

**ME 450 Fall 2021**

**System for Detecting and Logging Strenuous ACL Loading Cycles**

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## **Executive Summary**

There are 100,000-200,000 ACLs torn in the United States every year<sup>[1]</sup>. Although these injuries can occur from contact, the large majority of them are thought by a U-M research team to be caused by fatigue failures after excessive sub-maximal ACL loading cycles. The ACL is a ligament that connects the back of the femur to the front of the tibia. It functions as an important checkrein to ensure that as the knee goes through strenuous or unusual motions, the femur and tibia do not separate due to excessive shear. If this shearing motion between the tibia and femur becomes overly excessive the ACL can tear. The ACL is normally able to repair itself naturally, as long as the rate of damage accumulation does not exceed the rate of repair. In this state, its cells are maintained in a state known as homeostasis. However, if the excessive strain is being put on the ACL day after day, it falls out of homeostasis in a process that is catabolic resulting in unwinding and weakening of its collagen fibrils and introducing the beginning of a fatigue failure. If that process becomes too widespread it can lead to the tearing of the ACL.

Not only is an injury of the ACL painful, but the quantity of diagnosed ACL injuries is increasing as well. Over the previous 20 years, ACL injuries have increased by approximately 2.3% each year<sup>[2]</sup>. Using 3-D knee loading, it has been determined that these ACL injuries normally occur during loads that are equal to approximately 3-4 times that of the athlete's body weight, combined with a flexion moment and internal tibial torque - something that can be identified as it is happening<sup>[3]</sup>.

Our project goal consists of attempting to decrease the number of ACL injuries that are endured by athletes, particularly in basketball, soccer, football, and volleyball, by designing a system that will help to measure these risky sub-maximal cycles. By giving the athlete, trainer, coach, or parent insight into the ACL loading trends during a normal day of practice or competition, it will allow these individuals to titrate the training intensity so as to avoid catastrophic weakening of the ACL so it fails under normally strenuous training loads. Once the training load has been moderated to give the athlete the necessary recovery time, (s)he will be able to return to normal activity, but with continued monitoring using the system we designed.

Throughout our final solution phase, we developed our selected design through engineering analysis, testing, verification, and validation while implementing the ME 450 learning blocks. Further, we incorporated the knowledge we have obtained throughout our engineering experiences to understand the relevant material related to the project.

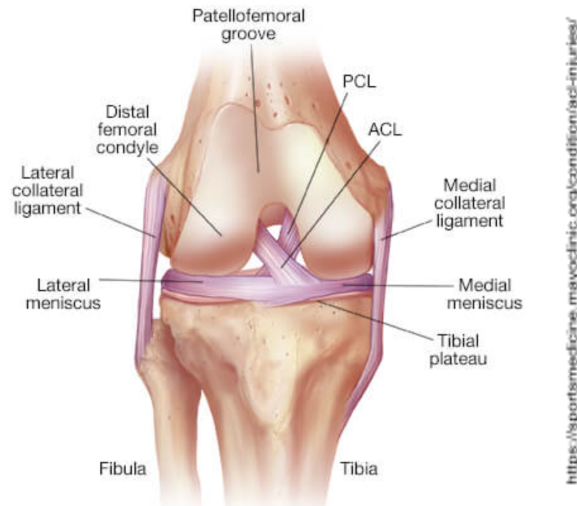
After conducting several sets of engineering analysis a prototype was designed along with a manufacturing plan. This plan was executed and several working models were made in order to conduct testing plans. Tests were conducted on the prototype to test the ability of the design to meet the engineering requirements and specifications set by our team and our sponsor. The design was successful in meeting some of these requirements, however others will require further development in order to meet the set requirements. Based on the result of our testing, we wrote several recommendations for a future team to consider if the product is to be further developed in the future.

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## Problem Description

The ACL is a ligament that connects the back of the femur to the front of the tibia (Fig. 1). It is an important safeguard within the knee to ensure the two bones do not separate from each other when the leg goes through strenuous motions. When the combination of ground force and internal tibial rotation becomes excessive, the ACL will often tear<sup>[4]</sup>. The path to recovering from such an injury is time-consuming, expensive, and painful. The most concerning fact about ACL tears is the rate at which they've been increasing. There has been an average increase in ACL injuries of 2.3% over the past 20 years and an overall increase of 924% from the year 1994 to 2006<sup>[2]</sup>.



**Figure 1:** Internal diagram of knee bones and ligaments.

Since ACL injuries have been trending in the wrong direction for so long and showing no signs of slowing down, the primary market focus has been to create preventative braces that restrict the motions commonly performed when ACLs are torn. However, not many people understand the impact submaximal loading cycles have on the knee. The ACL can tear when a large load is applied, around 3-4 bodyweight of force, combined with an internal tibial rotation moment, especially when that type of load is repeated between 2 and 100 times<sup>[4]</sup>(Lipps et. al). Prior to tearing, excessive loads and high strains on the ACL unwind the triple helix of its collagen fibrils (the smallest building block of the ligament that forms its bundles of collagen fibers ) thereby weakening them and the ligament. If this damage progresses and becomes more widespread whole collagen fibers start to fail within the ACL and there may not be enough time for the body to repair them before the ACL ligament partially or completely tears under what would usually be a normal maneuver for the athlete. This can help explain why approximately 70% of ACL injuries occur in non-contact situations<sup>[5]</sup>.

Other ACL tear prevention devices include wearable neuromuscular devices (Fig. 2) that reduce peak ground reaction forces and net center of pressure velocities to reduce the likelihood of an ACL injury<sup>[6]</sup>. However, this device only lowers the absolute risk reduction by 1.5%. There are also current methods to measure strain in the ACL *in vivo*. These methods can be invasive by requiring surgical placement of measurement devices within the knee or by requiring MR imaging and computer models to assess ACL strain<sup>[7]</sup>. These methods of ACL strain measurement are simply not practical and infeasible for our



intended use on the playing field or court. We need data to be readily available to help the coach/trainer maximize training benefit but minimize the risk of ACL injury.



**Figure 2:** Neuromuscular compression device provides bi-lateral, topical pressure to the medial quadriceps and hamstring muscles above the knee.

Our team has identified many of our stakeholders to be members of professional sports organizations. This includes the athletes who will be wearing our device on the field as well as those that they are competing with. The trainers are stakeholders as they will be utilizing our device to make educated recommendations for the athletes training schedule. Coaches and team owners are stakeholders in our project as the successful implementation of our device would result in their players spending more time on the field and improving team performance. Additional stakeholders include our team, the professors aiding us in our work, the University of Michigan, orthopedic specialists who aid in clinical testing of the device, and manufacturers of the device. There are approximately 75 million people who play basketball, football, soccer, and volleyball in the US of all ages. This is our targeted market and we can assume many in this population would be interested in using our product. This market is currently unsaturated and a safe device that can aid in preventing ACL injuries could have great market viability.

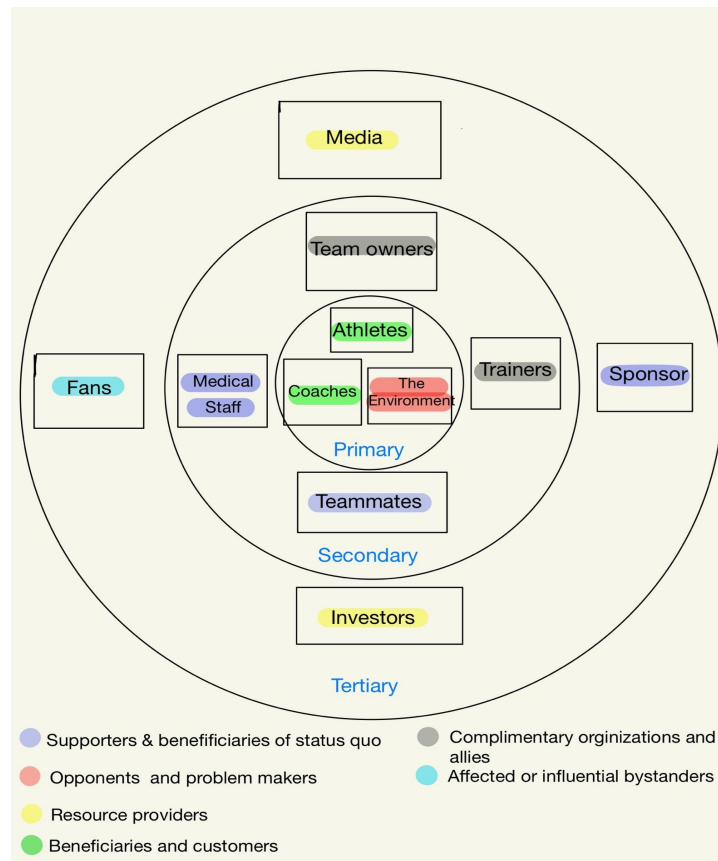
### **Intellectual Property**

Dr. James Ashton-Miller, who has partnered with the University of Michigan has the intellectual property for much of the background knowledge that we used within our concept. As a group, we also came to a royalty agreement with our sponsor, should our designed device be marketed in the future.

### **Social Context Assessment**

A stakeholder that will be positively affected by our project would be the users, or the athletes using our device, because of the functionality of the design in protecting the ACL. Our design will help the athletes determine when their ACL is at critical conditions to tear, before their ACL actually tears, saving them months or even years of pain and frustration. This would also be a benefit to the trainers monitoring the device, allowing them to be more effective within their jobs. The collegiate and professional organizations may benefit from the athletes protecting their ACL because the athletes can perform year round without a long period of rehabilitation due to a long term ACL injury. Additionally, the team owners and coaches would benefit from this device because it will help maximize their players to their full potential.

Some stakeholders that may be negatively affected by our device would be physical therapists. If our device started to noticeably impact sports by reducing ACL tears, physical therapists of all kinds, or those that specialize in ACL tears would receive less patients. Another negative stakeholder that we have identified is the environment, as our design at the moment includes a small amount of plastic, and these materials take extremely long times to completely decompose back into the earth. At the moment, the only method of disposing of our device would be throwing it away and buying another product. This could benefit stakeholders in the manufacturing industries and also University of Michigan in the long run because of the multiple product purchases that an athlete will have to make throughout their career.



**Figure 3:** Stakeholder/ecosystem map for primary, secondary, and tertiary stakeholders

In general our design will improve public health, safety, and welfare since the main goal of the design is to prevent injury. The global marketplace will benefit from the device because it can be used by athletes all over the world and would be available to a wide variety of social classes due to the low cost of building materials. This means that the product would be available to both developed and developing economies. Some social impact that the product may have would be an increase in pollution associated with the manufacturing and disposal. Since important components of the product are made of non-recyclable plastic, this could negatively impact waterways if it is improperly disposed of. Additionally an economic impact would be the monetary cost for the athlete since the product is single use, implying a recurring cost if this device is to be worked into a normal practice routine. We determined the social and economic impact by using the stakeholder map in order to determine who and what would

be affected by our device. The stakeholders were labeled as the primary, secondary, and tertiary stakeholders according to their impact from the device. As well, the stakeholders that we identified were broken down into categories such as resource providers, supporters and beneficiaries of the status quo, complementary organizations and allies, beneficiaries and customers, opponents and problem makers, and affected or influential bystanders.

### **Library**

At the beginning of our project, there was some interaction between our group and the engineering librarian, Joanna Thielen. Most of the interaction happened in the beginning of the term because of the background research that had to be completed in order to understand the structure of the ACL and the cause of the injuries. As a group, we split up the necessary research and divided up work within our group in order to gather as much information about the ACL as quickly as possible. We did experience some challenges during our research phase of the project, mostly concerned with finding viable sources. Firstly, the sheer amount of articles about ACL injury made it difficult to find sources specific to our application. Secondly, the type of ACL tear that we were looking to analyze within the scope of this project, (submaximal loading), was mostly covered only by Dr. Ashton-Miller. This meant that once we had read through his papers having to do with the topic, it was difficult to find external sources that related directly to our design constraints. Due to some new research done by Dr. James Asthon Miller, the hypothesis of multiple submaximal loading cycles on the knee causing ACL injuries did not have much sources to support it besides the data from our stakeholder.

### **Inclusion and equity**

The power dynamics between us and our stakeholders, end users, and other team members were different. Our stakeholder Dr. James Asthon Miller had a great influence towards our work because he was helping guide us to understand his own research and his advancement on ACL injury prevention. The power dynamic between us and the end users is that as engineers we are designing this device for athletes, all the way up to the collegiate and professional level. No one within our team are collegiate athletes but we are the ones making decisions that affect a group where we do not have first-hand experience. Within our group, there was not a noticeable negative power dynamic from teammate to teammate. Each of us are seniors who have taken a very similar mechanical engineering course load at the University of Michigan before taking this class. Our expertise and knowledge surrounding engineering concepts are similar, and therefore we were each able to contribute within the project. Furthermore, each of us are 21 year old males, with most of us being from the midwest. Although our design decisions were not made with this fact in mind, it is likely that it had an effect on our final design. It is possible that if a group of significantly younger mostly female engineers had begun the project and come up with a solution, they would have reached a very different conclusion compared to our final design. One approach that we took to ensure that our project was not designed specifically for males, was to complete verification testing on both male and female participants, where applicable.

