

Alternative Knee Brace Design

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Submitted by:

Amanda Cormier

Sarah Cook

Zachary Tomkinson

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Approved by:
Prof. C A Brown, Major Advisor

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Abstract

The objective of this project is to reduce Anterior Crucial Ligament (ACL) injury during alpine skiing through the design of a novel bracing system to protect the ACL. ACL tears as a result of alpine skiing account for 20% of all skiing injuries (Johnson, 1997). The most common causes for ACL injuries during alpine skiing are Boot Induced Anterior Drawer (BIAD) and valgus collapse. Axiomatic design, which includes two axioms, maintains independence and minimizes information, was used to generate and evaluate design alternatives and final design selection. Tolerances and material selections were determined based on the laxity of the ACL. Force analysis was used to finalize the computer model. Finite Element Analysis (FEA) was completed to evaluate how the device will perform under injurious loads (Dargel, 2007) seen by the ACL during alpine skiing.

1. Introduction

1.1 Objective

The objective of this project is to create a knee brace that will protect the ACL of alpine skiers while skiing by preventing Boot-Induced-Anterior Drawer (BIAD), preventing valgus collapse, and actively taking up extra laxity in the system. BIAD is when the tibia moves forward in relation to the femur. Valgus collapse is the inward rotation of the hip with a 10-degree external rotation of the tibia and a 30-degree knee flexion (Utturkar, G. M, 2014). This brace is innovative because of the upper body component and the novel hinge design.

1.2 Rationale

With the advancement of skiing technology and equipment in the last few decades, overall ankle and foot injuries have decreased drastically (Pennington, 2008). Modern ski boots and bindings, while they protect the foot and ankle, displace harmful loads to the knee (Majewski, 2006) causing the ACL to see a higher load. ACL tears as a result of skiing accounts for 20% of all skiing injuries (Johnson, 1997), and costs approximately \$250 million dollar a year due to initial costs of brace systems, surgery, rehabilitation, and physical therapy (Sigward, 2013). There are many types of athletic knee braces; however, there are numerous limitations, which are discussed later in the paper.

1.3 State of the art

The standard knee brace (Figure 1) aims to protect the knee by using a simple mortise hinge, similar to a door hinge, to simulate movement in the knee (Basic Vacuum Bagging Set-up, 2014). The main problem with these designs is that they allow for movement in only the sagittal plane; however, the knee naturally moves in the sagittal, coronal, and the transverse planes. As a result these standard knee braces limit the natural flexion and extension of the knee. Current knee braces are heavy and cumbersome, with an average weight of 3-5 lbs. (Basic Vacuum Bagging Set-up 2014). Standard knee braces also have a tendency to slide down the leg due to the weight of the brace and the tapered nature of the human thigh (Cawley, 1991). If the knee brace is moved from its initial central point of rotation then it will not allow for normal knee flexion and extension. Restricting the knee from bending makes wearing the brace more dangerous than not having the brace on at all (Cawley, 1991).



Figure 1: Industry standard knee brace.

No current knee brace designs or patents use a hinge other than a mortise hinge. The patent closest to our design is Patent US 8060945 B2 (Adarraga, 2011). This patent is for a design made of a rigid material and spans from the hip to the ski boot (Adarraga, 2011). This design claims to prevent knee, leg, and hip injuries by preventing torsion of the knee. This design uses sensors to detect movement and pressure to transmit a signal to the clutch mechanism. This uses a cardan or universal joint, which only allows for movement in the coronal plane. While this design is similar to ours because it includes an upper body component, our novel hinge sets it apart.

Patent searches concluded that no knee brace systems has been patented or documented that uses a hinge system similar to ours. There has been research on how to move the loads from the lower body to the upper body during skiing; however, this research uses a more rigid approach following the HKAFO bracing models used by polio patients. Concepts from parts of the hip bracing system from the HKAFO were used in our design, but our system varies from this model because our overall objective is to protect the ACL. Our design is unique because it uses bands with high tensile strength to displace the loads across the back of the thigh and up to the lower back.

1.4 Approach

After conducting research on current patents, our brace would advance the state-of-the-art in two ways. Our novel hinge has been designed to allow for normal knee flexion and extension and is unlike any other knee brace hinge currently on the market. Our design has an upper body component to transfer loads to the upper body. Upper body components of the knee bracing systems were rarely reported and out of those reported none of them used the upper body to help protect the ACL. Using the upper body to disperse harmful loads eliminates any concerns of the brace moving during use.

Axiomatic design was used to technically and strategically evaluate our design to optimize design success (Suh, 1990). The base of this method consists of two axioms, otherwise known as “laws”: to maintain the independence and minimize information. The Functional Requirements (FRs) were developed based on customer needs and the Design Parameters (DPs) were determined based on the FRs. For this project computer software, Acclaro, was used to assist in developing out design (figures 2 and 3 below).

