System Design of a Biofeedback Active Sensor System (BASS) to Mitigate the Probability of ACL Injuries

Technical Report

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Executive Summary

Abstract - The anterior cruciate ligament is a main stabilizer between the tibia and femur. Tearing it causes loss of mobility and need for surgery. There is a 13% chance for a National Collegiate Athletic Association athlete to tear their anterior cruciate ligament each year. The recovery process can take to 6 – 9 months, and only forty – four percent (44%) of those who complete rehabilitation return to the same level of athletic participation. Seventy percent (70%) of anterior cruciate ligament injuries occur from non-contact mechanisms. These decompose into 5 types of failure mechanisms. An analysis was performed on flexion/extension (37%) failure mechanisms. Examinations of the equations of motion of the knee shows the ground reaction and muscle force have the highest contributing weight when compared to the four (4) main contributing factors. The proposed solution includes a biofeedback sleeve that stores inputs and converts it to a tibial shear force approximator. From there, the sleeve warns the athlete if they are approaching a dangerous tibial shear force level. The proposed plan for preventing anterior cruciate ligament will produce $593,400,000, with $483,341 startup costs. The breakeven point occurs at 3 months, with a NPV of $15,968,608 and a return on investment of 18,284.59% after 5 years.

Index Terms – Anterior cruciate ligament, Biofeedback, Prevention, Tear

1 Concept Definition

The knee contains five major sets of components, bones, muscles, cartilage, tendons, and ligaments. The bones include the femur (1), patella (2), tibia (3), and fibia (4). The femur is the thigh bone. The fibia and tibia make up the shank, (the lower part of the leg) and the patella is also known as the knee cap. The next section are the muscles, these include the quadriceps (8),
hamstrings (9), and gastrocnemius (calf) (10). After that, there is the meniscus (11) which acts as a cushion to absorb shock in dynamic movement. The tendons in the knee system are the hamstring tendons (7) (on the back of the knee), and patellar (6) and quadriceps tendons (5) that connect the quadriceps to the quadriceps to the patella to the tibia. Finally, there are the ligaments, posterior cruciate ligament (PCL) (12), medial collateral ligament (MCL) (13), lateral collateral ligament (LCL) (14), and anterior cruciate ligament (ACL) (15). The Anterior Cruciate Ligament (ACL) is the primary stabilizing knee ligament preventing the anterior translation of the tibia. [1]

![Figure I Knee](image)

ACL tears can be broken down into two categories, contact, and noncontact. These make up 30 % and 70 % of ACL injuries respectively. Noncontact injuries can be broken down even further into three categories, flexion/extension, internal/external rotation, and abduction/adduction, with two sub categories, flexion/extension with rotation and abduction/adduction with rotation. [2] For the purpose of this paper, flexion/extension injuries
will be the focus at 37% of noncontact injuries which is 77,700 ACL injuries per year out of the total 300,000 ACL injuries per year. [1]

The ACL tears at 2100 N. The tears associated with flexion injuries are due to a phenomena known as Tibial Shear Force (TSF). When the leg is fully extended, there is a high amount of strain on the ACL from the tibia. The PCL, on the other hand, is relaxed. When the knee is flexed, the properties of the ACL and PCL switch. Once, the ACL tears, an event known as anterior tibial translation occurs. When the ACL tears, the tibia is released and moves forward.

![Figure II Sagittal View of the Knee](image1) ![Figure III Anterior Tibial Translation](image2)

1.1 Gap Analysis

There are ACL injury repression programs in place like the Santa Monica Sports Medicine Research Foundation’s Prevent Injury and Enhance Performance (PEP) program. These exercise programs have been proven effective [3]. They focus on building muscle memory of good form and developing the muscles that support knee ligaments in an attempt to lower the probability of injury. The limitations on these programs occur in their implementation however. Only about 30% of coaches implement these programs correctly. [4][5][6]
That could be from limitation on how well a coach or trainer can observe the prevention exercises as well. The head weight training and fitness coach at George Mason University, John C Delgado, highlighted it was hard to observe an entire team and therefore it was probable that some participants form was not corrected. The method of observing an athlete’s form was based on theories of kinesiology and experience of being a coach. These methods are subjective to what he knows as good form and also to what he can see when observing athletes. There was not any quantitative method to determine good form and the resultant ACL strain.

1.2 Problem Statement

There are 300K anterior cruciate ligament tears every year, of which, 78K are flexion / extension related and 19 K are abduction / adduction caused. There is no system that currently quantifies the strain being applied to the anterior cruciate ligament. In addition to the above, there is no system that actively mitigates the strain placed on the anterior cruciate ligament due to dynamic sports.

1.3 Stakeholder Analysis and Tensions

The primary stakeholders comprise of seven groups: the athletic team, coaching staff, rehabilitation and reconstruction team, athletic gear manufacturers, family, insurance, and sponsors. The athletic team is comprised of the player with an ACL tear and their teammates. Before the tear, the team works as a unit to win competitions, playing off of each other’s strengths. After the tear, the team loses some of their chemistry due to missing a player. The team also has a fear instilled in the rest of the members about tearing their ACL. This may cause them to be more hesitant in a game. The coaching staff consists of a coach, trainer and team physician. This group of individuals acts as a unit to protect the athletic team from injury and increase the overall chance of winning a competition. The rehabilitation and reconstruction team
is made up of surgeons and physical therapists. Their job is to help an athlete return to sports in a smooth and timely manner. The to-be system may reduce the need for them. The athletic manufacturing companies produce many different types of sports equipment, from support gear, to monitoring tools, to motion analysis equipment. The-to be system will create a new market of biofeedback. This will create a new revenue stream for the companies. This category includes the parents, siblings, and anyone else who greatly cares about the well-being of the athlete. An ACL tear may take time, money and effort from the family to support the athlete during the recovery period. Since the to-be system will reduce the probability of a tear, it correlates with the goals of the family. These insurance companies will pay for the ACL reconstruction surgery. Their main objective is to make profit. The to be system will be beneficial to them because it will cut down on the number of ACL injuries per year and therefore it will reduces their average spending on ACL surgeries. This category contains individuals or companies that are monetarily invested in an athlete. In this relationship the sponsor gives the athlete or organization the athlete plays for, money, in return the athlete promotes the person or company through wearing their brand. When the team wins, it has a positive effect on the sponsor, when they lose or are injured, a negative one. The to-be system will decrease the number of negative effects on a sponsor due to injury.

The main tensions that appear in the to-be system are on the orthopedic surgeons and physical therapists. The to-be system will aim to decrease the need for these groups of people due to fewer injuries.
2. Concept of Operations

The solution is a wearable device that uses a Biofeedback Active Sensor System (BASS) to actively quantify the ACL strain during flexion modes, and then warning the user when they reach a high reading. In this way, a user is given knowledge of their bad form and can actively change their form to mitigate their probability of tear.
2.1 System Components

To actively monitor all the contributing factors to TSF, there are sensors for measuring all the factors, knee flexion, shank angle, acceleration of the shank, acceleration of the foot, and the earth's ground reaction forces. The system will route the sensor readings to a microprocessor that will actively run the data against a TSF algorithm. When the sensor reading reach above a threshold, then the processor will then cause a beeper and light to go off which will actively alert the user to their bad form.
2.2 Design Alternatives

The goal of the BASS system is to identify and warn the user of high TSF strain on the knee system dynamically. The sensitivity analysis done on the TSF equation gave the two largest contributing factors for TSF being ground reaction force in the vertical direction and flexion angle. Using a value hierarchy, utility can be broken down into three main sections, technology readiness level (TRL), usability, and performance. Usability is further broken down into length, width, weight, and durability. Performance is broken down into maintainability and accuracy.

![Value Hierarchy Diagram]

3. Method of Analysis

3.1 Reference Frame

The physics of the knee flexion tear need to be understood for a system to be put into place to mitigate it. The knee flexion tear is caused by Tibial Shear Force (TSF). TSF needs to be able to be quantified. To do so, all relative forces to the knee need to have a relative reference frame. This is done by using the shank angle, or the angle of the tibial head to the earth's X-axis. This reference frame is important because the x-axis of this reference frame is line of action of the ACL ligament. Therefore any forces on the shank reference frame in the X can be quantified as approximate ACL strain. [7]
3.2 Angles

In the model uses flexion angle b. The quadriceps muscle connects to the patella (knee bone) by a tendon which then connects to the tibia via a tendon. [8] The relative force on the tibia is therefore relative to the position of the patella. The patella position changes due to knee flexion. Therefore the relative contribution to TSF from the quadriceps is due to flexion angle.

3.3 Equations

Tibial Shear Force results from inputs from the force supplied by the momentum of the shank, the momentum of the foot, the earth’s ground reaction forces, and the relative contributions of the Gastrocnemius muscle, the quadriceps muscle, and the hamstring muscle.

\[ TSF = F_{\text{Shank}} + F_{\text{Foot}} + F_{\text{Ground Reaction}} + F_{\text{Muscles}} \]  \hspace{1cm} (1)

\[ TSF = m_s[a_{sx}\cos(\theta_s) - (a_{sy} + g)\sin(\theta_s)] + m_f[a_{fx}\cos(\theta_s) - (a_{fy} + g)\sin(\theta_s)] - F_{grx}\cos(\theta_s) + F_{gry}\cos(\theta_s) - \Sigma F_{\text{GastroX}} - \Sigma F_{\text{QuadX}} - \Sigma F_{\text{HamX}} \]  \hspace{1cm} (2)

The muscle force contributions to TSF have to be understood by the flexion angle. Flexion angle is the relative angle between the femur and the tibia.
\[ \Sigma F_{\text{Quad}X} = F_{\text{Quad}} \sin((-0.238)(180 - \theta_{\text{flexB}})) + 22.2 \] (3)

\[ F_{\text{Ham}X} = F_{\text{Ham}} \cos(90 - \theta_{\text{flexB}}) \] (4)

The gastrocnemius muscle (calf) contributes to TSF by connecting to the lower part of the femur. In this way it also creates a TSF force in the opposite direction of the quadriceps. It mitigates TSF but not in the magnitude of the hamstring muscles. \( d \) in this model is the distance between the center of the knee to the connection point of the gastrocnemius to the femur, which is about 3 centimeters.

\[ F_{\text{gastro}X} = F_{\text{gastro}} \sin(\sin^{-1}((d \sin(\theta_{\text{flexB}}))/(d^2 + \text{tib}_{\text{length}}^2 - 2 \times d \times \text{tib}_{\text{length}} \cos(\theta_{\text{flexB}}))^2)) \] (5)

Ground Reaction Force contribution comes from the body’s dissipation of the earth's forces due to Newton's laws. These forces have not been theoretically measured for this problem due to the complexity of the system. The Ground reaction forces would counteract the body's center of mass and momentum which is based on the athletes predetermined neuromuscular response to their landing goals. It can be thought of as a smart spring that an athlete's form would have to be analyzed to derive.

