Tri-Axial Hinge Knee Brace

Mid-Semester Report

Biomedical Engineering Design 400
Department of Biomedical Engineering
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Abstract

Mueller Sports Medicine specializes in prevention and rehabilitation of sports related injuries by producing braces. More specifically, this company produces many knee braces that utilize their patented tri-axial hinge. Currently, the hinge properly mimics knee flexion and provides a sufficient amount of knee stabilization. However, the tri-axial hinge's shape does not match the profile of many of the patients' knees. As a result, the hinge causes pain and discomfort as the straight arm pinches the distal end of the thigh. The client, Dr. Sarah Kuehl, wishes for a more ergonomic design in hopes of reducing the pain. She also wants the hinge to fit as many people as possible in order to reduce the manufacturing costs. Therefore, the first step of the project was to determine an average leg size which was used to design the new arm of the tri-axial hinge. The leg dimensions were determined using anthropometric data found in literature and experimental data collected by the team. Once these were found, the team determined that a Y-arm, Curved-arm, or Adjustable-Hinge design would best solve the client's problem. The Y-arm and Adjustable-Hinge designs had very similar scores when assessing them using a design matrix. After discussing with Dr. Kuehl, the Y-shaped design will be pursued as it is the simplest design and most logical to manufacture. Additionally, the Adjustable-Hinge design will be engineered as well and offered as a premium for patients wishing for an optimal fit. The remainder of the semester will be devoted to fabricating and testing both of these designs.

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Background

The tri-axial hinge knee brace project pertains directly to the anatomy of the knee joint and surrounding tissues. The femur, tibia, fibula, and patella bones are present at the knee joint; however, only the femur and tibia make up the joint itself.[1] The knee is stabilized by four ligaments: the anterior cruciate ligament (ACL), the posterior cruciate ligament (PCL), the medial collateral ligament (MCL) and the lateral collateral ligament (LCL). The ACL prevents the femur from sliding backward on the tibia while the PCL prevents the femur from sliding forward on the tibia.[1] The MCL and LCL prevent lateral motion of the knee joint.[1] The medial and lateral menisci absorb shock between the femur and tibia while bursae help the knee to move smoothly.[1] Knee flexion and extension is accomplished by tendons connecting the knee bones to muscles. More specifically, the knee extends when the quadricep, which is connected to the tibia by tendons, contracts. Additionally, the hamstring muscle causes the knee to flex when it contracts.[2]

According to Mueller Sports Medicine, the ACL, MCL, and PCL are the three most common knee ligament injuries.[3] The ACL usually is torn by rapid changes in motion and frequently occurs in athletes who play basketball, football, and ski.[3] Direct lateral blows to the outside of the knee as seen in football or soccer can injure the MCL.[3] A direct blow to the front of the knee can injure the PCL.[3] Finally, damage to the cartilage, more commonly known as a torn meniscus, can result from twisting, cutting, pivoting, decelerating, or being tackled.[3] These are the injuries that Mueller Sports Medicine focuses on and hopes to prevent in the future.

Client

Mueller Sports Medicine is a company located in Prairie Du Sac, Wisconsin that specializes in prevention and rehabilitation of sports related injuries. Curt Mueller, a power forward for the University of Wisconsin basketball team, started the company in 1960 after graduating.[4] Calling on his experiences from basketball and pharmacology, Mr. Mueller, as seen in Figure 1, wanted to prevent sports related injuries and enhance athletes’ performance using what he called sports medicine.[4] Since then, the company has expanded to provide braces for a wide variety of users.

Figure 1: Curt Mueller at the onset of Mueller Sports Medicine[4].

The client for this project is Dr. Sarah Kuehl who is a project engineer at Mueller Sports Medicine. While Mueller produces braces for nearly every joint, Dr. Kuehl wants this project to focus on the knee brace. There are numerous styles and sizes of the hinged knee braces as seen in Figure 2; however, they all have one thing in common: the tri-axial hinge.

