# Tri-Axial Hinge Knee Brace

## Final Report

*Biomedical Engineering Design 400*
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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.

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. After testing, it was determined that there was a reduction in force when using the redesigned Y-arm compared to the straight arm design.

## Table of Contents

## 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, as seen in **Figure 1**.[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. The MCL and LCL prevent lateral motion of the knee joint.[3] 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.[4]

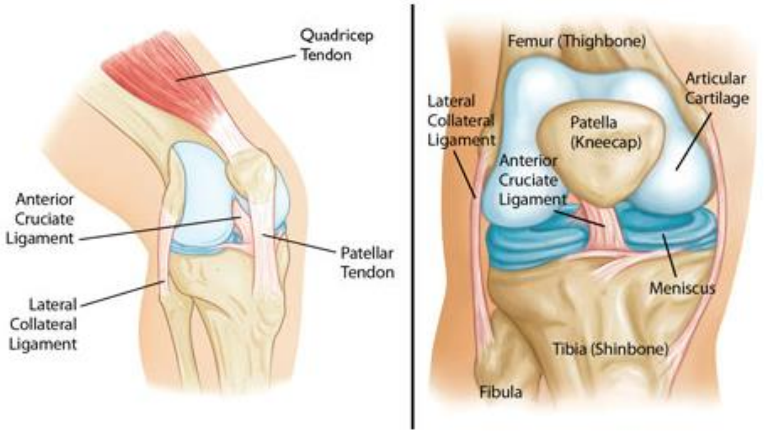


**Figure 1: Knee Anatomy.** Two different views of the normal anatomy of a knee, illustrating the bones, tendons, ligaments and cartilage. All these structures can be the source of a knee injury.[2]

Unfortunately, the knee is one of the most common parts of the body to be injured. The different types of knee injuries are defined by the affected anatomy of the knee and the mechanism by which it is injured.[5] Knee sprains are injuries to the ligaments that hold the knee together. The three most common knee ligament injuries are: ACL, MCL, and PCL tears. The ACL is commonly torn by rapid changes in motion and frequently occurs in athletes who play basketball, football, or ski. Direct lateral blows to the outside of the knee as seen in football or soccer can injure the MCL. A direct blow to the front of the knee can injure the PCL.[6] Knee sprains are the most common knee injuries, but not the only type.

Knee strains occur when tendons or muscles surrounding the knee are overstretched, typically due to hyperflexion or hyperextension. Knee bursitis occurs when a fluid-filled pouch that commonly serves as a shock absorber in the knee is irritated, inflamed, or infected. Meniscus tears damage the cartilage due to twisting, cutting, pivoting, decelerating, or high impact.[7] The bones of the knee can also be a source of knee injuries with both knee joint dislocations and knee fractures commonly seen due to high impact found in sports or falling.[8] Lastly knees can become weaker, the cartilage can begin to degenerate and improper mechanics of the knee movement can develop.

Regardless of the type of knee injury, a common solution to all these injuries is the use of a knee brace. Knee braces have become a common treatment option for millions of Americans, who suffer from knee pain. They are inexpensive, easy to find and comfortable to wear.[9] The two main purposes of wearing a knee brace are to provide structural support and reduce knee pain Last year over $852 million was spent on knee braces in the US. This number is expected to grow by 4.9% by 2018.[10] The users of these knee braces included females and males of all sizes and ages, from teenagers to the elderly. Therefore, in order to stay a competitor in this market, it is vital to provide a supportive, yet comfortable knee brace for a low cost.

## 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. Calling on his experiences from basketball and pharmacology, Mr. Mueller, as seen in **Figure 2**, wanted to prevent sports related injuries and enhance athletes' performance using what he called sports medicine.[11] Since then, the company has expanded to provide braces for a wide variety of users.

The client for this project is Dr. Sarah Kuehl, 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 3**; however, they all have one thing in common: the Tri-Axial hinge.

**Figure 2: Founder of Mueller.** Curt Mueller founded Mueller Sports Medicine in 1961. Mr. Mueller was inspired to start a company that focused on the prevention of

**Figure 3: Mueller Knee Braces.** These are all examples of Mueller Sports Medicine knee braces. The brace on the right is the HG80 Premium Hinged Knee Brace.[12] The brace in the middle is the Pro Level Hinged Knee Brace Deluxe.[13] The brace on the right is the MuellerHinge 2100 Knee Brace.[14] Although each of these different models is geared toward a specific clientele range; however, they all 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. All of Mueller’s knee braces use the Tri-Axial hinge. The Tri-Axial hinge is lightweight, sleek, thin and made of aluminum. The Tri-Axial hinge closely simulates the natural tracking of the knee joint. It is sturdy, providing support in the medial-lateral direction while still allowing for 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 at the knee location. This outward curvature allows room for a fabric sleeve that slips over the hinge to provide protection. To keep costs low, the Tri-Axial hinge is manufactured in one size only. This hinge is then inserted into the lateral sides of the fabric sleeve, as seen in **Figure 6**. There are several different models of fabric sleeves, each geared towards a different clientele range. These sleeves come in various sizes, depending on the size of the user.[15]

**Figure 4: Tri-Axial Hinge.** The Tri-Axial hinge provides medial lateral support while still allowing for rotation of 180°.

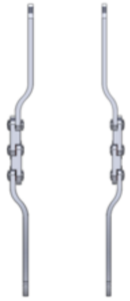


**Figure 5: Side view of Tri-Axial Hinge.** The Tri-Axial has a straight leg profile, causing pressure in the upper thigh.

**Figure 6: Tri-Axial Hinge in Knee Brace.** The Tri-Axial hinge is inserted into the lateral sides of the knee brace.[16]

Since the Tri-Axial hinge is used in all of Mueller's knee brace models, it must work for a variety of patients. 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 be used universally and maximize comfort.