2. Design Decompositions and Constraints

FR0, is to protect the ACL during alpine skiing. The DP that will achieve this FR is a bracing system that protects the ACL by moving harmful loads past the knee, up the femur, and onto the bony structures of the upper body. Constraints to achieving these upper level requirements and parameters are laxity of the system, demographics, manufacturability, and patent infringement.

Constraints play a major role in the overall design of the system. The laxity allowed by the bracing system in the direction of the ACL must be less than that of the ACL itself, approximately 2mm. The demographics of the target population must also be taken into consideration as well as providing a bracing system that is comfortable and does not limit normal body movements. To file for a provisional patent, it was necessary that each component was unique in that they do not infringe on any current patents. Below is a more detailed evaluation of the FRs and DPs, as well as an image of the upper level FRs and DPs for Acclaro.



Figure 2: Upper Level FRs

DP	System providing support to the tibia, through the knee, to the femur and displaces the load to the boney structures of the upper body
DP	System preventing tibia displacement from the femur when catastrophic loads are applied
DP	Cushion structure surrounding the upper tibia
DP	Plastic piece surrounding the upper tibia and connects to the load barring structure
DP	Cushioned material that stiffens upon impact
DP	Modified Universal hinge interlinking the tibia and femer at the knee joint
DP	Connection bar
DP	Internal interface of the hinge system
DP	Compression short and belt system
DP	Screw holding together the fem side of the hinge to the fem stop
DP	A loop structure on the fem stop connecting to a band on the compression shorts
DP	Sewn in bands with a higher Elastic Modulus than the compression shorts
DP	Hinge and load relieving system at knee joint
DP	Limiting barrier on the outer edge of the modified universal hinge
DP	Rounded geometrical hinge with two flattened sides and a rear cut out acting as motion limiter between upper and lower components

Figure 3: Upper Level DPs

2.1 Design Decomposition Level 1

Level 1 focused on preventing the forward movement of the tibia in relationship to the femur to protect the ACL, while staying within the laxity budget. This part of the decomposition also accounts for when the laxity of the system is used and any extra slack must be taken up.

2.1.1 Functional Requirements (FR)

FR1 is to prevent BIAD, FR2 is to prevent valgus collapse, and FR3 is to counteract the load with equal and opposite loading. These FRs can be seen in figure 2 above.

This level of FRs is collectively exhaustive because the two major causes of forward movement of the tibia in relationship to the femur are accounted for and described in detail. This list of FRs is also mutually exclusive because each individual FR details a different cause of injury to the ACL. FR3 differs from the first two because it addresses protecting the laxity budget rather than preventing harmful loads. These FRs are collectively exhaustive and mutually exclusive because it prevents the brace from moving during use.

2.1.2 Design Parameters (DPs)

DP1 is a system that prevents tibia displacement in the sagittal plane from the femur when dangerous loads are applied. This DP was chosen because to prevent an injury caused by BIAD, the dislocation of the femur and tibia must be prevented, and the dangerous load applied in the sagittal plane must be transferred.

DP2 is a system that prevents dangerous movement in the coronal and transverse planes when dangerous loads are applied. This was chosen because to prevent valgus collapse it is important to prevent rotational displacement of the tibia in relationship to the femur in the coronal and transverse planes. This will

ultimately be a rigid system that prevents dangerous twisting rotation about the knee, yet allows for normal knee flexion and extension.

DP3 is a system that tightens when a dangerous load is applied in the opposing direction. This was chosen because of the strict laxity budget of the ACL. This system will take up any extra slack in the overall brace and will look like an active system connected to the bands in the compression shorts.

2.2 Design Decomposition Level 2

2.2.1 Design Decomposition Level 2.1

This part of the decomposition focused on a mechanism that transfers the load seen on the tibia to the hinge and ultimately to the lower back when BIAD loads are applied.

2.2.1.1 Functional Requirements (FRs)

The FR's for this part of the decompositions are to transfer the load from the tibia to the brace, transfer load through the brace by the knee, transfer load from the hinge unit to the femur unit, transfer loads from the femur unit to the hip, transfer loads from the hip hinge to the upper body system, transfer load by the hip to the lower back. These FRs can be seen in figure 2 above.

This design decomposition is collectively exhaustive because all of the points at which the load will be transferred to and from are accounted for. This is also mutually exclusive because each FR isolates a particular part of the body and describes how it will absorb initial loads and displace the loads to the next part of the system.

2.2.1.2 Design Parameters (DPs)

The first DP on this level is a surface with direct contact on the tibia, just below the knee, and attached to the knee hinge. This will allow for a system to absorb and relocate initial load seen by the tibia. This will be a ridged material that will be able to transfer loads.