3.2 Results

The results of the muscle force contributions, varied by flexion angle, show that at approximately 160 degrees, the quadriceps muscle force dominates the hamstring and gastrocnemius muscle in the TSF reference and therefore contributes more overall force to TSF. This verifies the concept of “Quad-Dominance” which refers to the tendency to absorb ground reaction forces with flexion angles lower than 20 degrees. [9] The last analysis shows the contributions of ground reaction forces to TSF by varying the magnitude of the ground reaction forces by body weights. The X axis ground reaction force actually dissipates overall TSF while the Y axis forces contribute linearly to a maximum of 700 N.
3.3 Business Case

There is a potential market size of just under $600 M. This includes a market of ACLI sufferers (300,000 per year), NCAA athletes (420,000 per year), and professional athletes (18,000 per year). With a selling price of $300 per sleeve, this equates to a total market value of $593 M.

Table I Business Scenarios

<table>
<thead>
<tr>
<th>Scenarios</th>
<th>Expected</th>
<th>Pessimistic</th>
<th>Optimistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market Share</td>
<td>25%</td>
<td>10%</td>
<td>50%</td>
</tr>
<tr>
<td>Penetration Rate</td>
<td>5%</td>
<td>2%</td>
<td>10%</td>
</tr>
<tr>
<td>Market Share Value</td>
<td>$148,350,000</td>
<td>$59,340,000</td>
<td>$296,700,000</td>
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</table>

The initial costs consist of startup and investment, $92 K and $391 K respectively.
<table>
<thead>
<tr>
<th>Costs</th>
<th>Amount per unit</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market Research (non-recurring cost)</td>
<td>3331</td>
<td>20 test product * cost of producing 1 unit</td>
</tr>
<tr>
<td>Overhead</td>
<td>63,200</td>
<td>Rent, Utilities, Health Ins</td>
</tr>
<tr>
<td>Rent + Utilities</td>
<td>54,000</td>
<td>$30/square feet* 1800 square feet</td>
</tr>
<tr>
<td>Utilities</td>
<td>6000</td>
<td>500/month*12 months</td>
</tr>
<tr>
<td>Health Insurance</td>
<td>3200</td>
<td>4 employees * cost of insurance/year</td>
</tr>
<tr>
<td>Marketing</td>
<td>20,000</td>
<td>visual design, programming, content</td>
</tr>
<tr>
<td>Website Development (non-recurring cost)</td>
<td>5640</td>
<td>support, client training</td>
</tr>
<tr>
<td>Signing for webhost</td>
<td>59.4</td>
<td>$4.95/month*12 month</td>
</tr>
<tr>
<td><strong>Total Startup Cost</strong></td>
<td><strong>92,230</strong></td>
<td></td>
</tr>
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</table>
Table III Operational Costs

<table>
<thead>
<tr>
<th>Operational Costs</th>
<th>Amount</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Component Acquisition Costs</td>
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<td></td>
</tr>
<tr>
<td>Potentiometer X2</td>
<td>0.34</td>
<td>Measures threshold</td>
</tr>
<tr>
<td>Knee Sleeves X2</td>
<td>4</td>
<td>Wearable component</td>
</tr>
<tr>
<td>Pressure Sensors X16</td>
<td>127.2</td>
<td>Measures Ground Reaction Force</td>
</tr>
<tr>
<td>Speakers X2</td>
<td>0.94</td>
<td>Beeps When 1900 N is reached</td>
</tr>
<tr>
<td>Accelerometers X2</td>
<td>1.02</td>
<td>Measures Acceleration</td>
</tr>
<tr>
<td>Processor</td>
<td>19.95</td>
<td>Process input and make calculations</td>
</tr>
<tr>
<td>Flexion Sensor X4</td>
<td>51.8</td>
<td>Measures Knee Flexion</td>
</tr>
<tr>
<td>Parts Cost</td>
<td>204</td>
<td></td>
</tr>
<tr>
<td>Labor</td>
<td>20</td>
<td>hourly rate</td>
</tr>
<tr>
<td>Total Variable Costs</td>
<td>307851.2</td>
<td>Production For 4 Employees*cost of components + labor cost * 4</td>
</tr>
<tr>
<td>Fixed costs</td>
<td>83,259</td>
<td></td>
</tr>
<tr>
<td>Overhead</td>
<td>63,200</td>
<td>Rent, Utilities, etc.</td>
</tr>
<tr>
<td>Marketing</td>
<td>20,000</td>
<td></td>
</tr>
<tr>
<td>Webhost</td>
<td>59.4</td>
<td></td>
</tr>
<tr>
<td>Total Operational Costs</td>
<td>391,111</td>
<td></td>
</tr>
</tbody>
</table>
4 Utility Analysis and Recommendations

A utility vs cost analysis was performed on each set of components using the value hierarchy to rate their utility. The most usable and cost effective alternative was selected for each necessary component.

Table IV System Components

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unit</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion &amp; Shank</td>
<td>Flex Sensor</td>
<td>$12.95</td>
</tr>
<tr>
<td>Muscle Activation</td>
<td>MyoWare Muscle Sensor</td>
<td>$37.95</td>
</tr>
<tr>
<td>Ground Reaction Force</td>
<td>Force Sensor</td>
<td>$8.50</td>
</tr>
<tr>
<td>Acceleration</td>
<td>3-axis Accelerometer</td>
<td>$7.95</td>
</tr>
<tr>
<td>Processor</td>
<td>Wearable Microcontroller Board</td>
<td>$19.95</td>
</tr>
</tbody>
</table>

Since the proposed system and analysis focused on one mechanism of injury, it is suggested that a thorough analysis on the rotation and abduction injury be made. In this way the overall causes of ACL injury can be understood and mitigated which would more fully contribute to decreasing the number of tears.
5 Executive Summary References


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Section I: Concept Definition

1.0 Context

1.1 The Epidemic
Every year hundreds of thousands athletes compete against each other in dynamic sports. And every year 300,000 anterior cruciate ligaments (ACL) are torn. [1] This means that 13% of NCAA athletes tear their ACLs each year [2]. However, the statistics are worse if you are female. Women athletes are 3 times more likely to tear their ACLs than their male counterparts. [3] With such a large number of one specific type of injury, it is odd that nothing is being done to reduce these statistics.

1.2 The Costs
The ACL tears at 2100 N [4]. When a tear happens, there is a large financial burden placed on the individual. Each tear costs the medical health care system around $60 K per ACL and $2 K per patient. [5] This cost includes, reconstruction, surgeons, anesthetics, equipment and reconstructive consumables (such as the screws that go into the leg). Not to mention there is usually a rehabilitation cost too, this covers the physical therapist and rehab equipment cost. Not only does an ACL tear have a large cost burden monetarily speaking, it also has a large cost time wise and to an individual’s quality of life. ACL tears take 6-9 months to recover from surgery. [6] However, some recoveries can take upwards of 12 months depending on the type of ACL graft. As for quality of life, only 44% of athletes return to their pre surgery level of athletic performance. This means that 56% of athletes either do not return to play sports, or if they do, it is at a much lower level. [7]
Figure I Total Cost

Total Cost

- Facilities: 41%
- Doctors: 28%
- Equipment: 17%
- Drugs: 10%
- Consumables: 4%

Figure II Return to Sports

Return to Sports

- Return to Previous Level: 43%
- Not Return for Social Reasons: 14%
- Not Return for Fear: 13%
- Not Return For Pain: 30%
- Not Return for Other Reasons: 13%
1.3 The Knee Joint System

The knee is a dynamic system made up of five subcategories that when combined, form a joint system. The five categories are the bones, ligaments, muscles, cartilage, and tendons. There are four bones involved in this system, femur (1), patella (2), tibia (3), and fibia (4). The femur is the thigh bone, this supports the muscles involved in the system. The patella is also known as the knee cap. This bone allows for joint movement. The tibia and fibia make up the shank (lower part of the leg). There are three tendons, the quadriceps tendon (5), the patellar tendon (6), and the hamstring tendon (7). The quadriceps and patellar tendons play a major role in the quadriceps force on the ACL. The hamstring and the patellar tendon are two places an ASL graft can be taken from. The next group is the muscles; there are three the quadriceps (8), hamstrings (9), and gastrocnemius (10). These are all mitigators of strain on the ACL. The quadriceps applies the most force, followed by the hamstrings, and then the gastrocnemius. The meniscus (11) makes up the cartilage category. This provides a shock absorber to the knee. The last category is the ligaments; these are the posterior cruciate ligament (PCL) (12), medial collateral ligament (MCL) (13), lateral collateral ligament (LCL) (14) and anterior cruciate ligament (ACL) (15). These ligaments are the four stabilizers of the knee, they prevent the tibia (shank) from sliding forward, out from under the femur.
1.4 Why ACLs Do Not Heal on Their Own

ACLs are about the size of a quarter, however, when they tear, the results can be devastating. The ACL must then be reconstructive through surgical means. This is due to the fluid in the knee, this is called synovial fluid. This fluid is a type of non-Newtonian fluid with an eye white consistency. This fluid reduces friction between the cartilage and the bones. However, it has a negative effect on the ACL healing process. Generally, when a body part tears, the body releases blood to that area, once there it forms a clot. This clot acts as a bridge between the two torn pieces; it holds them together while the body heals itself. This fluid, however, prevents blood from clotting. [7]

1.5 Surgery

Reconstructive surgery is done arthroscopically. This means that small incisions (about 2-4 cm) are made on the front of the knee. Then an arthroscope is inserted, a small tool with a camera on
the end. This allows the surgeon to perform a minimally invasive surgery, instead of a total open knee surgery. When a surgeon performs an ACL surgery he has two main options, to replace the ACL with a cadaver or with the patient’s ligament. If he decides to go the route of the patient’s ligament then he has two more options, a bone tendon bone (BTB) or a bone tendon ligament (BTL) graft. A BTB graft has bone on the end of it, and the surgeon is trying to graft the bone on the ligament to the bone where the ACL should be connected. Patellar tendons are double sided and quadriceps tendons are single sided BTB grafts.

Figure IV Bone Tendon Bone [9]

The other main type of ACL reconstructive surgery is the BTL or Bone tendon Ligament surgery. This means that the replacement ACL is harvested from a bone connection point with muscles and ligaments interwoven to facilitate the replacement ACL.

Figure V Bone Tendon Ligament [10]

Bone tendon ligament reconstructive surgeries can be very strong and are increasing in popularity. Their main downside is that since only one side of the graft has bone and the other
has soft tissue, the graft takes about 3 months longer to bond and heal with the bone that it’s being set to. This increases the risk of set movement and reconstructive surgery failure from a ligament not being in the right place. This would require a graft revision, where the patient would have to get additional surgery to reset the graft which would lengthen the healing time and keep the patient from the next steps in recovery. Hamstring tendons are double sided and quadriceps tendons are single sided BTL grafts.