The Tri-Axial hinge has been a success thus far. Although there are several competitors that make low-cost knee braces such as DonJoy, Asterisk and Corflex, Mueller has a patent on the Tri-Axial hinge so there is no other knee brace on the market that uses this technology. For example, Don Joy has a knee brace called the Hinged Lateral "J" which is a similar structure as the Tri-Axial hinge, as seen in **Figure 7.** This model does not provide quite as much rotation as the Tri-Axial hinge. Customer reviews of this brace mention that it does provide support but the proper size puts too much pressure from the upper seam of the brace and the next size up is too loose.[17]

**Figure 7: DonJoy Hinged Lateral "J".** This model is similar to Mueller's Tri-Axial Hinge; however, it does not allow as much rotation as Mueller's version.[17]

Mueller has heard consistent feedback from customers that they are pleased with the rotation that the hinge provides and that it does not impede their gait. However, Mueller has received feedback that the brace is not the most comfortable. In fact, over the past month, Mueller has received 20 complaints about the fit of the knee brace. Each of these complaints focused on the brace causing too much pressure on the lateral sides of the upper thigh.[18]

## Anthropometric Data Collection

In order to know how to best re-design the Tri-Axial hinge, anthropometric data was collected. Both literature and experimental research were completed to determine the average leg size. Subjects included females and males, ranging from ages of 18-86. The activity of these subjects varied from college athletes to geriatric patients with a sedentary lifestyle. Five circumferences of the leg were taken, as seen in **Figure 8**. It was determined that the further away from the knee, the greater the variability in leg sizes. This stresses the importance to keep the hinge as short as possible to limit variability. The other important measurements were the angle from the knee to the mid-calf and the angle from the knee to the mid-thigh, as seen in **Figure 9**. The angle from the knee to the mid-calf was not found to be significant and can be considered relatively straight; however, the angle from the knee to the mid-thigh was significant, varying between 14° to 28° with an average of 20° for the adult population.[19, 20] This corresponds with that fact that Mueller has only received one patient complaint about the knee brace imposing calf pain in the past 20 years whereas they constantly receive complaints of too much pressure, bruising, and an overall discomfort in the upper thigh. 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.

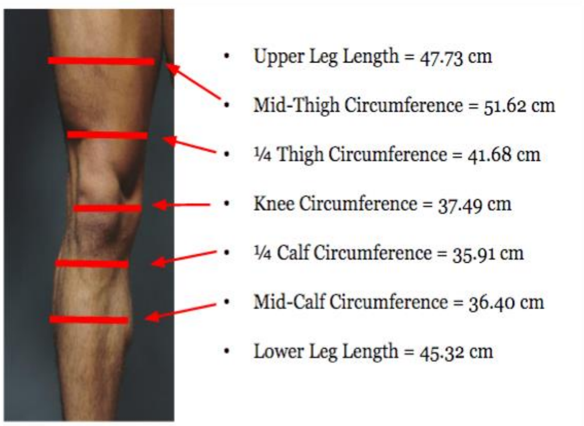


**Figure 8: Leg Circumferences**. Five circumferences were taken at the points marked in red. It was determined that the further away from the knee, the greater the variability in leg sizes.

**Figure 9: Leg Angles.** The angle from the knee to the mid-calf was found to be insignificant; however, the angle from the knee to the mid-thigh was significant.

## 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 ergonomic to various clients' leg sizes. The design should continue using the general model of the current hinge, keeping the center 180° mobility hinge portion, and solely modify the hinge's arms. The final hinge will use the same aluminum that is currently used because Mueller is pleased with the strength to weight ratio that it provides. Each hinge should be able to hold at least 300 lbs. of compressive force. No changes to the current hinge should reduce the durability of the product; specifically, it must be able to endure at least 15,000 bends a day for over one year. 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 opposite leg from moving through proper motion.

## Design Alternatives

### *Y-arm*

The first design considered was the most simplistic solution to the current comfort issue. The proximal arm is angled at 20° from its axis, as seen in **Figure 10.** 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 and rigid, the hinge is easier to manufacture and conform to the current knee brace sleeve design.

**Figure 10: Y-arm.** The proximal arm is angled at 20° from its axis, allowing more room for the thigh to reduce pinching.

*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 11**. 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 11: Curved-arm.** This design includes a curve before the outward angle of the distal end, to better conform to the thigh muscle as it flexes and relaxes.

*Adjustable-Hinge*

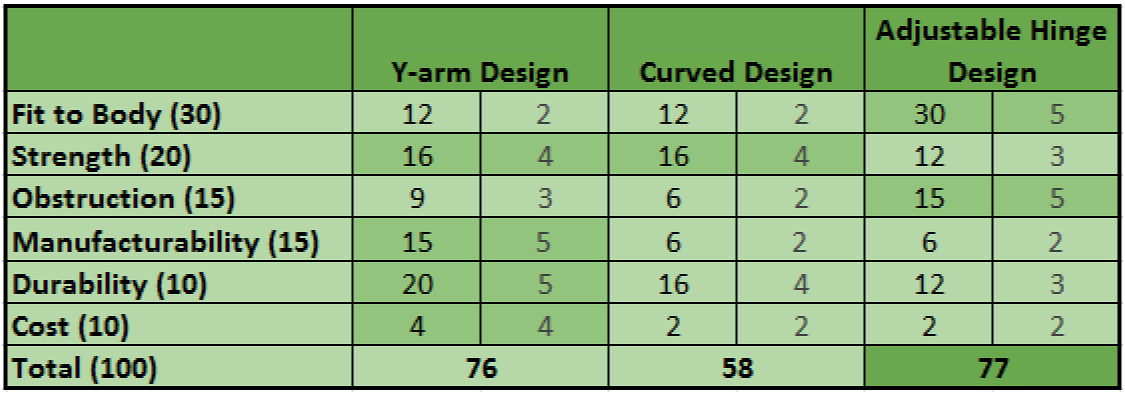
The Adjustable-Hinge design features the Y-design concept of angled, planar arm, but makes it variable. An image of this design is seen in **Figure 12**. There will be a hinge placed immediately following the curve sectioned from the Tri-Axial hinge that can be locked into different angles. This maneuverability 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 12: Adjustable-Hinge.** A hinge is placed following the curved section of the Tri-Axial Hinge, which can be locked into place. This provides more versatility for the user.

## 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: Hinge Design Matrix.** This design matrix compares the Y-arm, Curved and Adjustable-Hinge design. It shows the Adjustable-Hinge design scores the highest, with a value of 77.



| | 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 criterion 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 criterion 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 13**. 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 13: The Adjustable-Hinge in Relation to the Knee.** The Adjustable-Hinge allows the user to set the angle of the distal end to conform to their thigh size.