The second DP is an interface between the tibia side and the femur side of the knee hinge. This was chosen because the hinge component will connect the tibia and the femur and will transfer the load by the knee. This will prevent BIAD and valgus collapse, while allowing the knee to flex and extend normally. This will be a modified saddle hinge that will be made out of carbon fiber.

Finite Element Analysis for the transfer of the loads through the hinge can be seen below for the event of a BIAD loading on the ACL. The normal load seen on the ACL in daily activities varies between 100N and 300N(Dargel, 2007). This FEA was modeled using a 450N load to insure that our device could withstand injurious

loads. Both sides of the hinge were fixed, and the loads were applied accordingly (figures 4 and 5).

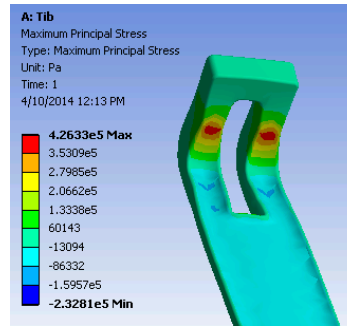


Figure 4: FEA modeling shows the areas of stress concentrations located on the tibia side of the hinge.

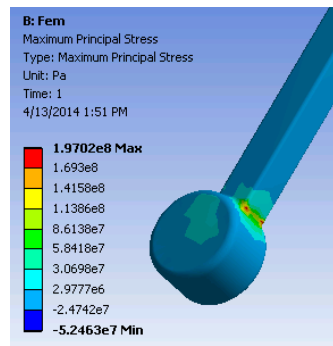


Figure 5: FEA modeling shows the areas of stress concentrations located on the femur side of the hinge.



Figure 6: Image of FRs/DPs 1.1 and 1.2 in our design.

The third DP is an interface between the femur side of the hinge component and the lower portion of the compression shorts. This is needed to connect the femur hinge component to the upper body through the means of the compression shorts to transfer the load. This will be a press fit component that will interlock a male connector located on the femur side of the hinge to a female component located on the lower portion of the compression shorts.

The fourth DP is the connection between the femur bar and the hip hinge. This will be achieved by casting the proximal end of the femur bar in epoxy with the distal end of the hip hinge. This is needed to transfer the load from the carbon fiber unit in the compression shorts to the hip hinge, to get the load from the femur and thigh area to the lower back. This will again be a press fit component, similar to the one in the third DP.

The fifth DP is the connection between the hip hinge and the rigid support around the waist. This was achieved by casting the hip hinge and the rigid support in epoxy. This transfers the loads that are in the hip hinge to the lower back.

The sixth DP is a strong material spanning from the right hip to the left hip including the plastic component on the lower back. This is needed to displace the load about a larger area on the lower back, thus reducing the load seen at any one spot. This will be a mesh and plastic component located on the lower back.

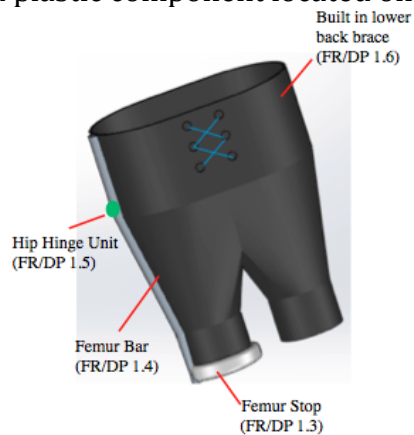


Figure 7: Image of DPs 1.3-1.6 in our design.

2.2.2 Design Decomposition Level 2.2

The theme for this part of the decomposition is to transfer the loads caused by valgus collapse to the upper body.

2.2.2.1 Functional Requirements (FRs)

The FRs for this part of the decomposition aim to prevent harmful rotational movement in the coronal plane, sagittal plane, and transverse plane, and to transfer the load from the femur hinge unit to the upper body. These FRs can be seen in figure 2 above.

This design is collectively exhaustive because it accounts for moving the loads that are caused by valgus collapse through the areas of the knee and up to the lower back. This is also mutually exclusive because each FR takes into consideration a different aspect of moving the loads from point one point to the next from the tibia all the way to the lower portion of the back.

2.2.2.2 Design Parameters (DPs)

The matching DP is a limiting component located on the outer side of the hinge in reference to the knee. This will act in the opposite direction of the dangerous load, thus preventing outward rotation of the tibia from the femur during valgus collapse conditions. This will look like a slot inside the tibia side of the hinge preventing the tibia from rotating more than 10 degrees (Utturkar, G. M, 2014).