The strongest graft is the patellar tendon graft, however, when it is harvested it creates stress points on the patella. This increases the likelihood of a patella rupture, this must be followed by a knee replacement surgery. [11]
1.6 Failure Mechanisms

ACL tears can be broken up into two main categories; contact and non-contact. These make up 30% and 70% of ACL tears respectively. [12] Contact can be broken down into three subcategories, Distraction / Compression, Lateral / Medial, and Posterior / Anterior. These types of injuries generally occur to an athlete playing sports when they come into sudden contact with another player. Distraction / Compression injuries happen when the shank and femur are either pulled apart or shoved together. Lateral / Medial injuries occur when the shank makes a horizontal translation to the side. And Posterior / Anterior injuries happen when the shank translates either behind the femur or to right in front of it due to contact. Non-contact ACL tears can be described in three types of failure mechanisms and two combinations; Internal / External, Abduction / Adduction, Flexion / Extension, Internal / External rotation with Abduction / Adduction, and Internal / External rotation with Flexion / Extension. These make up 16%, 9%, 37%, 1%, and 37% [13].

![Figure V Failure Mechanisms](image-url)
1.6.1 Flexion / Extension Injuries

Flexion / Extension injuries usually occur due to low flexion angles and make up 37% of total ACL tears. [12] This is because of a phenomenon known as quad dominance where the quadriceps, instead of preventing an ACL tear, it actually applies strain to it and tears the ACL. This happens because of the way all the components are linked in this system. The quadriceps muscle is attached to the quadriceps tendon which is connected to the patella which is connected to the patellar tendon which is finally connected to the shank, specifically the tibia. When in a low squat, the quadriceps is pulling the shank backwards, and reducing strain on the ACL. When straight legged, the quadriceps chain is actually pulls the shank forward. This produces strain on the ACL and may cause it to break. If and when that happens, a phenomena known as anterior tibial translation occurs. Anterior tibial translation is the shifting of the tibia forwards, out in front of the femur. This distance is about 16.7 mm but that varies from person to person. [14]

Figure VII Flexion / Extension Failure Mechanism
1.6.2 Abduction / Adduction Injuries
Abduction / adduction injuries make up 9% of ACL injuries[12]. These types of injuries are structural based injuries. This means that they happen to people whose structure is favorable to this type of tear. The main factor is the quadriceps angle, more commonly known as the q-angle. The q-angle is the angle the femur connects with the hip in reference to the knee. Generally speaking, the q angle is larger in females than males, [16], 15° and 12° respectively. This accounts for a large number of females receiving ACL tears each year. The q angle applies...
torque on the knee, the larger the q angle, the larger the torque. When there is too much torque, either the MCL or LCL (usually the MCL) will tear. All the ligaments in the knee have a similar tear threshold of 2100 N [4]. So when enough force is applied to the MCL, the ACL will tear along with it.

Figure X Abduction / Adduction Failure Mechanism

Figure XI Q Angle [17]
1.7 Current Prevention
There are some ACL tear preventions that are currently being implemented today. These types of techniques are called neuromuscular training. The idea behind this, is to retrain your mind and body how to respond in a potential tear situation. The two main programs are Prevent Injury and Enhance Performance Program (PEP) and Knee Injury Prevention Program (KIPP).[19]

These programs are typically done in a sterile environment, such as a gym, with a trainer. The trainer will require the athlete to perform some type of athletic movement. The trainer will then critique the athlete’s form, breaking down each step in the activity before retraining the athlete on how to perform that movement. The problem with this is that it is done in a non-dynamic, sterile, environment. This means that the athlete might perform well in the trainer’s office but this does not necessarily translate to the dynamicness of the field. These types of programs have been shown to reduce the probability of an ACL tear by 62% overall, 52% in females and 85% in males [20]. However, only 30% of coaches actually apply injury prevention programs. This is due to the fact coaches see it as taking away from their time with the player. And of those 30%
that apply injury prevention programs, only 10% follow a proven guideline, the other 90% make up what they feel might work [20]. These programs have a monetary cost of about $300 per 6 week session which can lead to an over $3 K per year [21].

Table I Injury Prevention Program

<table>
<thead>
<tr>
<th>Program Name [19]</th>
<th>PEP</th>
<th>KIPP</th>
</tr>
</thead>
</table>
| Program Components|● Running  
● Flexibility  
● Strength  
● Plyometric  
● Agility  |● Plyometric  
● Strength  
● Agility  |

Table II Injury Prevention Program Cost

<table>
<thead>
<tr>
<th>Prevention Program [21]</th>
<th>Cost</th>
<th>Duration</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$300</td>
<td>6 weeks</td>
<td>3x per week</td>
</tr>
</tbody>
</table>

2.0 Problem Statement

2.1 Problem Overview
Humanity likes to compete in activities with dynamic movements. These dynamic and activities cause strain on the body. When too much strain is applied to one area, this can lead to negative impacts, specifically in the knee. Knee injuries are fairly common and can have negative results that last a long time into the future, especially ACL injuries. These types of injuries can occur through both contact and non-contact means. Non-contact injuries tend to happen more often. The main types of injuries are caused by a lack of flexion or an increase in abduction. When knee flexion is low, the body actually works against itself by pulling on both ends of the ACL.
Eventually, this causes the ACL to tear. Abduction injuries happen due to falling or landing with a higher force than usual, this applies significant torque to the knee due to the q-angle of the athlete. When the ACL tears, surgery is necessary. The surgeries cost allot, takes a significant amount of time to recover from, and then not all athletes will return to the same level of sports after the injury. Therefore an ACL tear costs an athlete money, time, and quality of life. The identification and mitigation of the likelihood of these types of injuries is faulty at best. The sterility of the environment the athlete performs the training in does not simulate the dynamic nature of the sports. The coaches also, do not often implement this type of program correctly. If they do implement it, they are likely to implement a program that does not actually help the athlete at all.

2.2 Gap Analysis
From the problem overview, two main gaps can be identified. These can be broken down into two categories, strain identification and strain mitigations. The first gap is that there is no method to actively quantifying ACL strain. The current prevention programs do not identify the strain placed on the ACL in a controlled environment, let alone during a game. Second, there is no method to actively mitigate the probability of an ACL injury during real time. The current prevention programs are performed in a sterile environment, this does not allow the athlete to mitigate their ACL strain during real time performance of a game but merely before the competition or after. This does not help the athlete much because most tears occur during a game or practice.

2.3 Problem Statement
To Summarize: There are 300K anterior cruciate ligament tears every year, of which, 78K are flexion / extension related and 19 K are abduction / adduction caused. There is no system that
currently quantifies the strain being applied to the anterior cruciate ligament. In addition to the above, there is no system that actively mitigates the strain placed on the anterior cruciate ligament due to dynamic sports.

3.0 Need Statement

3.1 Previous Studies
A number of studies have been published regarding ACL tears in athletes by the Journal of Athletic Training, Journal of Science & Medicine in Sports, American Journal of Sports Medicine, and Journal of Biomechanics. One study conducted in 2008 by Yohei Shimokochi, one in 2015 by Marc Norcross, one in 2010 by Gregory Myer, and one in 1010 by Casey Myers highlight and evaluate the factors of ACL tears.

3.1.1 Yohei Shimokochi: Mechanisms of Noncontact Anterior Cruciate Ligament Injury
Shimokochi performed 33 studies assessing ACL load patterns using in vivo, in vitro, and computer simulations. The results found the percentages of the different types of non-contact ACL tears. [13]

<table>
<thead>
<tr>
<th>Observed Population</th>
<th>Internal Rotation</th>
<th>Internal rotation with valgus</th>
<th>Internal rotation with extension</th>
<th>External rotation</th>
<th>External rotation with valgus</th>
<th>External rotation with extension</th>
<th>Extension</th>
<th>Valgus</th>
<th>Varus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>211</td>
<td>18</td>
<td>28</td>
<td>1</td>
<td>6</td>
<td>27</td>
<td>1</td>
<td>5</td>
<td>11</td>
</tr>
</tbody>
</table>

3.1.2 Marc Norcross: Factors influencing high school coaches' adoption of injury prevention programs.
Norcross conducted a web based survey of 141 coaches in Oregon on their knowledge and implementation of injury prevention programs. The results showed that 52% of coaches are
aware of these programs, 30% implement them, and of that 30% only 10% actually implement them correctly.[20]

3.1.3 George Myer: Development and Validation of a Clinic-Based Prediction Tool to Identify Female Athletes at High Risk for Anterior Cruciate Ligament Injury
Myer conducted a lab based study of 100 female athletes. The people in this study were used to validate a probability of ACL tear tool. The results of the tool were 84% accurate and it was determined that a more usable version of the tool must be developed [22].

3.1.4 Casey Myers: Alterations to movement mechanics can greatly reduce anterior cruciate ligament loading without reducing performance
Myers conducted a lab based experiment on 14 female athletes. The results found that by changing jump mechanics you can lower ACL strain [23].

3.2 Gaps in Previous Studies and Need for Current System
There are a few gaps in the above mentioned studies, however, the main gap is that there is allot of identification of what the problems are but nothing is being done about it. Therefore, there is a need for a precise system that quantifies the strain on an anterior cruciate ligament and for a system that gives the athlete a chance to mitigate the situation during real time and not just in a laboratory.

4.0 Scope
The prompt for the system was to design of an ACL prevention and rehabilitation system. If one were to model what that system looks like, from an athlete starting an athletic program until they leave, one would notice several random distributions and exit points. From there, one could be able to determine three subsystems; repression, reconstruction, and rehabilitations.
The failure rates for each subsystem can be identified as 63.38%, 3.63%, and 32.99% respectively. This shows that the most failures occur in the repression subsystem. It is also worth note that the subsystems are purely linear. Therefore, if failure does not occur in the first subsystem, it will not happen in the second or third.

\[
\text{Repression Failure Rate} = \frac{\text{Failure During Repression}}{\text{Athletes in the System}} = 63.38\% \tag{1}
\]

\[
\text{Reconstruction Failure Rate} = \frac{\text{Failure During Reconstruction}}{\text{Athletes with a Tear}} = 3.63\% \tag{2}
\]

\[
\text{Rehabilitation Failure Rate} = \frac{\text{Failure During Rehabilitation}}{\text{Athletes with Successful Reconstruction}} = 32.99\% \tag{3}
\]

After noticing this trend, it was determined that the scope needed to be narrowed due to the fact that there were no unifying stakeholders governing all three processes. Since the simulation shows that repression contributes the most error to our system it therefore had the
most opportunity for mitigation.

Figure XIV System Boundary

5.0 Stakeholder Analysis
The primary stakeholders comprise of seven groups: the athletic team, coaching staff, rehabilitation and reconstruction team, athletic gear manufacturers, family, insurance, and sponsors.

5.1 Athletic team
The athletic team is comprised of the player with an ACL tear and their teammates. Before the tear, the team works as a unit to win competitions, playing off of each other’s strengths. After the tear, the team loses some of their chemistry due to missing a player. The team also has a fear instilled in the rest of the members about tearing their ACL. This may cause them to be more hesitant in a game.
5.1.1 Player
Their main objectives are to increase average playing time and increase media exposure. An ACL tear may end their career, decreasing both objectives. It may reduce their opportunity in going to the professional level if the player is not already. It may develop a fear from the sport. It may develop depression and anxiety that affect their performance. The player would benefit from the ACL to-be system because it would reduce the probability of an ACL tear.