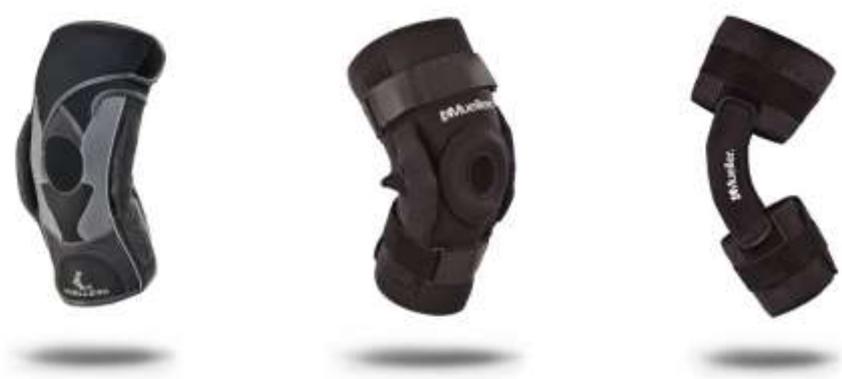

Figure 2: A variety of Mueller Sports Medicine knee braces that use the tri-axial knee brace hinge.

Problem Statement

Mueller Sports Medicine currently uses a generic, tri-axial hinge in the majority of their knee braces. This hinge properly mimics the knee flexion and provides a sufficient amount of knee stabilization; however, the issue lies in its shape. The straight shape of the tri-axial hinge does not match the knee profile of many of the patients and as a result causes pain and discomfort primarily in the thigh. Dr. Sarah Kuehl desires a redesign of the profile of the hinge to make it more comfortable and improve the fit while limiting the number of hinge shapes as much as possible. Using literature and experimental data, the group will determine the average leg size and redesign the tri-axial hinge profile to improve the fit and comfort.

Current Knee Brace

There are a few standards seen across the various Mueller knee brace models. They are all extremely lightweight and are fully enclosed in a breathable, fabric sleeve. The sleeve contains Velcro straps to allow for adjustability to create a secure, snug fit for a wide range of users. An example of one of Mueller's popular models, the HG80 Premium Hinged Knee Brace is seen in Figure 3.[5] In addition, all their knee brace models include the tri-axial hinge. The tri-axial hinge closely simulates the natural tracking of the knee joint and provides maximum medial-lateral support to help protect weak or injured knees. The hinge is sturdy as it is made of aluminum and allows for great rotation of 180°, as seen in Figure 4. Figure 5 provides a side view of the tri-axial hinge and shows the straight profile of the hinge with a slight outward curvature of the hinge at the knee location. This outward curvature allows room for the fabric sleeve that slips over the hinge to provide protection. Both Mueller and clients are very satisfied with the tri-axial hinge and the motion that it allows.[6]

Although the hinge is successful, the straight profile of the arms is the source of issues. The human leg does not follow a straight profile. After completing literature research and data acquisition, it was concluded that the angle from the knee to the calf is insignificant and can be considered relatively straight. This corresponds with that fact that Mueller has only had one patient complain about the knee brace imposing calf pain in the past 20 years. Contrastingly, the angle from the knee to the mid-thigh is significant and varies between 14° to 28° with an average of 20° for an adult population.[7,8] Therefore, the straight profile of the hinge is often too tight for the clients around the bottom portion of the thigh. Clients have complained of too much pressure, bruising, and an overall uncomfortable fit. Thus, there is a need to redesign the straight profile of the tri-axial hinge to better conform to the shape of the human leg.

The specific model being redesigned is for Mueller's pharmacy market, which consists of an older population recovering from knee surgeries or dealing with various knee problems. Therefore, it is crucial that the knee brace is low cost, as insurance companies will often be requested to cover this expenditure. In order to reduce manufacturing costs and create a low-cost knee brace, Mueller would like to have a one-size fits all, that can fit as many patients as possible, as comfortably as possible.

Figure 3: Current knee brace with tri-axial hinge, usually covered by fabric but exposed for visibility in magnified view[3].

Figure 4: The Tri-Axial Hinge, made of four parts connected by bolts and capable of 180° of motion.

Figure 5: Side-View of Current Tri-Axial Hinge.