In terms of different viewpoints throughout the project, most opinions and decision making actions were coming from the five members on our team, as well as our project sponsor. Throughout the concept generation phase, we received input from stakeholders such as Professor Noel Perkins and Dr. James Ashton-Miller. At some points within the project, it was difficult to not bias our ideas toward our sponsors recommendations, as both Professor Perkins and Dr. Ashton-Miller had much more experience with ACL

injury and engineering design, respectively, than any of us had. For this reason, we actively worked to make sure our own ideas were heard from each other, reaching this goal by enacting brainstorming sessions and holding team meetings after sponsor meetings to discuss what we had learned.

Our cultural similarities and differences between each team member influenced the way we approached the project. In this particular assignment our cultural similarities were far more noticeable than our differences as we are all men in our early twenties attending the University of Michigan. This led us to choose experiments with equipment we were familiar with. An example of this could be the way we selected an Instron machine to determine the properties of a monofilament fuse, similar to our common previous course, ME 395. With a large difference of age between our team and our sponsor, Dr. Ashton-Miller, this also influenced our project to some extent. Our sponsor has built up a career with a multitude of years focusing on ACL strain, and for that reason, may have been more inclined to suggest to us ideas that he has seen in his past experiences. This may mean that he was less receptive to novel ideas that use technology less familiar to him. As a similarity between us and our sponsor, we were fortunate enough to have a sponsor who was very active athletically throughout their life, running marathons and playing soccer regularly. As a group of young men who are all interested in watching and playing sports, this may have made it easier for us to concentrate and feel invested in our project goal of protecting athletes.

### **Ethics**

Throughout the project, our main focus was not on the ethical dilemmas of our design. However, at the end of our project, we realized some ethical dilemmas that we encountered along the way. One of the biggest ethical dilemmas was designing the prototype for females who play sports. There were points where we were too focused on making the device actually function that we did not take into consideration the different targeted audiences. Young female athletes are the most vulnerable to ACL injuries, and for that reason it would make sense for us to design the fuse to accommodate young female athletes. Due to the class deadlines, our design focused on a male knee as a reference so we could test it on ourselves. With more time, we would alter the design and create separate, standard fuses that would fit different users.

As a group, our personal and professional ethics were the same as the ethics we are expected to uphold here at the University of Michigan. Throughout the entire project, we tried to follow and implement the fundamental canons for engineers into every decision and actions we made. To begin with, we held paramount the safety, health, and welfare of the public by making safety a primary focus throughout our design process. We all agreed that safety should be prioritized in concept generation and concept selection so our finished product could be used in real-life situations without imposing any risks to the device wearer. We also took safety into consideration for every test performed in engineering analysis and for all of our verification and validation methods. Next, throughout our presentations and reports, we as a group individually performed services only in areas of competence and issued reports to the rest of our class and sponsors in an objective and truthful manner. In areas where certain team members had better understandings of topics covered within reports or reviews, they would primarily cover them in the presentations and reports. We split the work evenly this way to ensure competence and truthfulness to the best of our abilities. Acting as faithful agents or trustees with our stakeholders was another focus of ours, striving to be on the same page with our sponsor in order to produce the best possible results given the

time we had. Lastly, our group avoided deceptive acts and conducted ourselves honorably, responsibly, ethically, and lawfully, abiding by the engineering honor code wherever applicable.

### **Design Process**

The design process that we followed throughout the semester included brainstorming, diagrams, functional decomposition, and design heuristics to arrive at five concepts to decide between. We found some of the advice that was provided at the beginning of the semester to be helpful in generating the different ideas. Some of the systematic design process helped us generate and evaluate some of the earlier ideas. For example, the functional decomposition table helped us isolate the functions we want to accomplish by categories rather than focusing on an overall design.

### **Requirements and Engineering Specifications**

As described in the project introduction, our design must accurately represent the number of submaximal loads an athlete's ACL endures during exercise. Therefore, our device must be practical to wear for extended periods of intense training and competition, as shown through the following specifications. Our device is required to be safe not only for the athlete who is wearing it, but also for other athletes on the field. The safety requirements for any device worn during competition are set by many professional organizations such as the NFL, NBA, and MLS<sup>[8]</sup>. Our device will also be required to have a protruding profile of rigid material (hard plastics or metals) of less than 1mm to ensure safety. In addition to safety requirements, our device must be comfortable for athletes to wear during exercise and maintain functions during these periods. To limit the performance impedance, we require that the device does not limit rotation of any joint by more than 5% of the joint's full range of motion<sup>[9]</sup> in any direction and does not require adjustment more than three times during a 60 minute period.

To ensure functionality during contact sports, our device will be required to withstand 3000 N of direct force which equates to a high tackling force of an NFL player<sup>[10]</sup>. We assumed this number to be at the top end of forces that any sport would be experiencing. Additionally, the system must have an IP rating of IP 54 which states that the device is resistant to dust and water splashing on the device from any direction<sup>[11]</sup>. This IP rating was chosen because it is important for the device to withstand any dirt transmitted onto the device during use, as well as rain and sweat from the user.

To determine an appropriate accuracy for our device we looked at other systems that athletes use during training to measure performance such as a heart rate monitor. The typical error in exercise heart rate was approximately 3%<sup>[12]</sup>. Additionally, the Omron Blood Pressure Monitor has an accuracy of 2% which meets AAMI (Association of Medical Instrumentation) standards<sup>[13]</sup>. Thus our device should replicate an accuracy similar to this during performance use. Using sensitivity and specificity variables to define the accuracy of the device shows which loads are most important to capture. The device must have a sensitivity of at least 97% so that almost all sub-maximal loading cycles are recorded as such. Additionally, the specificity of the device should be more than 95%. The specificity is appropriately lower than the sensitivity because if slightly more negative values are reported as positive then the device will err on the side of caution. Additionally, it is important that our device operates under varying temperature conditions as athletes skin temperature fluctuates during exercise ( $\pm 5$  °C<sup>[14]</sup>) as well as outdoor temperatures changing throughout the year (-15 °C to 40 °C). Finally, it is necessary for our device to

accurately translate the information it records (relative rotation, ground reaction forces, relative strain) into direct ACL strain within 10%<sup>[15]</sup>.

For our project, it was determined that safety and accuracy of the device are the most important requirements. Since this device is projected to be used by professional athletes, compliance with all safety regulations is crucial to ensure its adoption by these organizations. Additionally, since the device is being used as a preventative measure for non-contact ACL tears, it is extremely important for the device to provide accurate information to the trainers and coaches so that they are best equipped to advise the athlete when they are reaching a dangerous amount of submaximal loads. If the information provided is not accurate, overtraining may occur and lead to a torn ACL, damaging the device's reputation.

**Table 1:** The following table includes the requirements provided to the team by the project sponsor and the related engineering specifications derived by the team.

<b>Sponsor Requirements</b>	<b>Engineering Specifications</b>
Safe to use during exercise	<ol style="list-style-type: none"> <li>1. Device must be compliant with equipment rules for the NFL, NBA, MLS, and other professional sports</li> <li>2. Device must not have a protruding profile of rigid material &gt; 2.5mm</li> </ol>
Accommodates athletes of varying size	<ol style="list-style-type: none"> <li>1. Device should fit 99% of humans with a BMI &lt; 30 (kg/m<sup>2</sup>)</li> <li>2. Device should be adjustable without requiring any additional tools</li> </ol>
Wearable during exercise	<ol style="list-style-type: none"> <li>1. Device does not limit joint rotation by more than 5% of the joint's range of motion</li> <li>2. Device does not impose torsional stiffness of &gt; 1N*m/deg</li> <li>3. Device does not require user adjustment &gt; three times during a 60 minute practice</li> </ol>
Durable	<ol style="list-style-type: none"> <li>1. Device has an IP rating of IP 54 (Protection against dirt and water from all angles)</li> <li>2. Device should be able to sustain a force of 3000 Newtons</li> </ol>
Readily provides data for analysis	<ol style="list-style-type: none"> <li>1. Device should provide ACL strain information within 10 minutes of data request</li> <li>2. Device should store the number of submaximal loads over 2 active hours for 24 hours</li> </ol>
Accurately reports data for ACL strain	<ol style="list-style-type: none"> <li>1. Translates recorded data to ACL strain within 10% of actual ACL strain</li> <li>2. Device must have a sensitivity of &gt;97%</li> <li>3. Device must have a specificity of &gt;95%</li> <li>4. Accuracy of device does not vary with temperatures ranging between -15 °C and 40 °C</li> </ol>

### Concept Generation

In our concept generation process, we applied brainstorming, diagrams, functional decomposition, and design heuristics to arrive at six plausible concepts to decide between. In our initial concept generation

meeting, we met virtually and held a brainstorming session via Google Docs. It was helpful to put all of our initial ideas on paper by encouraging wild ideas, building off of one another, and focusing on quantity rather than quality, but we weren't very organized and did not use the most appropriate approach. For starters, we focused on two different ideas: a knee mounted apparatus and a foot/ankle apparatus. We thought of different equipment to implement in order to measure and calculate strain with the two apparatuses and had subcategories within each concept for ways to attach the device to its users and ways to alert and inform athletes when their load limit was reached. After meeting with our sponsors and presenting a brief update to the class, we realized our initial concept generation was flawed. We were trying to build off of ideas already in mind rather than starting from square one, which is a backwards approach. Thus, we decided to hold another brainstorming session and applied two new techniques, functional decomposition and design heuristics, to really expand our concept generation.

We decided a better approach would be to create a functional decomposition table in order to isolate the functions we want to accomplish by categories rather than focusing on an overall design. We started by creating a table made up of five different functional categories we wanted our device to achieve; ways to measure strain, secure or mount the system, alert the athlete or trainer, store data, and transfer data. Isolating each category in our brainstorming session allowed us to come up with individual solutions that could accomplish each function. The functional decomposition table can be found below. From here, we were able to combine our function decomposition ideas with a few design heuristics to produce six design concepts to weigh out and compare.

**Table 2:** The following table includes the five functions we decided to isolate and the solutions we could implement into our five design concepts.

<b>Measure Strain</b>	<b>Secure/Mount System</b>	<b>Alerting Athlete/Trainer</b>	<b>Store Data</b>	<b>Transfer Data</b>
Force Gauge	Compression Sleeve	Electronic Indicator	Microcontroller	Bluetooth
IMU	Athletic Tape	Vibration	Cloud	USB
Strain Gauge	Sleeves/Tights	Sound	Micro SD Card	Near-Field Communication
Extensometer	Velcro	Break-off		Contact data transfer like wireless phone charging
GPS Locator		Ball-Bearing		
Special Turf		Ink Blot		
Motion Capture				
Fiber Optic Sensor				

The first design we came up with is a knee sleeve that has Inertial Measurement Units (IMU) embedded within the sleeve's fabric material on the proximal tibia and distal femur. A strap at the top and bottom of the sleeve would hold the device in place on the user's knee to make sure the measured values necessary to calculate strain on the ACL are accurate. Some of the design heuristics we used to come up with this concept were to attach product to user, use common base to hold components, and align components around the center. These were applied with the notion of embedding the IMUs symmetrically around the knee within the material of sleeve that athletes can wear on a regular basis. An initial sketch of this conceptual design can be found in Appendix A.

Our second design is a shoe insole with a pressure sensor embedded in the heel of the insole. The sensor would be capable of measuring the ground force on the user's leg which could then be translated to load on the ACL. A microcontroller would also be embedded within the insole somewhere capable of transferring its data to a phone, watch, or tablet through Bluetooth. We used the following design heuristics to generate this concept: hollow out, use common base to hold components, and add to existing product. A shoe insole is the existing product and common base we will use to hollow out and embed our pressure sensor and microcontroller to measure and transfer the load data on the ACL. Our initial sketch of the shoe insole can be found in Appendix B.

The third design concept we came up with is similar to our first one but it involves a fiber optic angular sensor rather than IMUs. The fiber optic sensor would run down the middle of a knee sleeve and measure the angular displacement along two reference points on the femur and tibia. This data could then be translated to detect submaximal loads on the ACL. We used the same design heuristics as our first concept in this generation process; use common base, attach product to user, and align components around the center. The knee sleeve is the common base that is attached to the user and the fiber optic sensor is the primary component aligned along the center of the knee and sleeve. A sketch of this conceptual design can be found in Appendix C.

Our fourth design concept involves an extensometer connected to the top and bottom of a knee brace. The extensometer would be on the inside of the knee measuring the displacement between the femur and tibia during motions on the playing field. It will accurately measure the strain on the ACL but will limit rotational motion on the knee as a whole. We have prior experience with this device in ME395 but it is a fragile device and it may not hold up well during exercise motions. The two design heuristics we used for this concept are attach product to the user and use a common base to hold components together. The knee brace is the product attached to the user and is also the common base used to hold the extensometer components. A sketch of this conceptual design can be found in Appendix D.

The fifth design concept we came up with is motion capture. The idea behind this method is a series of infrared cameras tracking and monitoring reflective markers on the athlete under consideration. Motion capture would track the speed, displacements, and angles of the athlete's legs. The data obtained from an athlete's motions could then be used to calculate the strain on the ACL but it would require a lot of equipment both on the player and on the field. The design heuristics we used for this concept generation are as follows: apply existing mechanisms in new ways and use multiple components for one function. The infrared cameras and reflective markers used to track and monitor an athlete's motions are the existing mechanisms and components used to complete one function.