## Adjustable-Hinge Design Alternatives

### *One Screw*

The One Screw design is meant to be simple and effective. The design will consist of four pieces: the proximal arm piece, the distal arm piece, the screw, and the pin, as seen in **Figure 14**. The proximal arm piece will be short and connect to the rest of the hinge. It will have two rings attached that complete the torsional hinge. The distal arm piece will be longer and offer the support to the user. It will be straight, and also have two rings that the screw will go through and make the hinge. The screw will be slightly longer than the width of the hinge and hold the two pieces together. The screw needs to be slightly longer so that a hole can be drilled in it where the pin will be inserted. The pin serves to prevent the screw from loosening and falling out of the rings. If a torque is applied to the arm and the screw begins to turn, the pin will prevent it from displacing a significant amount. The benefits of this design are its simplicity and ease of manufacturing. The downside is that the single screw may not be strong enough to keep the two pieces tight and may allow them to slip.

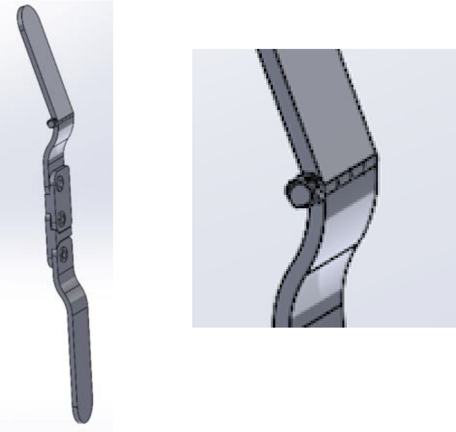


**Figure 14: One Screw.** The One Screw is a simple design that consists of the distal and proximal portions of the hinge, connected by one screw. A pin will also be used to prevent the screw from loosening.

### *Two Screw*

The Two Screw design is very similar to the One Screw design, but with the addition of a second screw to increase the strength of the hinge. It will consist of four pieces: the proximal arm piece, the distal arm piece, and 2 screws, as seen in **Figure 15**. The Two Screw design will have the same components as the One Screw alternative with a few exceptions. The main difference between this design and the One Screw design is the addition of a second screw opposite the first. Tapping and using a second screw in the opposite orientation will hold any torque applied to the hinge, which could cause loosening of one screw, to be held in place by the second screw. While one screw may loosen, the other screw would tighten, thus preventing the hinge from falling apart. This increases the safety of the design and only requires the addition of an extra screw.

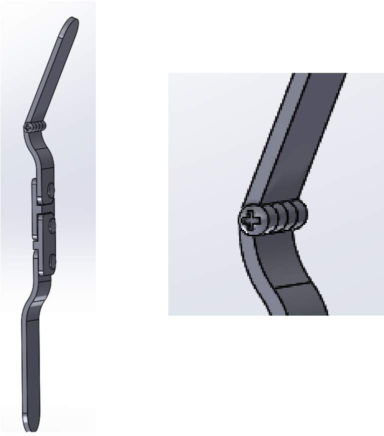


**Figure 15: Two Screw.** The Two Screw design consists of the distal and proximal portions of the hinge, connected by two screws. The screws will be tapped in opposite orientation of each so while one screw may loosen, the other screw will tighten.

### *Static Angle Bars*

The Static Angle Bar design is the strongest design; however, it does not accomplish our client's requirements. As seen in **Figure 16**, the design would consist of at least 8 pieces: the distal arm pieces, the proximal arm piece, the two angle bars, and four nuts. The angle bars are what make this design unique. Angled bars would be fabricated at certain angles that could then be attached to the sides of the hinge. They would then be held in place by nuts that would screw on to the proximal and distal arm pieces. While this design would be strong, it has many more setbacks. First, it would be much more expensive to fabricate. Additionally, it would not be easily adjusted and would limit the user to the predetermined angles of the bar. Thus, it would require multiple bars to be fabricated in order to offer a satisfactory amount of variability.

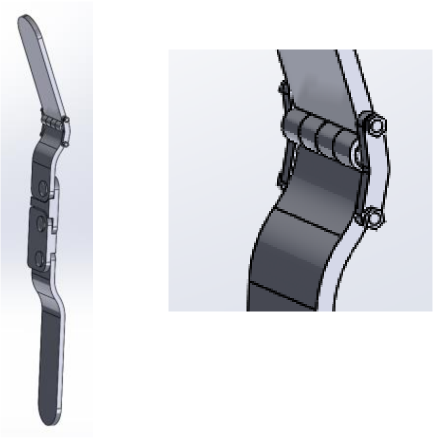


**Figure 16: Static Angle Bars.** The Static Angle Bars design would consist of the distal and proximal ends of the current hinge, connected using two angle bars and four nuts. The angled bars would be fabricated at specific angles and then would be attached via nuts to the hinge.

## Adjustable-Hinge Locking Mechanism 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 2.**

**Table 2: Adjustable-Hinge Locking Mechanism Design Matrix.** This design matrix compares the 1 Screw, 2 Screw and Static Angle Bars., Curved and Adjustable-Hinge design. It shows the 2 Screw design scores the highest, with a value of 90.

| | 1 Screw | | 2 Screw | | Static Angle Bars | |
|---|---|---|---|---|---|---|
| Locking Ability (40) | 3 | 24 | 4 | 32 | 5 | 40 |
| Adjustability (25) | 5 | 25 | 5 | 25 | 3 | 15 |
| Cost (15) | 4 | 12 | 5 | 15 | 2 | 6 |
| Manufacturability(15) | 3 | 9 | 5 | 15 | 3 | 9 |
| Ease of Use (5) | 3 | 3 | 3 | 3 | 4 | 4 |
| Total (100) | 73 | | 90 | | 74 | |

*Locking Ability*

Locking ability was allotted the highest weight since the functionality of the Tri-Axial hinge depends on it. If the adjustable hinge is not strong enough to be held in place, then the entire brace will be useless, as it cannot support the knee. Static Angle Bars scored the highest because the angle bars would be locked into slots, preventing any motion. When experiencing torque and high forces, screws can begin to unscrew due to angled threads. The Two Screw design scored higher in locking ability than the One Screw since two screws would thread in, each from opposite thread directions on each side. Although one may begin loosening, the other would tighten so at least one is always locked.

