ACL Recovery Aid

Sponsor: Dr. Whitt

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Executive Summary

This project changed its scope throughout the two quarters. Originally, it was a student proposed project to create a low-cost brace to help patients after anterior cruciate ligament (ACL) reconstruction surgery. The brace was to be worn during the day and help stretch the ACL to speed up the recovery time. After meeting with Dr. McSorley, a physical therapist local to San Luis Obispo, we decided to change the scope of the project. Dr. McSorley mentioned that the recovery process for ACL patients stops at night when they go to sleep. Creating a brace that could be worn at night would improve the recovery process. The brace had to be adjustable for different extends of stretching and comfortable to be worn overnight.

Most of the design was done before the project change was made. However, most of the elements could be kept as mainly the application was changed. The brace fits around the knee and attaches at the upper and lower leg. There is a gear mechanism on the side that allows the user to adjust the stretch of the knee. One important aspect that Dr. McSorley brought up was that the brace had to apply the correct forces on the leg to prevent reinjury of the ACL. The brace must apply a force on the top front of the knee and the bottom back of the leg.

The device functions by attaching around the knee. The user can adjust the brace, so it stretches the knee to a comfortable degree. Although most testing was not possible because of the COVID-19 situation, the brace should work as intended. The brace is made of aluminum and attaches to the leg with Velcro straps to provide support and durability. The padding provides comfort to the user.

Abstract

The purpose of this document is to establish the expectations and scope of this senior project to provide an ACL recovery aid. This document covers background information regarding ACL recovery and current options for patients. It will also discuss the objectives and project management techniques to achieve those objectives.

Introduction

The purpose of this project is to provide a low cost device that can help patients with their recovery after ACL reconstruction surgery. Part of the recovery process involves stretching the ACL while preventing it from hyperextending. This device will aid in that stretching process and prevent hyperextension of the ACL. This is a student sponsored project, so Dr. Whitt is our sponsor. The project scope will be discussed with and agreed with him.

The background will provide more information on current ACL reconstruction treatment techniques and devices. The objectives will provide the project scope and specifications of the design. The project management section will discuss the steps and plans to meet the project goals. The conclusion restates the project scope and the next steps for the project.

Background

This senior project, proposed by a student named Dylan Meinster was to “develop and prototype a device that aids in the extension of the leg after anterior cruciate ligament (ACL) surgery” [1]. The ACL stabilizes the knee by preventing it from hyperextending. However, the reconstructed ACL is shorter than the original, resulting in a stiff knee. Stretching is necessary to develop a full range of motion but current options are either difficult to use or expensive [1].

Currently, there are different devices that aid in ACL recovery. Table 1 compares these products.

Table 1

	Cost	Ease of Use	Range of Motion
Rolyan Defender Post-Op Knee [2]	Starts at $100.95	Very easy	4 ranges (0, 15, 30, 45 degrees)
Mueller Hinged Wraparound Knee Brace [2]	Starts at $41.42	Very easy	No range of motion
Day Standard Aluminum Crutches [2]	$31.45	Difficult to learn	No range of motion
Weight	~$10. Free if already at home	Difficult to use	Full range of motion. Does not limit motion
Smart Recovery Foam Roller [2]	$50	Easy to use	Full range of motion. Does not limit motion

Table 2 provides related patents to ACL reconstruction aids.

Table 2 [3]

Patent	Purpose of Patent
Methods and devices for knee joint replacement with *anterior cruciate ligament* substitution Patent Number: 9,707,085	This patent outlines possible prosthesis that can be used to replace the knee after the ACL is torn
Anterior cruciate ligament prosthesis Patent Number: 4,828,562	This patent outlines a knee prosthesis design that can be used for ACL tears. It can withstand high loads and be retensioned.
Anterior cruciate ligament substituting knee implants Patent Number: 9,861,484	This patent discusses a prosthesis design that can replicate part of the function of the knee
Anterior cruciate ligament support band Patent Number: 10,285,840	This is a band developed that allows the user to move their leg using their arms.
Prosthetic *anterior cruciate ligament* design Patent Number: 5,004,474	This is another patent for a prosthesis design for ACL tears.

According to Dr. Spindler and Dr. Wright in the article “Anterior Cruciate Ligament Tear”, the ACL is the most commonly injured ligament in the body. In the year 2000, 170,000 ACL reconstructions were performed with an estimated cost of $2 billion. Recovery to the point where an athlete can play again takes around 6 months [4]. There is a large market for a device that help ACL reconstruction patients recovery faster.

In addition to the need of this product, studies have shown that a patient's psychological approach also affects the recovery outcome. According to the Scandanavian Journal of Medicine & Science in Sports, an athlete with a low level of fear had the best knee recovery outcome. Additionally, they were also less likely to reinjure the ACL later on. Having a device that will help ACL patients can improve confidence and lead to a better recovery [5].

In terms of treatment options, an article in the American Journal of Sports Medicine compared ACL reconstruction with and without a brace. Results were collected at 6 weeks, 3 months, 6 months, 1 year, and 2 years. At all the follow up times, there were no significant differences between the brace and no brace groups in terms of knee joint laxity, range of motion, muscle strength, functional knee tests, or pain. However, the knee brace group had significantly improved knee function [6]. Although the results of this study are not promising, it indicates that more needs to be done in the recovery process than the use of a solid brace.

In an authored manuscript by Dr. B.D. Beynnon, there was no significant difference in range of motion between the groups that wore a brace and did not wear a brace. However, the braces also did not produce any adverse effects [7]. This study further backs up that a brace alone is not enough to aid in ACL recovery.

According to the Journal of Orthopaedic & Sports Physical Therapy, a progressive 5 week exercise therapy program significantly improved ACL recovery patient knee stability [8]. This indicates that the brace made should be incorporated into a therapy program and not a firm unmoving brace. The patient should be able to perform a range of motion for best recovery results.

Objectives

For individuals who are recovering from ACL reconstruction surgery, we will provide a device that aids stretching of the recovering knee. The goal of our project is to design this device and design and test a functional prototype. We will not apply for patents or bring this design to market. We will provide this device as a smaller, lighter, and most importantly, cheaper alternative to current range of motion devices on the market.