The last design concept we generated is a mechanical fuse that attaches to the skin of a participant's knee. The fuse will fatigue after a certain number of specific loading cycles occur that aim to approximate strain across the ACL. The ends of the fuse will be mounted or taped to the participant's skin at a specific spot on the lateral skin bridging the meniscus. The fuse will be made of one or several fibers that will fatigue, informing the athlete that they are at elevated risk for ACL injury. The design heuristics we applied for this concept generation are as follows: attach product to user and simplify. The simplified design approach with this concept generated a device (the fuse) to deform or break indicating a load limit is reached rather than referring to data that is outputted to a respective microcontroller. The heuristic, attach product to user, is met because the mechanical fuse will be mounted to the athlete's skin around the femur and tibia.

### **Concept Selection Process**

We converged to our top six designs by addressing which designs were possible to construct, simple in design, and able to meet the requirements and specifications we previously set. The first design, our baseline in the Pugh chart, is a knee sleeve embedded with 2 IMUs. The other five designs we compared with to our baseline concept are as follows and more thoroughly discussed in the concept generation section: a shoe insole embedded with a pressure sensor, a knee brace / sleeve embedded with a fiber optic sensor, a knee brace / sleeve design involving an extensometer, motion capture, and a mechanical fuse that attaches to an athlete's knee.

To choose the best concept, we generated a Pugh chart to determine which requirements and specifications each concept will be capable of completing compared to the baseline concept. Each of the requirements and specifications used in the Pugh chart were weighted in terms of importance of our design. The most important guideline was weighted 5 while the least important was weighted a 1.

The requirements and specifications that were the most important and weighted a '5' were being "safe to use during exercise" and "accurately reporting data". The requirement of accurately reporting data for ACL strain was rated as a '5' on the Pugh chart because the ultimate goal of the design is to help determine when an athlete needs to decrease exercise intensity. We weighted "safe to use during exercise" as a '5' because the device has to be worn while an athlete is participating in practice, games, and/or other physical activities. Since this is the case, we need to ensure the device is safe for both the wearer themselves, as well as not imposing any risk on other athletes in play.

"Wearable during exercise" was weighted as a '4' because if the selected design must be worn while the athlete is exercising, it should not be affecting their performance significantly. Furthermore, the athletes should not need to adjust the device often. "Readily provides data for analysis" was weighted a '3' on the Pugh chart because ideally, the athlete will know when they have reached their limit during action, but it is possible that the data might not be processed until after the athlete's exercise session.

The last two requirements and specifications we used are "durability", and "accommodated athletes of varying size". These were weighted a '1' and '2' respectively within the Pugh chart. The device could be durable, but it could also be a disposable product which does not play a large role within the data collection of the device and the general safety of the athlete. For these reasons, durability was weighted to be the least important of the primary goals of the design. Accommodating athletes of varying size was

weighted a ‘2’ because creating a functioning design capable of providing accurate and reliable data is a priority compared to creating a device that could potentially be one size fits all. Accommodating various sizes of athletes is also potentially a task to focus on later, after addressing how the device will actually provide necessary data while simultaneously ensuring the safety of the athlete.

**Table 3:** The following table includes the Pugh chart we used to rate the six conceptual designs we generated. The weights of each requirement vary depending on importance and concept designs 2 through 5 are weighted in comparison to the baseline concept, the knee sleeve with the IMUs.

Requirements	Weight	#1 Knee	#2 Insole	#3 Fiber Optic	#4 Extens	#5 MoCap	#6 Fuse
Safe to use during exercise	5	0	+1	-1	-1	+1	0
Accommodates athletes of varying size	2	0	-1	0	0	+1	-1
Wearable during exercise	4	0	0	-1	-1	+1	0
Durable	1	0	0	-1	-1	+1	-1
Readily provides data for analysis	3	0	-1	1	0	-1	+1
Accurately reports data for ACL strain	5	0	-1	1	0	-1	+1
	Total	0	-5	-2	-10	4	5

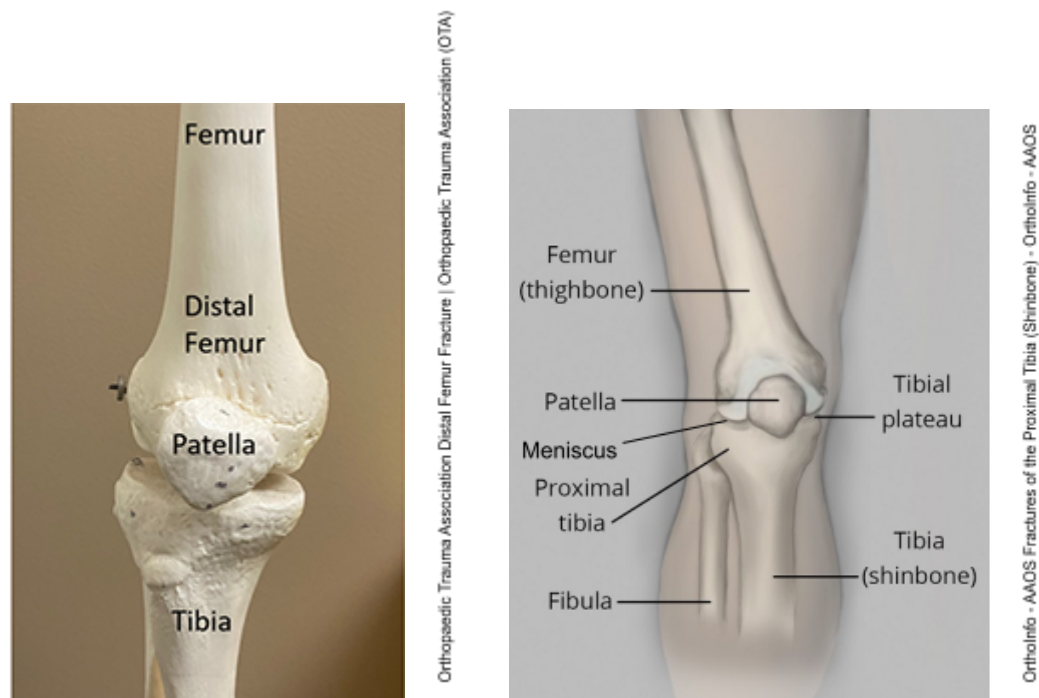
After weighing the requirements and specification, the total scores of each design were calculated. The insole scored a -5. The shoe insole design earned this score because it is difficult to accurately calculate the data for the strain of the ACL using a pressure sensor at the bottom of the foot. However, a serious advantage of this device is the athlete being able to comfortably wear the insole inside their shoe for the full duration of practices and games. The fiber optic sensor scored a -2 because it would be difficult for the athlete to wear the device during practice or game time. Through further research, we learned the sensor has to be connected to a large data machine to produce our desired results, which isn’t feasible. Not only that but the cost of the fiber optic sensor is well beyond the ME 450 price range. Our fourth design, the extensometer-focused knee sleeve, had a total score of -10 because of how it would interact with an athlete wearing it during exercise, practice, or games. The extensometer would be on the outside of the brace which isn’t safe to wear and would not meet our durability requirement. Thus, athlete’s wouldn’t be able to wear it during exercise which is a crucial part of our design requirements. The motion capture design scored an impressive 4 but was deemed to be infeasible due to the issue of accurately isolating an individual athlete through video. In addition there is a high monetary cost to set up the conditions

necessary to gain accurate data using this method, meaning that it would be impractical for the scope of this project.

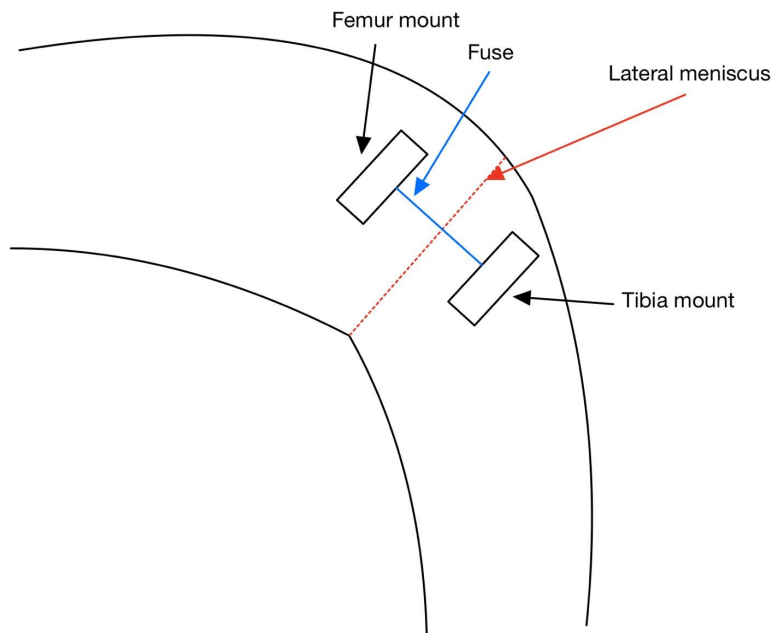
Ultimately, we decided to pursue the fuse design concept given the fact it scored the highest in the Pugh chart, 5, and is possible to complete over the course of the semester. The fuse could be worn during the athlete's physical training and it should not interfere with the safety of those who wear it or are on the same playing field. The fuse also easily accomplishes many of the design requirements since it indirectly gauges ACL strain from lateral skin as the athlete moves and it immediately reports that data in the form of fatigue failure.

### Concept Description

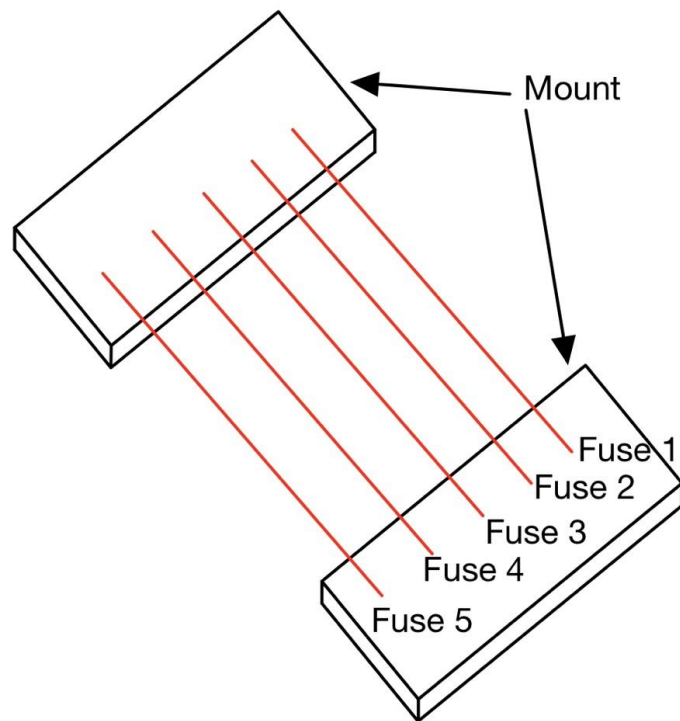
The concept that we have selected is a fuse that bridges the lateral meniscus from the distal femur to the proximal tibia as shown in Figures 4 and 5. This fuse will be able to sense strain as the tibia rotates relative to the femur and will fatigue after an inner tibial rotation of 12 degrees. This rotational value was selected as it represents 80% of a maximal loading cycle of 15 degrees. The fuse will be secured directly onto the skin as displayed in the side view presented in Figure 6.



**Figure 4 and 5:** Location of distal femur, proximal tibia, and meniscus



**Figure 6:** Side view of fuse concept, Alpha design



**Figure 7:** Mount and fuse setup, with multiple fuses instead of singular fuse

By sensing the relative rotation of the tibia with respect to the femur, we hope to be able to calibrate our fuse to fatigue after a set number of loading cycles, more specifically a very low number such as five cycles. Once the fuse has fatigued and subsequently broken, the athlete will be removed from competition to prevent future loading cycles that could cause the ACL to tear. If the athlete is removed quickly enough after the fuse is broken, it is reasonable to expect the ACL to not sustain any long-term injuries. It is important to note that fatigue is a process which has an element of randomness due to the way microcracks propagate during loading cycles. This means that our design may require multiple fuses to account for such randomness. In this case, after a set number of fuses were torn within the device, the athlete would be able to realize that they were approaching a dangerous point in regards to their ACL, and they would be promptly removed from activity. In this alternative concept, the design would incorporate multiple fibers with each fuse designed to break at different ultimate tensile forces, depending on the material properties of the fuses, such as cross-sectional area, and individual young's modulus. As more fuses break, the force necessary to rupture each sequential fuse will decrease due to the increased load across a smaller number of fuses, each of which are experiencing the same amount of elongation within the device. Ultimately, after speaking with individuals such as Andy Poli who had worked extensively with cyclic loading, we determined that it was not reasonable to expect that a fuse could fail after an amount of loading cycles as low as five. For this reason, we moved forward with a design that incorporated fuses that failed sequentially.