5.1.2 Teammates
The teammates’ main objectives are the wellbeing of their fellow athlete who is at risk of injury, as well as to increase their own average playing time and media exposure. The to-be system will also benefit them because it would reduce their probability of an ACL tear.

5.2 Coaching Staff
The coaching staff consists of a coach, trainer and team physician. This group of individuals acts as a unit to protect the athletic team from injury and increase the overall chance of winning a competition.

5.2.1 Coach
The coach’s main objective is to increase winning percentages. In order to achieve that, the coach needs to have the whole team available, ready, and at the desired level of fitness. If an athlete is injured, they may need to change the lineups and the way the whole team plays. The to-be system will have a side effect of increased winning percentages, which correlates with the goals of the coaching staff.
5.2.2 Trainers
The trainers are professional who are assigned to develop sport medicine programs that aim to maintain or improve the athlete's fitness level. The to-be system will not have any effect on the trainers but may instead help them by pinpointing a specific problem.

5.2.3 Team Physician
Team Physicians have the power to determine athletic exposure and prescribe training exercises to improve from an injury. If the athlete was injured or at high risk levels of injury, the team physician to develop a sport medicine program that meets the need of the athlete.

5.3 Rehabilitation and Reconstruction Team
The rehabilitation and reconstruction team is made up of surgeons and physical therapists. Their job is to help an athlete return to sports in a smooth and timely manner. The to-be system may reduce the need for them.

5.3.1 Orthopedic Surgeons
An ACL reconstruction surgery is one of the most common procedures done by orthopedic surgeons. The to-be system would reduce the amount of ACL reconstruction surgeries needed per year which may decrease the demand for orthopedic surgeons. However, the impact may not be detrimental to the surgeons because the ACL reconstruction surgery is just one out of many surgeries performed by them.

5.3.2 Physical Therapists
Physical therapists are experts who have the knowledge to restore an athlete to their pre-injury fitness level. Although the to-be system would decrease the amount of patients who would attend therapy sessions through rehabilitation, physical therapists are still needed to develop injury prevention programs.
5.4 Athletic Manufacturers
The athletic manufacturing companies produce many different types of sports equipment, from support gear, to monitoring tools, to motion analysis equipment. The to-be system will create a new market of biofeedback. This will create a new revenue stream for the companies.

5.5 Family
This category includes the parents, siblings, and anyone else who greatly cares about the well-being of the athlete. An ACL tear may take time, money and effort from the family to support the athlete during the recovery period. Since the to-be system will reduce the probability of a tear, it correlates with the goals of the family.

5.6 Insurance
These insurance companies will pay for the ACL reconstruction surgery. Their main objective is to make profit. The to be system will be beneficial to them because it will cut down on the number of ACL injuries per year and therefore it will reduces their average spending on ACL surgeries.

5.7 Sponsors
This category contains individuals or companies that are monetarily invested in an athlete. In this relationship the sponsor gives the athlete or organization the athlete plays for, money, in return the athlete promotes the person or company through wearing their brand. When the team wins, it has a positive effect on the sponsor, when they lose or are injured, a negative one. The to-be system will decrease the number of negative effects on a sponsor due to injury.
5.8 Stakeholder Interactions and Tensions
The main tensions that appear in the to-be system are on the orthopedic surgeons and physical therapists. The to-be system will aim to decrease the need for these groups of people due to fewer injuries.

![Stakeholder Diagram](image)

Figure XV Stakeholder Diagram

Section II: Concept of Operations (CONOPS)

6.0 Mission Requirements
After going over the method of analysis, it was determined that there are four main mission requirements that must be satisfied. First the system has to warn the user when they are approaching a dangerous level of strain. Second, there needs to be a way for the system to
quantify that strain. Third, the system needs to actually work and lower the total number of ACL tears. Since 70% of ACL tears are non-contact and 37% [12] of those tears are flexion / extension related, 25.9 % of the total number of ACL tears are flexion / extension related. If it is assumed that the system will be able to capture 25% of the market then the system will be able to reduce the total number of ACL tears by 6.5 % or flexion / extension tears by 25%. Lastly, the system needs to make a profit, so there need to be a ROI in the near future.

Table IV Mission Requirements

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>M.1</td>
<td>The system shall warn the user of increased probability of ACL tear.</td>
</tr>
<tr>
<td>M.2</td>
<td>The system shall quantify ACL strain.</td>
</tr>
<tr>
<td>M.3</td>
<td>The system shall lower the total number of ACL injuries by 6.5%</td>
</tr>
<tr>
<td>M.4</td>
<td>The system shall have a return on investment (ROI) after 1 year.</td>
</tr>
</tbody>
</table>

7.0 Solution

The proposed solution is to implement a biofeedback active sensor system (BASS). This system will intake inputs from sensors and convert them into useable data. This data will then be used in equations to determine if an athlete is at risk of a tear. After the risk is evaluated, the system will be able to warn the user of an elevated risk. This will give the athlete an opportunity to retrain and mitigate the situation before a tear occurs.

8.0 Functional Requirements

In order to meet the mission requirements and make the solution, functional requirements were derived. There are three main categories for the functional requirements; TSF calculations, input sensors, and performance. For TSF calculations, the system is going to use the TSF model for
calculating strain on the ACL, if the TSF is higher than 1700 N then it will warn the athlete of high TSF. Second, for input sensors, if the TSF model is being used then the system needs to have angle sensors, ground reaction force sensors, and an accelerometer. Since mass stays relatively constant during athletic movements, there is no need for a mass sensor, it will be input into the system by the user instead. Lastly, the system can not deter from an athlete’s overall performance, it must not be too heavy or made of un regulatory materials.

Table V Functional Requirements

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>F.1</td>
<td>The system shall calculate the tibial shear force.</td>
</tr>
<tr>
<td>F.2</td>
<td>The system shall acquire data from the sensors.</td>
</tr>
<tr>
<td>F.3</td>
<td>The system shall translate the data into usable form.</td>
</tr>
<tr>
<td>F.4</td>
<td>The system shall measure the ground reaction force in the x and y directions.</td>
</tr>
<tr>
<td>F.5</td>
<td>The system shall measure the shank angle.</td>
</tr>
<tr>
<td>F.6</td>
<td>The system shall measure the acceleration of the foot in the x and y directions.</td>
</tr>
<tr>
<td>F.7</td>
<td>The system shall measure the acceleration of the shank in the x and y directions.</td>
</tr>
<tr>
<td>F.8</td>
<td>The system shall measure flexion angle.</td>
</tr>
<tr>
<td>F.9</td>
<td>The system shall warn of TSF greater than the warning threshold, 1700 N.</td>
</tr>
<tr>
<td>F.10</td>
<td>The system shall be able to be worn during exercise.</td>
</tr>
<tr>
<td>F.11</td>
<td>The system shall not deter performance.</td>
</tr>
</tbody>
</table>

9.0 Operational Scenario

There are two main operational scenarios for the BASS product:

1. Identification
2. Mitigation
The identification is an active process that occurs in real time during dynamic movements. The mitigation is twofold, the first part is done actively during a competitions. The second is performed afterwards with the aid of a trainer.

9.1 TSF Identification
The athlete will wear the BASS sleeve during dynamic practices and competitions. During these events the athlete will perform as they normally do. The BASS will be continuously monitoring and calculating strain. If there is a point when the strain is too great, then the BASS system will alert the athlete by beeping.

9.2 TSF Mitigation
The mitigation scenario activates when the athlete is alerted by a beep. The athlete can then make a mental note to have better form. Over the course of a dynamic event, the athlete will grow annoyed of the beeping and correct their form. After the game, the athlete can plug the BASS into a computer and pull up the TSF data while watching a video of their performance. The athlete can then talk to a trainer about the situation and their TSF and how to reduce the strain. The data will start off with many high strain levels at the beginning of a game, as the game goes on, there should be a decreasing trend in the data due to the athlete’s ability to neuromuscularly retrain themselves.
10.0 Components

The components necessary to create the system are depicted below in the component diagram. In the left column there are inputs, on the right there are user interfaces, in the center there is the processor chip and battery system, and across the bottom there is the power communication. The inputs can all be traced back to the TSF equation. The microcontroller is the data center that converts the inputs to usable data to a TSF output. In the user interface column, the data storage records the TSF for the user for post dynamic activity review. The potentiometer is where the user can input their weight as a constant. The beeper and light are a dual warning system. The beeper alerts the athlete of high strain and the light alerts the coach. The battery management system, depicted in the middle, shows the displacement of the power source. The block along the bottom of the diagram shows the power communication.
The system should look similar to this picture. It will be a combination of a knee sleeve and a shoe. The sleeve will have a beeper, light, and microcontroller on the front, depicted in purple. On the back of the knee sleeve and shoe are the flexion and shank angle sensors respectively, shown in red. The blue strips are the accelerometers, the one on the shoe will also hold the potentiometer. Lastly, the green bars are ground reaction force sensors.
11.0 Design Requirements

The design requirements were derived from the list of necessary components. There are eight main components: muscle EMGs, ground reaction force sensors, accelerometers, angle sensor, processor, beeper, potentiometer, and light.

The requirements for the muscle EMG sensor include size, accuracy, precision, and weight.
Table VI Muscle EMG Design Requirements

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>D.1</td>
<td>The muscle EMG sensor shall have specific measurements.</td>
</tr>
</tbody>
</table>
| D.1.1  | The muscle EMG sensor shall have a length of less than 2.5 inches.
| D.1.2  | The muscle EMG sensor shall not have a width of less than 1 inch.
| D.1.3  | The muscle EMG sensor shall have an accuracy of at least 90%.    |
| D.1.4  | The muscle EMG sensor shall have a precision of at least 95%.    |
| D.1.5  | The muscle EMG sensor shall weigh less than 50 grams.            |

The requirements for the ground reaction force sensor include size, accuracy, precision, capability, and weight.

Table VII Ground Reaction Force Sensor Design Requirements

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>D.2</td>
<td>The ground reaction force sensor shall have specific measurements.</td>
</tr>
<tr>
<td>D.2.1</td>
<td>The ground reaction force sensor shall have a length of less than 1.5 inches.</td>
</tr>
<tr>
<td>D.2.2</td>
<td>The ground reaction force sensor shall have a width of less than 1.3 inches.</td>
</tr>
<tr>
<td>D.2.3</td>
<td>The ground reaction force sensor shall have an accuracy of at least 92% in the x and z components.</td>
</tr>
<tr>
<td>D.2.4</td>
<td>The ground reaction force sensor shall have an accuracy of at least 90% in the y component.</td>
</tr>
<tr>
<td>D.2.5</td>
<td>The ground reaction force sensor shall have a precision of at least 95%.</td>
</tr>
<tr>
<td>D.2.6</td>
<td>The ground reaction force sensor shall read forces up to 2100 N.</td>
</tr>
<tr>
<td>D.2.7</td>
<td>The ground reaction force sensor shall weigh less than 50 grams.</td>
</tr>
</tbody>
</table>

The requirements for the accelerometer include size, accuracy, precision, capability, and weight.
Table VIII Accelerometer Design Requirements

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>D.3</td>
<td>The accelerometer shall have specific measurements.</td>
</tr>
<tr>
<td>D.3.1</td>
<td>The accelerometer shall have a length of less than 5 mm.</td>
</tr>
<tr>
<td>D.3.2</td>
<td>The accelerometer shall have a width of less than 5 mm.</td>
</tr>
<tr>
<td>D.3.3</td>
<td>The accelerometer shall have an accuracy of at least 95%.</td>
</tr>
<tr>
<td>D.3.4</td>
<td>The accelerometer shall have a precision of at least 95%.</td>
</tr>
<tr>
<td>D.3.5</td>
<td>The accelerometer shall be able to read acceleration as low as (0.03) m/s(^2).</td>
</tr>
<tr>
<td>D.3.6</td>
<td>The accelerometer shall be able to read acceleration as high as 10 m/s(^2).</td>
</tr>
<tr>
<td>D.3.7</td>
<td>The accelerometer shall be able to read 3 axes.</td>
</tr>
<tr>
<td>D.3.8</td>
<td>The accelerometer shall weigh less than 50 grams.</td>
</tr>
</tbody>
</table>

The requirements for this sensor include size, accuracy, precision, capability, and weight.