	Lasts 500 bends	100 lb-ft torque resistance	Less than 10 lb	1 ft tall or less	All day wear	Material cost analysis	110 deg bend
Low Cost						X	
Durable	X	X					
Light			X				
Small				X			
Comfortable					X		X
Range of Motion	X						X

Cost to produce will be evaluated by a material cost analysis with the goal of keeping production cost under $15. Durability metrics will be met if the device can last 500 bends and hold still when subjected to 100 lb-ft of torque. Lightness is considered to be 10 lb or less. Smallness is considered 1 ft in length or less. Our device will be considered comfortable if it can be worn all day without irritation. Range of Motion specification will be met if the device lasts 500 bends and can bend 110 degrees.

High risk specifications are durability and comfortability. Durability is high risk because a failure in the bending mechanism while stretching could cause the knee to bend beyond where it is supposed to. This could cause the patient discomfort and pain or even prolong the recovery process. Comfortability is high risk because if the product is not able to be worn all day then there would be parts of the day when the knee is exposed and unprotected. This is more important earlier in the recovery when the knee is weak.

Project Management

Our general plan is to select a design for our device, determine best materials, build a prototype, test this prototype, and reiterate until we have a workable prototype. Abstract goal such as design and material selection will be finished by Spring break. Tangible goals such as prototyping and testing will be finished by the end of May.

Task Name	Duration	Start	Finish	Predecessors
Research ACL Recovery and Preliminary Planning	**8 days**	**Tue 1/21/20**	**Thu 1/30/20**	
ACL reconstruction operation	5 days	Tue 1/21/20	Mon 1/27/20	
ACL reconstruction recovery options	5 days	Tue 1/21/20	Mon 1/27/20	
Current market competition	5 days	Tue 1/21/20	Mon 1/27/20	
Budgeting	3 days	Tue 1/28/20	Thu 1/30/20	4,3,2
Research Complete	0 days	Thu 1/30/20	Thu 1/30/20	5
Conceptual Design	**27 days**	**Fri 1/31/20**	**Mon 3/9/20**	
Create design specifications	6 days	Fri 1/31/20	Fri 2/7/20	6
Brainstrom potential designs	10 days	Mon 2/10/20	Fri 2/21/20	8
Material Selection	3 days	Fri 1/31/20	Tue 2/4/20	6
Pro and con anaylsis	8 days	Mon 2/24/20	Wed 3/4/20	10,9
Pick final design	2 days	Thu 3/5/20	Fri 3/6/20	11
Design Report with Detailed Drawing	1 day	Mon 3/9/20	Mon 3/9/20	12
Conceptual Design Complete	0 days	Mon 3/9/20	Mon 3/9/20	13
Product Development	**55 days**	**Tue 3/10/20**	**Mon 5/25/20**	
Prepare final report	55 days	Tue 3/10/20	Mon 5/25/20	14
Manufacture Prototype	18 days	Tue 3/10/20	Thu 4/2/20	14
Test for failure points	18 days	Fri 4/3/20	Tue 4/28/20	17
Reiterate the prototype	13 days	Wed 4/29/20	Fri 5/15/20	18

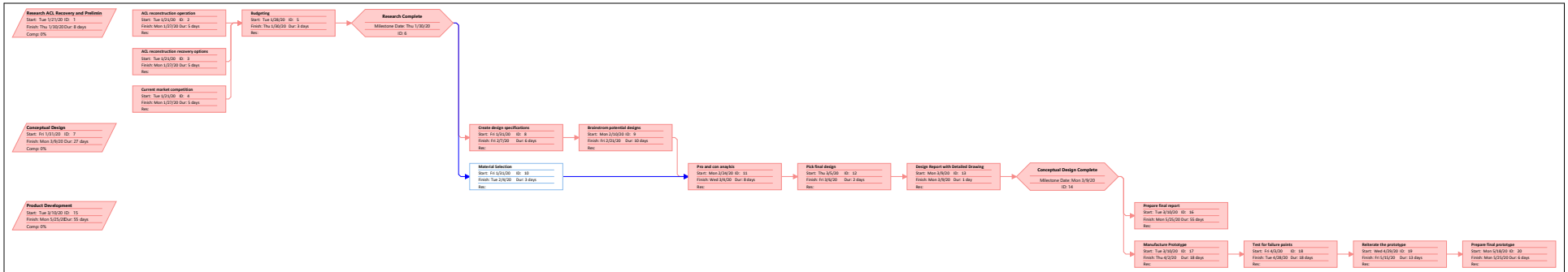
We will discuss techniques as we decide on design and materials. At this point in the process our next step are product design. After the completion of the items on the Gant chart above if we were to pursue this product further we would look for FDA approval and apply for a patent. Based on our PERT chart our critical path is mostly linear. We start with research and preliminary planning with things such as competitor research and budgeting. After planning we move into design starting with brainstorming and finishing with picking final design. The last step in our process is product development involving manufacturing and testing our prototype.

Conclusion

The purpose is to establish expectations and goals of our senior design project for approval with our sponsor. Our next deliverables are patent and competitor research by the end of week 4 1/31/20.

Device Name:
ACL Recovery Aid

Indications for Use:
The ACL Recovery Aid (ACLRA) system is indicated as a post-surgery aid in developing a full range of motion after anterior cruciate ligament (ACL) surgery. The ACLRA system is indicated for use in patients who are recovering from ACL reconstruction surgery. In conjunction with physician recommended rehabilitation, the ACLRA will work to progressively and safely stretch the reconstructed ACL to provide healthy extension and painless full range of motion throughout the standard recovery period. The ACLRA is especially recommended for use in athletes in need of full range of motion among other benchmarks in order to return to sport, although all those recovering from ACL reconstruction are viable users of the ACLRA.