This concept was chosen for its ability to be used safely during practice, competitions, or any activity chosen by the athlete. With the locations of the fuse being retained very close to the surface of the knee, the risk of impact towards the outer elements of the athlete's knee or leg remain low as long as the load does not exceed the force outlined within the engineering specifications. As well, with the construction components within this chosen design being relatively cheap and readily available, the product market is scalable for different groups and ages of competitors. If this design is chosen to be implemented within an athletic knee sleeve, this should cause no additional impact to the athlete. Athletic sleeves are usually between 5 mm and 7 mm in thickness, so the addition of small fibers within the athletic apparel will cause minimal risk to the athlete's safety. If the fuse or fuses are chosen to be implemented directly to the skin, with tape or another method of securement, then the profile of the device is even thinner, which should cause minimal negative athletic influence to the device wearer.

For whichever securement method is selected, there is no need for constant adjustment throughout use from the athlete. More importantly, fuse strain data must correlate accurately with internal tibial rotation, to give the athlete a realistic idea of when their ACL is overloaded. The material of the fuses selected are going to have to be able to withstand a variety of weather conditions and exhibit similar properties in each scenario. As long as the selected material can withstand dirt and moisture, there is little concern for performance differences across outdoor sports. As well, sports and activities performed indoors will not cause additional issues, as indoor conditions are more mild than their outdoor counterparts. Furthermore, with a design built to allow for accurate fuse placement, it will be possible to find a location on the knee with a strong correlation to inner tibial rotation, with the aim to approximate ACL strain within 10%.

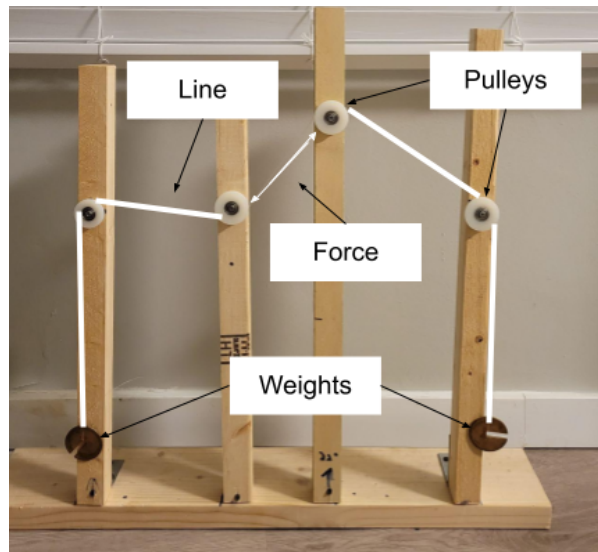
A concern we have within this design is that the fuse may rupture when loaded by a significant normal or glancing force. For this reason, the product may be more valuable for practice situations in sports where large direct forces onto the knee are common during competitive events. This would likely only affect

sports where collision is common, such as rugby, football, or hockey, as most other sports do not involve violence of such a manner. Another option to reduce this issue would be to include a cage or other protective layer above the fuse system to protect the fuses from breaking unnecessarily.

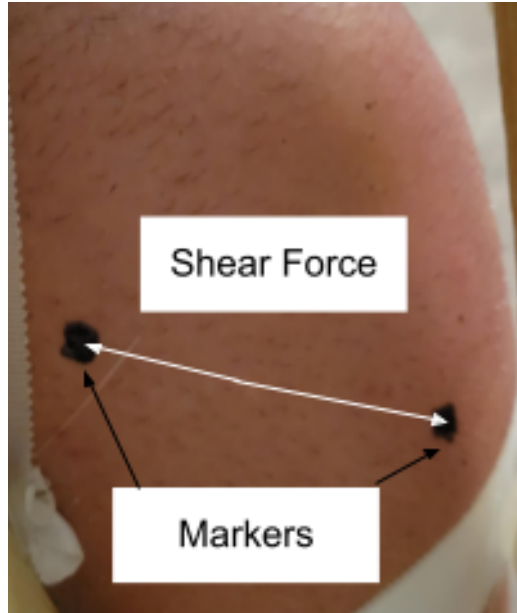
**Engineering Analysis:**

The first physical property to be considered when designing the fuse prototype is the elasticity of the lateral skin on the knee, as the device is to be attached directly to the skin with an adhesive. When the fuse fibers tense, they apply a shear force on the top skin. As a result, some level of skin displacement in relation to the distal femur and proximal tibia has to be considered against the device's performance. For this purpose, it was important to determine a mathematical model that governs the relationship between applied shear force and skin displacement.

In order to ascertain the skin's elastic response to shear forces, a test was performed that involved applying various loads and measuring the resultant change in two points on the skin. First, we created an apparatus that was capable of creating measurable tensile forces by employing a series of pulleys, fishing line, and precision weights as pictured in Figure 8 below. Next, a subject's knee was marked with two points as shown in Figure 9 and inserted to the center of the apparatus as shown in Figure 10. Then, we conducted an iterative process of measuring the distance between the two points on the subject's knee followed by increasing the tensile force on the apparatus by 50 grams between each measurement. In due course, this procedure was repeated for weights ranging from 0 grams to 600 grams.



**Figure 8:** Testing apparatus used to apply load to skin of lateral portion of knee

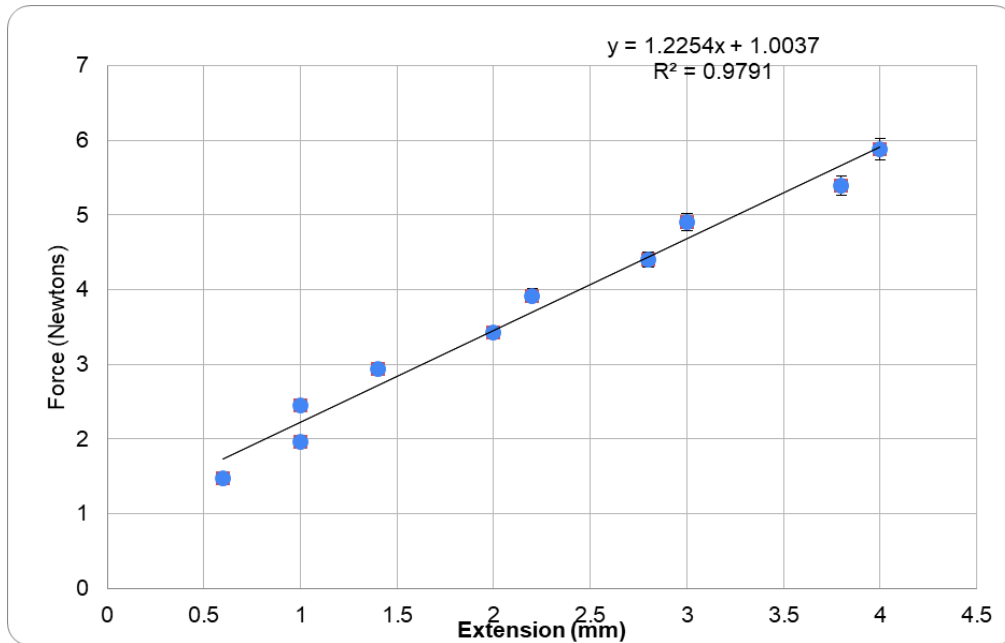


**Figure 9:** 2 Markers on the knee and direction of shear force applied.



**Figure 10:** Location of knee in apparatus

The result of this experiment was a series of data points that related average skin displacement with applied shear force as shown in Figure 11. From this chart, we concluded that it was valid to model the skin as an ideal spring with a constant value of  $k_s = 1.23 \pm \text{N/mm}$ . This model was found to be valid due to the high correlation value of  $R^2 = 97.91\%$ . In addition the short time interval of risky ACL loading cycles will mitigate any damping properties that the skin may have. Importantly, there are many other factors that can influence the skin spring constant value determined by the results of this experiment, such as age, body fat content, gender, temperature, and genetics. However, we made the assumption that a majority of athletes have minimal variance in skin properties, since most athletes are relatively young and have similar body compositions.



**Figure 11:** Graph showing skin displacement on lateral knee compared to applied shear force

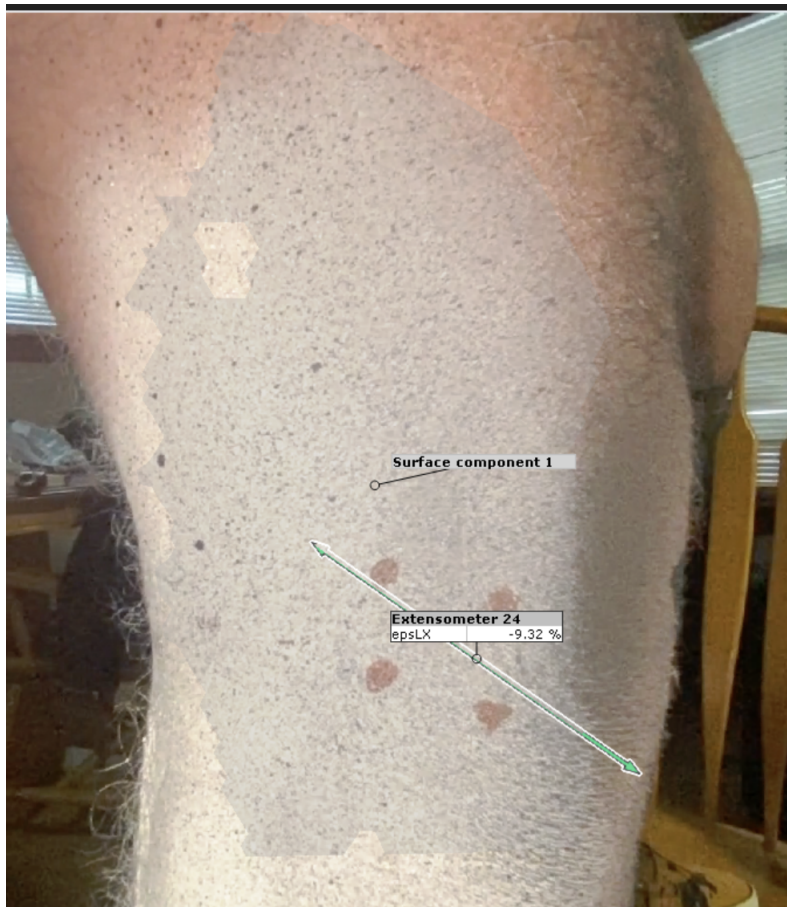
The second piece of engineering analysis completed for the success of the fuse prototype design is skin behavior during internal tibial rotation. Since the fuse is mounted directly onto the skin and is designed to tense as the tibia rotates, knowing the properties of the skin under the ends of the fuse is critical to ensure proper functioning of the prototype. These properties include: 1) the optimal placement of the ends of the fuse to correlate internal tibial rotation, 2) the strain in the skin during flexion, and 3) the strain of the skin during rotation at the ends of the fuse.

In order to determine these three properties, the skin was marked with spray paint in a speckled pattern and filmed while undergoing internal tibial rotation as shown in Figure 12. The angle of flexion in the knee was measured to be fifteen degrees, and then the knee was rotated twelve degrees internally as shown in Figure 12<sup>[22]</sup>. This process was repeated five times to generate an array of data points. After the experiment was concluded, the videos were loaded into the GOM Inspect software to determine the dynamic properties of speckles on the skin as shown in Figure 13. A hundred distances on the speckled portion were analyzed using the software, and their locations and strain values at twelve degrees internal rotation were recorded. This process was repeated with the knee undergoing flexion instead of internal rotation.





**Figure 12:** Applied knee speckling and direction of rotation



**Figure 13:** Strain data collected from speckled portion using GOM Inspect software

Key information regarding the dynamic properties of the lateral skin on the knee during internal tibial rotation was gathered as a result of the GOM Software experiment. The location of the speckle that was to be used as a marker for the end of the fuse and best correlated to internal tibial rotation as identified by the software was determined to be 1 mm below the proximal tibia (upper most point on the shin below the meniscus) and 1 mm along the lateral skin toward the back of the knee. The second point was determined to be 23.47 mm above the first point and 42.14mm towards the back of the knee. A line between these two points creates a 62 degree angle with respect to the meniscus, and the length of the skin in this region is 50 mm. The software also identified that during rotation the skin strained by a maximum of 9.32% during a twelve degree internal rotation. From the maximum strain value of 9.32% and the initial skin length of  $x=50$  mm, it can be determined that the change in length of the skin was  $\Delta x=4.66$  mm from the formula  $\text{Strain}\% = \Delta x/x$ . The amount of strain during flexion from the same points was analysed and found to be 5.12%. Although this may cause varying performance in the device, in most athletic competitions we made the guided assumption that competitors rarely exceed fifteen degrees of flexion in the knee joint<sup>[22]</sup>. If they do, it is likely even more rare to have an internal tibial rotation occur at the same time. Some notable exceptions to this assumption include downhill skiing and other extreme sports. However, since the majority of athletes in the United States do not compete in extreme sports or downhill skiing, the 5.12% strain caused by flexion was determined to be of minimal risk. We have confidence in this statement because the fuse will be designed to fail during internal rotation, and since the strain value of internal rotation exceeds the value at knee flexion by a considerable margin, it is unlikely that flexion alone will cause false failures.