Table IX Angle Sensor Design Requirements

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>D.4</td>
<td>The angle sensor shall have specific measurements.</td>
</tr>
<tr>
<td>D.4.1</td>
<td>The angle sensor shall have a length of less than 1.3 inches.</td>
</tr>
<tr>
<td>D.4.2</td>
<td>The angle sensor shall have a width of less than 1.2 inches.</td>
</tr>
<tr>
<td>D.4.3</td>
<td>The angle sensor shall have an accuracy of at least 99%.</td>
</tr>
<tr>
<td>D.4.4</td>
<td>The angle sensor shall have a precision of at least 95%.</td>
</tr>
<tr>
<td>D.4.5</td>
<td>The angle sensor shall be able to read angles as low as 0 degrees.</td>
</tr>
<tr>
<td>D.4.6</td>
<td>The angle sensor shall be able to read angles as high as 180 degrees.</td>
</tr>
<tr>
<td>D.4.7</td>
<td>The angle sensor shall be no more than 50 grams.</td>
</tr>
</tbody>
</table>

The requirements for the processor include size, weight, and capability.
### Processor Design Requirements

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>D.5</td>
<td>The processor shall have specific measurements.</td>
</tr>
<tr>
<td>D.5.1</td>
<td>The processor shall have a length of less than 3 inches.</td>
</tr>
<tr>
<td>D.5.2</td>
<td>The processor shall have a width of less than 2.5 inches.</td>
</tr>
<tr>
<td>D.5.3</td>
<td>The processor shall have a weight less than 30 grams.</td>
</tr>
<tr>
<td>D.5.4</td>
<td>The processor shall have an operating voltage of at least 5 volts.</td>
</tr>
</tbody>
</table>

### Beeper Design Requirements

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>D.6</td>
<td>The beeper shall have specific measurements.</td>
</tr>
<tr>
<td>D.6.1</td>
<td>The beeper shall warn the user at greater than 85 dBA.</td>
</tr>
<tr>
<td>D.6.2</td>
<td>The beeper shall weigh less than 5 grams.</td>
</tr>
</tbody>
</table>

### Potentiometer Design Requirements

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>D.7</td>
<td>The potentiometer shall have specific measurements.</td>
</tr>
<tr>
<td>D.7.1</td>
<td>The potentiometer shall have a length of less than 2.5 inches.</td>
</tr>
<tr>
<td>D.7.2</td>
<td>The potentiometer shall not have a width of less than 1 inch.</td>
</tr>
<tr>
<td>D.7.3</td>
<td>The potentiometer sensor shall have an accuracy of at least 90%.</td>
</tr>
<tr>
<td>D.7.4</td>
<td>The potentiometer sensor shall have a precision of at least 95%.</td>
</tr>
<tr>
<td>D.7.5</td>
<td>The potentiometer shall weigh less than 50 grams.</td>
</tr>
</tbody>
</table>
The requirements for the light include size, capability, and weight.

### Table XIII Light Design Requirements

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>D.8</td>
<td>The light shall have specific measurements.</td>
</tr>
<tr>
<td>D.8.1</td>
<td>The light shall have a length of less than 2.5 inches.</td>
</tr>
<tr>
<td>D.8.2</td>
<td>The muscle EMG sensor shall not have a width of less than 1 inch.</td>
</tr>
<tr>
<td>D.8.3</td>
<td>The light shall produce 800 lumens.</td>
</tr>
<tr>
<td>D.8.4</td>
<td>The light shall weigh less than 50 grams.</td>
</tr>
</tbody>
</table>

12.0 Design of Experiment

The design of experiment for the BASS includes a prototype, since there are many parts to the system, it should be broken down into working one set of sensors at a time. The first sensors that will be tested are a combination of the flexion angle sensors and the ground reaction force sensors. The design of experiment included four scenarios, with two possible outputs. The scenarios were low flexion angle with low ground reaction force, this simulates standing and walking. There should be no beep. The second scenario is low flexion angle with high ground reaction force. This simulates a dangerous dynamic movement done with bad form. This will result in a beep. In the third scenario there will be high flexion and high ground reaction force. This simulates an athlete performing a dangerous move in a safe way with good form. There will be no beep. Lastly, high flexion and low ground reaction force simulates an individual stretching. There will be no beep. Below are a sample table of the expected scenarios and their outputs along with an image of the first prototype. This prototype is a rapid build prototype meaning it is designed to observe how components interact with each other, not for aesthetic purposes.
### Table XIV Design of Experiment

<table>
<thead>
<tr>
<th>Input</th>
<th>Output</th>
<th>Beeping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>Ground Reaction</td>
<td></td>
</tr>
<tr>
<td>&lt; 20 Deg</td>
<td>Low</td>
<td>No</td>
</tr>
<tr>
<td>&lt; 20 Deg</td>
<td>High</td>
<td>Yes</td>
</tr>
<tr>
<td>&gt; 20 Deg</td>
<td>High</td>
<td>No</td>
</tr>
<tr>
<td>&gt; 20 Deg</td>
<td>Low</td>
<td>No</td>
</tr>
</tbody>
</table>

![Figure XIX BASS Prototype](image)

13.0 Design Alternatives

The goal of the BASS system is to identify and warn the user of high TSF strain on the knee system dynamically. The sensitivity analysis done on the TSF equation gave the two largest contributing factors for TSF being ground reaction force in the vertical direction and flexion
angle. Using a value hierarchy, utility can be broken down into three main sections, technology readiness level (TRL), usability, and performance. Usability is further broken down into length, width, weight, and durability. Performance is broken down into maintainability and accuracy.

![Figure XX Value Hierarchy]

13.1 Ground Reaction Force Sensor

The design alternatives for measuring ground reaction force are the triaxle accelerometer and pressure sensors. The triaxle accelerometer measures the vertical ground reaction by recording the acceleration along the y-axis of the knee system. The acceleration is then multiplied by the weight of the user to calculate the force. In order to measure the total ground reaction force, the accelerometer needs to be able to measure acceleration up to 8g. The accelerometer is positioned along the side of the knee [23]. The pressure sensors are able to directly measure the vertical ground reaction force. This is done through placing a high number of pressure sensors in the insoles of shoes. The total vertical ground reaction force is found through totaling the forces measured by each pressure sensor [25]. For performance, both sensors scored similarly. This was due to both of their high levels of accuracy in measuring the vertical ground reaction force. This
was the same for TRL. The triaxle accelerometer out ranked the pressure sensor. This is mostly due to the need of having 99 pressure sensors to gather accurate results.

<table>
<thead>
<tr>
<th>Alternative</th>
<th>Utility</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-axis accelerometer</td>
<td>0.635</td>
</tr>
<tr>
<td>Pressure Sensors x99</td>
<td>0.601</td>
</tr>
</tbody>
</table>

Figure XXI Ground Reaction Utility

Figure XXII Ground Reaction Cost VS Utility
13.2 Angle Sensor
The design alternatives for measuring flexion angle are flex sensors and IMU (Inertial Measurement Unit) sensors. The flex sensor is a bendable angle measuring device that calculates angle displacement based on change in resistance. As the bend of the flex sensor increases, so does the resistance. To measure flexion angle two flex sensors would be fitted to the front side of the knee brace. The readings from the flex sensors are then used in the Extended Kalman Filter (EKM) to minimize the error of the flexion angle reading [26]. The inertial measurement unit (IMU) sensor comprises of accelerometers and gyroscopes, used in order to measure acceleration and angular acceleration. In order to measure flexion angle, three IMUs would be needed. The IMU sensors would be placed on the femur, the shank, and the foot. The positioning of the IMU sensors set up a coordinate axis on the knee joint axis. The estimation of the flexion is angle is found through the difference of angular accelerations of the IMU sensors placed on the shank and femur. The main difference in these two sensors is the TRL. The flex sensor is more developed than the IMU in terms of body angle estimation. The flex sensor also, beats the IMU in usability, this is due to the need for 6 sensors in order to have usable data [27].

<table>
<thead>
<tr>
<th>Alternative</th>
<th>Utility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flex Sensors</td>
<td>0.844</td>
</tr>
<tr>
<td>IMU Sensors</td>
<td>0.615</td>
</tr>
</tbody>
</table>

Figure XXIII Flexion Sensor Utility
Section III: Method of Analysis

In the course of the project a system was modeled with different strategies. In the beginning of the fall semester, a probabilistic chain model was used to simulate athletes going into surgery.
Figure XXV System Model

The probability an athlete has to be injured was modelled, which at the time this CPN tool was made, was 10%. Then, after an injury the athlete has a choice of three types of surgery. The first is a bone tendon bone graft; this is when the replacement ACL is harvested from the bottom of the patella tendon to the top of the tibia. This surgery has a 1% failure rate that occurs when micro fractures happen in the patella during the harvest the patella ruptures later one. As a result, this requires a much more costly and time consuming surgery than an ACL surgery.

If the patient chooses a bone tendon ligament surgery then they have a 56% chance of having to get the graft redone or what's called as a graph revision. This is because of the slow
healing time of a bone tendon ligament surgery compared to a bone tendon bone surgery causes more risk of a surgery not being correctly set and therefore need to be revisited.

The last surgery node is called other and embodies some surgery types not currently used in America. This is due to their not yet proven durability and some, like a Kevlar solution, have been microscopically shredding from use and then rupture after a certain amount of time.

After surgery, low rate of athletes returning to their previous level of sport due to psychological reasons was modelled. This could be due to fear of reinjury, social pressures, or pain.

Lastly if the patient makes it through these process and returns to sports, then there is still a small chance that they will suffer from medical difficulties due to the surgery and not be able to return to play.

This CPN tool model was a beneficial starting point to weigh the different sub systems against each other. An analysis was performed on what sub-system could have the most overall effect on the entire system and therefore have the best effect on the ACL injury epidemic.