Research ACL Recovery and Prelimin
Start: Tue 1/21/20 ID: 1
Finish: Thu 1/30/20 Dur: 8 days
Comp: 0%
ACL reconstruction operation
Start: Tue 1/21/20 ID: 2
Finish: Mon 1/27/20 Dur: 5 days
Res:
ACL reconstruction recovery options
Start: Tue 1/21/20 ID: 3
Finish: Mon 1/27/20 Dur: 5 days
Res:
Current market competition
Start: Tue 1/21/20 ID: 4
Finish: Mon 1/27/20 Dur: 5 days
Res:
Budgeting
Start: Tue 1/28/20 ID: 5
Finish: Thu 1/30/20 Dur: 3 days
Res:
Research Complete
Milestone Date: Thu 1/30/20
ID: 6
Conceptual Design
Start: Fri 1/31/20 ID: 7
Finish: Mon 3/9/20 Dur: 27 days
Comp: 0%
Create design specifications
Start: Fri 1/31/20 ID: 8
Finish: Fri 2/7/20 Dur: 6 days
Res:
Brainstrom potential designs
Start: Mon 2/10/20 ID: 9
Finish: Fri 2/21/20 Dur: 10 days
Res:
Material Selection
Start: Fri 1/31/20 ID: 10
Finish: Tue 2/4/20 Dur: 3 days
Res:
Pro and con anaylsis
Start: Mon 2/24/20 ID: 11
Finish: Wed 3/4/20 Dur: 8 days
Res:
Pick final design
Start: Thu 3/5/20 ID: 12
Finish: Fri 3/6/20 Dur: 2 days
Res:
Design Report with Detailed Drawing
Start: Mon 3/9/20 ID: 13
Finish: Mon 3/9/00 Dur: 1 day
Res:
Conceptual Design Complete
Milestone Date: Mon 3/9/20
ID: 14
Product Development
Start: Tue 3/10/20 ID: 15
Finish: Mon 5/25/20Dur: 55 days
Comp: 0%
Prepare final report
Start: Tue 3/10/20 ID: 16
Finish: Mon 5/25/20 Dur: 55 days
Res:
Manufacture Prototype
Start: Tue 3/10/20 ID: 17
Finish: Thu 4/2/20 Dur: 18 days
Res:
Test for failure points
Start: Fri 4/3/20 ID: 18
Finish: Tue 4/28/20 Dur: 18 days
Res:
Reiterate the prototype
Start: Wed 4/29/20 ID: 19
Finish: Fri 5/15/20 Dur: 13 days
Res:
Prepare final prototype
Start: Mon 5/18/20 ID: 20
Finish: Mon 5/25/20 Dur: 6 days
Res:

Item Description (McMaster Carr)	Product Number	Purpose	Associated Task	Planned				
				Unit	Quantity	Cost/Unit	Total Cost	Notes
Neoprene 1/32" Thick, 30A (soft), 3'	9455K91	Knee brace wrap	Prototyping	EA	1	$40.05	$40.05	May change after final design
6061 Aluminum 1/16" Thick, 1" Width, 6' Length	8975K196	Knee brace support	Prototyping	EA	1	$25.40	$25.40	May change after final design
Velcro 2" Width, 10' Length	9273K23	Knee brace wrap	Prototyping	EA	1	$11.68	$11.68	May change after final design

Customer Requirements

For individuals who are recovering from ACL reconstruction surgery, we will provide a device that aids stretching of the recovering knee. The goal of our project is to design this device and design and test a functional prototype. We will provide this device as a smaller, lighter, and most importantly, cheaper alternative to current range of motion devices on the market.

Specification Development

	Lasts 500 bends	100 lb-ft torque resistance	Less than 10 lb	1 ft tall or less	All day wear	Material cost analysis	110 deg bend
Low Cost						X	
Durable	X	X					
Light			X				
Small				X			
Comfortable					X		X
Range of Motion	X						X
Capable of Stretching	X						X

TAM:
~2.3 million ruptures globally per year (extrapolated from US rupture rates)

SAM:
~100,000 ruptures in the US per year

- FDA approval for the device would give access to the US market
- Market could be expanded to other less stringent regulatory jurisdictions

SOM:
~12000 ruptures in California per year (extrapolated from population data)

- Reasonable to consider California as a good starting point for distribution and marketing
- High rupture risk sports like soccer and American football are popular

Competitive Advantage

	Cost	**Ease of Use**	**Range of Motion**
Rolyan Defender Post-Op Knee [2]	Starts at $100.95	Very easy	4 ranges (0, 15, 30, 45 degrees)
Mueller Hinged Wraparound Knee Brace [2]	Starts at $41.42	Very easy	No range of motion
Day Standard Aluminum Crutches [2]	$31.45	Difficult to learn	No range of motion
Weight	~$10. Free if already at home	Difficult to use	Full range of motion. Does not limit motion
Smart Recovery Foam Roller [2]	$50	Easy to use	Full range of motion. Does not limit motion

Intellectual Property Identification

Issued Patents

1. Anterior cruciate ligament support band (PN 10,285,840)

This patent discusses a band that can be used to help treat patients that underwent ACL reconstruction surgery. The band is an elastic band that is in the shape of an X. Two arms go through one side of the X and two legs go through the other side of the X.
The claim that this product uses elastic bands to treat ACL recovery may be an issue because an elastic material will likely be used in some form on the final product. However, the design will be different enough to not infringe on this patent.

2. Knee brace with adjustable strut length and dynamic strut lengthening (PN 10,524,949)

This patent discusses a knee brace that has moveable and adjustable struts. There are multiple rotational points that act as the hinge to the brace.
The claim that this product uses adjustable struts for a knee brace can be problematic. The design for the ACL aid will likely be in the form of the brace. However, after reading the claims, the product will have many moving parts and be expensive. The goal of this project is to create a low-cost aid so there will not be as many parts that interact.

3. Intelligent compression wrap (PN 10,524,976)

This patent discusses a compression wrap that can provide heat and compression to the user. This claim has less of an impact compared to the first to claims. The brace may be in the form of a wrap in order for the patient to easily tighten it on their knee. However, it will not have any circuitry connected to it. Therefore, infringing on this patent should not be an issue.

Patent Applications

1. Ligament fixation device (PA 20030009219)

This patent discusses a fixation device that holds the ACL in place.
This claim does not have a significant impact on our project. The goal for our device is to allow the patient to develop a range of motion; however, this device is to hold the ACL in place. Although both are meant to stabilize the ACL, there are different goals so patent infringement is not an issue.

2. Knee brace (PA 20190358072)

This patent discusses a knee brace with multiple features. There are tightening and compressing mechanisms and many of the parts are 3-D printed.
This claim could be an issue for our project. 3-D printing parts may be the most convenient way to prototype a knee brace we make. However, the final product that is manufactured will most likely not be 3-D printed. Additionally, there are many features to this brace. Due to the low-cost nature of this project, those features will be unable to be implemented. As a result, this patent will not be infringed.