The goal of testing the monofilament was to determine if the properties of the selected fuse matched the required material properties. This was one of the most important pieces of the puzzle within our design, as the selection of the fuse material would dictate at what point it broke. With an inner tibial rotation of 12 degrees correlating to an elongation within the skin of 9.32%, we were searching for a material that snapped at this extension. By using an Instron machine for this empirical testing, we were able to determine the ultimate tensile strength and the spring constant of our selected monofilament. The values of the spring constant and ultimate tensile strength would help determine how much pre-tension force was necessary when applying the fuses to the knee.

The first round of testing was to determine the spring constant of the 4lb monofilament that we had purchased. Because the spring constant is not determined from the length of the specimen, it was not important that we test monofilaments of similar length to our final design, of 50mm. The fishing line tied securely around the end of a split shot, and then the clamp was inserted into the clamps on either side of the Instron. By marking the fishing line at either end, directly where it had been tied to the split shot with a sharpie, we were able to determine if there had been any slipping within the knot, and throw out any of those results from our final calculations. With the monofilament attached on either end, the Instron machine was set with a speed of 10mm/minute, with a sampling rate of 20 hertz. We conducted five different tests on the monofilament to determine the spring constant, removing one of them from our results due to slipping within the knot.

Using the spring constant equation of  $F = \frac{k}{\Delta x}$ , we took the output force from the Instron, multiplied by the extension of the monofilament within each data point to determine an average spring constant for the

4lb fishing line. This result among the four tests was  $k_{average} = 0.192 \frac{N}{mm}$ . Taking the standard deviation of the spring constant values generated a value of  $0.024 \frac{N}{mm}$ . From here, we were able to calculate an upper and lower bound for spring constant values.

**Equation 1:** 4lb monofilament minimum spring constant value

$$k_{min} = (0.192 - 3 \cdot 0.024) \frac{N}{mm} = 0.122 \frac{N}{mm}$$

**Equation 2:** 4lb monofilament maximum spring constant value

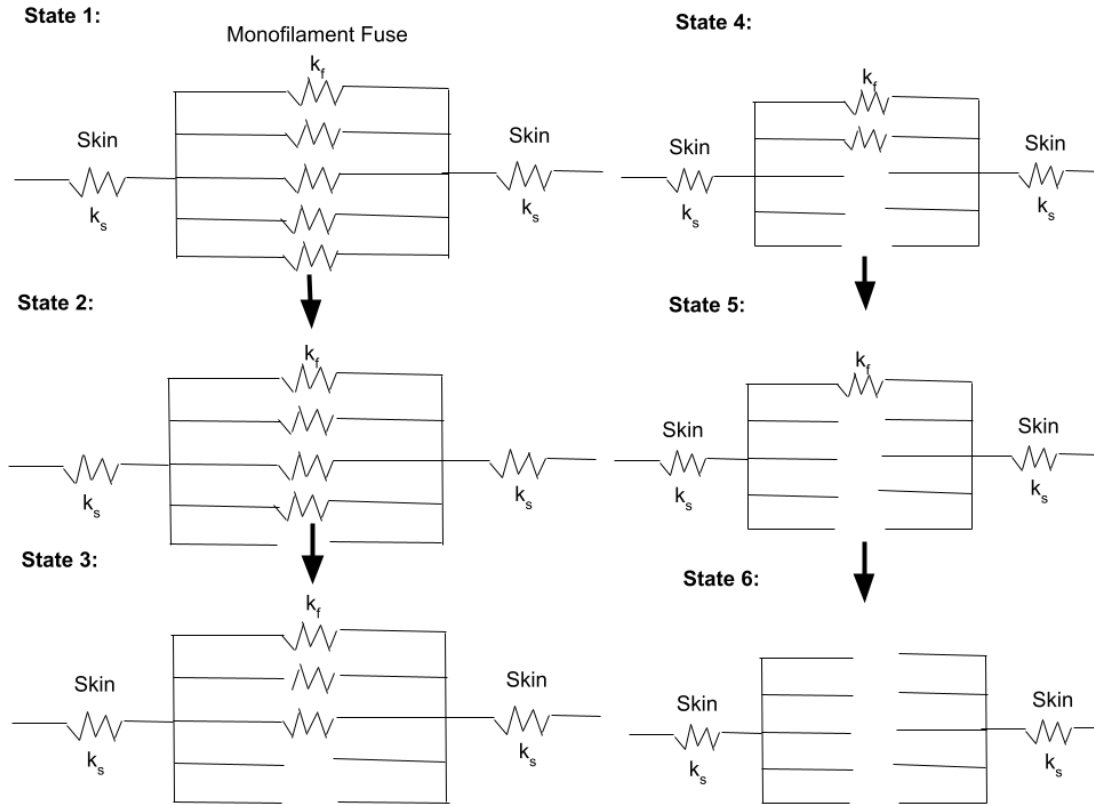
$$k_{max} = (0.192 + 3 \cdot 0.024) \frac{N}{mm} = 0.263 \frac{N}{mm}$$

The determined average spring constant of the monofilament of  $0.192 \frac{N}{mm}$  was more than 6 times less than the calculated spring constant for the skin, of  $1.23 \frac{N}{mm}$ . This aligned with our expectations, indicating that for an inner tibial rotation that extended the fuse, there would be considerably less stretch within the skin on the knee, compared to the amount of stretch applied to the fuse, which was an important facet within our design.

The next test that we performed on the 4lb monofilament was to determine its ultimate tensile strength. The monofilament was inserted into our testing device in the same manner that we had for the previous tests. The fuse was cut, and then marked with a sharpie at both ends to alert us of slippage throughout the test. After the monofilament was extended at the same speed and time rate as the previous tests, the force at which it failed was recorded. For five 4lb monofilaments, the average UTF was 20.69N, with a standard deviation among them of 2.92N. To attempt to lower the UTF, we began by tying 10 knots evenly throughout the line. When we repeated the test, the UTF came out to 19.06N. This was a slight decrease but was not as large of a difference in final strength of the material as we had hoped. In our second method, sanding the monofilament 50 passes with 100 grit sandpaper along the middle 80% of the line, the UTF dropped significantly. Repeating the test with the sanded monofilament resulted in an ultimate tensile strength of 4.55N. This value represents the amount of force that the skin on the knee would have to experience during inner tibial rotation before being able to break the fuse.

The final piece of analysis was to calculate the failure conditions of the monofilament fuse. This was important to the design because indication of a risky ACL loading cycle was to be communicated with the athlete through a single fuse failing. As a result, the success of the design was heavily reliant on the ability to predict the failure modes of the fuse during known loading conditions. The goal of this set of analyses was to determine how much pre-tension force was necessary for five fuses to fail sequentially during loading cycles.

The analysis was performed by first assuming a simplified mechanical model that treated each fuse and the skin at the attachment site as ideal springs. The model included six distinct “states” that represented different quantities of loading cycles. Initially, all six fuses are intact meaning that the device has not undergone any loading cycles. After the first loading cycle one fuse would fail leaving the device in “state 2” as shown in Figure 14. This process would repeat until all fuses were broken marking the end of the device's intended operation.



**Figure 14:** Shows three states of the device. State one is before any loading cycles have occurred. State two is after one loading cycle. State six is the final state after five loading cycles.

After the idealized model, the first calculation was performed to determine the amount of force transmitted to the skin from the knee during rotation. This value was computed to be 5.71 N using the formula  $F=k_s\Delta x$  in addition to the constants established through previous experimentation. 5.71 was then accepted as the net force acting on the system through each loading cycle.

The next step was to determine the force needed to cause failure of one fuse in each state, which was accomplished by first calculating the amount of load that the fuses bore during loading cycles compared to the skin using Equation 1:

**Equation 3:** Load on fuse from skin at each state

$$F_{Fuse} = F_{Total} / N_{Fuses}$$

with  $F_{Fuse}$  being 5.71N and  $N_{Fuses}$  being the array {5,4,3,2,1}. The load on each fuse fiber was found to be 1.142N, 1.428N, 1.903N, 2.855N, and 5.710N for State 1, State 2, State 3, State 4, and State 5 respectively during loading. This meant that the ultimate tensile force (UTF) for each fiber of the fuse would need to match these values.

After the desired ultimate tensile strength was confirmed for each fuse fiber the next step was to determine the pre-tense force, and thus the pre tense length, required for the monofilament to fracture at

the required loads. This was critically important for the success of the design because we decided to use four pound monofilament as the material for our fuse fibers and thus different pre-tension values were required to cause different failure modes.

The pre-tension force was determined by taking the known UTF of the sanded monofilament fiber of 4.445N and subtracting the force for each failure mode. The load on each fiber for each state was subtracted from the UTF and resulted in pre-tension forces of 3.303N, 3.017N, 2.542N, 1.59N, and 0N (fifth fuse has zero pre-tension due to internal rotation alone providing sufficient tension for failure) for fuses one through five respectively. These values were then used to find the pre tense length, that the mono would have to be cut to before application, using Equation 2:

**Equation 4:** Finding initial length of fuse fiber

$$L_0 = ((F/(AE) + 1)/Lf)^{-1}$$

with Lf being the final length of the fuse (50mm), F being the pre tense force, A being the cross sectional area of monofilament (0.0706mm<sup>2</sup>), and E being the elastic modulus (1530MPa<sup>[21]</sup>). From this equation the pre-tensioned length for each monofilament was determined to be 48.518mm, 48.643mm, 48.852mm, 49.276mm, and 50mm.

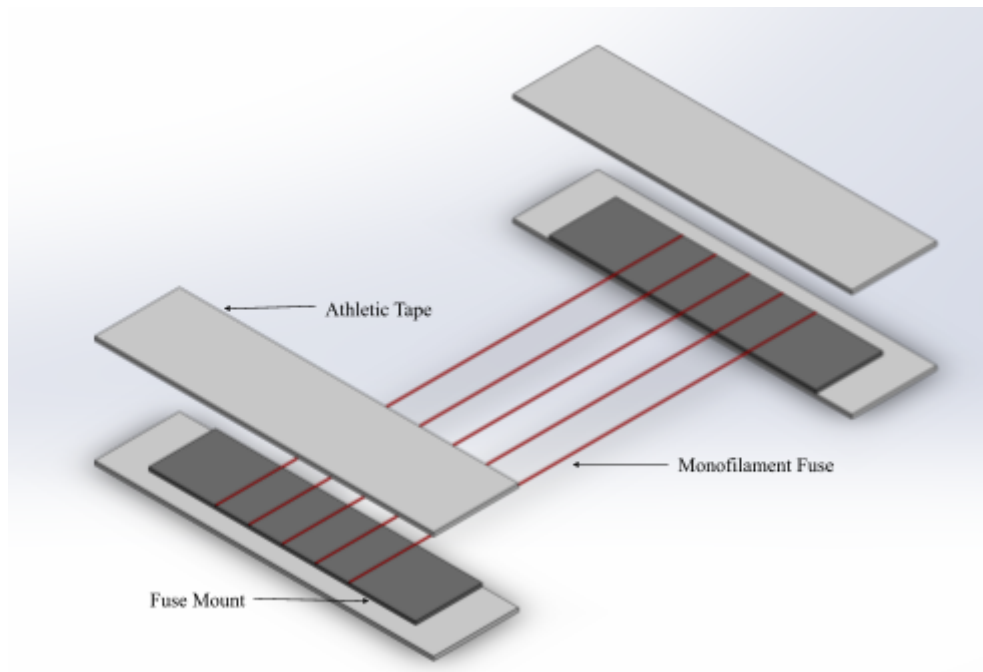
It is important to acknowledge that these values are valid for a very idealized system making any assumptions. Those assumptions include that our idealized system accurately represents dynamic behavior of the lateral skin on the knee, force is evenly distributed across all of the fuses, skin stretch caused by the pre-tensed force of the fuse is negligible, and all values remain constant.