*Adjustability*

Adjustability received the second highest weight because the Tri-Axial hinge needs to fit as many people as possible. The purpose of the Adjustable-Hinge design is to be offered as a premium for those want a perfect fit to their leg. The design should be able to be able to fit any user and be able to be changed if the user wishes. The screw designs both scored the highest because they can fit any angle, whereas the Static Angle Bar design scored lowest since it would have preset angles.

*Cost*

It is important to consider the cost due to the fact that we are designing this for a company where they want to increase profits as much as possible. The Two Screw scored better than the One Screw design because the One Screw design requires a pin in order to restrain loosening which would be more expensive than two generic screws. The Static Angle Bars also scored the lowest as it would be made of steel and require many different angled bars to be fabricated.

*Manufacturability*

Mueller Sports Medicine produces these braces and hinges on a large scale. Thus, it is important to consider how hard it will be for Mueller to generate each design in mass quantities with high precision. Once again, the Two Screw design scored the best because of its use of generic screws. In order to fabricate the One Screw design, a hole would have to be drilled in the screw for the pin to fit in, which is more time consuming than using generic pieces. This hole would also need to be precisely drilled so as to lock the screw in and not allow movement that may loosen the design. The Static Angle Bar design scored the worst because multiple individual bars would need to be manufactured.

*Ease of Use*

Finally, the lowest weighted category is ease of use because once the angle is set, the customer should not have to change it unless in extreme circumstances. The idea is that Mueller would be able to set the angle for the user so that they would not need to interact with the adjustable hinge unless they had significant changes in leg size. The Static Angle Bar scored the highest because the generic angled pieces are the easiest to use.

## Adjustable-Hinge Locking Mechanism Final Design

The Two Screw design scored the highest overall of the three adjustable hinge alternatives. This design allows for the best adjustability, manufacturability, and cost while still allowing for strong locking ability. An image of the Two Screw design can be seen in **Figure 17.**

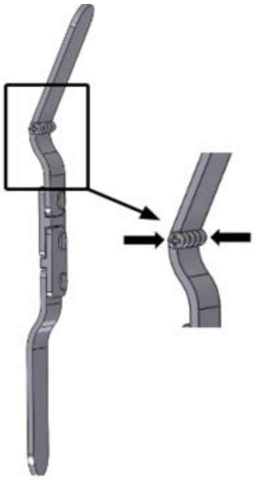


**Figure 17: Two-Screw Final Design.** This design scored the highest due its high capability of adjustability, manufacturability and cost while still providing a stable lock.

## Fabrication & Assembly

In order to fabricate the two final designs, a 3-D printer was used to create the complex geometry involved. Using 3-D models rendered in SolidWorks, a Dimension Elite 3-D printer created the new designs in ABSplus plastic. Once the parts were finished printing, the Y-arm design was ready to be attached to the metal Tri-Axial hinge in place of the current straight arm. The Adjustable-Hinge arm's torsional hinge needed to be tapped once the part was printed. To do this, a 4-40 tap was used to create threads in two consecutive hinge rings. The tap was then used to tap the other two hinge rings in the opposite direction to create the two opposite threads within the hinge.

The straight arm had to be removed from the current Tri-Axial hinge to accommodate the new designs. Using a hammer and a chisel, the rivet that locked in the straight arm was sheared. To add the Y-arm and Adjustable-Hinge design to their own Tri-Axial hinge, a nut a bolt was used to lightly lock in the new arms to allow for rotations about the bolt but still prevent vertical motion along the axis of the bolt, as seen in **Figures 18 & 19**.

**Figure 18: Y-arm.** The distal end that was 3D printed was attached to the current hinge.

**Figure 19: Adjustable-Hinge.** The distal end that was 3D printed was attached to the current hinge and two screws were inserted in opposite directions.

## Results & Discussion

The Adjustable-Hinge design failed immediately under low loads, so no further testing was completed. The following static and dynamic tests were only conducted on the Y-Arm.

### *Static Testing*

Mueller Sports Medicine currently conducts uniaxial tests on their Tri-Axial hinge. In order to comply with their procedures, this test will be replicated with the Y-arm design. Compressive load testing was carried out using the MTS machine located in the BME biomaterials lab. To perform this test, the Y-arm was gripped on the bottom of the 3-D printed part that connects to the rest of the hinge. Due to the angled shape of the design, a flat load cell was used to compress the piece. The full set up can be seen in **Figure 20.** The MTS machine was set to a load rate of 10 mm/min and the test was conducted. The Y-arm design began to bend significantly while the load was increased. As seen in **Figure 21**, instead of breaking, the design bent until the load started decreasing after reaching a maximum load of 163 lbs. Due to the fact that the primary goal of this testing was to determine where failure would occur on the part, the test was restarted with a load rate of 50 mm/min. This higher load rate resulted in failure at 85 lbs. immediately above the clamping site, suggesting an end boundary stress concentration failure.

**Figure 20: MTS Testing.** To perform the MTS testing, the Y-arm was gripped on the bottom of the 3-D printed part that connects to the rest of the hinge. A flat load cell was used to compress the piece due to the angled shape of the design.

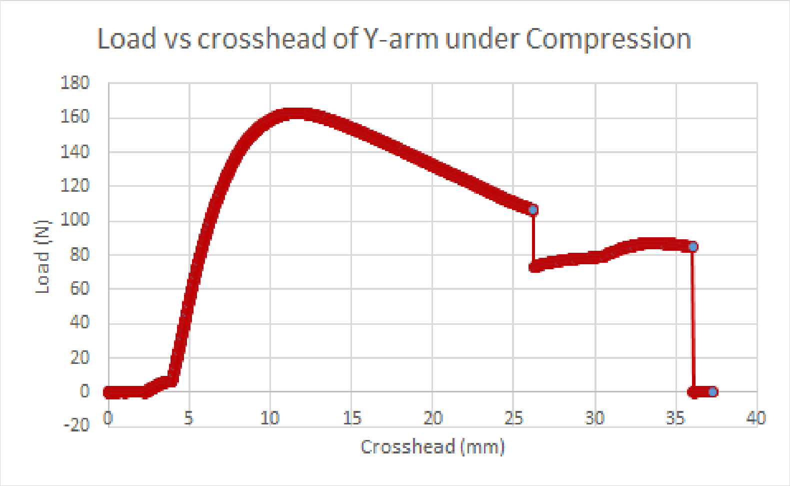


**Figure 21: MTS Graph.** At a load rate of 10 mm/min, the Y-arm began to bend at a load of 163 lbs. The test was restarted with a load rate of 50 mm/min, causing the Y-arm to break at a load of 85 lbs.