Design Requirements

The most important requirement is that our final design must be able to perform as well as the current design, but be more comfortable and universal. The design is to use the same aluminum that is currently used because Mueller is happy with the strength to weight ratio that it provides. No changes to current hinge should reduce the durability of the product, specifically it must last for over one year in daily use. The redesigned arms shall not allow for knee movement in the medial or lateral direction and hyperextension. However, it should allow for normal flexion and extension during gait; the arms should not protrude from the leg as to impede the other leg from moving properly.

Design Alternatives

Y-arm

The first design considered was perhaps the most simplistic solution to the current comfort issue. The proximal arm would be bent at a 20° angle from the curve adjacent to the hinge to the proximal tip, as seen in Figure 5. This bend allows more room for the thigh between each of the two hinge arms and reduce pinching. Also, the bend will angle the tip of the arm outward so as to not point directly up the thigh, which could lead to prodding if the thigh bulges around the tip. By keeping the arm planar, it will make it easier to manufacture as well conform to the current knee brace sleeve design.

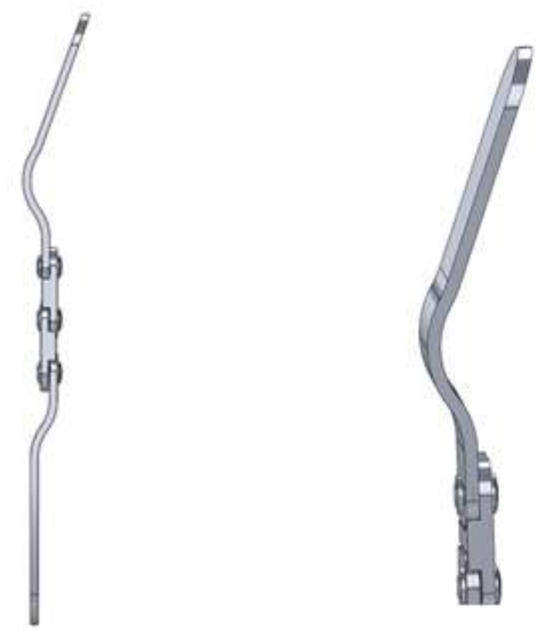

Figure 6: Side views of Y-arm design.

Curved-arm

The Curved-arm utilizes the same 20° angle from the base of the curve to the proximal tip as the Y-arm design, but inserts a curve in between those two points, as seen in Figure 6. This curve better conforms to the thigh muscle as it flexes and relaxes. The curve would allow the thigh more room towards the distal end so that there is less pinching and bulging. This would lead to an increase in comfort as long as the curvature best matched the thigh shape. If there was a mismatch in curvature there could be increased pressure as it forces the thigh to odd positions. The curvature might also be weaker than a planar arm since it the forces on it would not be evenly distributed and could concentrate on a weak point. The curve also presents the greatest chance of impeding the other leg as it protrudes the farthest from the leg at the most points.

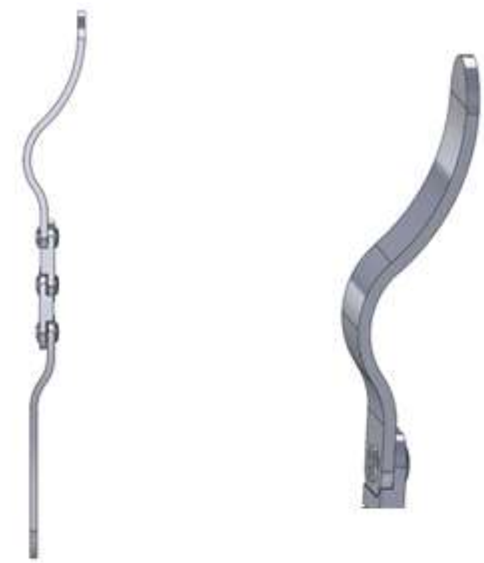

Figure 7: Side views of Curved design, top end corresponds to the thigh.

