Redesign of the Knee Brace

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Revising Knee Rehabilitation

Handicap can be used to describe many different types of disabilities. Many disabilities can come from sports injuries, specifically knee injuries. Knee injuries are very common in modern sports. With that comes the side of rehabilitation; and the final step in that is the process of getting back on the field. This is a key time where sport devices are few and far between. The goal of the product is to provide a healthy comfortable knee support device that is productive in the return to play in the portion of rehabilitation. The process of interviewing athletic trainers, athletes, coaches, and several entities that work in this field will help provide information to the new knee support design.

Potential customers

The potential customers are the people, organizations, communities, etc. that would benefit the most from this new invention. In our project we have decided that our main goal is going to understand how athletes from all over the world feel when they have a knee injury. Also, knowing the perspective of the people that treat those athletes is going to be very helpful such as doctors, athletic trainers or physician assistants. These two types of customers are in two spectrums of the medical chain; the people who treat patients and the patients. Knowing the point of view of those people is going to provide us with the feedback we need to design the best knee brace.

Players

Julia Kolderman

1. What is the reason in the past you had to wear a knee brace? And how?

I had torn my ACL (Anterior Cruciate Ligament) three times now, and they were all during lacrosse… games, practices etc. They were all during a cut movement where my leg planted (L) acl was torn.

2. How long were you told to wear the knee brace?

I was told I was required to wear it for a year after my first surgery, I wore it for longer, and continue to wear it today three years and three years later.

3. What would you say was the worst/best thing about your last knee brace?

The worst thing is the heaviness and how big it is, but the mental stability it brings outweighs all of the cons.

4. Did you feel comfortable wearing the knee brace once you were cleared to play again? (Explain).

Yes, because it brought me comfortability mentally, so it made me feel very comfortable wearing it once I was cleared to play.

5. How many times do you think you had to take the knee brace off and on during a week period? (Ex. shower, sleep, cleaning the brace, etc.)

I took it off for showering, sleep and when it was off for those things, I cleaned it. I wore it when I needed to so that I could get back onto the field asap...

6. How did you get the knee brace? (Ex. doctor, local pharmacy, trainer, etc.)

I got the brace from my doctor.

Maartje Van Dam

1. What is the reason in the past you had to wear a knee brace? And how?

I had badly damaged my mcl in my left knee, during sailing I had twisted my knee too far inwards without any other part of the leg twisting as well. In my right knee, my fibula and tibia bones are not well connected during a jump with skiing the locked together but now are too loose.

2. How long were you told to wear the knee brace?

My left knee: I was told to wear it until I felt like I could trust the knee again and it was stable enough, which was about 10 weeks. My right knee: I was told to always wear it whenever it hurts, because the doctors don't want to
screw the bones together.

3. What would you say was the worst/best thing about your last knee brace?

The brace for my mcl was not waterproof at all, so I had to buy new ones after sailing with it a a couple times. The brace helps you feel more confident in your knee again, it stabilizes the knees a lot.

4. Did you feel comfortable wearing the knee brace once you were cleared to play again? (Explain).

With my right knee I still have to wear the brace whenever it hurts, but I don't mind wearing that one at all as it is just a small brace that is not in my way when sailing or running. I don't like wearing my brace for my mcl, it stops the motion of bending the knee – as this was what I
couldn't do for weeks.

5. How many times do you think you had to take the knee brace off and on during a week

period? (Ex. shower, sleep, cleaning the brace, etc.)

It was not waterproof, so I had to take it off when showering, but for the first few weeks I only took it off for showering, later on I only wore it while walking. So, during a week, in the beginning it was once every day. Later on, it was about 5 times a day.

6. How did you get the knee brace? (Ex. doctor, local pharmacy, trainer, etc.)

The knee brace for my right knee, I got from my doctor. The knee brace for my left knee, the doctor told me the option I had for which one I could buy at the pharmacy.

Natalia Gagliano

1. What is the reason in the past you had to wear a knee brace? And how?

Because of my knee issues

- Chondromalacia: knee cartilage deteriorating
- Patellofemoral syndrome: kneecap tracking wrong
- Tendonitis: swollen tendons in the knee
- Torn ligaments

2. How long were you told to wear the knee brace?

While doing physical activity such as walking, working out, going up stairs, sailing, etc.

3. What would you say was the worst/best thing about your last knee brace?

Best thing seemed to reduce knee inflammation, the straps and hinges did not work well they were flimsy and did not react well to getting wet.

4. Did you feel comfortable wearing the knee brace once you were cleared to play again? (Explain).

Yes, I felt comfortable wearing it made me feel more stable and gave me support when it was

working correctly but the Velcro straps never stayed on correctly and with time the hinges rusted became hard to move.

5. How many times do you think you had to take the knee brace off and on during a week period? (Ex. shower, sleep, cleaning the brace, etc.)

I wore it whenever I had to walk long distances, go up or down stair, workout or sail so almost all the time except while, sitting, sleeping and showering.

6. How did you get the knee brace? (Ex. doctor, local pharmacy, trainer, etc.)

I bought the knee brace off a website don Joy recommended to me by my doctor and physical Therapist.

Jon McNemar

1. What is the reason in the past you had to wear a knee brace? And how?

I tore my ACL and MCL in a Pre-Season Football Scrimmage while trying to runblock a defensive player that came from behind and rolled into my right knee.

2. How long were you told to wear the knee brace?

I was told it was mandatory to wear my knee brace for a year post surgery and any time that I do any lateral movements occurring during sport.