### **Final Design Description:**

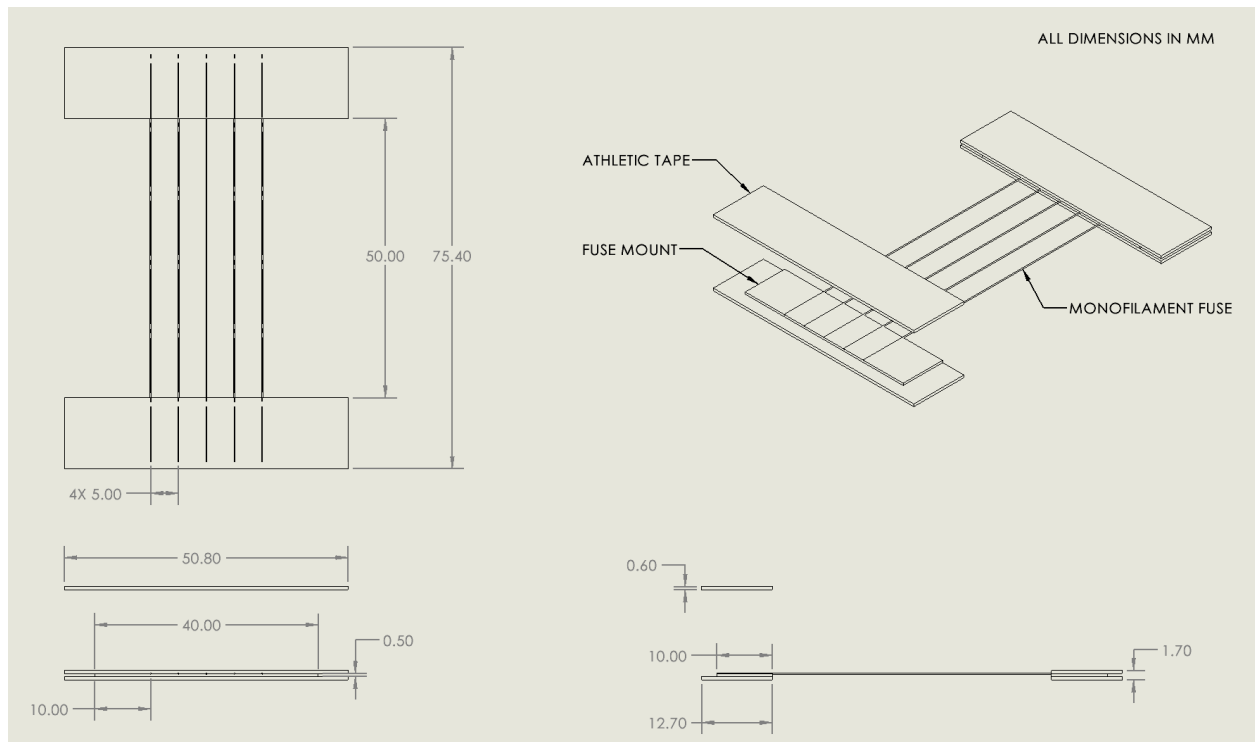
Our selected concept will be a knee-mounted fuse that utilizes the mechanical failure properties of monofilament line to alert the athlete when they are overloading the ACL. It will consist of five monofilament lines tensioned between two pieces of athletic tape. The device will also utilize machined HDPE mounting strips to minimize the displacement of the fuses not associated with internal-tibial rotation. The fuse will then be attached to the distal femur and proximal tibia, bridging the meniscus of the athlete as seen in Figure 15. It is important that the fuse is placed at an angle of 62° relative to the plane of the meniscus as discussed in the engineering analysis. To ensure that the fuse is properly placed it will be secured to a thin plastic film that will pre-tension the fuse and will be illustrated with proper orientation markings to instruct the trainer on placement. Once the fuse is secured to the athlete this jig can be removed. CAD models of our final device are shown in Figure 16 and 17.



**Figure 15:** Shows the placement of the monofilament fuse prototype on a subject's knee



**Figure 16:** Exploded view of selected fuse design using monofilament



**Figure 17:** Dimensions of monofilament fuse device

Our device is required to alert the athlete when a submaximal load is applied to the ACL. A dangerous number of submaximal loads can be described as five cycles of 80% loading which equates to 12° of internal-tibial rotation<sup>[22]</sup>. Therefore our device utilizes sequential failure of five monofilament fuses to indicate when each submaximal load is met. As shown in Figure 14 and the engineering analysis, the force applied to each fuse increases as each fuse breaks. Each fuse is thus pre-tensioned with a prescribed force so that the total force experienced by the fuse exceeds its UTF in the desired stage as shown in Eq. 5.

**Equation 5:** The total force experienced by the fuse during a given stage of failure.

$$F_{Total} = F_{Fuse, Stage} + F_{Fuse, Pre-Tension}$$

After our engineering analysis it was determined that the stock 4lb monofilament line was too strong for our application. However, monofilament can be physically manipulated to alter the ultimate strength of the line<sup>[19]</sup>. Thus each fuse was sanded using 100 grit sandpaper to reduce the force required to break each fuse from 20.69N to 4.45N as described in Appendix D. Having a lower ultimate tensile force allows each fuse to be pre-tensioned with a lower force reducing the initial skin displacement the device places on the athlete's knee.

Our initial build solution was similar to the final build solution shown in figures 16 and 17, however, it utilized five fuses that were not pretensioned. When the build is being constructed the tolerances for the distance between fuse mounts and initial lengths of each monofilament line must be very small. The

failure of each fuse depends on the amount of strain it undergoes during 12° of rotation so it is critical that the initial lengths of each fuse are accurate. The spacing between each fuse is less critical as long as they remain parallel and the length of each mounting strip can also experience some variation as it is not critical. A complete bill of materials and manufacturing plan for the build design can be found in Appendices C and D respectively.

The build design has the same physical embodiment as the final design solution and can be used throughout verification and validation to ensure the final design would meet several of the requirements such as being wearable during exercise, had a minimal profile, durability, and met various safety requirements. The pre-tensioning of each fuse for the final design solution should not affect the performance of the device in any of these categories.

### **Verification and Validation Approach**

The verification methods for our final design consisted of multiple tests to confirm the satisfaction of all the requirements and specifications.

The first requirement to be tested was the wearability of the device during exercise. The test designed to verify this requirement was measurement of athletic performance in vertical reach and standardized agility before and after the device was applied. The vertical reach was determined by leaping and sticking tape to the top of a wall then measuring the distance to the ground. Agility was determined by timing sprints from the baseline of a basketball court to the foul line then back to the baseline and again to the foul line. This method is valid for verifying wearability since a design that drastically hinders athletic performance during use would most certainly limit joint rotation and impose torsional stiffness on the knee. Thus it was assumed that if there was less than 8% decrease in athletic performance that would be sufficient to verify this requirement.

Additionally, another requirement that will be tested will be how accurately does the device report the data collected from the fuse. This test will consist of using a participant's knee to know if the fuse will fatigue after 5 different loads of 12 degrees internal tibial rotation. From research, it was determined that the maximum load would come from 15 degree rotation, but we want to have the athlete recognize when they have undergone 5 different loads at 80% maximum internal tibial rotations. The recorded data must translate to the ACL strain within 10% of the actual ACL strain. This is one of the most important requirements and specifications to the overall design of the ACL strain device. As a result this test was considered valid since it will test to see if the monofilaments in the fuse will actually break while undergoing the different tensions and compressions.

Another part of the verification process will be whether the device will accommodate athletes of different sizes by having athletes of different BMIs under 30kg/m<sup>2</sup> try the device on. In all sports, athletes of different sizes participate in the training and the competitive play. The fuse must accommodate the athlete whether they are female or male and also their physical traits. The athletes had the fuse applied to their knee while their knee was bent in a 90 degree angle. The fuse was then applied using a jig with a 62 degree angle relative to the plane of the lateral meniscus. The athletes were then asked to perform some simple movements to observe if the fuse would accommodate their knee. This verification method would be the best to verify the accommodation of athletes because of the time constraint we have and the



different body types.

To test the durability of the device there are three lab tests that are being planned to test the design of the device. The first test would be dropping different weights on the fuse to calculate the 3000 newtons of force that the device can withstand. The results of different weights will help recognize when the fuse could break and stop calculating the strain. Another test would be how much force does the fuse take from different objects such as a soccer ball or a football. This way the athlete will not worry of the device breaking during the training or games. Both of these experiments will help portray some of the different possibilities that an athlete can undergo from different external forces. The final test that will help determine the durability is making sure that the device has an IP rating of 54. The device will be tested in different environments such as water, first, oil in order to withstand the different environments. Moreover, the device needs to ensure that it will not shift under these different circumstances. The data collected will check the durability of the product under different environments was chosen because it will mimic the athletes training environment in a short period of time.

**Table 6:** The verification methods that will be tested to fulfill the requirements and specifications

<b>Requirement</b>	<b>Specification</b>	<b>Verification Method</b>
Wearable during exercise	<p>Device does not limit joint rotation by more than 5% of the joint's range of motion</p> <p>Device does not impose torsional stiffness of <math>&gt; 1N \cdot m/deg</math></p> <p>Device does not require user adjustment <math>&gt;</math> three times during a 60 minute practice</p>	<p>Determining decrease in athletic performance during cutting and jumping</p> <p>Rate Comfortability During Exercise</p>
Accurately reports ACL strain data	<p>Translates recorded data to ACL strain within 10% of actual ACL strain</p> <p>Device must have a sensitivity of <math>&gt; 97\%</math> and a specificity of <math>&gt; 95\%</math></p>	<p>Test device on a participant's knee to see if all fuses fail after five loads of 12 degrees internal tibial rotation.</p>
Accommodates athletes of varying size	<p>Device should fit 99% of humans with a BMI <math>&lt; 30 (kg/m^2)</math></p> <p>Device should be adjustable without requiring any additional tools</p>	<p>Applying the fuse on different participants' right knees to determine if the fuse would accommodate the athlete.</p>
Durability	<p>Device has an IP rating of 54 (Protection against dirt and water from all angles)</p>	<p>Tests with water, dirt, and oil to make sure the fuse doesn't misalign on participant's knee</p>

Some validations that must be done in order for the device to satisfy the requirements and specifications

successfully would include discussing with some stakeholders and doing some product trials on users. In order to figure out whether the device is compliant with rules of professional sports, we will have to discuss our design and equipment rules with officials or other representatives of those professional sports. This will guarantee the use of the device in professional sports and also be ruled as safe to use. Furthermore, the product will have to be used by an athlete to help validate the safety of the athlete. The athlete who will be wearing the device will also help determine how much will the athlete need to adjust the fuse in a period of 60 minutes during the physical activity. Ideally it should be less than 3 times during the elapsed time.

Another requirement we needed to validate was how well the device accommodates athletes of varying size. The test consisted of attaching the fuse to 6 different athletes, 3 female and 3 male knees. We performed this test to see if our standard prototype will function universally or if the device needs to be made specifically to order based on the uniqueness of a participant's knee. Ideally, the device fits and functions on athletes of different genders and sizes. If not, we're prepared to make different standard sizes of the fuse to lump athletes into their respective categories, but based on the results of this test, we may have to create custom-fit fuses for each and every individual that uses our product.

**Table 7:** The validation methods that will help answer questions to the final product of the fuse

Question / Assumption	Validation Method
Is the device compliant with the equipment rules of professional sports?	Discuss with representatives and officials the equipment rules of their sport
Does the device accommodate athletes of varying sizes?	Product trial with different users of BMIs under 30 kg/m <sup>2</sup>
Is the device safe to use during exercise?	Product trial with representative users
Can a user practice for 60 minutes without adjusting the fuse more than three times?	Product trial with representative users

### Verification and Validation Results

For the result of the athletic performance test there was observed to be a 4.11% increase in agility time and a 5.6% decrease in vertical leap as shown in Appendix B. This was below the set threshold of 8% decrease in performance meaning that the design would likely fulfill the requirement of wearable during exercise. Steps that could be taken to further validate this requirement would be to measure the exact limits of joint rotation using imaging software and to measure the torsional stiffness increase using a device that could create a controlled force to twist the knee joint.

In our second verification test, we wanted to see how accurately the device reports data collected from the fuse. We tested this by applying 5 different loads of 12 degrees internal tibial rotation to see if the monofilament lines in the fuse would actually break from the applied tensions and compressions. As a result, the fuse did not break or fatigue. The monofilament line used within the fuse is too strong of a material to meet our fatigue requirements, therefore, we have to research and pursue other materials to test and incorporate. During the test, there was also slippage between the mounting strips and the skin.

To address this matter, we plan to find a better alternative than athletic tape to mount the fuse to a participant's skin. In conclusion, our device did not fatigue or break after applying the loads we expected it to due to the strength of the fuse material we used and slippage between the mounting strips and skin.

From our verification test to test the accommodation of the sue on different athletes, it was determined that our fuse did not accommodate the different athletes. Instead of making our jig to the average athlete, we made it to accommodate one athlete which did not fit the other athletes as the fuse needed to in order to calculate submaximal loading on the ACL. For males, The fuse was usually too large for the different athletes that we chose to perform the test on. Additionally, it was too large of a fuse to be attached to the female athlete's knee. This could have been avoided by making different jigs for different ranges of different athlete's body measurements. At first, we did not really take this requirement into consideration and realized at the end of the validation process that our jig was not really made to accommodate the different athletes. This was also a problem because of the time we had to test, which we did not go back and modify our jig.

Our final verification test was performed to determine the durability of the device, primarily focusing on whether or not the device had an IP rating of 54. We tested the IP rating of the device by applying water, dirt, and oil to the fuse but not while it was attached to a user. We wanted to make sure the super glue and mounting strips within the fuse would be able to independently withstand the application of water, dirt, and oil. In conclusion, the device holds together and we expect the same results when these conditions are applied and the fuse is being worn by a participant. Unfortunately, we didn't get around to testing this because we couldn't get a prototype to meet our other fatigue requirements, but we know what to expect. In the future, if we were to test the IP rating of the fuse while it's being used by an athlete, we would assume water, dirt, and oil would only affect the tape used to mount the device rather than the fuse itself. Again, we will have to look into better alternatives than athletic tape to reduce slippage of the device on an athlete's skin.