Adjustable-Hinge

The Adjustable-Hinge design features the Y-design concept of angled, planar arm, but makes it variable. An image of this design is seen in Figure 7. There will be a hinge placed immediately following the curve sectioned from the tri-axial hinge that can be locked into different angles. This maneuverability best matches the concept of being as universal as possible, since it can be set to match the angle of the patient's thigh angle perfectly. There will be a lockable hinge that can be set by the doctor or patient, and then it will slid into the brace sleeve as the current hinge’s arms do. The Adjustable-Hinge, however, will need to be able to have a solid lock as to not adjust the angle under extreme loading. If the hinge was loose and could change angles under extreme loads it would either pinch the thigh or collide with the other leg.

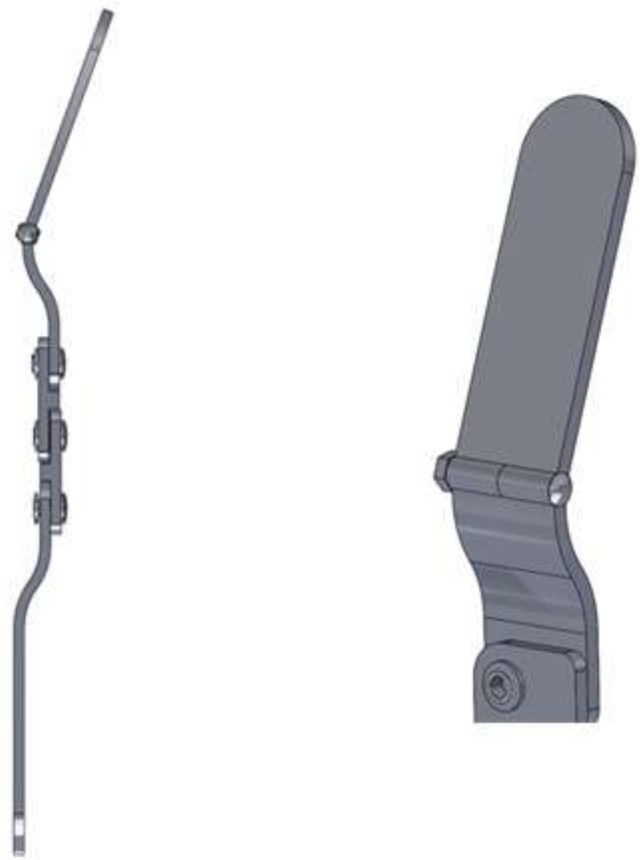

Figure 8: Side and close inside view of the Adjustable-Hinge design.

Design Matrix

To determine which of the three designs would be the best, a design matrix was made with six criteria weighted high to low for most important to least important respectively, as seen in Table 1.

Table 1: Design Matrix of Three Designs

	Y-arm Design		Curved Design		Adjustable Hinge Design	
Fit to Body (30)	12	2	12	2	30	5
Strength (20)	16	4	16	4	12	3
Obstruction (15)	9	3	6	2	15	5
Manufacturability (15)	15	5	6	2	6	2
Durability (10)	20	5	16	4	12	3
Cost (10)	4	4	2	2	2	2
Total (100)	76		58		77	

Fit to Body

Fit to body criteria includes how well the design conforms to various legs as well as the comfort level. As this was the source of complaints for the brace and the main scope of the project stated by the client, comfort and conformity is the priority and thus allotted the most points. The client wants a one-size-fits-all type of model and the Y-arm and Curved-arm designs scored much lower. If these designs were to be created to have a bend of 20° (the average knee-thigh angle for anthropometric data collected) the brace would not be comfortable for people with thigh sizes on both ends of the spectrum. The brace would still pinch if the client's thigh was large or would stick out from the leg if their thigh was thinner. The Adjustable-Hinge model scored perfect for this category as it could adjust to the angle of any sized thigh.

Strength

This criteria is one part of safety. The main purpose of a brace is to be able to support the wearer without failing. The current model has been rigorously tested to withstand considerable loading, however any changes made for the new model must not sacrifice this strength. The Y-arm and Curved-arm designs scored slightly higher as the upper arm of the hinge is still in one piece and with such a small bend there is still near-straight axial loading. The Adjustable-Hinge model scored lower as the lockable hinge could be prone to failing if the hinge did not have enough torsional resistance or strong enough parts.