3. Adjustable knee brace (PA 20190298563)

This patent discusses an adjustable knee brace based on multiple cuffs. The cuffs are moveable with relation to each other.

This claim is the most likely to be infringed on in our product. The goal of our design is to allow the patient to have a range of motion in their knee while that is adjustable. The best way to avoid infringing on this patent is to create a different mechanism to adjust the degree in which the knee can move.

Conjoint Analysis

1. Factors and Levels

Design	Cost	Weight	Comfortability
1	$25	1 lb.	All day
2	$100	1 lb.	2 hours at a time
3	$25	5 lb.	2 hours at a time
4	$100	5 lb.	All day

2. Conjoint Cards

Card #	Cost	Weight	Comfortability
1	0	0	0
2	1	0	1
3	0	1	1
4	1	1	0

3. Multivariate Regression Model

SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.574233646
R Square	0.32974428
Adjusted R Square	0.284045026
Standard Error	0.971175483
Observations	48

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	3	20.41666667	6.805555556	7.215528782	0.00048464
Residual	44	41.5	0.943181818		
Total	47	61.91666667			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	1.333333333	0.280354213	4.755888339	2.14974E-05	0.768316543	1.898350124	0.768316543	1.898350124
Cost	0.75	0.280354213	2.675187191	0.010447628	0.184983209	1.315016791	0.184983209	1.315016791
Weight	0.833333333	0.280354213	2.972430212	0.004776922	0.268316543	1.398350124	0.268316543	1.398350124
Comfortability	0.666666667	0.280354213	2.37794417	0.021818722	0.101649876	1.231683457	0.101649876	1.231683457

$$\gamma = 1.33 + 0.75x_{cost} + 0.833x_{weight} + 0.667x_{comfort}$$

4. Analysis

All three factors (cost, weight, comfortability) are important to our customer. Based on the P-values we were able to reject the null hypothesis for all factors based on $\alpha = 0.05$. The equation above shows that weight is the most important factor to the customer,

followed by cost, then comfortability. Lower weight is better, lower cost is better, and longer wear ability is better.