The next DP is a system made up of a rotational limiting factor in the hinge and a rigid piece within the compression shorts. This will be a rigid strong beam, preferably made of carbon fiber, which will go from the upper femur side of the hinge to along the femur and connecting to the hip hinge area. This component will also be connected to the compression shorts through the system of bands that will be strategically woven through the compression shorts to allow for load displacement.

2.2.3 Design Decomposition Level 2.3

The focus of this part of the decomposition was to provide a system that will take up extra slack to protect the laxity budget of the ACL.

2.2.3.1 Functional Requirements (FRs)

The first FR for this level of the decomposition is to provide a system that will contract if the laxity is used up when a dangerous load is applied. The second FR is to provide re-loading after dangerous loads are seen. These FRs can be seen in figure 2 above.

These FRs are collectively exhaustive because it accounts for when the laxity budget is used up and it is mutually exclusive because this is the only area in which the case of the laxity budget being exceeded is accounted for.

2.2.3.2 Design Parameters (DPs)

The first DP is an active system connected to the bands that will retract and take up any extra slack in the system when dangerous loads are applied. The second DP is a system that allows the bands to return to their initial length before retraction.

3. Physical Integration

3.1 Knee Hinge Design Alternatives

We developed various design alternatives for the knee hinge. After carefully evaluating and analyzing these alternatives we found that one of our design alternatives met our needs best.

3.1.1 Alternative 1

FR1, preventing BIAD and FR2, preventing valgus collapse were the two FRs that shaped our design. To accomplish FR1, the hinge must have an interface that would stop the tibia side from moving forward in reference to the femur. To accomplish FR 2, the hinge needs an interface preventing the tibia side from rotating in reference to the femur side. To meet these needs our first design alternative was a modified ball and socket joint (figure 8).

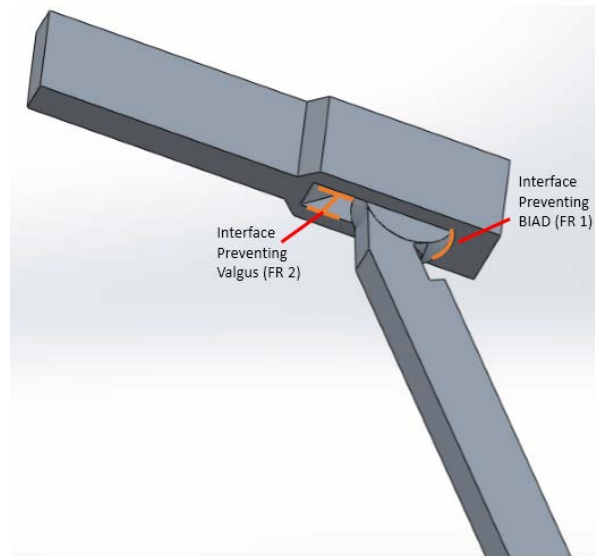


Figure 8: First design alternative highlighting how this design addresses FR1 and FR2.

In this design, the tibia unit had a rounded top that allowed for the piece to rotate within the femur unit. The interface between the rounded component of the tibia side and the rounded inside pocket of the femur unit prevents BIAD while bent and straight. The cuts in the tibia side unit allowed for the hinge to rotate. This design allowed for natural knee flexion and extension. The encasement of the rounded top within the femur unit prevents the tibia side from rotating outward with respect to the femur side. After careful review of our decomposition and this design we determined that this is not the best design alternative to accomplish our objectives because this design causes a central point of rotation. This would limit the consumer's natural knee flexion and extension.

3.1.2 Alternative 2

To create our next design alternative, we researched current hinges to determine whether or not any of them could be modified to meet the needs of our FRs and DPs. We were able to modify a universal hinge such that the design would look like two interlinking loops (figure 9). This would allow for the two sides to move relatively independent of each other but still have an interface that would

prevent BIAD in either standing or bent position. By adding a wall on the femur side of the hinge we could then limit the tibia side from harmful rotational loads to prevent valgus collapse.

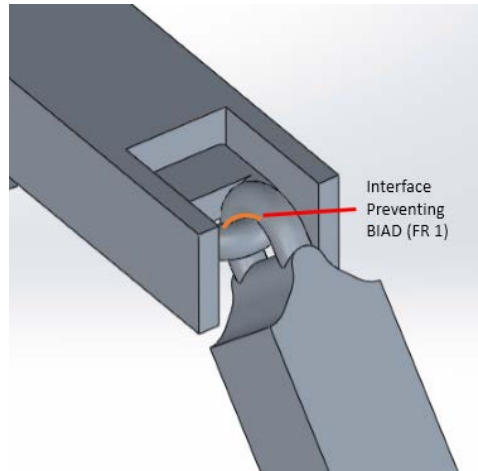


Figure 9: Second design alternative is a modified universal hinge with connecting loops. This image shows how FR1 is addressed; however, this design allowed for too much laxity.