Obstruction

The obstruction criteria is how much the knee brace impedes on a person's normal gait. The brace should allow for full range of knee flexion, not hit the other knee, and not be too heavy such that the wearer must move with a limp. The current product is light enough and provides proper flexion without hyperextension. Any changes are unlikely to impact this range of motion. The Y-arm and Curved-arm designs scored lower; if the person has thinner thighs, the hinge may stick out and knock into their other leg as they walk. The Adjustable-Hinge design would once again account for any leg and conform to it so that there would be no impact on the other leg.

Manufacturability

Mueller Sports Medicine produces these braces on a large scale, on the order of many thousands. Thus, the designs must be as simple to manufacture as possible. The Y-arm design scored the best as it is dissimilar to the current model and engineering a 20° bend would be relatively simple. The Curved-arm design and Adjustable-Hinge design scored lower as it would be more difficult to create the proper curve required. Also, it would be more difficult to make sure the hinge and pin were made to the proper dimensions such that the locking hinge is not loose. Since the Curved-arm and Adjustable-Hinge designs are more difficult to manufacture, they could also cost the company more money to make.

Durability

Durability is the second half of safety. Over continuous usage, even over a year, the brace should not fail due to fatigue. The Y-arm design scored highest as it is still near-axial loading and not too different from the current model. There will be some extra stress concentrations where the bend occurs. The Curved-arm design scored a little lower because it would be slightly weaker than the Y-arm design that has planar arms and less bending moments. The Adjustable-Hinge design scored the lowest since tightening and moving the hinge repeatedly could weaken the lockable hinge over time so that it no longer can support the person's loading.

Cost

This category is weighted the least. The client wants the model to remain inexpensive as it will be a base commercial model, the adjustments should not raise the price drastically. The Curved-arm and Adjustable-Hinge designs scored lower due to higher manufacturing costs.

Final Design

After assessing each of the proposed designs using the design matrix and the criteria outlined above, it was determined that the Adjustable-Hinge design was the best fit to adequately solve the problem that has been proposed. An image of the Adjustable-Hinge in relation to the knee can be seen in Figure 9. The Y-arm design scored only one point lower than the Adjustable-Hinge design, as it is substantially more durable, less expensive, and easier to manufacture in bulk. After discussion with the client, it was decided that both the Adjustable-Hinge design and the Y-arm design would be pursued.

The Y-arm design will be the basic design used, with the angle determined by both testing and literature data. This will improve on the simplicity of the current design, without adding large amounts of extra material or parts that would hamper the manufacturing process. The Adjustable-Hinge design will be pursued as an optional upgrade to the Y-arm design. This will allow the customer to decide if they would like a standard fit, or if they would like to pay a premium for an adjustable fit that can be customized to the individual user. This course of action will reduce the manufacturing and material costs, while still providing a one-size-fits-all option for the customer.

Figure 9: Image on how the Adjustable-Hinge design would conform to each side of knee.

Future Work

Several steps still need to be accomplished before the final prototype is completed. The first step is to determine the best adjustable hinge that can be used. Next, parts need to be ordered and fabrication will need to be completed. Finally, testing of both of the final products, the Y-arm design and the Adjustable-Hinge has to take place.

Adjustable-Hinge Selection

In order to develop the Adjustable-Hinge prototype, the optimal type of hinge still needs to be determined. The hinge will need to meet a few important criteria in order to be selected. First and foremost, the hinge needs to be strong. The entire purpose of the knee brace is to reduce lateral and medial movement of the knee. In order to accomplish this, the hinge must be strong enough to lock into position, otherwise the leg will be able to move medially or laterally. Additionally, the hinge must be easily adjustable, so that the customer may move to conform well to their individual knee. This will preferably not need any tools or extra pieces to lock into place, however something extra might be necessary in order to guarantee the proper amount of strength. Some additional criteria that may be included in the decision process are the ease of fabrication as well as cost.