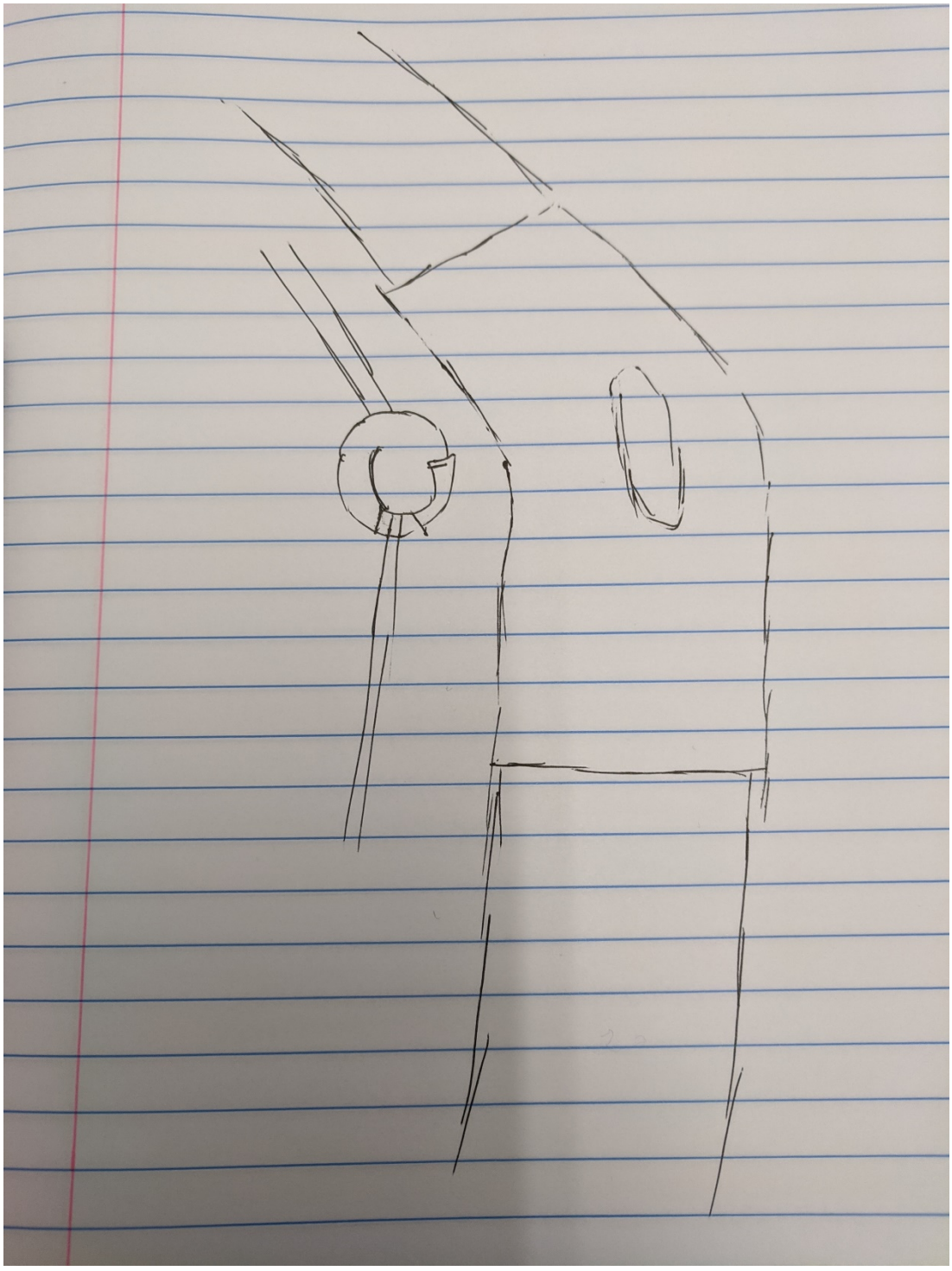
Morphology

Product:ACL Recovery Aid	Organization Name : Senior Project

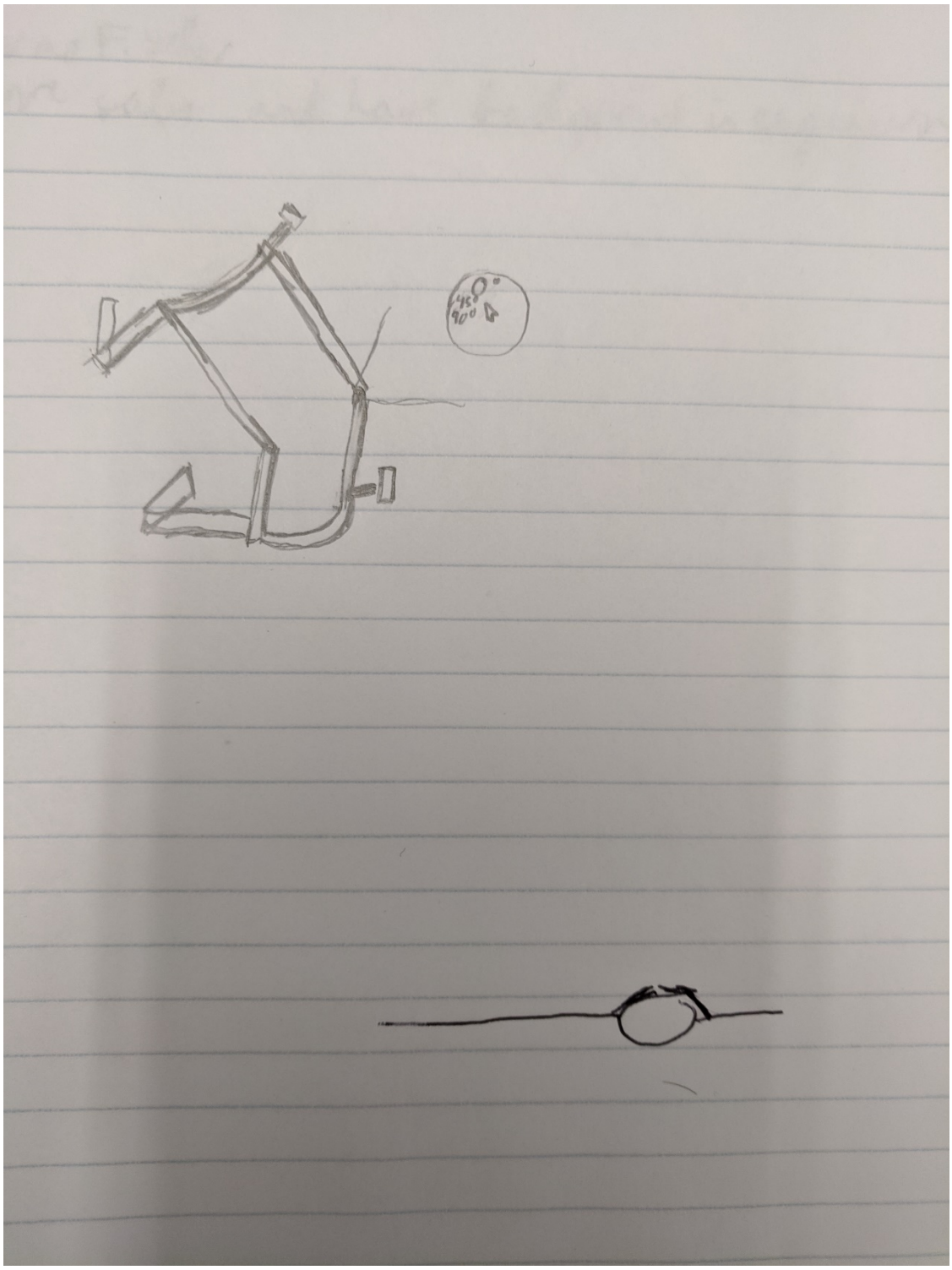
Function	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5	Concept 6
Adjustable range of motion	Dial system with set increments (5, 10, 15 degrees)	No set increment lock system	Screw tightening dial			
Durabiility	Aluminum brace across front of leg	Aluminum struts				
Adjustable for size	Velcro	Stretchable neoprene	Extendable struts			
Prevent hyperextention and flexion from lock point	Physical prevention/two pieces contacting	Gear locking				

Team member: Zongyi Li	Team member: Jarrett Shirouzu	Prepared by:	
Team member: Nate Huck	Team member:	Checked by:	Approved by:

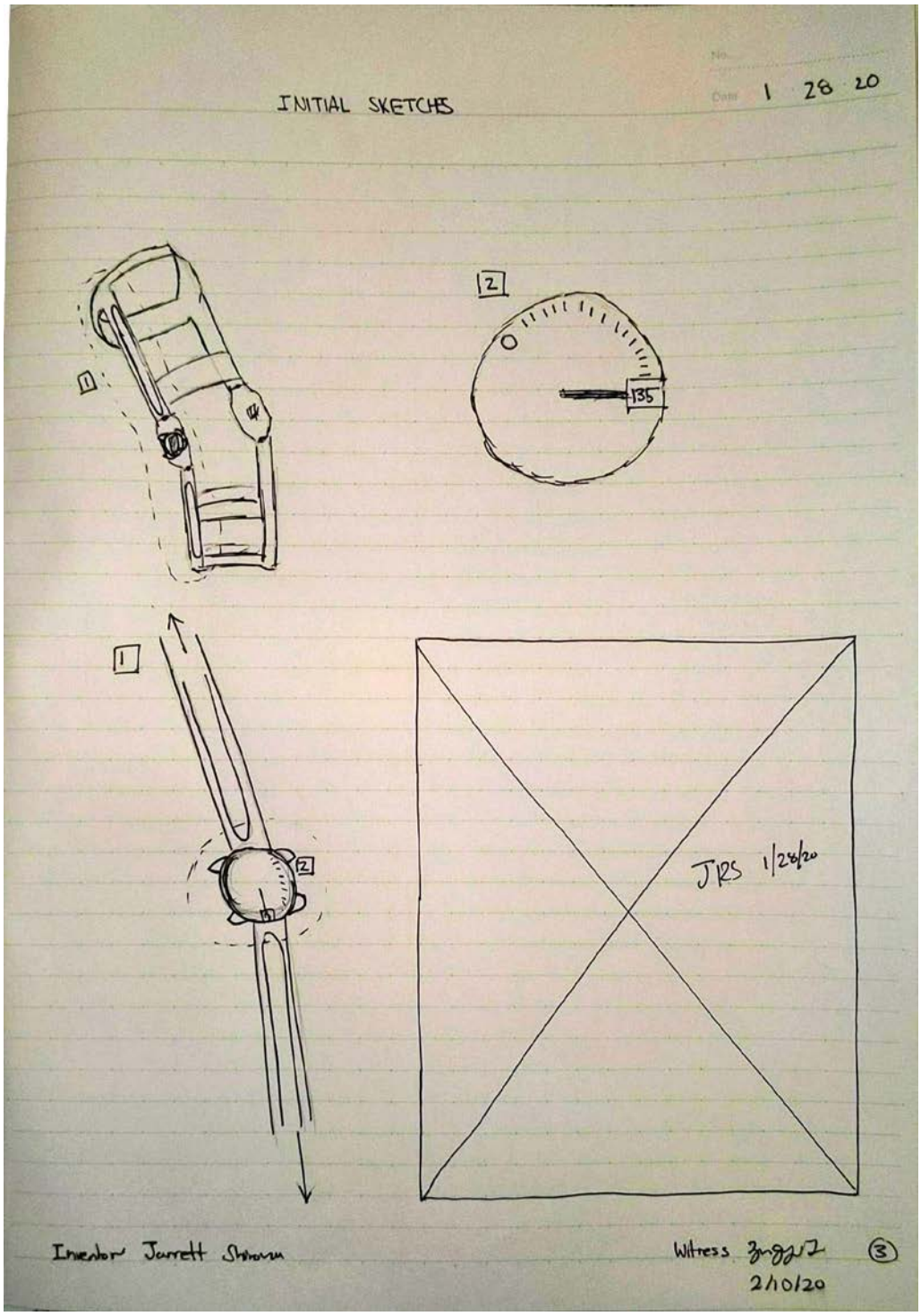
Designed by Professor David G. Ullman
Form # 15.0



This concept contains a neoprene sleeve with a hole cutout for the knee. This hole cutout will help locate the device is the correct place every time. The hinge system contains places where the two struts physically contact each other, preventing hyperextension and flexion.



This design has two aluminum struts across the front of the brace. These struts will provide a solid fit and durability. The dial shown above will allow movement through 90 degrees. Additionally, the design will have a physical stop the prevents movement past 0 degrees as shown at the bottom.



This design has an adjustable dial that provides up to 135 degrees of range motion. The design diverges primarily through its more robust support plates and straps that provide more support at other points on the leg. The design also reduces weight by removing potentially extraneous material from the aluminum supports.

Issue: Choose a concept to streamline			Concept 1	Concept 2	Concpet 3
Adjustable R.O.M	25	Datum		0	1
Durability	20			1	1
Adjustable for size	10			-1	-1
Cost	25			1	0
Prevent hyperextention and flexion	20			0	0
	Total			1	1
	Weighted Total			35	35

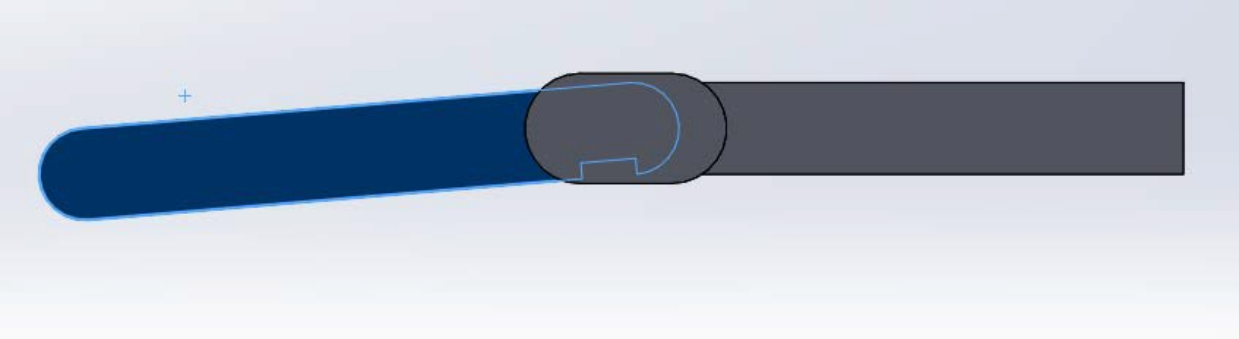
Issue: Choose a concept to streamline			Concept 2	Concept 1	Concpet 3
Adjustable R.O.M	25	Datum		0	1
Durability	20			-1	0
Adjustable for size	10			1	-1
Cost	25			-1	-1
Prevent hyperextention and flexion	20			0	0
	Total			-1	-1
	Weighted Total			-35	-10

Issue: Choose a concept to streamline			Concept 3	Concept 2	Concpet 1
Adjustable R.O.M	25	Datum		-1	-1
Durability	20			0	-1
Adjustable for size	10			1	1
Cost	25			1	0
Prevent hyperextention and flexion	20			0	0
	Total			1	-1
	Weighted Total			10	-35

According to our Pugh chart, Concept 2 has the best weighted total of the three concepts. At this point, concept 2 has the features we want to pursue for modeling and prototyping. However, we still want to develop our ideas further and possibly 3D print and prototype the designs before making a finalized decision.

Conceptual Model

At this point we have not performed analysis on our concept design. We will perform stress testing when we have a prototype model. Our CAD design works as expected.



Above are one of two struts that will compose the bulk of the ALCR. Aesthetics will continue to be fleshed out, but for now the prevention of hyperextension and excessive flexion has been fully implemented.
The full strut is composed of a fixed unit and a rounded unit that rotates in the recessed base of the fixed unit. Next to be implemented in the design is a locking mechanism that can lock the struts at an angle desirable to the user.

Measurables will be obtained through visual inspections or testing. Certain measurables, such as form factor and weight, can be verified visually and do not require testing. Other measurables, such as the number of bends and torque resistance, will require testing. Number of bends can be measured through accelerated wear testing. Torque resistance can be tested on an Instron and forces that obtained from the readings.

