be approved by the ethics board when testing the knee brace on athletes for optimal shape and size. Extensive knowledge of human kinetics and motions surrounding knee moments and angles will be necessary to understand dangerous knee positions resulting in a torn/damaged ACL. This will be obtained through journal articles, existing support devices, and conversations with academic and industry leaders in the field.

1.8 Required Information from the Client

For the success of this project, it must follow the constrains and criteria set by the primary consumer, which in this case are high level athletes. This design is tailored to those of high athletic performance and must not restrict or inhibit any movements that can inhibit performance. This device is to be created as a protective measure to allow athletes with a safety device the athlete and coach will find very useful. Primary information about athletes constraints and criteria must be obtained along with measurements and data of athletes range of movements through gait analysis. By understanding how athletes move this will allow for the creation of a device specially tailored to high performance athletes.

2 Schedule and Fee Estimate for Design

2.1 Define Problem

Table 1: 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 ($)

2.2 Gather Information

Table 2: 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 ($)

2.3 Concept Generation

Table 3: 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 ($)
Decomposition	Creating a system to interface important components	20 (H)	1,500 ($)

2.4 Evaluation of Concepts

Table 4: 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 ($)

2.5 Configuration Design

Table 5: Configuration Design

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

2.6 Parametric Design

Table 6: Parametric Design

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

2.7 Detailed Design

Table 7: 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 our 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 dollars 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.

2.8 GANTT Chart

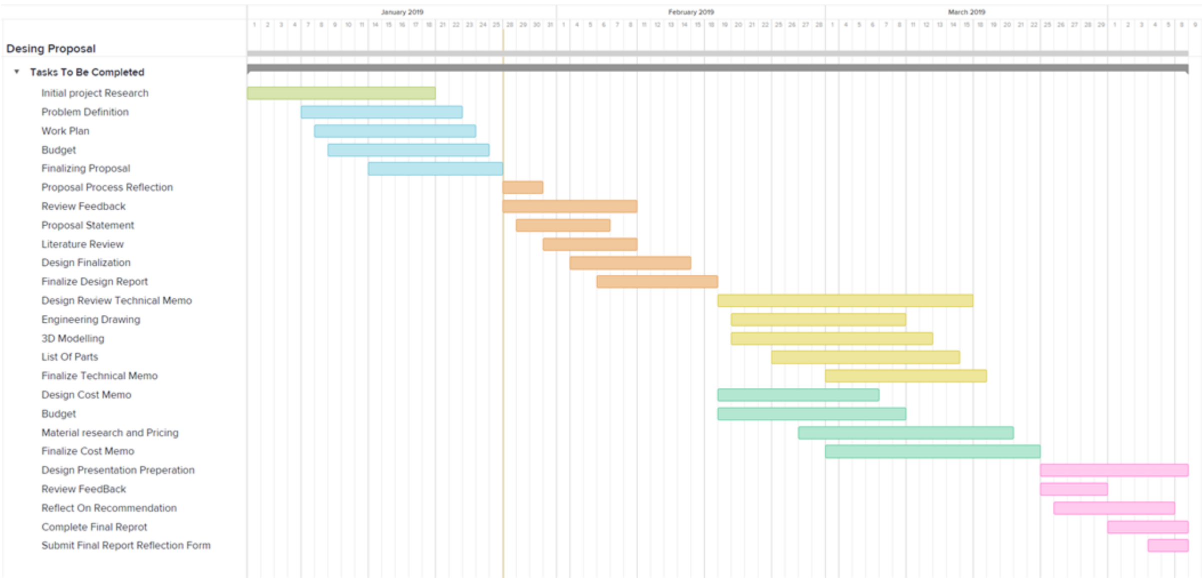

Figure 5: Project Gannt Chart

Next Step

The next steps involved with this project will be narrowing the project's scope down to identify which specific part of the problem can be solved with a new technology. This will also ensure that the problem will have attainable goals. Once the variable of interest is clearly identified, brainstorming of multiple approaches to solve the problem will begin. Each solution will provide a different approach to the problem which will then be narrowed down based on the constraints and criteria. Any solution that does not meet all constraints will immediately be changed or disregarded. Once the criteria are weighted appropriately, an educated decision using a decision matrix can be made. This brainstorming solution phase will occur within the following days for the progression of the project problem toward a solution. Further steps will include modelling with digital software. This will allow for any major inconsistencies or flaws in the design to be visible, and to be resolved in a timely manner. This solution will continue to go through revisions, modelling, testing, and re-visioning, until the final solution is acceptable and meets all criteria the best it can.

Appendix

References

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