The other verification test we performed to determine the durability of the device focused on whether or not the fuse could withstand a force of 3000 newtons normal to its plane, which is much higher than we would expect a tackle to be on a football field. We tested this method by dropping a 25 lb dumbbell on the fuse from a second floor balcony of a team member's house which is approximately 4.25 meters high. The device was able to withstand this force, which is around 4700 newtons, and did not break. We did not have other weights to test with the drop, but the results are still strong. We also did not have a chance to test the impact of a soccer ball or football on the fuse, but given the results of the device withstanding the force of 4700 newtons, we can assume that the force from a soccer ball or football that is applied to the fuse will not be nearly as much. In conclusion, we are satisfied with the result of this experiment, but we would like to test this again in a more controlled environment to gain a better understanding of how the device is affected by force rather than will the fuse withstand specific forces and impacts.

### **Discussion:**

If our team had more time and resources to collect data and better define the problem for our project we would want to further investigate the effects of various demographic factors on ACL tearing mechanisms and skin displacement. To better understand the variation of skin displacement between subjects our team could repeat the first test of our engineering analysis with a wide range of subjects. This would allow us

to categorize the associated skin spring constant needed for our calculations based on a variety of demographic factors. This would greatly improve the accuracy of our final design.

The strengths of our design is that the data it provides can be easily and quickly analyzed by both the player and the trainer as each broken fuse corresponds to a dangerous sub-maximal load and once all fuses have failed the athlete knows they must rest. It is also an inexpensive design which can be afforded by athletes at any level. The sleek profile of the design also greatly reduces the chance of incurring an injury on the athlete wearing the device or other athletes on the field.

A current weakness of our design is the strength required to fracture each fuse. Our current prototype utilized a sanded 4lb monofilament fishing line which required a pre-tensioning force of over 3N which might cause discomfort to the athlete while wearing the device. Additionally, sanding of the monofilament to reduce its ultimate tensile strength can produce varying results depending on sanding pressure and inconsistencies in the grit pattern. Thus it is important to utilize a material which is extruded with the properties desired for our fuse. A monofilament line with a test strength of 0.5 lbs would have an ultimate tensile force of 2.22N. This is approximately half of the ultimate tensile force of the sanded monofilament used in our prototype. Therefore, the highest pre-tensioning force required would be around 1N.

### **Recommendations:**

Based on the outcomes of the verification and validation tests there are several recommendations if our concept is to be further developed. The first recommendation would be to redo the testing with materials that have different properties than monofilament lines. Although monofilament is inexpensive and readily available, it is much too strong in terms of ultimate tensile strength for the skin alone to cause it to fail. One material that shows promise is rubber filament which is often used for 3D printing. The elastic modulus of rubber filaments is 100 MPa and the ultimate tensile stress is 5MPa<sup>[20]</sup>. This means that a thin fiber of rubber filament will stretch more and break earlier which would reduce the amount of pre-tension force required before application. Some other viable materials would include Nylon 6 with an elastic modulus of 1.3 GPa and ultimate tensile strength of 50 MPa. In addition to changing the materials of the fuse, increasing the adhesion between the apparatus and the skin would increase the product's performance. Skin-Tac is often used in a wide variety of applications, such as cosmetics and medical research, to increase adhesion between tape and skin. Applying a layer of Skin-Tac before applying the athletic tape will increase adhesion between the skin and the apparatus and thus reduce error caused by the mounting strips slipping. Additionally, to improve the design we would need to develop the jig that we have built. There could be a jig made that could alternate from a fixed position for different body types of the athlete. This could be made by making slots that would slide on the jig in order to correctly place the fuse in place. This way the athletes' trainers may apply the fuse without needing specific measurements.

### **Conclusion:**

To conclude, the goal of our project was to create a device capable of logging strenuous ACL loading cycles and alerting a trainer or athlete after a submaximal loading threshold is met. ACL tears affect athletes across all sports and can be detrimental to their performance and long term health. With increasing rates in ACL tears it is important to develop a solution for the sake of improving public health. The ACL itself is a ligament which connects the back of the femur to the tibia. When an ACL tears the

ligament is separated from the cartilage which connects it to the bone. These tears often occur when there is significant loading on the knee joint combined with an interior-tibial rotation. Contrary to popular belief, many ACLs tears are caused by fatigue failure due to several loading cycles rather than one massive incident. When tracking these loading cycles it is important to create a product that provides accurate results but does not have a negative effect on the athlete during competition. This means that our solution must be safe, accommodating a wide range of athletes, wearable, and durable and capable of providing accurate data in a timely fashion. In order to decide on a design, we applied concepts of brainstorming, diagramming, functional decomposition, and design heuristics to arrive at six unique concepts. We created a Pugh chart to compare and contrast the top six designs with a focus on player safety, durability, the different sizes of athletes, wearability during exercise, and readily providing ACL strain data for analysis. In order to come up with such a product we had to set several deadlines to organize specific tasks associated with our design. We followed this timeline in order to generate a working prototype by the end of the fall semester. Along the way, we anticipated several engineering challenges and had several plans put into place to overcome these difficulties. We incorporated the use of course material in the ME450 learning blocks to aid us in our design process and help us create a product that accomplished the goal while considering social, economic, and environmental factors. The design we ended up selecting is a fuse placed on the lateral skin on the knee. Ideally, the fuse will break after five loading cycles of 12 degrees internal tibial rotation at 15 degrees flexion. The components of the fuse include monofilament line, i.e. the fuse itself, a mounting fixture, and an apparatus connecting the skin to the fuse. To make sure that our design satisfies all requirements and specifications laid out for us at the beginning of this report, we performed detailed analyses. This included both theoretical analysis and empirical analysis. An example is testing the finished prototype in expected-use conditions to evaluate performance according to our requirements and specifications. The final prototype failed some of our requirements and specifications like accommodating different athletes of varying size and accurately reporting ACL strain data. However, the requirements, wearable and safe to use during exercise, were up to standards but we had to deem the durability of the fuse to be inconclusive as we were only able to perform one of its verification tests. All in all, we have provided our recommendations for different materials to use for the fuse that could provide more appropriate results when measuring ACL strain. This could be a future project for another ME 450 group to investigate in order to help prevent ACL injuries among athletes.

### **Acknowledgements:**

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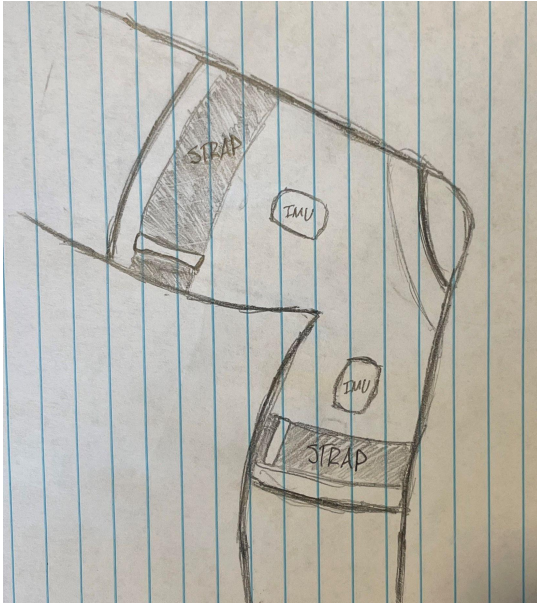
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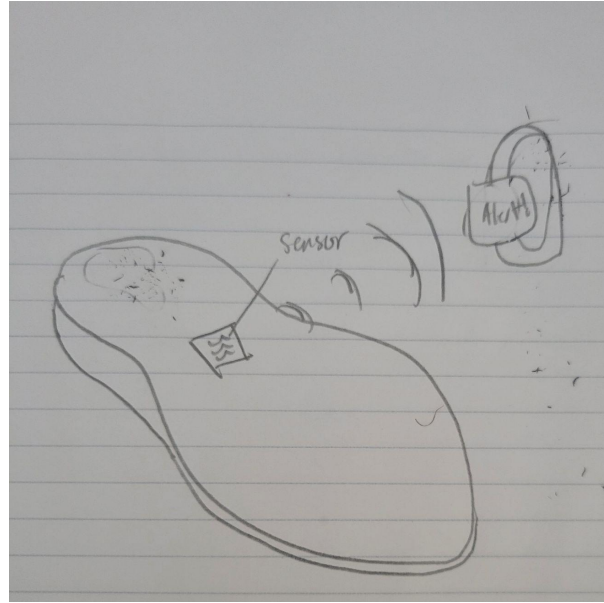
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## Appendix

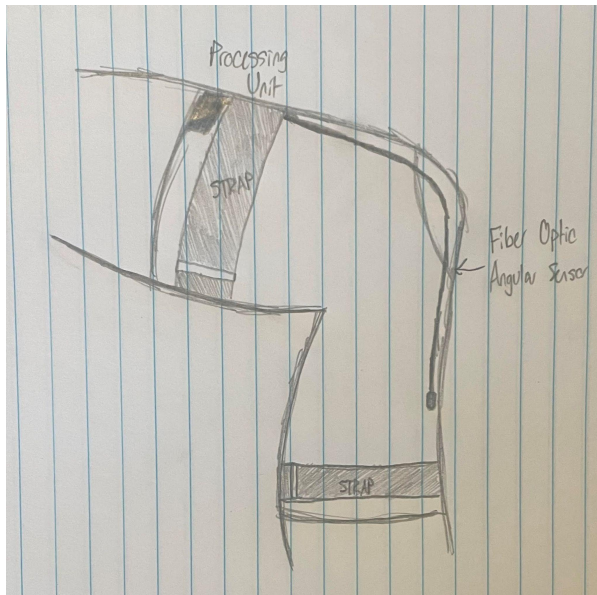
### Appendix A: Concept Generation



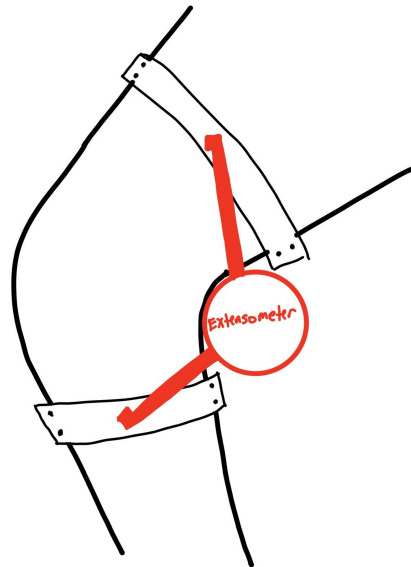
**Knee brace embedded with IMUs**



**Shoe insole design with pressure sensor**

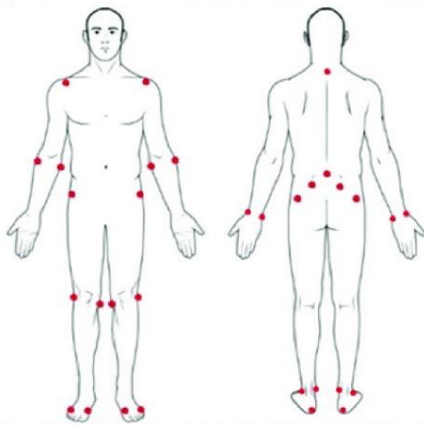
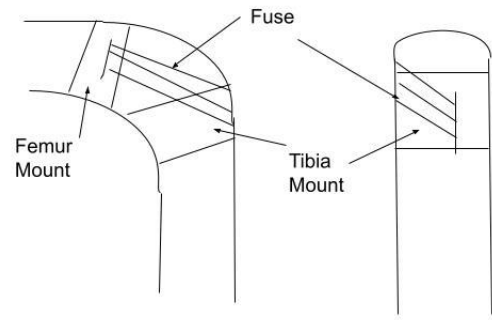


**Knee brace design with fiber optic angular sensor**



**Knee brace design with extensometer**





**Motion Capture Design**

**Fuse Design**

## Appendix B: Empirical Trials

Sprinting trials of 60 feet with/without fuse design

<b>Trial #</b>	<b>Time, Fuse Design Not Attached</b>	<b>Time, Fuse Design Attached</b>
<b>1</b>	9.29	9.45
<b>2</b>	9.47	9.89
<b>3</b>	9.20	9.79

Jumping trials with/without fuse design

<b>Trial #</b>	<b>Vertical Reach with Jump(ft,in) Fuse Design Not Attached</b>	<b>Vertical Reach with Jump (ft,in) Fuse Design Attached</b>
<b>1</b>	9'4"	8'10"
<b>2</b>	10'	9'7"
<b>3</b>	9'11"	9'2"

### Appendix C: Bill of Materials

Item	Quantity	Source	Catalog Number	Cost	Contact
<b>Suffix Ice Magic Fishing Line - 4lb Test</b>	1	Dick's Sporting Goods	024777067837	\$3.99	1-877-846-9997
<b>HDPE Strip - 1/32" x 2" x 5 Feet</b>	1	McMaster-Carr	8619K721	\$5.00	cle.sales@mcmaster.com
<b>6061 Aluminum Stock - 3/8" x 2 1/2" x 6"</b>	1	McMaster-Carr	8975K468	\$8.19	cle.sales@mcmaster.com
<b>P-TEX Athletic Tape</b>	1	Dick's Sporting Goods	889751514635	\$4.99	1-877-846-9997
<b>Gorilla Super Glue XL - 25g</b>	1	Meijer	5242700591	\$7.99	1-877-363-4537
<b>Scotch Double-Sided Removable Tape</b>	1	Meijer	2120051201	\$5.99	1-877-363-4537