FMEA Analysis

Function Affected	Potential Failure Mode	Potential Effect(s) of Failure	OCC	DET	SEV	RPN	Cause of Failure	Recommended Actions	Responsible Person	Taken Actions
Durability	Aluminum struts break	Total failure	1	4	6	24	Material imperfection	Inspect material before maufacturing	Zongyi Li	None as of now
Prevent hyperextension	Gear mechanism breaks	Knee hyperextends/ damages ACL	3	1	8	24	Improper construction of gear	More training for operators/ More stingent QC	Jarrett Shirouzu	None as of now
Adjustable ROM	Gear mechanism breaks	Unable to adjust ROM	3	1	3	9	Improper construction of gear	More training for operators/ More stingent QC	Jarrett Shirouzu	None as of now
Adjustable for size	Sleeve rips	No snug fit on knee	2	1	2	4	Improper manufacturing process	Visual inspection	Nate Huck	None as of now

Detailed Design

The design for this ACL brace will include a gear moving mechanism on both sides of the knee. There will be a padded support that rests on the leg, as shown in Figure 1. The other aspect is that the brace must have the correct forces applied to the tibia to prevent reinjury of the ACL, as shown in Figure 2.

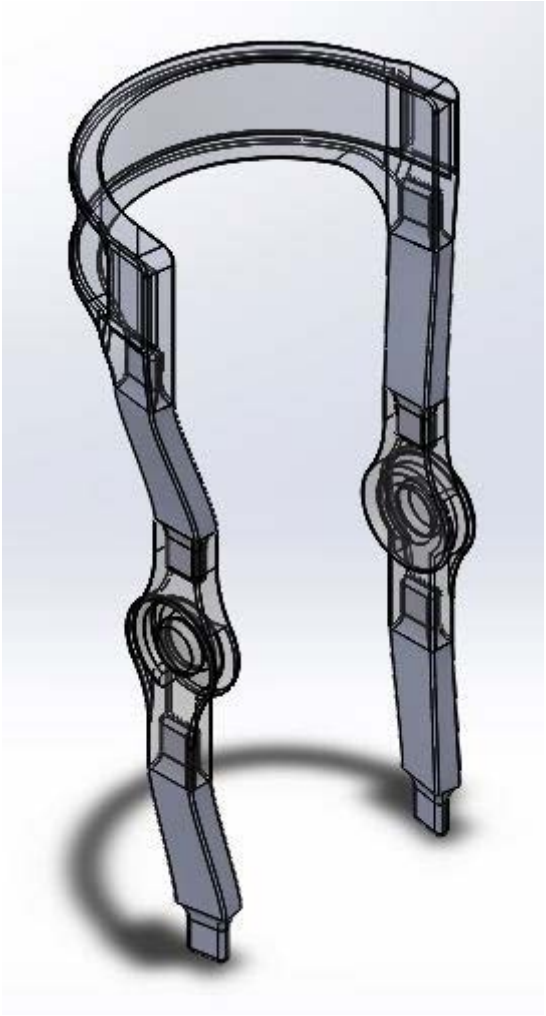


Figure 1: Solidworks design of ACL brace

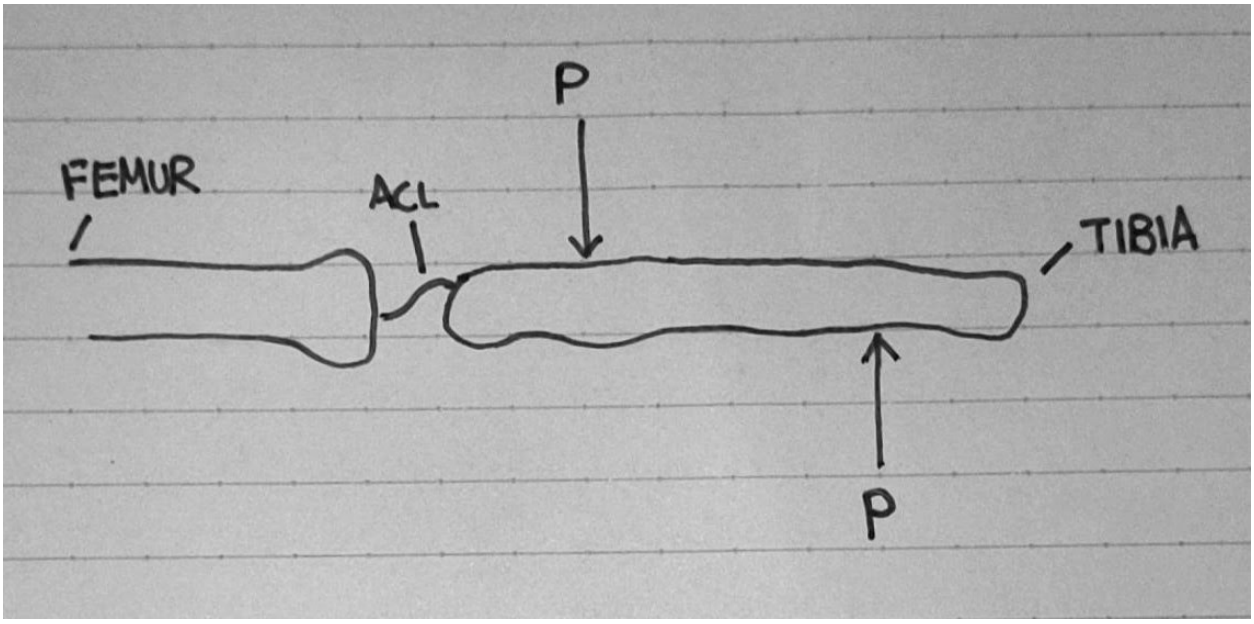


Figure 2: Forces applied to the tibia

Prototype Manufacturing Plans

The original manufacturing plan was to buy raw materials in the budgeting spreadsheet to create the ACL recovery aid. Parts such as the neoprene sleeve and Velcro could be created easily by cutting the material to the right shape. The gear mechanism to allow for the range of motion would be machined from aluminum in the machine shop.