This design alternative would allow for too much laxity in the system. Therefore, we concluded that this design would not be acceptable.

3.1.3 Alternative 3

The next design alternative focused on preventing BIAD and valgus collapse and minimizing laxity in the entire system. This will prevent the brace from restricting any natural, healthy movements of the knee. This design alternative had a rounded ball shaped top on the femur side, and an L-shaped bracket on the tibia side (figure 10).

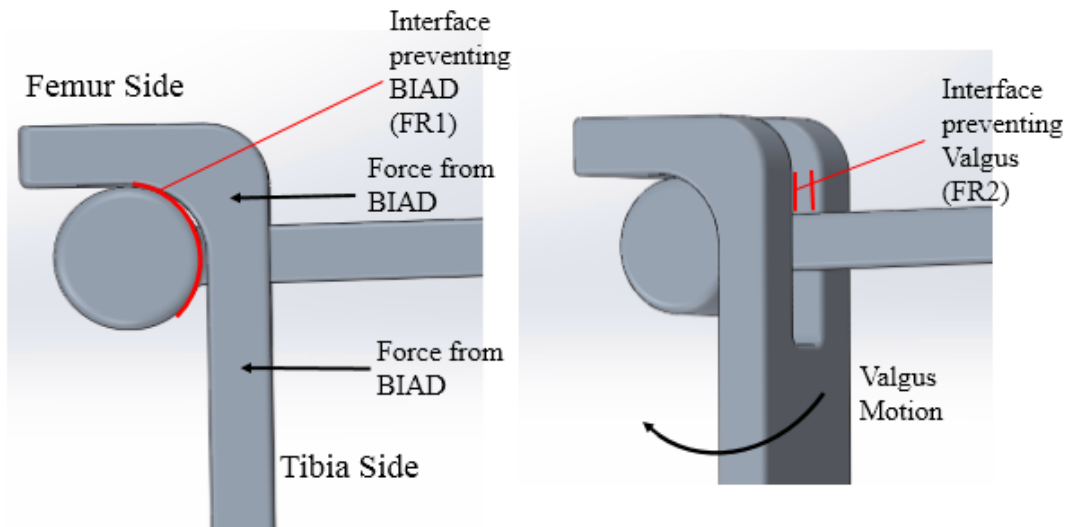


Figure 10: Third design alternative, which was successful in preventing both BIAD (left) and valgus collapse (right). The interfaces of interest that prevent these harmful movements are highlighted in red.

This curved interface of the rounded femur and tibia components prevents BIAD without limiting normal knee flexion and extension. This hinge works similarly to a saddle joint, seeing how it does not have a fixed axis of rotation, similarly to the anatomy of the knee (Standring, 2005). The curved part of the femur side can move up or down to make the adjustment in the axis of rotation as the knee is bent and straight. The open slit through the L-bracket on the tibia side allows for the knee to bend, but limits dangerous movements in the coronal plane. The tolerances within the slot were determined to allow for a natural amount of rotation in the coronal and transverse planes. Drawings and tolerances can be found in appendix A and B.

3.2 Full Brace Unit

Our knee brace design involves the use of the novel hinge design along with compression shorts, bands, femur bar, femur and tibia stop, and a lower back brace. This system will allow us to transfer the loads from the tibia, by the knee, up the thigh, around the hip, and to the lower back. The goal of the upper body unit is to carry the dangerous loads that were displaced from the knee to the boney areas of the lower back, while dispersing some of the load along the back of the hamstring. The full system can be seen in figure 11.

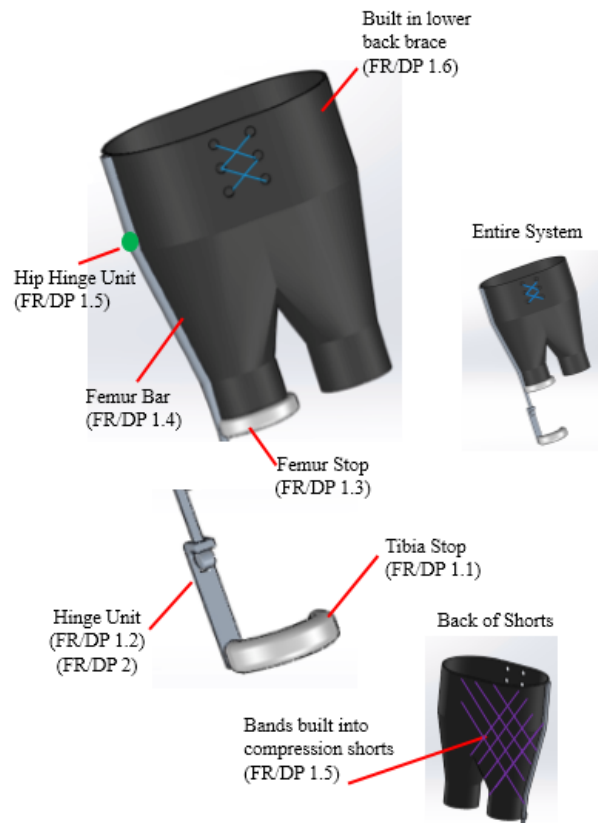


Figure 11: Full brace design as well as each aspect broken down by FR.