<table>
<thead>
<tr>
<th>Sub-System</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repression</td>
<td>0.631</td>
</tr>
<tr>
<td>Reconstruction</td>
<td>0.037</td>
</tr>
<tr>
<td>Rehabilitation</td>
<td>0.332</td>
</tr>
</tbody>
</table>

After running simulations in the CPN tool model it was found that the preventive sub-system called repression has the most error and therefore the most room for improvement. This was followed by some preliminary design alternative research, which produced many different alternatives in repression. Of those, many could also be used for rehabilitation; it was decided to focus on repression as the main system to model and solve.
14.0 Simulation & Modeling Design

Since repression and preventative methods were chosen to be focused on, it was necessary to understand the failure mechanisms of an ACL injury. As stated before there are 5 different types of injury mechanism. The types of injuries are resultant of the different movement modes possible to a joint in absence of a supporting ligament.

Probability of Tear model:

First, the inputs and outputs of the tear mechanism were modelled with flow charts on causes and effects.

Figure XXVI Markov Chain
This method did give insight to how the failure mechanisms occurred and the best assumptions to make were on how they happened. For instance, understanding that there was no mental input (neuromuscular form), or muscular input to the pure abduction injury simplified that model by giving the powerful assumption that it could be treated as a static mass problem. This is because if a person's body is allowed to move through its allowable range then the person has the opportunity to correct and mitigate their form and then mitigate it. Whereas if you assume that the lower leg at full extension will act like a static object upon impact with the ground, you can use different more simple models to simulate it.

A Bayesian probability model was developed and created to affect the overall probability of tear.

\[
P(\text{tear}) = P(\text{tear from abduction}) + P(\text{adduction}) + P(\text{tear from flexion}) + P(\text{tear from extention}) + P(\text{tear from internal rotation}) + P(\text{tear from external rotation}) + P(\text{tear from combinations of above})
\]  

(4)

Modeling this allowed a clear view of what mechanisms of injuries’ probabilities were possible to change, once changed, one could affect the overall probability of tear and thus achieve the need statement.

After considering the flow chart models that had done before, it was decided to model the abduction/adduction injury mechanism first. This was because if the logic that an abduction/adduction injury can occur if and only if the MCL or LCL was torn first, then the model could be easily made.
14.1 Abduction

An abduction/adduction injury without rotation or flexion can only occur straight legged. If the abduction injury occurred with what's known as “phantom foot” or foot angle placement that it as an angle of more than 15 degrees away from the acceleration angle of the bottom of the femur, then that injury would be the abduction + rotation injury. If the Abduction injury occurs with any degrees of knee flexion then that injury would be the abduction + flexion injury. It is very important to note and understand that the abduction injury results from a straight legged landing with no phantom foot placement and then to also understand that the only way to tear an ACL in this way is for the MCL or LCL to tear first.

![Abduction/Adduction](image)

Figure XXVII Abduction / Adduction

The Previous logic that the MCL has to tear first before an ACL can tear creates a starting point of creating a knee moment reference frame at the center of the knee and then using the known distance to the MCL as a force equation.
The combination of the femur forces resulting from the upper body's momentum and the tibial forces resulting from the lower body's acceleration due to the earth’s ground reaction creates what is called a joint reaction force in the knee. This joint reaction force has a translation and momentum.

Figure XXVII Free Body Diagram Upper Body Contribution[17]

This free body diagram shows the upper body's contribution to MCL strain as transferred through the femur. The two masses that are described in this equation are the Mass of the body
and the Mass of the lower leg. It has a ½ constant because for this abduction model to be reasonable the total forces divide between two legs. Then the lower leg, the shank and foot, is subtracted because these masses do not contribute to the femur force. It is also shown how the Q-angle contributes to this injury mechanism through the use of the torque applied by the femur. For there to be torque by the femur there must be an x component of the femur that works with the body's momentum in the Y direction to apply torque.

\[ \text{Moment Arm} = (length_{femur} \times \sin(q - \text{angle})) \]  

(5)

\[ F_{femur_y} = \frac{\frac{1}{2} \times M_{\text{bodyAboveKnees}} \times \text{heightOfFall} \times g}{\Delta Y \text{impactDistance}} \]  

(6)

This is taken to be in the Y direction and with force equating to mass * acceleration. Acceleration equates to positions second derivative. Next, the relative force in the Y as compared to the height of the fall and the impact distance or the energy that is returned or absorbed due to newton's third law of conservation of energy.

This gives us the equation for torque on the knee as contributed by the femur force (upper body) and the acceleration of earth's gravity.

\[ \tau_{knee_{femur}} = F_{femur_y} \times (length_{femur} \times \sin(q - \text{angle})) \]  

(7)
This free body diagram illustrates the contributions of the earth's ground reaction forces on MCL strain.

\[ F_{gr} = \sqrt{F_{grx}^2 + F_{gry}^2} \]  

This shows that ground reaction force is a vector with X and Y components.
\[ F_{gy} = \frac{M_{b} \cdot h \cdot g}{\Delta_{impactDistance}} \] 

This shows that the Y component of ground reaction force is equal to the mass of the body multiplied by the height of the fall and gravity. It is all divided by the impact distance in the Y direction as denoted by delta Y.

\[ F_{gx} = \frac{M_{b} \cdot D_{x}}{\sqrt{\frac{2 \cdot h}{g}}} \] 

This shows that the force of ground reaction on the X is equal to the body's mass multiplied by the distance traveled in the X all divided by the square root of two multiplied by the height of the fall divided by earth's gravity. This is because acceleration is the second derivative of position and therefore subject to this transformation.

This gives the final Ground reaction force equation:

\[ F_{gr} = \sqrt{\left( \frac{M_{b} \cdot h \cdot g}{\Delta_{impactDistance}} \right)^2 + \left( \frac{M_{b} \cdot D_{x}}{\sqrt{\frac{2 \cdot h}{g}}} \right)^2} \] 

After this one can find the force contributions of the lower leg to the MCL strain.

\[ F_{tibia_{x}} = \frac{M_{lower\ leg\ lever} \cdot distance\ traveled\ in\ the\ x\ direction}{\sqrt{\frac{2 \cdot h}{g}}} \] 

This explains the force of the tibia as the mass of the lower leg multiplied by the distance it travels in the X direction multiplied by the square root of 2 times the fall height divided by earth's gravity.

Using this equation one can then find the torque moment on the knee:

\[ \tau_{knee_{lower\ leg}} = \frac{M_{lower\ leg\ lever} \cdot distance\ traveled\ in\ the\ x\ direction}{\sqrt{\frac{2 \cdot h}{g}}} \cdot length_{lower\ leg} \]
This free body diagram shows that the total torque is derived from the combinations of the torques in the X and Y of the Femur and the individual torque of the tibia.

\[
F_{\text{femur}_x} = \frac{\left(\frac{1}{2}M_{\text{body above knees-suppleleg}}\right) \times \text{distance traveled in the x direction}}{\sqrt{\frac{2 \times \text{leg length}}{g}}} \times \text{length}_{\text{femur}}
\]  

(14)
The torque of the knee from the femurs movement in the x direction is a result of half the mass above the knees times the distance traveled divided by the square root of 2 times the height divided by the gravity. This is all multiplied by the length of the femur times the cosine of the q-angle.

Given the above three torque equations, the total torque on the knee system itself embodied in this equation:

\[ \tau_{\text{knee total}} = \tau_{\text{knee femur}} + \tau_{\text{knee lower leg}} - \tau_{\text{knee femur x}} \]  \hspace{1cm} (15)

This is for if the knee that the torque is being multiplied at is the following knee, or the knee that the MCL is leading the motion in. Using the above equations and assumptions, it is much more likely that this knee will be the one to fail due to the contributions of the Q-Angle.

Then there is the moment arm of the torque moment of the knee to the MCL which is about 3 centimeters. This is adjusted to a force vector called:

\[ \text{Force At A} = \frac{\text{Total Knee Torque}}{\text{Distance of Knee Vector Center to MCL}} \]  \hspace{1cm} (16)

This force then needs to be translated to the MCL using what is called the action angle giving this final equation of:

\[ \text{Force at the MCL} = \text{Force At A} \times \cos(\text{actionAngle}) \]  \hspace{1cm} (17)
14.2 Sensitivity Analysis

After doing a sensitivity analysis on the abduction model one can see the exponential increase of torque force as related to the delta Y parameter. This parameter was used to model shoe thickness and therefore cushioning. As one can see the force rises exponentially with the decrease of the shoe sole size.

Figure XXIX Sensitivity TimeY VS Torque

Figure XXX Sensitivity Q Angle VS Torque
In this above sensitivity analysis, one can see how the q-angle contributes to the torque force on the knee. Torque increases with a slope of 20 N/Degree of q-angle.

Figure XXXI Sensitivity Tibia Length VS Torque

Here is the contribution of the tibia length to total torque on the knee. Nothing can be done to change this with technology, but one can see how height has a contributing factor to knee injuries.

Figure XXXII Sensitivity Mass VS Torque
Here it can be seen how the body’s mass can have a detrimental effect on MCL/ACL injuries, the increase of knee torque here is about 380 N per 10 kilograms of body mass.

14.3 Flexion / Extension
The knee flexion injury makes up about 37% of total ACL injuries a year. It occurs when the knee system compensates for high ground reaction force with low flexion angles. When this happens, the quadriceps muscle has pulled the tibia hard enough to stop the upper body’s momentum from collapsing it into itself. The quadriceps is attached to the patellar tendon and bone chain to increase the torque on the knee so the tibia and foot can have a greater range of motion and maximum velocity. Unfortunately the trade off to this wonderful anatomical system is that at high forces, and low flexion angles, the quadriceps patellar chain system actually pull the tibia forward enough to tear the ACL.

14.3.1 Reference Frame

![Shank Reference Frame](image)

Figure XXXIII Shank Reference Frame
To quantify ACL strain by the flexion injury, one needs to use the bio-mechanical physics model used in the study “Alterations to movement mechanics can greatly reduce anterior cruciate ligament loading without reducing performance” by Casey A. Myers, David Hawkins. In their model they transformed all the forces in the knee to an approximation of where the ACL lays, their approximation states that it lays on the tibial head. So the knee reference frame is formed by transforming the contributing forces of the knee to the tibial reference frame.

14.3.2 Angles

The parameter used to describe the tibial head is the shank angle. The shank angle on the above diagram is denoted by $\theta_s$. The shank angle is the angle between the flat head of the tibia relative to the earth, or to put it another way, the tibial vector relative to the Y axis of the earth.