The next test procedure conducted was a Finite Element Analysis (FEA) in order to validate that the Y-arm design would bend a significant amount before failure. Using SolidWorks, the Y-arm design was constrained at its base mimicking the MTS machine results. A load of 163 lbs. was applied vertically to the apex of the arm, as seen in **Figure 22**. The results were very similar to those seen during the physical test of the piece validating that FEA can be used to model the compressive test. Since an aluminum prototype was not feasible to manufacture, the next step of static testing was to conduct FEA testing using the aluminum mechanical properties. An FEA was ran on 1060 Aluminum with an applied load of 163 lbs., as seen in **Figure 23**. When comparing these results to the ABSplus (used to model the 3-D printed part) results, the aluminum part did not bend nearly as much, as would be expected for a stronger material. Another FEA was ran with a compressive load of 300 lbs., which is the value set in the product design specifications, as seen in **Figure 24**. The Y-arm did bend; however, the Von Mises stress gradient suggests failure would not occur. Thus, based on the validation of the FEA by the 3-D printed part as a tool to predict compressive testing, it was determined that the an aluminum Y-Arm would bend, but not fail at the load set in the product design specifications.

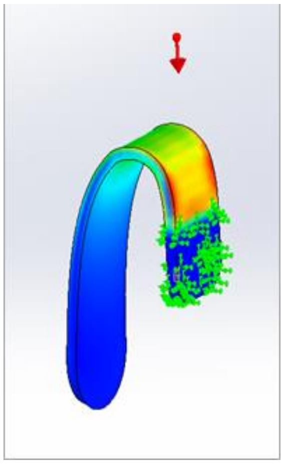


**Figure 22: ABSplus at 163 lbs.** A load of 163 lbs. was applied vertically to the apex of the arm. Results validate that FEA can be used to model the compressive test.

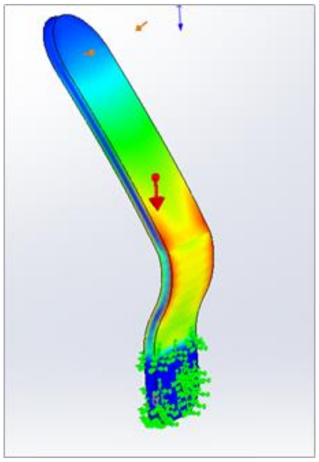


**Figure 23: 1060 Aluminum at 163 lbs.** Conducted FEA on 1060 Aluminum with an applied load of 163 lbs. In comparison to ABSplus results, the aluminum part did not bend nearly as much.

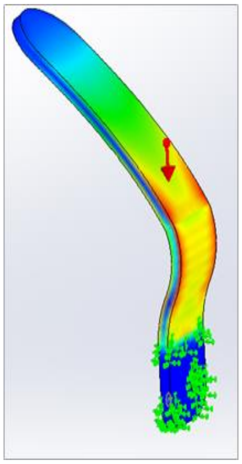


**Figure 24: 1060 Aluminum at 300 lbs.** Conducted FEA on 1060 Aluminum with an applied load of 300 lbs. The Y-arm did bend; but the Von Mises stress gradient suggests failure would not occur.

### *Dynamic Testing: Protocol*

While the static test using the MTS machine is beneficial, dynamic testing of the Y-arm hinge is much more important in assessing the forces experienced by the user while wearing the brace. The Tri-Axial hinge is continuously subjected to varying loads when the user is moving. The goal of this testing was to determine whether the Y-arm hinge design reduced the pinching force in comparison to the model currently used. In order to accomplish this, force sensitive resistors (FSRs) were used to monitor how much force was exerted at the hinge pressure points along the leg. FSRs resistance varies inversely with the force applied.[21]

Eight Intertek 402 FSRs were purchased. Both of the leads on each FSR were soldered to six-foot long wires to allow for more mobility during testing. Extra care was taken during soldering in order to make sure they were not damaged which is a frequent problem. In order to improve the precision and accuracy of the FSRs, hot glue domes with a similar circumference to the FSRs were fabricated. These domes were fabricated by continuously adding hot glue to a single spot until the proper area was covered, and then allowed to cool. By covering the FSR with the domes, forces that are not perfectly perpendicular to the plane of the FSR will still be properly recorded.

In order to determine the applied forces, each FSR needed to be individually calibrated. In order to do so, an FSR was placed in a voltage divider circuit, with the first resistor having a 5.1 kΩ resistance, as seen in **Figure 25**. An Arduino Uno was used to supply 5 V of power in addition to reading in the analog data. A Shimpo Digital Force Gauge was used to exert loads of 0.5, 0.75, 1, 2, 4, 6, and 8 lbs. and the corresponding voltages were recorded. These seven data points were used to create a calibration curve of force versus voltage for each sensor. Once each FSR was calibrated, it was implemented into a circuit.