This figure shows each aspect of the brace and the corresponding functions. The lower back brace is built into the compression shorts and laced up the front to ensure the brace is tight and secure. The bands shown in purple will be sewn into the shorts and will displace the injurious loads along the back of the thigh, which will lessen the total load before it reaches the lower back. The green dot in this figure, labeled “Hip Hinge Unit”, is a hinge that does not constrict normal hip movements. Lastly, the bar connecting the femur stop to the hip hinge unit provides a method for transferring the load and prevents a moment about the knee caused by dangerous loads associated with BIAD and valgus collapse.

The femur stop and the tibia stop will be held in place by Velcro straps connected to the back half of the stop units and will wrap around the back of the knee allowing for tightening and loosening of the system. This will help keep the knee brace in place and prevent unwanted shifting.

3.3 Material Selection

One customer need is to have the design to be as light and strong as possible; therefore, when choosing materials we looked for materials that contain those characteristics. Carbon fiber was chosen for our hinge and femur bar. The carbon

fiber that was chosen was pre impregnated with epoxy. This allows for the material to adhere to itself when subjected to a pressure tight vacuum when the fibers are properly aligned (Carbon Fiber, 2014). This allows the material to be strong and lightweight. Instamorph material was used for our tibia and femur stop components. Instamorph is a strong polymer that is heated and modeled into a desired shape (Basic Bagging Vacuum Set-up). It is important that our femur and tibia stop are perfectly molded to the users body to ensure even loading and to prevent bruising. By using Instamorph we can make sure the femur and tibia stop are in full contact with the boney areas of the tibia and femur when being molded.

Compression shorts with sewn in wire bands and a lower back brace was used for the upper body system. The wire bands used were fishing wire that is thin, strong, and high in tensile strength. To minimize the use of our laxity budget we made sure to choose a material that could not stretch.

4. Prototype Production

Prototype production began with the hinge design alternatives. We began producing prototypes of the hinges using clay and Instamorph. This allowed us to quickly produce multiple alternative hinge designs (figure 12). From this we were able to quickly analyze a wide variety of design alternatives in conjunction with our decomposition to determine the best design.



Figure 12: First prototype of hinge ideas made using modeling clay.

Once the design was determined, we created our first hinge prototype. This prototype was created in the machine shop at Washburn Shops with the help of Connor Morette. The material chosen for the first prototype was aluminum. This is because it was cheap, easy to manufacture, and readily available. After this first prototype was created, we re-evaluated the design and made minor changes. Based on these changes and a re-evaluation of the FRs and DPs we created a second prototype. Once again this prototype was created in aluminum in Washburn Shops with the help of Connor Morette for the same reasons listed above.



Figure 13: Second prototype of hinge made in the machine shops at Wasburn Labs using Aluminum.



Figure 14: Second prototype of hinge shown at a different angle.

5. Iteration

Our design has been modeled through Finite Element Analysis, as stated in previous sections. Through this analysis we have found that there will be stress concentrators, throughout the hinge. These concentrators can be seen in figure 4 and figure 5, the red portions of the image are where the stress is highest within the component. In order to ensure that our design will be able to withstand these stress concentrators, we believe that adjusting fillet size and adding a coating on the hinge will be the best way to prevent the hinge from either degradation or dynamic failure.

6. Discussion

6.1 Accomplishments

We designed a novel hinge and traced the loads from the tibia to the upper body. The hinge is unique in that it uses a modified saddle hinge design and will prevent harmful BIAD and valgus collapse loads without limiting the knee's normal flexion and extension. The hinge will allow for some abduction and adduction movement, as well as internal and external rotation about the knee. We traced the transfer of the loads from the tibia, by the knee, up the leg, and to the lower back, where the load is dispersed.

6.2 Critical Assessment

Overall, axiomatic design was an effective design method. The process allowed for our design to achieve our objectives and meet our customer needs. Our team wishes that we had studied and mastered axiomatic design prior to starting our MQP. We recommend that future design MQP groups study axiomatic design before starting their MQP.