Figure XXXIII Shank Angles

$x_e = x$-axis of the earth
$y_e = y$-axis of the earth
$x_s = x$-axis of the shank
$y_s = y$-axis of the shank
$\theta_s$ = shank angle
14.3.3 Forces

Figure XXXIV Shank Forces

Here one can see the contributing forces to the shank reference frame and therefore the best approximator for ACL strain. Starting from the bottom of the free body diagram, the ground reaction force gets transferred through the foot then the tibia and then the knee. The force from the foot itself is also a contributor. Then one can see the force from the gastrocnemius muscle (Calf Muscle) as its force vector points in the relative direction of the calf muscle. The force from the shank itself is also here as denoted from the vector originating from its center of mass. Then the hamstring force which is a vector connecting the tibial head in the direction of the hamstring. The last force in this equation is the quadriceps force which is a vector that originates on the front of the tibia and follows the patellar

$x_e$ = x-axis of the earth
$y_e$ = y-axis of the earth
$x_s$ = x-axis of the shank
$y_s$ = y-axis of the shank
$\theta_s$ = shank angle
$F_f$ = Foot Force
$F_s$ = Shank Force
$F_g$ = Ground Reaction Force
$F_q$ = Quadriceps Force
$F_h$ = Hamstring Force
$F_c$ = Gastrocnemius Force
Here one can see the foot force contributors to TSF. The ground reaction forces have an X and Y component that creates a translation and torque at the ankle. The foot's acceleration due to its momentum and the effect of earth’s gravity is also translated and creates a moment at the ankle. The outputs of the foot forces are the ankle forces that get transferred into the shank in the next free body diagram.

Here the shank forces are decomposed. The inputs to this system are the ankle forces in the X and Y and the moment at the ankle. Also there is the momentum of the shank and the
contribution of gravity located at the shank center of mass. The outputs of this equation are the knee forces in the X and Y directions and the moments resulting from the previous inputs.

Here are the contributions from the muscle forces. These muscle force contributions depend on what is called the flexion angle \((\theta_{\text{flexb}})\). The reason for this for the quadriceps is due to the change of the relative position of the patellar to the tibia as flexion angle changes. For the hamstrings, the direct counter x force derived is due to the flexion angle. The gastrocnemius muscle contribution also ranges with flexion angle as the force vectors contribution is connected to the bottom of the femur and therefore changes its X contribution.

14.3.4 Equations

\[ TSF = F_{\text{Shank}} + F_{\text{Foot}} + F_{\text{GroundReaction}} + F_{\text{Muscles}} \]  
\[ TSF = m_s[a_{sx} \cos(\theta_s) - (a_{sy} + g) \sin(\theta_s)] + m_f[a_{fx} \cos(\theta_s) - (a_{fy} + g) \sin(\theta_s)] - G_{rfx} \cos(\theta_s) + G_{rfy} \sin(\theta_s) - \sum F_{\text{GastroX}} - \sum F_{\text{QuadX}} - \sum F_{\text{HamX}} \] 

Figure XXXVII Leg Free Body Diagram
Above is the final TSF equation that includes the contributing forces from the above free body diagrams. Notice how the muscle forces do not have a shank angle transformer. This is because the muscle forces contributions have to do with something called flexion angle, which is the relative angle between the femur and the tibia.

Foot Force:

\[ F_{AX} = m_F a_{FX} - R_x \] (20)

This equation is the ankle force in the X direction as derived from the foot force and the ground reaction force Rx in the X direction.

\[ F_{AY} = m_F (a_{FY} + g) - R_y \] (21)

This equation is the ankle force in the Y direction as derived from the foot force, gravity and the ground reaction forces in the Y.

\[ M_A = -R_y (X_{AB} - X_{CB}) + R_x (Y_B - Y_{CB}) - \left[ m_F (a_{FY} + g) \right] (X_{CB}) + \left( m + m_F a_{FX} \right) (Y_{CB}) + I_F a_F \] (22)

This equation is the moment at the ankle which results from the added torques from the different ground reaction force inputs and the different inputs from the foot forces and the angular momentum.

\[ F_{KX} = m_s a_{sx} + m_F a_{FX} - R_x \] (23)

This equation is the knee force in the X direction that results from the added forces from the shank and the foot plus the ground reaction force in in the X.

\[ F_{KY} = m_s (a_{sy} + g) + m_F a_{FY} - R_y \] (24)

This equation is the knee forces in the Y direction that result from the forces from the shank in the Y the foot in the Y and the ground reaction force in the Y

\[ M_K = M_A - F_{AY} (X_{DC}) + F_{AX} (Y_{DC}) - F_{KY} (X_{ED}) + F_{KX} (Y_{ED}) + I_s a_s \] (25)
This equation is the moment at the knee which is a result of adding the moments of the ankle, the force contributions of the ankle with the tibial lever arm, the knee contributions in the Y and X and the angular momentum of the shank itself.

\[ F_{QuadX} = F_{Quad} \sin((-0.238)(180 - \theta_{flex_b}) + 22.2) \]  

The above equation is the quadriceps force as ranged by the flexion angle. The 22.2 degree constant at the end shows the relative position of the patellar bone at a straight leg stance. This equation was derived from data from a study on patellar bone to flexion angle positioning. “The Biomechanical Function of the Patellar Tendon During In-vivo Weight-bearing Flexion”

\[ F_{HamX} = F_{Ham} \cos(90 - \theta) \]  

The above equation is the hamstring force contribution to the shank reference frame. This equation was just derived from simple anatomical understanding in that the hamstrings will always lie underneath the femur.

\[ F_{GastroX} = F_{Gastro} \sin^{-1}\left(\frac{d\sin(\theta_{flex_b})}{\sqrt{d^2 + \text{tib}_b^2 - 2dd\text{tib}_b \cos(\theta_{flex_b})}}\right) \]  

The above equation is the contribution of the gastrocnemius muscle to the shank reference frame. Its complexity is due to the way the flexion angle contributes to shank reference X. This equation was derived from simple anatomical understanding of the placement of the calf muscle and then the assumption that the calf muscle adds certain forces to the shank X reference frame.

14.3.5 Sensitivity Analysis
To understand how the force equations depend upon each other, and to find key tradeoffs to each other, a sensitivity analysis was performed for different parameters of the TSF Equation.
14.3.5.1 Muscles

Figure XXXVIII Muscle Forces Sensitivity Analysis

Above is the sensitivity analysis on muscle force contributions to TSF. The blue line is the quadriceps and the TSF contribution is linear ranging from -550 N at 60 degrees flexion to 750 N at 180 degrees flexion. The quadriceps becomes a positive contributor to TSF at 105 degrees flexion.

The red line is the hamstring contribution which ranges parabolically from -1600 N at -60 degrees flexion with a maximum contribution of -2000 N at 90 degree flexion all the way to a 0 TSF contribution at 180 degrees.

The green line is the gastrocnemius contribution that follows a parabolic distribution with a -50 newton contribution at 60 degrees, a maximum of -100 N at 90 degrees and a minimum of 0 at 180 degrees flexion.
The purple line is the summation of the muscle forces, and this line confirms what a lot of studies have observed in that ACL strain is high ranging from 160-180 degree flexion. This is because in this range the summation of the forces contributes to TSF and ACL strain due to the increasing X contribution of the quadriceps muscle and the diminishing negative X contributions of the hamstring and gastrocnemius. Notice how at 160 degrees the muscles start adding to ACL strain and increase to 180 degrees flexion.

14.3.5.2 Acceleration

![Acceleration Graph](image)

**Figure XXXIX Shank Acceleration Sensitivity Analysis**
The above analysis shows the contribution of the foot and shank force as their acceleration vector is varied in degrees. Notice how their max contributions are at 18 degrees which correspond with the shank angle constant = 18 degrees that was held for this analysis.

14.3.5.3 Ground Reaction

Figure XXXX Shank Ground Reaction Force Sensitivity Analysis

The above analysis shows the ground reaction force contributions to the TSF. The purple line is the ground reaction force in the X direction and ranges from 0 N at 0 bodyweights of magnitude to -375 N at .5 bodyweights of magnitude. The negative values mean the ground reaction force is going in the opposite direction of the body’s momentum.
The green line is the ground reaction force in the Y direction. This ranges from 175 N at 1 body weight of magnitude (standing normal force) to 700 N at 4.5 bodyweights of magnitude.

15.0 Business Case

15.1 Market
The BASS creates value for customers who recognize that ACL injuries are possible and costly in terms of time and money. The BASS allows the buyers of the product to avoid the injury, thus increasing the expected playing time. Those customers can be broken into three categories: people who suffered an ACL injury in the 5 past years, NCAA athletes, and professional athletes; with a total industry sector count of 1.98M people (300,000 injuries/year * 5 years + 420,000 NCAA athletes + 18,000 Professional Athletes) [19]. With a selling price of $300, the total market value for this product is $593,400,000.

People who already suffered an ACL injury are being overprotective of themselves due to fear of re-injury. This is because an ACL becomes more prone to injuries if the native one teared initially, and a new one was reconstructed [19]. Sadly, only a 44 percent of people return to sport after injury; 56 percent of them have a fear of reinjury. The BASS will increase the amount of people who return to sport.

NCAA athletes are student athletes who care both about their studies and the sport they are in. Because there is so much going on their life, they do not have the time think of the risk they put themselves into. The BASS will act as the best trainer for them while they are in the field, constantly reminding them that they are doing something wrong. However, there is a risk that they will not buy this product due to its costly nature because they are still students and most likely do not have a steady income.
Professional athletes are a large target customer although they represent a very small portion of the overall market. If only small percentage of them bought the product, people will start recognizing the value of the product. It will not only create demand for the product, but it will also help their coaches, since professional athletes’ time out of their sport is more costly than NCAA athlete or a recreational one.

Since the product is new, it is fair to analyze the sales expectedly, optimistically, and pessimistically. The expected scenario is to capture 25% of the market in 5 years with 5% penetration rate and a market share value of 148M. The optimistic scenario is capturing 50% of the market in 5 years with 10% penetration rate and a market share value of 296M. The pessimistic scenario is capturing only 10% of the market in 5 years with 2% penetration rate and a market share value of 59M.

15.2 Costs and Investments
The business model assumes no inventory. The customer makes the order, is received and processed. Then the suppliers for the components are contacted, they ship out the parts. Once the components are received, the BASS is built and sent directly to the customers.