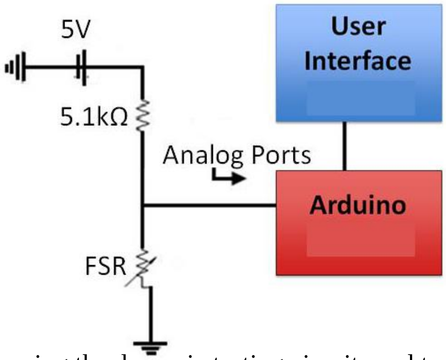


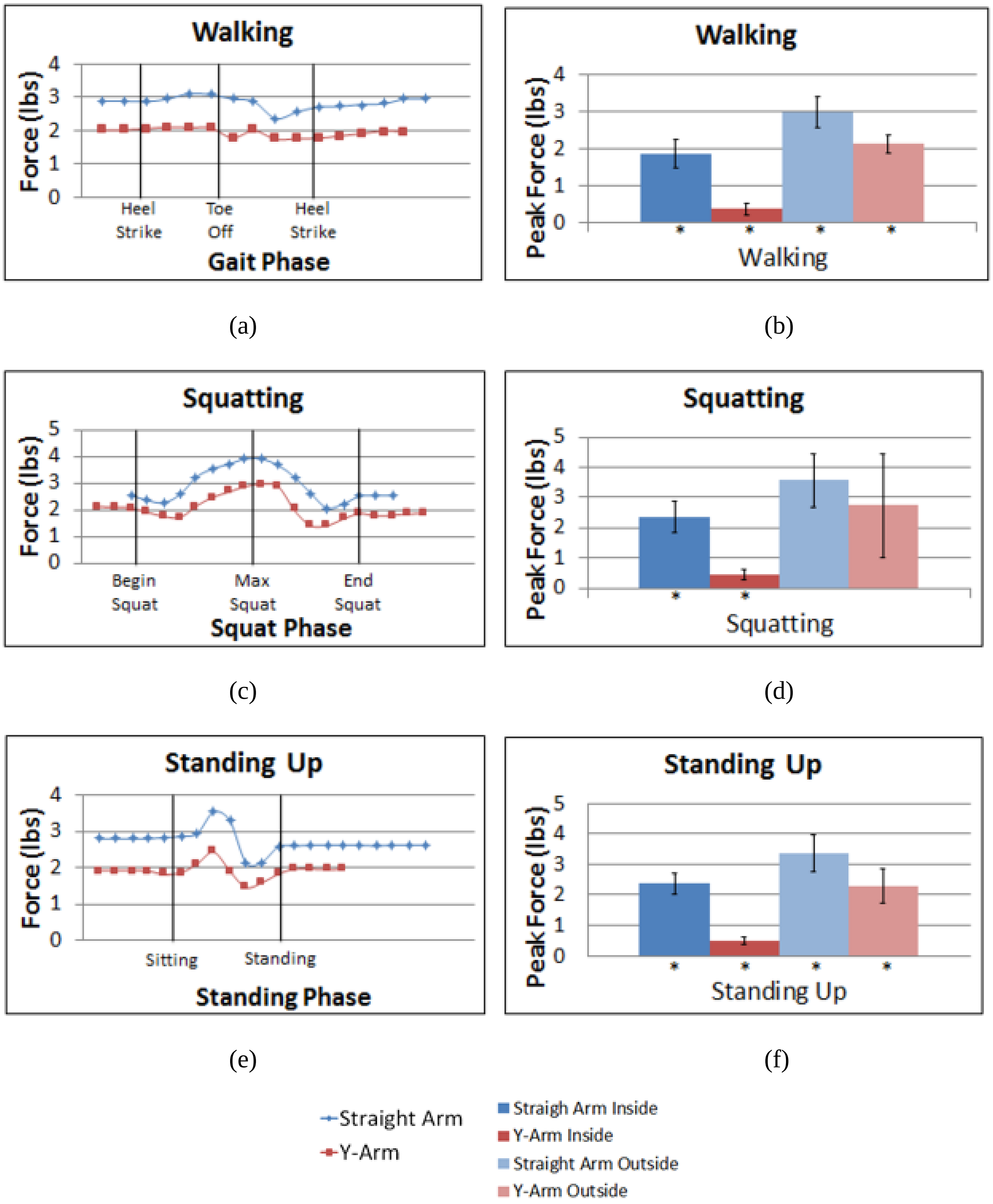
**Figure 25**: A circuit diagram showing the dynamic testing circuit used to monitor the forces during movements. The Arduino supplies 5 V of power to the voltage divider circuit and reads in the voltage generated from the variable FSR. The user interface was the Arduino serial monitor, which we used to monitor the forces.

The circuit was constructed with each of the leads for the two FSRs in series with 5.1 kΩ resistors. The circuit then fed into an Arduino microprocessor, which collected and stored the voltage data. The Arduino then processed these voltage values and converted them into force values using the calibration equations.

In order to test the prototype, three force sensors were attached to each of the two hinges in the knee brace. The FSRs were taped at the most proximal position of the hinge. The hinges were then placed back into the sleeve with the FSRs facing inwards towards the body. During this process, three of the FSRs were damaged so that they were no longer functional. As a result, only one FSR was fastened to the tip of each of the hinges and used to collect data. The subject then performed multiple actions including standing still, walking, squatting, and standing up from a sitting position. Force values were recorded with a frequency of 4 Hz. The process was then repeated three times for each movement for both the Y-arm prototype and the original hinge.

*Dynamic Testing: Standing Still*

While standing still in an upright position, the straight arm design exerted a maximum pressure of 1.7 lbs. on the medial portion of the thigh. It also produced a maximum force of 2.78 lbs. on the lateral portion of the thigh. In contrast, the redesigned Y-arm exerted a maximum force of 0.32 lbs. on the medial side and 2.16 lbs. on the lateral side of the thigh. This corresponds with an 81% decrease in pressure on the medial side, and a 22% decrease in pressure on the lateral side. These tests showed results that matched those that would be expected. The redesigned arm saw a significant decrease in pressure while holding a static standing position.



(a) (b)

(c) (d)

(e) (f)

**Figure 26: Forces experienced during various movements.** Both the straight arm and Y-arm designs were compared over walking, squatting, and standing after sitting movements while the peak forces experienced were compared.

### *Dynamic Testing: Walking*

During walking, the straight arm design applied a maximum of 1.8 lbs. of pressure on the medial side and 2.95 lbs. of pressure on the lateral side of the thigh, as seen in **Figure 26a.** The redesigned Y-arm applied a maximum force of 0.35 lbs. of medial pressure and 2.1 lbs. of lateral pressure, **Figure 26b**. This corresponds with an 81% decrease on the medial side and a 28% decrease of lateral pressure that can be seen in **Table 3**. In both of the designs, there was a very slight increase as the subject transitioned from heel strike into the toe off phase of gait. As the toe leaves the ground and enters swing phase there is a noticeable drop in pressure, as the weight of the leg no longer needs support from the brace. Pressure levels once again rise as the gait cycle reaches heel strike.