Ordering Materials and Prototype Fabrication

As of now, the only part that needs to be ordered is the hinge for the Adjustable-Hinge design. The main body of each of the prototypes will consists of the current hinges which are supplied by the client. For the Y-arm design, the hinge will be modified to incorporate a lateral bend just above the previously existing hinge. The Adjustable-Hinge will need slightly more modification. The hinge that is decided upon will need to be integrated into the current design. In order to do this, the metal just above the current hinge will need to be cleaved, and the hinge then incorporated into the gap.

Final Testing

Two main tests will be conducted on each of the prototypes once they have been fabricated. The first test will be tensile load testing using the MTS machine. To perform this test, a simple program for an MTS machine will pull on one end of the prototype, while keeping the other end still. A force sensor will allow the MTS machine to determine the amount of force that each prototype can withstand in tension before it fails. This test will be crucial, as much of the loading that the prototype will encounter when in use will be in the tensile direction.

The second test will be a three point bend test, also performed on an MTS machine. In this test, the prototype will be laid flat on two struts, and a third strut from above will press down on the prototype. A force sensor within the MTS machine will pick up the amount of force that the prototype can withstand before it buckles under the loading. This test will give us an idea of how much force the prototype can withstand in a lateral direction. This will be similar to the type of load that the final design must be able to withstand in order to prevent the lateral or medial movement of the leg.

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Appendix

Project Design Specifications

Function:

The function of the design project is to improve the current knee brace model of Mueller Sports Medicine Inc. The company currently uses a straight tri-axial hinge in their brace which effectively mimics the motion of the knee; however, the straight profile of the hinge does not match the profile of the human leg. The client, Dr. Sarah Kuehl, desires a knee brace that more closely conforms to the shape of the leg, while still generic enough to fit a variety of users. In order to improve the knee brace, data will need to be collected to determine an average adult leg size. Using this "standard" leg, the knee brace will be designed to more accurately match the distal portion of the thigh, the knee, and the posterior portion of the calf.

Client Requirements:

- Hinge made out of aluminum
- Lightweight
- Continue to use the tri-axial hinge
- Conform to as many patient's legs as possible
- Prevent leg movement in lateral direction and hyperextension
- Allow for proper range and motion of flexion
- Comfortable for patients to wear
- Durable

Design Requirements:

1. Physical and Operational Characteristics

a. **Performance Requirements**: The knee brace will be used daily, so it should be able to bend at the hinge 15,000's times a day. It needs to be able to withstand a load of 1000 lbs a day. In addition, it must prevent lateral movement of the knee under normal gait conditions and prevent hyperextension.

b. **Safety**: The brace cannot catastrophically break under corrosion and prolonged wear. The hinge should not protrude more than 3 cm from the leg.

c. **Accuracy and Reliability**: Should not inhibit normal gait of the patient. Should not decrease gait speed.

d. **Life in Service**: The brace should be able to be used everyday for at least 1 year.

e. **Operating Environment**: The tri-axial hinge is inserted into a fabric sleeve, which is securely wrapped around the knee. It will be worn during everyday activities, both inside and outside.

f. **Ergonomics**: Augment the current design with a hinge that more effectively conforms to the patient's leg and provide natural motion for knee flexion.

g. **Size**: The brace should be a one size fits all and be able to be adjustable for a wide range of users.

h. **Weight**: The knee brace should be below 4 lbs since it must be easily wearable by the patient and not exert stress on their stride.
i. **Materials**: The tri-axial hinge is made of aluminum and the sleeve of the knee brace is made out of Mueller-exclusive HydraCinn fabric. The prototype can be made out of plastic.
j. **Aesthetics, Appearance, and Finish**: Should match the aesthetics of the current knee brace. Should be sleek and without rough finish.

2. Production Characteristics
a. **Quantity**: For the purpose of this design project, only 1 knee brace needs to be made. Ideally, the improved design would be manufactured in mass production for commercial use.
b. **Target Product Cost**: The budget for the project is $500. Commercially, the knee brace should cost less than $100.