6.3 Constraints

6.3.1 Demographics

The demographics of the target population must also be taken into consideration when designing a bracing system. The brace must also be comfortable and not limit natural body movements. Our design targets alpine skiers that have already torn their ACL and skiers that are concerned they could tear their ACL.

6.3.2 Patent infringement

The components of our design must be unique and not infringe on any patents. Since we have applied for a provisional patent, it is important that we do not have similar design components as any other patents. Similar patents are mentioned above in section 1.3. The US Patent and Trademark Office will decide if our entire design is patentable.

6.3.3 Laxity Budget

The laxity of the system is accounted for by providing a system in the brace that will take up any extra laxity. When the laxity budget of 2mm in the direction of the ACL is used up, there will be an active system that will take up the extra laxity.

6.4 Impact of solutions in a global, economic, environmental, and societal context

On a global scale, our brace will be able to benefit thousands of skiers because it can be customized to the consumer. Economically, our design will change the current brace market because our design limits only the dangerous movements and allows normal knee flexion and extension. Future brace designers could embrace this concept; therefore revolutionizing the brace market.

6.5 Deficiency in the prior art

As stated above, current knee braces aim to protect the knee by using a simple mortise hinge. The problems with these designs are that they only allow for movement in the sagittal plane and cause a central point of rotation. Current knee braces are also heavy and cumbersome, causing discomfort to the consumer. These knee braces tend to slide down the leg due to the weight of the brace and the tapering nature of the human thigh. If the knee brace is moved from the central point of rotation the brace will not allow for bending, ultimately restricting any normal knee flexion and extension. Restricting the knee from bending makes wearing the brace more dangerous than not having the brace on at all.

6.6 Potential commercial use of the invention

Our design benefits many individuals including but not limited to; skiers, athletes, orthopedic surgeons, and doctors. This design benefits the field by introducing the concept of designing a brace that prevents only dangerous

movements, while still allowing natural body movements. This is a system that could be adapted to work across most athletic areas. Although our brace may cost more than current braces, the advancements in technology of our brace significantly outweighs the difference in price.

6.7 Critical Assessment

Axiomatic design was a useful method to use in this design project. Using axiomatic design allowed us to evaluate the design down to the smallest components. We were unfamiliar with axiomatic design at first, which caused confusion in the early stages of the design. This resulted in several unacceptable design alternatives. We found it difficult at first to only evaluate the design on paper without actually producing tangible outcomes. Once this problem was overcome the process of creating an effective brace design became easier.

6.8 Issues remaining

Some issues remaining in our design include developing an active system that can take up the extra laxity, developing a hip hinge, and allowing for the transfer of the load to the lower back. Finally, the concept of dispersing the load across the lower back safely and effectively needs to be further developed.

7. Concluding Remarks

1) Designed a novel hinge that protects the ACL against BIAD and Valgus collapse. We were able to trace the load transfer from the tibia, up the body, and to the lower back. A provisional patent was filed on the intellectual property.

2) Axiomatic design was used to decompose our design, and was effective in allowing us to design a brace that will meet all of our customer needs and objectives.

3) Issues remaining include: design of a hip hinge, development of an active system to take up the laxity, system to disperse the load across the lower back.