### *Dynamic Testing: Squatting*

During squatting, the straight arm exerted a maximum force of 2.4 lbs. on the medial side and 3.6 lbs. on the lateral side, **Figure 26c**. The Y-arm design had a peak force of 0.46 lbs. on the medial side and 2.7 lbs. on the lateral side, **Figure 26d**. The medial side had a statistically significant decrease of pressure of 80%. When looking at the overall squatting phase, these peak forces occurred when the maximum squat position was achieved. The overall shape of the loads exerted on the FSR is symmetrical about this maximum position.

### *Dynamic Testing: Standing Up*

When standing up from a sitting position, the thigh contracts to generate force; this increases the thigh size, creating an increase in force on the brace as can be seen in **Figures 26e&f**. A decrease in force was observed on the brace as the thigh begins to relax as it approaches the standing position. Finally, the thigh increases in size again to stabilize standing upright, thus increasing pressure. As seen in **Table 3** there was a 79% and 32 % decrease in force on the brace on the medial and lateral arms, respectively, when comparing the Y-arm design to the straight arm design.

**Table 3: Reduction in Pinching Force.** The percent reduction of pinching force on thigh from straight arm design to Y-arm design.

| | Walking | Squatting | Standing from Sitting Position |
|---|---|---|---|
| Medial Arm | 81% | 80% | 79% |
| Lateral Arm | 28% | 24% | 32% |

## Future Work

Next semester, the focus will be primarily on testing. However, before testing can be performed on the Adjustable-Hinge, improvements to the design must be made. The design needs to be much stiffer and sturdier to support a load of 300 lbs. The knee brace arm sleeve will also need to be improved to better fit with the y-shape of the redesigned hinges.

More dynamic testing must also be conducted. This will be conducted using Motion Capture and force plates for both the Adjustable-Hinge and Y-Arm design. Reflective trackers can be placed on various parts of the leg and both motion and force plate data can be collected. From this data, inverse dynamics can be utilized to determine the forces and moments in the knee as well as the limitation in power generation caused by the knee brace. A sample size of 10 or more subjects is desired, including a broad range of users, ages, and leg sizes.

A larger and more diverse group of subjects is also desired for conducting qualitative testing. The qualitative test consists of the subject wearing the HG80 Premium Hinged Knee Brace with the original straight arm hinges for one full day while completing normal daily activities. One week later, the subject then wears the HG80 Premium Hinged Knee Brace with the re-designed Y-arm hinges, once again wearing it for the full day. The subject is not told which hinge should be better. At the end of each day, after the subject had completed all their normal daily activities while wearing the brace, the subject is given a short questionnaire to assess the comfort of the brace. The subjects’ responses to the questionnaire after using both the straight arm and the Y-arm can be found in the appendix.

For the adjustable and y-arm, a final prototype of each will be fabricated out of aluminum. Ideally, at the end of second semester, Mueller Sports Medicine will be pleased with the modifications in the design of the Tri-Axial hinge and will begin utilizing this new design.

## Acknowledgements

The Tri-Axial Hinge Knee Brace Team would like to take this opportunity to express gratitude to the all the individuals who provided guidance and knowledge throughout the entire design process. The team would like to formally thank their client, Dr. Sarah Kuehl from Mueller Sports Medicine for presenting the design project to the team and providing the team with the necessary financial resources. Dr. Joseph Towles also deserves recognition for not only guiding the team during the entire design process, but also for emphasizing the lifelong learning aspect of successful design. The team would also like to thank several individuals who helped with specific aspects of the design project. This includes Dr. John Puccinelli for coordinating the 3D printing of the designs, Alex Nguyen for helping with the MTS testing, Dr. Thomas Yen for support about the use of force sensors and the UW-Madison COE Student Shop for providing guidance during the fabrication process.

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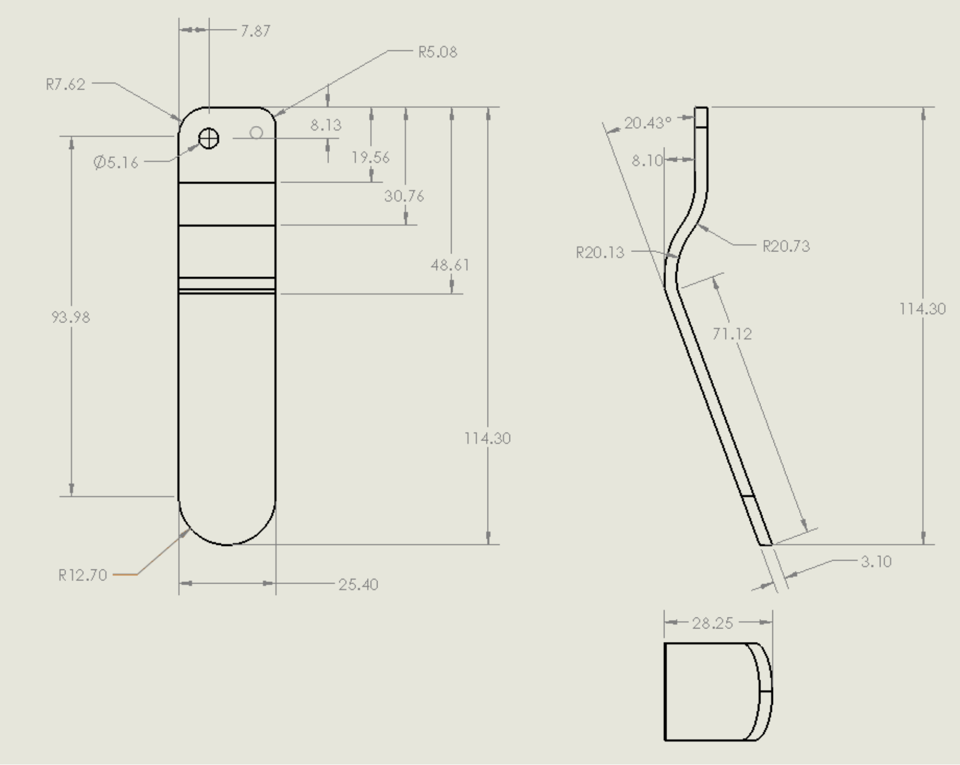
## Appendix