3. Miscellaneous
a. **Standards and Specifications**: The knee brace requires FDA approval. In addition, it must meet Mueller SOP and quality requirements.
b. **Customer**: Mueller Sports Medicine
c. **Patient-related concerns**: Should be comfortable, easily removable and adjustable, and supportive but allowing of flexion.
d. **Competition**: Ossur, Breg, DonJoy

Compiled Data of Literature Measurements

Men:

Males	Height (cm)	Total Leg Length	Upper Leg Length	Lower Leg Length	Knee Height	Height to Widest Point of the Thigh	Height to Widest Point of the Calf	Knee Circumference	Thigh Circumference	Calf Circumference
Source 6	152.396		40.17894737						49.53684211	36.1
Source 3									51.1	34.7
Source 5					56.7		36.2	34.6	51.6	34.1
Source 7	175.26		59.182		49.53					
Source 10			60.5	55.3						
Average	163.828		53.28698246	55.3	53.115		36.2	34.6	50.74561404	34.96666667

Women:

Females	Height (cm)	Total Leg	Upper Leg Length	Lower Leg	Knee Height	Height to	Height to	Knee Circumference	Thigh Circumference	Calf Circumference

		Length		Length		Widest Point of the Thigh	Widest Point of the Calf			
Source 6	145.356		37.55789474						49.03684211	35.58947368
Source 5					45.6		28.9	39.4	60	37.6
Source 10			57.8	50.2						
Average	145.356		47.67894737	50.2	45.6		28.9	39.4	54.51842106	36.59473684

Experimental Anthropometric Data

Subject	Gender	Age	Height	Total Leg Length (Image J)	Upper Leg Length (Image J)	Lower Leg Length (Image J)	1/2 Calf Circumference (cm)	1/4 Calf Circumference (cm)	Knee Circumference (cm)	1/4 Thigh Circumference (cm)	1/2 Thigh Circumference (cm)
Tyler	male			89.322	48.27	41.052	41.0	38.0	41.0	42.0	49.0
Webster	male		6' 1"	91.868	49.338	42.53	31.8	33.3	39.4	39.4	39.4
Towles	male		5' 11"	87.074	47.042	40.032	36.2	36.8	40.0	41.9	50.2
Pucinelli	male		5' 7"	81.644	46.312	35.332	40.0	38.1	43.2	45.7	59.7
Krafft	male		5' 10"	75.652	37.073	38.579	38.1	36.8	41.9	48.3	63.5
Meyerand	female		5' 1"	70.966	40.085	30.881	38.1	38.7	35.6	39.4	46.4
Lyle	female		5' 4"	62.721	34.072	28.649	41.9	39.4	39.4	43.8	47.0
Kevin	male	21	5' 8"	70.868	39.001	31.867	38.1	36.8	38.1	44.5	52.1
Kaitlyn	female	22	5' 1"	68.374	39.225	29.149	35.6	34.3	34.3	36.8	43.8
Sauer	female		5' 3"	81.406	42.513	38.893	34.3	29.8	31.1	35.6	45.7
Yen	male		5' 6"	73.274	41.493	31.781	39.4	34.3	37.5	40.0	47.0
D Knapp	male	56	5'7"				38.1	36.195	39.37	43.815	50.8
J Knapp	female	55	5'6"				36.83	34.29	39.37	40.64	50.165
Levin	male	53	5'9"	96.52	53.34	43.18	36.83	34.29	38.735	41.91	53.34
Levin	female	55	5'10"	96.52	53.34	43.18	40.64	40.64	43.815	45.72	57.15

Semester Timeline

Task	Sept				Oct					Nov				Dec	
	4	11	18	25	2	9	16	23	30	6	13	20	27	4	11
Groundwork															
Set Meeting Times	x	x													
Talk with anatomy specialists		x	x	x	x										
Research															
Anthropometric Data		x	x	x											

Related Products		x	x	x	x										
Possible Designs		x	x	x	x										
Prototyping															
SolidWorks Design					x										
Order Materials															
Fabrication															
Testing															
Deliverables															
Progress Reports			x	x	x										
Online Notebooks	x	x	x	x	x										
PDS		x	x	x	x										
Midsemester Prestentation					x										
Poster															
Meetings															
Advisor Meeting	x		x	x											
Team Meeting	x	x	x		x										
Client Meeting		x			x										
Website															
Updates and Uploads	x	x	x	x	x										