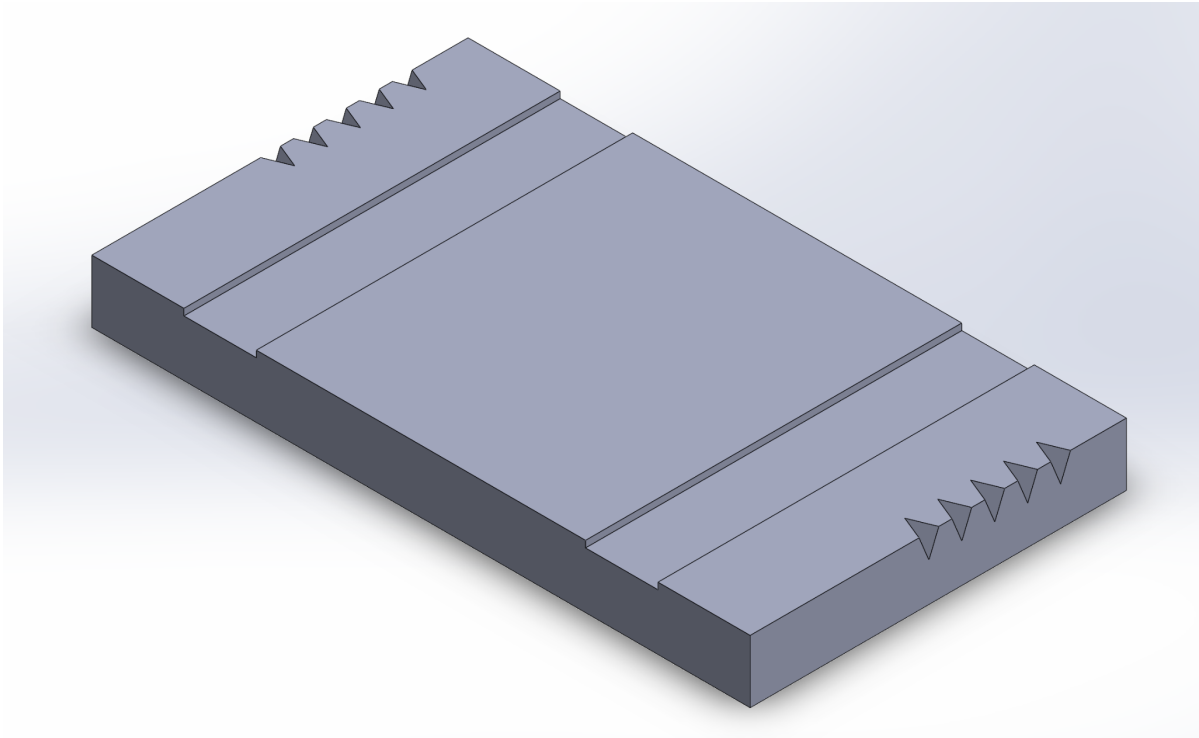
## Appendix D: Manufacturing Plan

**Necessary materials:** Scissors, calipers, X-Acto Knife or small paring knife, pencil, 100 grit sandpaper, table/work surface, set of at least 34 10-gram weights, weight hanger

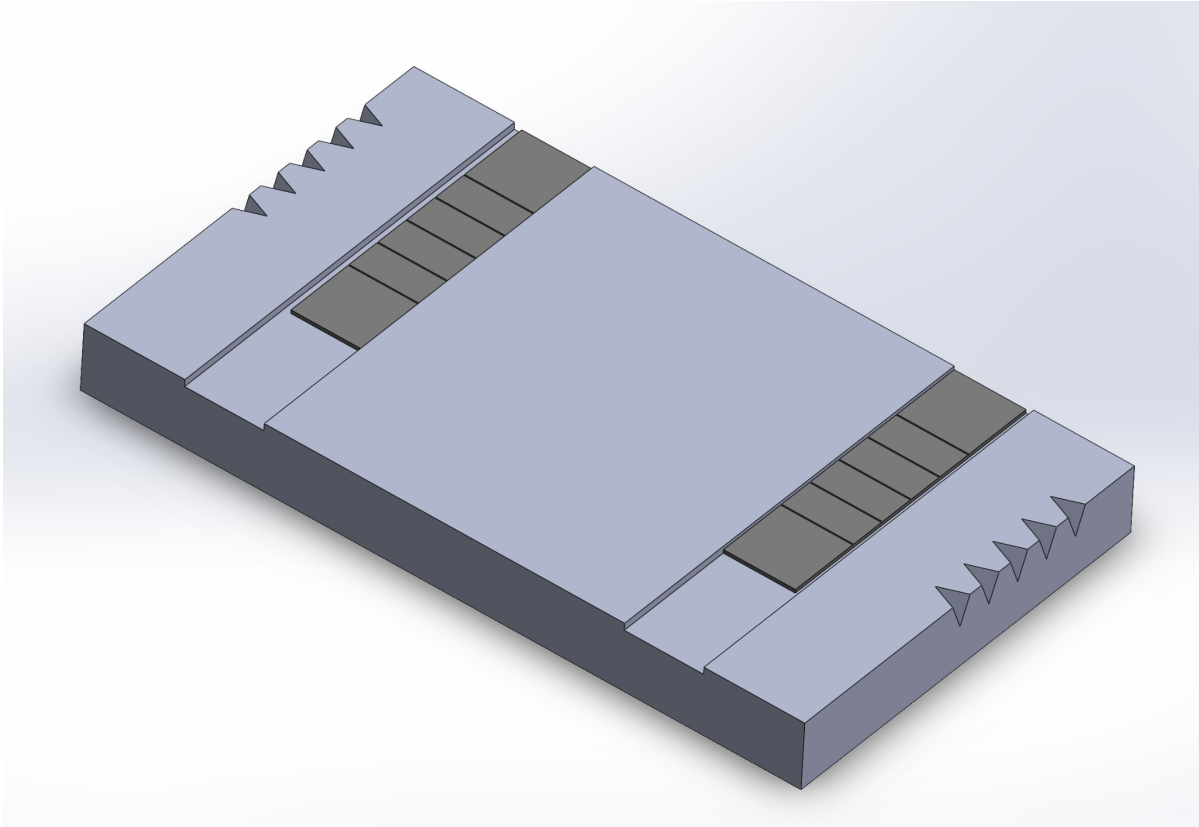
1. Begin by measuring out two 10mm x 35mm strips of HDPE from the sheet, cutting slowly in order to retain its accuracy. Measure the 10mm distance of the strip with calipers after it is cut down, trimming or sanding until it measures to within 0.05mm of the 10mm distance.
2. Measure out and use a pencil to mark spots 5mm apart on the 35mm length of the HDPE strip, leaving 5 different locations where the monofilament will be attached. Repeat for both HDPE strips.
3. Cut out five strips of monofilament of approximately 500mm. The exact length is not important in this step, you just want enough to work with later.
4. Position these five strips of monofilament onto your work surface, and secure both ends with tape, so that they are close to each other, but not touching. Ideally the monofilaments should be as straight as possible, a small amount of tension is fine within each fuse.
5. With the 100 grit sandpaper, complete 50 total passes on the monofilament. Ensure that the pass covers at least 70mm of monofilament throughout the movement. Stack 100 grams of weight on top of the sandpaper as you are making each pass, and try to not push down with your hand onto the sandpaper as much as possible. (One pass is characterized by moving the sandpaper away from yourself and moving back towards yourself)
6. Remove the sanded monofilaments from their secured position and trim each monofilament on one end so that the sanded section starts at the end of the monofilament.
7. Position each HDPE strip within the respective slot of the aluminum block, pushing each strip so they are as close to each other as possible. This will help guarantee the two HDPE strips are as close to 50.00mm apart from each other. (Reference Figure 19 if necessary)
8. Using the back of the slot as a hardstop for the monofilament, take the fishing line, and place it so that the sanded end lies over the first mark on the HDPE within the aluminum jig, with the end of the monofilament lying flush with the 35mm edge of the HDPE. There should be a 10mm overlay of monofilament on the HDPE strip. The other end of the sanded monofilament should be hanging off the end of the aluminum jig.
9. Place a small dot of superglue over the entire area of the monofilament that lays over the HDPE strip, wiping away any excess superglue from the aluminum jig.
10. Repeat the process with the second monofilament, and attach it in the same way, in the location next to the first monofilament.
11. Repeat the process for monofilaments 3 to 5, until all monofilaments are secured in place with superglue, and ensure that all fuses are as parallel as possible.
12. Wait for superglue to dry completely.
13. Take the monofilament in the first position, tie it securely to the weight hanger and let the weight hanger hang off the table. The monofilament should cross over its designated spot on the opposite HDPE strip, and should fall into its designated V-cut slot within the aluminum jig. The sanded area of the monofilament should extend all the way to the end of the other HDPE strip.
14. Add weights onto the weight hanger until the total weight reaches 340 grams. This will pre-tension the first fuse to break when a force of only 1.14N is applied. Once the weight is

applied, add a dot of superglue along the entire area of the monofilament touching the HDPE strip. Wait for it to dry.

15. Repeat the process on the second fuse, and add weights totaling 310 grams. Add a dot of superglue in the same way you did for the first fuse. Wait for it to dry.
16. Repeat the process on the third fuse, and add weights totaling 260 grams. Add a dot of superglue in the same way you did for the second fuse. Wait for it to dry.
17. Repeat the process on the fourth fuse, and add weights totaling 160 grams. Add a dot of superglue in the same way you did for the third fuse. Wait for it to dry.
18. Add the fifth fuse, and hang the weight hanger off the end of the table, but do not add any weight. The purpose of this is just to add enough tension to make it lie straight. Add a dot of superglue in the same way you did for the last fuse. Wait for it to dry.
19. Once all superglue on the fuses have dried, trim the ends of the fuses as closely to the opposite end of the HDPE strip as possible. It might be easier to complete this step by removing the product from the aluminum jig.
20. Measure two pieces of athletic tape to 100mm and cut them out.
21. Remove the product from the aluminum jig if you have not done so already. Place the edges of the athletic tape so that they are collinear with the inner edges of the slots on the jig. The tape should be applied sticky side down.
22. Cut out two strips of double sided tape, with a length of 35mm. Apply a piece of double sided tape inside the slot, on top of the non-sticky side of the athletic tape, along the edge of the athletic tape that aligns with the jig's slot.
23. Repeat for the other piece of athletic tape in the opposite slot.
24. Picking up the prototype, carefully apply one side so the bottom of the HDPE strip (side without any superglue or monofilaments attached), attaches directly to the double sided tape. Ensure the inner edge of the HDPE strip is flush with the inner edge of the aluminum jig's slot.
25. Repeat the last step with the other HDPE strip within the design, ensuring the edge of the HDPE strip is completely collinear with the athletic tape edge, double sided tape edge, and aluminum jig surface. At this point, the inner edges of both HDPE strips should be exactly 50mm away from each other.
26. If this step and the last step were done correctly, the fuses within the prototype as a whole should be pre-tensioned in the correct way.
27. After the HDPE strips are connected securely onto the athletic tape, cut out another two strips of athletic tape (100mm each) and place these on top of the other pieces of athletic tape. This should encase the fuses and HDPE strips, protecting the athlete from any rough or sharp surfaces.



**Figure 18:** Aluminum jig used for monofilament alignment and attachment



**Figure 19:** Insertion of HDPE strips into aluminum jig before monofilaments are glued into place



Part Name: Mount Assembly Jig

Team Name: ME450 #19

Raw Material Stock: 6061-T6 Aluminum, 3/8 x 2-1/4 bar stock

<b>Step #</b>	<b>Process Description</b>	<b>Machine</b>	<b>Fixtures</b>	<b>Tool(s)</b>	<b>Speed (RPM)</b>
1	Cut stock on band saw to 4.00"	Band saw			300 feet/min
2	Secure part in vise	Mill	Vise		
3	Mill one end of part, just enough to provide a fully machined surface.	Mill	Vise	3/4 inch 2-flute endmill, collet	500
4	Repeat on opposite side of part	Mill	Vise	3/4 inch 2-flute endmill, collet	500
5	Remove part from vise. Break all edges by hand, file any rough edges, and measure longest dimension			Calipers	
6	Find X and Y datum for bottom right corner of part	Mill	vise	edge finder, drill chuck	900
7	Using Endmill, square off end of part until total length is 3.937"	Mill	Vise	3/8 inch 2-flute endmill, collet	<del>500</del> 1000
8	Using Endmill, make through pass of 0.04" depth at location of -0.739"	Mill	Vise	3/8 inch 2-flute endmill, collet	<del>500</del>
9	After pass, move endmill over to -.797" and repeat pass at 0.04" depth	Mill	Vise	3/8 inch 2-flute endmill, collet	500
	Make through pass of 0.04" depth at location of -3.198"	Mill	Vise	3/8 inch 2-flute endmill, collet	500

	After pass, move endmill over to -3.140" and repeat pass at 0.04" depth	Mill	Vise	3/8 inch 2-flute endmill, collet	500
10	Remove part from vise.				
11	Using calipers, mark part in 5 indicated notch locations on both sides of part			Calipers	
12	Using triangular file, create grooves in all marked caliper locations		Vise	Triangular file	
13	Deburr and file any rough edges		Vise	Deburring tool, file	