### *Product Design Specifications*

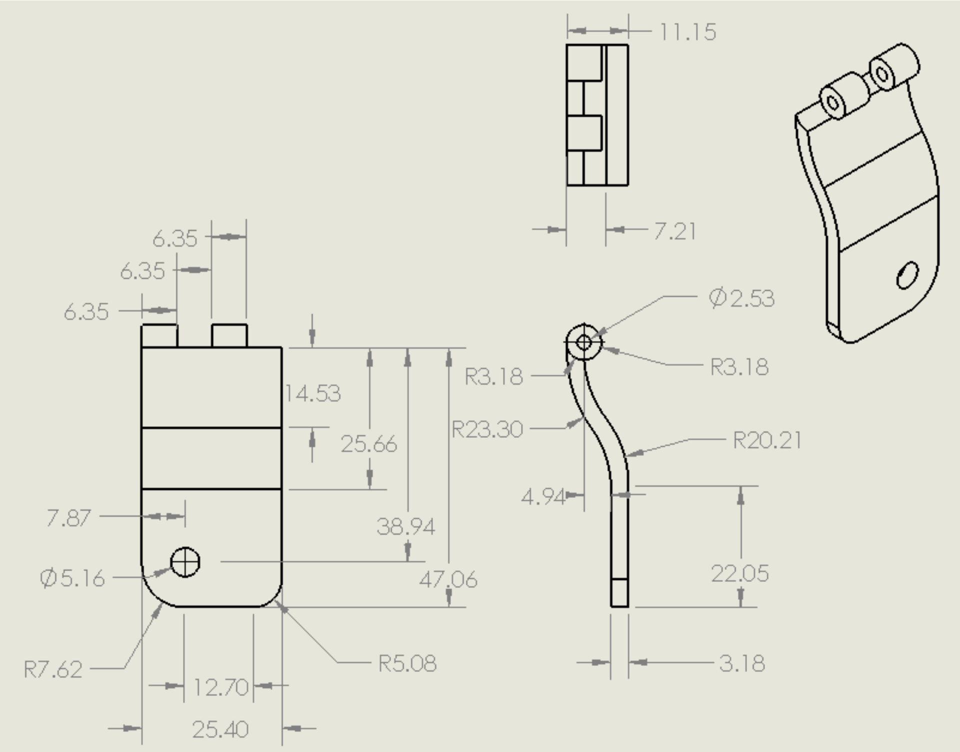
Product Design
Specifications.docx

### *Drawing of Hinge Final Design: Y-arm*

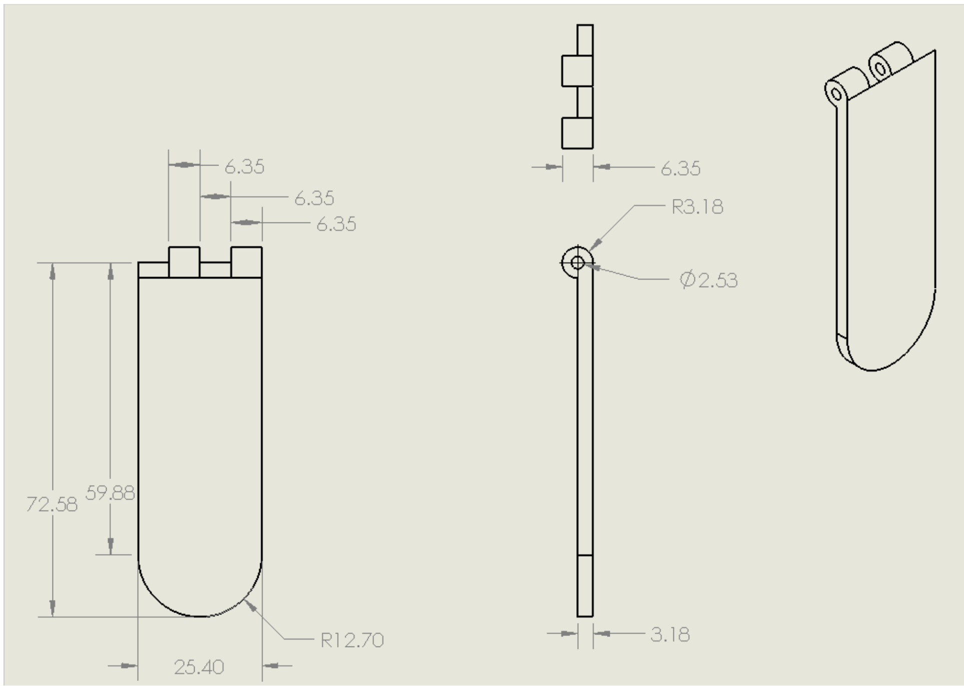


## ***Drawing of Adjustable Hinge Locking Mechanism Final Design: Two Screw***

### *Base*



### *Distal End*



### *Anthropometric Research: Literature Data*

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### *Anthropometric Research: Measured Data*

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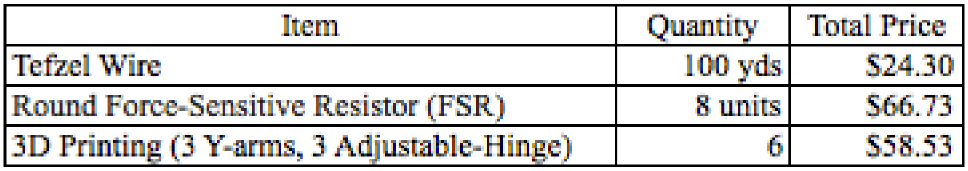
Measured Data.

### *Qualitative Survey*

Qualitative Survey.docx

### *Summary of Expenses*



| Item | Quantity | Total Price |
|---|---|---|
| Tefzel Wire | 100 yds | $24.30 |
| Round Force-Sensitive Resistor (FSR) | 8 units | $66.73 |
| 3D Printing (3 Y-arms, 3 Adjustable-Hinge) | 6 | $58.53 |