Table XVI summarizes the needed costs to start the business. The startup cost includes the market research, where the phase 1 of the BASS is distributed to 20 individuals to try the product and give feedback about the product, and any changes that should be made. It also includes overhead such as rent, utilities, and health insurance plans for employees. In addition, marketing and website development are included in the startup costs.
### Table XVI Startup Costs

<table>
<thead>
<tr>
<th>Costs</th>
<th>Amount/unit</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market Research (non-recurring cost)</td>
<td>3331</td>
<td>20 test product * cost of producing 1 unit</td>
</tr>
<tr>
<td>Overhead</td>
<td>63,200</td>
<td>Rent, Utilities, Health Ins</td>
</tr>
<tr>
<td>Rent + Utilities</td>
<td>54,000</td>
<td>$30/square feet* 1800 square feet</td>
</tr>
<tr>
<td>Utilities</td>
<td>6000</td>
<td>500/month*12 months</td>
</tr>
<tr>
<td>Health Insurance</td>
<td>3200</td>
<td>4 employees * cost of insurance/year</td>
</tr>
<tr>
<td>Marketing</td>
<td>20,000</td>
<td></td>
</tr>
<tr>
<td>Website Development (non-recurring cost)</td>
<td>5640</td>
<td>visual design, programming, content support, client training</td>
</tr>
<tr>
<td>Signing for webhost</td>
<td>59.4</td>
<td>$4.95/month*12 month</td>
</tr>
<tr>
<td><strong>Total Startup Cost</strong></td>
<td><strong>92,230</strong></td>
<td></td>
</tr>
</tbody>
</table>

Table XVII summarizes the operational costs of the business (recurring costs). The variable costs are the component and labor costs. It cost $204 to build the product for 2 knees, and 20/ hour for labor. The fixed costs include marketing, overhead, and webhost. The total operational cost assumes 4 employees working 2088 hours and producing at their maximum capacity.
### Table XVII Operational Costs

<table>
<thead>
<tr>
<th>Operational Costs</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensors Acquisition Costs</td>
<td></td>
</tr>
<tr>
<td>Potentiometer X2</td>
<td>0.34</td>
</tr>
<tr>
<td>Knee Sleeves X2</td>
<td>4</td>
</tr>
<tr>
<td>Pressure Sensors X16</td>
<td>127.2 Measures Ground Reaction Force</td>
</tr>
<tr>
<td>Speakers X2</td>
<td>0.94 Beeps When 1900 N is reached</td>
</tr>
<tr>
<td>Accelerometers X2</td>
<td>1.02 Measures Acceleration</td>
</tr>
<tr>
<td>Processor</td>
<td>19.95 3 sensors * 30.36/sensor</td>
</tr>
<tr>
<td>Flexion Sensor X4</td>
<td>51.8 Measures Knee Flexion</td>
</tr>
<tr>
<td>Total Cost of Components</td>
<td>204.91</td>
</tr>
<tr>
<td>Labor</td>
<td>14 hourly rate</td>
</tr>
<tr>
<td>Total Variable Costs</td>
<td>570525. Maximum Production for 4 employees*cost of components * number of workers</td>
</tr>
<tr>
<td>Fixed costs</td>
<td>83,259</td>
</tr>
<tr>
<td>Overhead</td>
<td>63,200 Rent, Utilities, Health Ins, Marketing</td>
</tr>
<tr>
<td>Marketing</td>
<td>20,000</td>
</tr>
<tr>
<td>Webhost</td>
<td>59.4</td>
</tr>
<tr>
<td>Total Operational Costs</td>
<td>653,785</td>
</tr>
</tbody>
</table>

#### 15.3 Projection
As previously stated, there were three scenarios considered in the market analysis. The first scenario is the expected scenario which captures 25% of the market in 5 years, and has a 5% penetration rate. In the first year the cumulative units sold equates to 98,900 units, has a revenue
of $29,700,000, operating cost of -$26,400,000, and profit of $3,300,000. By the 5th year the cumulative unit sold is 494,500 units, revenue of $148,400,000, operating cost of -$131,500,000, and a profit of $16,900,000.

The second scenario is the pessimistic one; this captures 10% of the market in 5 years, and with a 2% penetration rate. In the first year the cumulative units sold equals 39,560 units, revenue is $11,900,000, the operating cost are -$10,600,000, and the profit is $1,300,000. By the 5th year the cumulative units sold equals 197,800 units, revenue equals $59,300,000, operating cost are -$52,800,000, and profit is $6,500,000.

The third scenario is the optimistic scenario which captures 50% of the market in 5 years, with a 10% penetration rate. In the first year the cumulative units sold equates to 197,800 units, revenue of $59,300,000, has an operating cost of -$52,500,000, and a profit of $6,900,000. By the 5th year the cumulative units sold is 989,000 units, with a revenue of $296,700,000, an operating cost of -$262,400,000, and a profit of $34,300,000. All of the values are summarized below.

---

**Figure XL Expected Scenario Profit**

---

Figure XL Expected Scenario Profit
### Table XVIII: Profit Key

<table>
<thead>
<tr>
<th></th>
<th>Red</th>
<th>Blue</th>
<th>Green</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revenue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Profit</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure XLIII Annual Revenue

Figure XLIV Unit Sales

Table XIX Revenue and Unit Key

<table>
<thead>
<tr>
<th>Yellow</th>
<th>Blue</th>
<th>Red</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimistic</td>
<td>Expected</td>
<td>Pessimistic</td>
</tr>
</tbody>
</table>
15.4 NPV and ROI

The expected scenario has a NPV of $3,000,000 and ROI of 3,600% in the first year and a NPV of $16,000,000, and ROI of 18,000% in the 5th year. The pessimistic scenario has a NPV of $1,000,000 and ROI of 1,400% in the first year. By the 5th year the NPV will be $6,000,000 and the ROI will be 7,000%. The optimistic scenario has a NPV of 6,000,000 and a ROI of 7,000% in the first year. By the 5th year the NPV will be $33,000,000 and the ROI will be 37,000%. All of the values are summarized below.

Figure XLV NPV

Figure XLVI ROI

Table XX NPV and ROI Key

<table>
<thead>
<tr>
<th>Yellow</th>
<th>Blue</th>
<th>Red</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimistic</td>
<td>Expected</td>
<td>Pessimistic</td>
</tr>
</tbody>
</table>
Table XXI Data Table I

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Investment</td>
<td>92,230</td>
</tr>
<tr>
<td>Discount Rate</td>
<td>0.05</td>
</tr>
<tr>
<td>Hours to Produce 1 unit</td>
<td>3</td>
</tr>
<tr>
<td>Hours of work per year</td>
<td>2088</td>
</tr>
<tr>
<td>Fixed Cost</td>
<td>83,259</td>
</tr>
<tr>
<td>Labor cost per hour</td>
<td>20</td>
</tr>
<tr>
<td>Component Cost</td>
<td>204.91</td>
</tr>
<tr>
<td>Profit Margin</td>
<td>0.4</td>
</tr>
</tbody>
</table>

Table XXII Data Table II

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<table>
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<tr>
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<th></th>
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</thead>
<tbody>
<tr>
<td>Industry Sector Count</td>
<td>1978000</td>
</tr>
<tr>
<td>Selling Price</td>
<td>300</td>
</tr>
<tr>
<td>Total Market Value</td>
<td>593400000</td>
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</tbody>
</table>

Table XXIII Market Analysis

<table>
<thead>
<tr>
<th>Market Analysis</th>
<th>Expected</th>
<th>Pessimistic</th>
<th>Optimistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market Share</td>
<td>25%</td>
<td>10%</td>
<td>50%</td>
</tr>
<tr>
<td>Penetration Rate</td>
<td>5%</td>
<td>2.0%</td>
<td>10%</td>
</tr>
<tr>
<td>Market Share Value</td>
<td>$148,350,000.00</td>
<td>$59,340,000.0</td>
<td>$296,700,000.00</td>
</tr>
<tr>
<td>Year</td>
<td>Expected Sold</td>
<td>Labor Unit OC</td>
<td>Cumulative Sold</td>
</tr>
<tr>
<td>------</td>
<td>---------------</td>
<td>----------------</td>
<td>----------------</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>9890</td>
<td>142</td>
<td>98900</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>M</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>9890</td>
<td>142</td>
<td>19780</td>
</tr>
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<td></td>
<td>0</td>
<td>0</td>
<td>M</td>
</tr>
<tr>
<td>3</td>
<td>9890</td>
<td>142</td>
<td>29670</td>
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<td></td>
<td>0</td>
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<td>M</td>
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<td>4</td>
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<td>142</td>
<td>39560</td>
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<td>0</td>
<td>M</td>
</tr>
<tr>
<td>5</td>
<td>9890</td>
<td>142</td>
<td>49450</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
<td>M</td>
</tr>
</tbody>
</table>
Table XXV Pessimistic Data

<table>
<thead>
<tr>
<th>Year</th>
<th>Unit Sold</th>
<th>Labor Unit Sold</th>
<th>Cum Labor OC Sold</th>
<th>Unit Labor OC</th>
<th>Production OC</th>
<th>Total Operation Cost</th>
<th>Annual Revenue</th>
<th>Profit</th>
<th>NPV</th>
<th>ROI</th>
<th>Breakeven Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3956</td>
<td>57</td>
<td>39560</td>
<td>$2.4</td>
<td>$8.1 M</td>
<td>-</td>
<td>$11,868,00</td>
<td>$1,298,18</td>
<td>$1,144,13</td>
<td>1407 %</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>M</td>
<td>$10,569,81</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td></td>
<td></td>
<td>-10,569,81</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>3956</td>
<td>57</td>
<td>79120</td>
<td>$2.4</td>
<td>$8.1 M</td>
<td>-</td>
<td>$23,736,00</td>
<td>$2,596,36</td>
<td>$2,380,49</td>
<td>2815 %</td>
<td>after 1 year</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>M</td>
<td>$21,139,63</td>
<td>0</td>
<td>2</td>
<td>6</td>
<td></td>
<td></td>
<td>-21,139,63</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>3956</td>
<td>57</td>
<td>11868</td>
<td>$2.4</td>
<td>$8.1 M</td>
<td>-</td>
<td>$35,604,00</td>
<td>$3,894,54</td>
<td>$3,616,85</td>
<td>4222 %</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>M</td>
<td>$31,709,45</td>
<td>0</td>
<td>4</td>
<td>9</td>
<td></td>
<td></td>
<td>-31,709,45</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>3956</td>
<td>57</td>
<td>15824</td>
<td>$2.4</td>
<td>$8.1 M</td>
<td>-</td>
<td>$47,472,00</td>
<td>$5,192,72</td>
<td>$4,853,22</td>
<td>5630 %</td>
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<td></td>
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<td>M</td>
<td>$42,279,27</td>
<td>0</td>
<td>5</td>
<td>2</td>
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<td>-42,279,27</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>3956</td>
<td>57</td>
<td>19780</td>
<td>$2.4</td>
<td>$8.1 M</td>
<td>-</td>
<td>$59,340,00</td>
<td>$6,490,90</td>
<td>$6,089,58</td>
<td>7037 %</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>M</td>
<td>$52,849,09</td>
<td>0</td>
<td>7</td>
<td>6</td>
<td></td>
<td></td>
<td>-52,849,09</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>
Section IV: Recommendations and Future Research

16.0 Recommendations

To lower the probability of ACL tears, athletes and other individuals should use the Biofeedback Active Sensor System (BASS). This will alert an athlete of high levels of TSF, thus allowing the athlete the chance to mitigate the situation. This, in turn, will lower the probability of an ACL tear and save an athlete a possible $60 K they would have otherwise spent on surgery. If there is a monetary investor in the system, the above business case shows the profit after five years is $17 M with 494 K units sold. This produces a net present value of $16 M which is 18K % return on the initial investment of 500 K.
17.0 Future Research

The next steps in this project are to finish up the prototype. Currently, the system is ahead of schedule, the next step will be validation testing. After that, the prevention analysis for the abduction / adduction failure mechanisms will be added to the sleeve. Since the equations and analysis have already been performed and calculated, it is simply a matter of creating the software and hardware to incorporate it. After the abduction / adduction portion is finished, the internal / external rotation mechanism will be added. There is currently no formal analysis on this failure mechanism.

![Figure XLVII Future Steps](image)

**Acknowledgements**

We would like to give a special thanks to the people that have helped us through this semester:
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References