8. References

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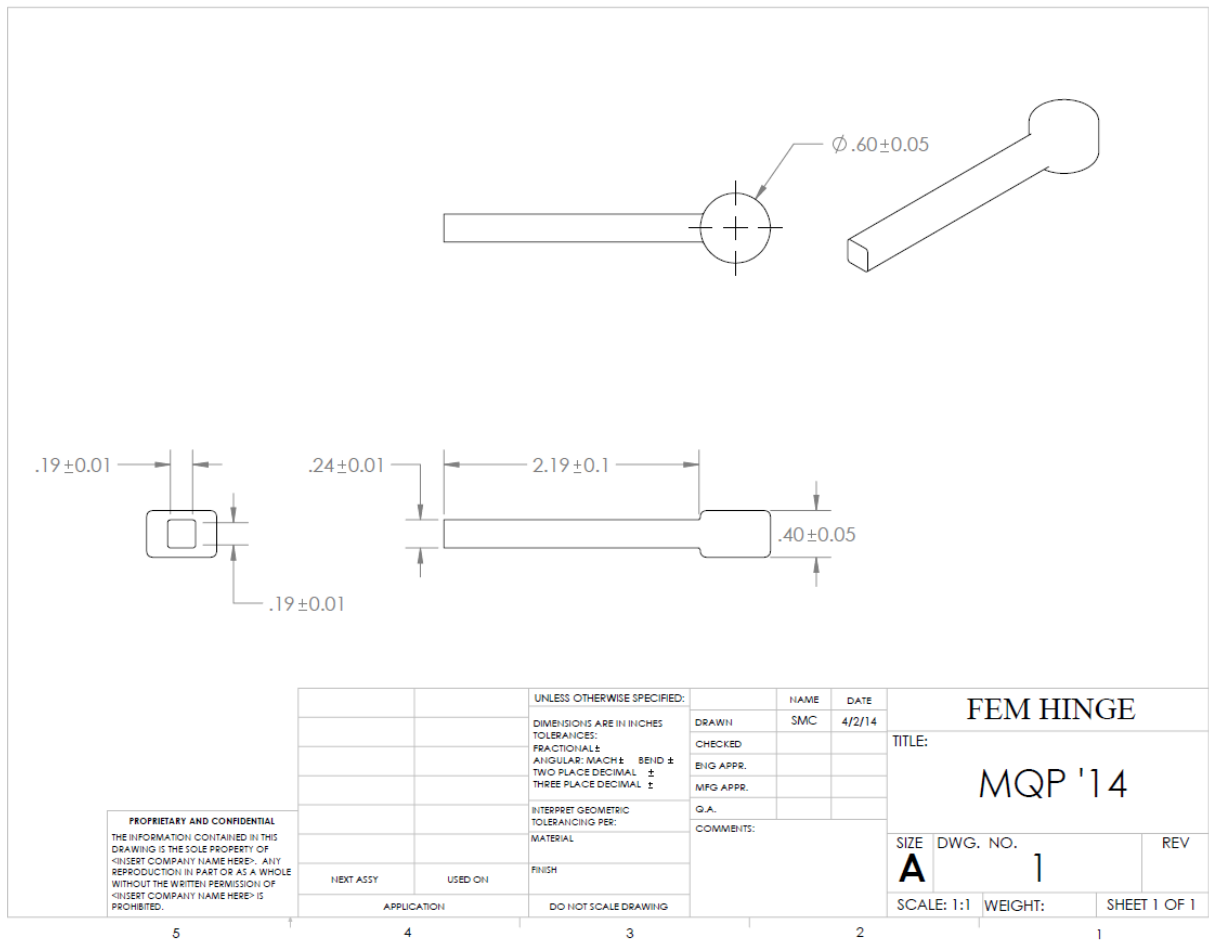
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9. Appendices

9.1 Appendix A: Drawings

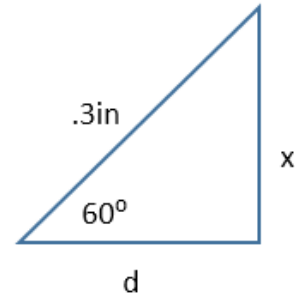
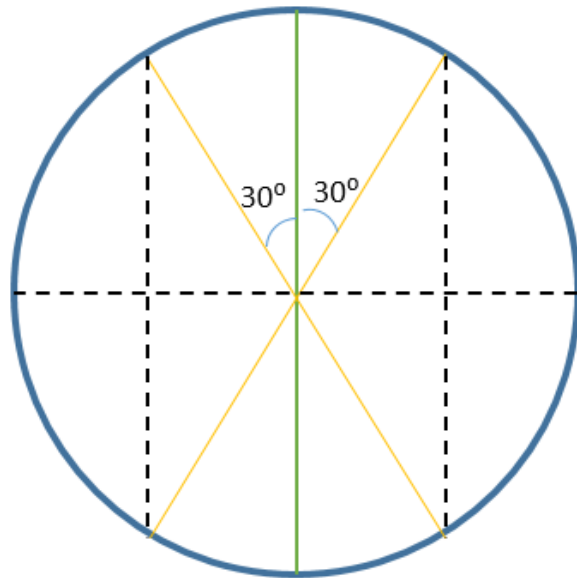
This appendix includes the detailed drawings of both the femur and tibia sides of the hinge.



Femur hinge with tolerances.

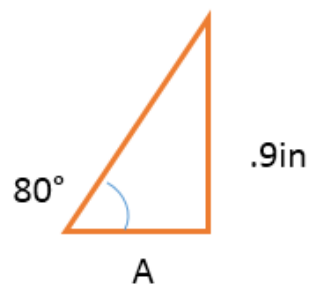
9.2 Appendix B: Tolerances/Dimensions

This appendix includes information on how we determined the dimensions used as well as the tolerances.



$$\cos(60) = d / .3\text{in}$$
$$d = .207\text{ in}$$

This figure shows how we determined the thickness of the Femur head based on the angle at which the knee can kick outwards before tearing the ACL.



$$\tan(80) = .9 / A$$
$$A = .159\text{in}$$

This shows the femur side within the slot of the tibia side and how much it can safely kick out without harming the ACL

This figure shows how we determined the distance between the slot in the tibia side and the stick on the femur side to ensure that valgus collapse would be prevented but normal flexion and extension could still be allowed.