After meeting with Dr. McSorley, a physical therapist that specializes in knee rehabilitation, we decided to go down a different design route. He provided us with a knee brace that we could use, saving us time and money. The brace has Velcro straps and neoprene padding. The two supports that are placed on the tibia will be machined from aluminum have a foam padding. The gear mechanism will still be machined from aluminum in the machine shop. Any connecting straps or bands can be cut and shaped into the correct size.

Test Plan

Due to the current situation with COVID-19, the original test plans are difficult to carry out so modifications will have to be made. The following describes the tests and the modifications made.

Visual Tests

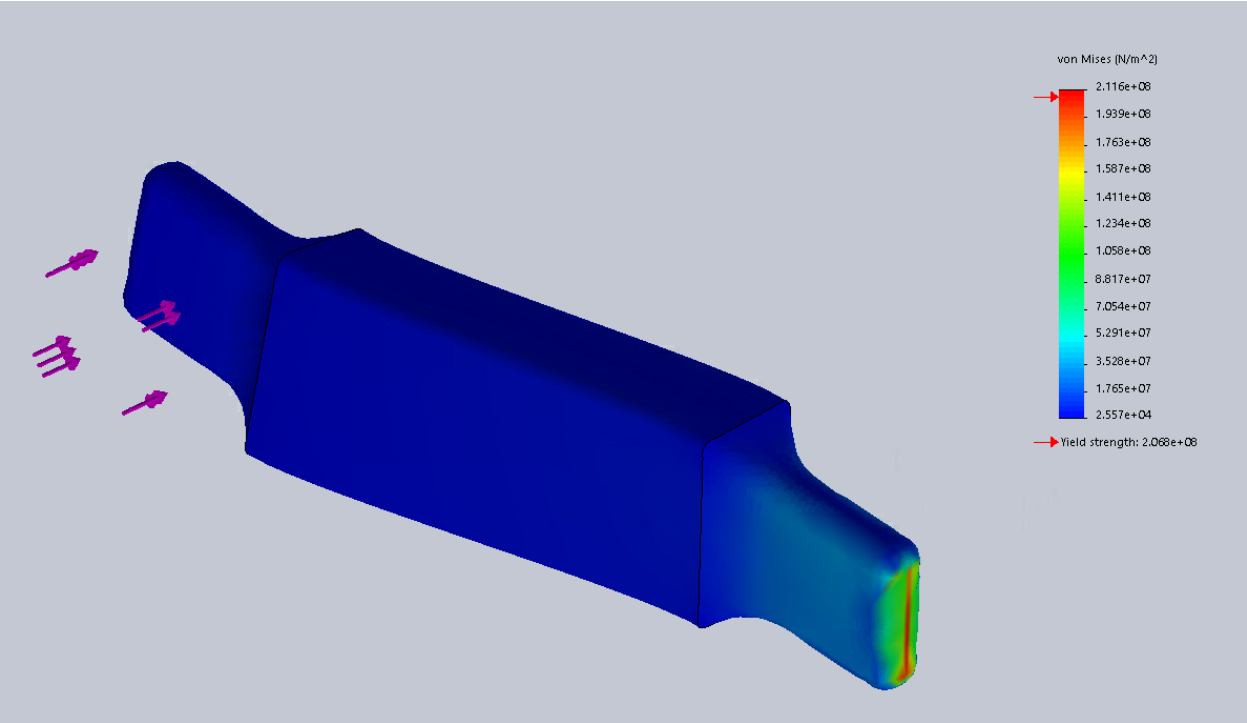
- Weight: Weight was originally planned to be tested by prototyping the brace and weighing the brace. However, it is no longer possible to machine a working prototype. As a result, we will assign materials in SolidWorks to estimate the weight. If the device is less than 10 pounds, it passes. If the device is more than 10 pounds, it fails.
- 90 degree bend: Previously, we planned to prototype the brace and try to bend it at the hinge 90 degrees. Now we will make sure the brace will bend 90 degrees in SolidWorks without any components interfering with each other. If the brace bends 90 degrees, it passes. If the device is unable to bend 90 degrees, it fails.

Quantitative Test

- Torque: The weakest points on the brace are the side struts. Originally we were planning to machine three side trusts for this test. Each strut would be placed in the Instron to determine the force required until the strut breaks. Now we will use FEA to simulate the force in SolidWorks. If the strut can withstand more than 100 ft lbs, it passes. We expect the brace to be able to withstand 100ft lbs of torque. If the struts do not pass, we will add more material to reinforce the brace.
- Durability: We originally planned to secure one end of the brace and attach the other end to a lever. The lever would be attached to an Arduino and program it to repetitively bend the brace. There would be three samples. However, there is not a possible replacement for this test because it is dependent on the material and wear. If the device can last 1000 bends, it passes. If the device does not last 1000 bends, it fails. We expect it to last 1000 bends. If it fails, we will increase the thickness of the material to increase durability.
- Comfort: We originally planned for each of the three team member to wear the prototype overnight and describe any issues with discomfort. There is not an alternative because the comfort depends on the materials. We could test it with a 3D printed model, but it may not have the same comfort. If the device is comfortable to wear overnight, it passes. If the device is uncomfortable to wear, it fails. If it fails, we will add more padding.

Testing Data and Analyses

As described previously, most of the testing could not be done due to the COVID-19 situation. A prototype could not be made and most tests would not provide any meaningful results. Most of the requirements should not be of concern. The brace will be used by people who had recently undergone ACL reconstruction surgery. This will also be worn during sleep, where there is little movement. As a result, the user will not be applying any extreme forces on the device that will break it. A Finite Element Analysis in Solidworks also reveals that there are not any high stresses placed on the brace.



Conclusions

This project provided insights into how medical devices are design, the considerations that need to go into them, and how they are manufactured. It was unfortunate that this project could not be prototyped due to the limitations placed by the government to reduce the spread of COVID-19. As a result, the prototype could not be properly tested. The need for an overnight ACL brace is there as many people receive ACL reconstructions, especially from sports. Such a device can reduce recovery time for patients. The design allows the ACL to stretch and under the way it is used, should not experience any issues that cause the brace to break.

Discussion

The next step would be to prototype the brace when possible. A prototype would provide more information about what works and what needs to be changed. A person would be able to test the brace for any discomfort or failure points. Changes could be made before a final prototype was made. Another step would be to file a patent for this brace. Both the brace and application are novel enough to grant a patent.

Appendices

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