3. What would you say was the worst/best thing about your last knee brace?

The worst part about my knee brace was how bulky it felt. The best part about my brace was how stable it made my knee feel.

4. Did you feel comfortable wearing the knee brace once you were cleared to play again? (Explain).

At first, I didn't feel comfortable wearing my brace because I felt like it restricted my natural movement but the doctors/AT's were really good about progressing my exercises/movements so that I gradually

became more comfortable in my brace. By the time I was cleared to play I felt like my brace was a natural part of my movement.

5. How many times do you think you had to take the knee brace off and on during a week period? (Ex. shower, sleep, cleaning the brace, etc.)

During my rehab I probably took my brace off 30+ times a week for showers, bed, rehab but after I was cleared to play again, I only wore it for practice/weights, so I only took it off 5-10 times a week.

6. How did you get the knee brace? (Ex. doctor, local pharmacy, trainer, etc.)

My doctor ordered the knee brace for me, but I had to go to a local orthopedic specialist to get fitted for it.

Athletic Trainers

Blas Ruelas

1. What are the top 3 injuries you diagnose in sports that require some sort of knee brace?

- A sprain to either the MCL or LCL

- A sprain or tear of the ACL or PCL

- Coming back to functional training from an ACL tear/reconstructive surgery

2. What are the biggest issues you see during the rehabilitation process that make the healing longer?

Giving the injured body part the right amount of time to heal and then rehab for the injured area to come back strong and be ready for dynamic movement. Sometimes student-athletes want to come back quicker because they don't like to be hurt or out and miss time in their sport.

3. What are the most common complaints you receive from athletes about wearing a knee brace?

It may feel too bulky or it feels “weird” when they are playing their sport while wearing the knee brace. Some also feel like wearing the knee brace during activity could show weakness to their teammates or an opposing team.

4. Do you wish athletes would wear their knee braces longer once they have been cleared to play again? Why

I think they should follow the doctor’s orders for when to start activity without the knee brace. Some doctors like to have the athlete wear the brace for a full year once they get back to organized sports. Others have a shorter time frame for knee brace usage. The biggest thing is making sure the athlete protects the knee for a little bit after being cleared to play again. You also want to make sure that the athlete is confident/comfortable enough in their movement and skills once the time comes to not wear the knee brace for activity.

5. What material do you believe has worked best for a knee brace? And why? (Ex. metal, plastic, fabric, etc.)

The material our braces come in is usually a hard but lighter metal like reinforced aluminum or magnesium, but they can also come in steel. It really depends on what type of sport you play, your position, and what your position movements are like. The harder the material is, the more structural support you will be giving to the joint that needs it. I like to lean towards the lighter metals. They offer both max support to the area and still allow for dynamic movement.

Dr. Dewayne DuBose

1. What are the top 3 injuries you have diagnosed in sports that require some sort of knee brace?

I have diagnosed an ACL tear, a that dislocated and have to be relocated, and a MCL tear.

2. What are the biggest issues you see during the rehabilitation process that make the healing longer?

Some of the biggest issues with patients during rehab are compliance of the patient, patients wanting to do too much too soon, and the patient's injury not responding to the treat

3. What are the most common complaints you receive from athletes about wearing a knee brace?

Some of the complaints include the following:

- The brace does not fit.
- It is bulky and will slow me down while I am playing.
- The other team will try to take advantage of me.
- Another player had the same injury and does not have to wear a brace. Why do I have to? wear one?
- It's not fair that I have to wear this brace.

4. Do you wish athletes would wear their knee braces longer once they have been cleared to play again? Why?

I believe that when it comes to braces, they should be worn based on the need of the athlete. If the athlete is unsure of the knee, they should wear it until they have confidence in the knee. Knee braces can be worn as a protective measure. Offensive linemen wear them all in practice and in games in college football. I think if you have a history of knee injuries, then you should wear the knee brace all the time when participating in sports.

5. What material do you believe has worked best for a knee brace? And why? (Ex. metal, plastic, fabric, etc.)

The knee braces that are plastic with metal hinges. For example, the Donjoy knee braces that are custom made for each individual are the best ones. Knee braces that are custom are measured to fit a specific individual.

Gemba

From an outside perspective people who have been seen wearing knee braces seem to look uncomfortable. Also, there is always this thought when watching someone play with a brace the knee seems to look unstable and they are nervous to play or make a move in the past. It is also seen that there are 2 main ways that knee injuries occur that require a knee brace of this caliber. One being twisting and other being force being applied to the knee from an outside person. These 2 actions can occur in sports at any time when playing within the game, meaning injuries can reoccur at any time when playing a game. Players who have been injured heal over time, but it is a slow and long process. This process is a time where the athlete goes through the 7 Stages of Grief. These stages are shock, denial, guilt, bargaining, depression, reconciliation, and acceptance. This is the process that goes through the mind of the player when they are going through the slow healing process. A way that this can be improved upon is by designing a brace that takes away some of the time in those stages. By taking away some of the time that the player in those 7 Stages of Grief the player will be more confident and stable when playing in the new brace.

What We Learned from Customers.

From the interviews and surveys what was learned were a few different types of knee injuries that occur, and other important ideas that happen during/post rehabilitation. What was also learned were the different types of needs that the players want, and the athletic trainers want as well. The reason why these

customers were chosen were a few different reasons. One they all come from different sports backgrounds. From collegiate sailing to collegiate football, there needs to be a large variety of sports that knee injuries come from so that there is a better understanding of how the knee brace can be successful. Also, athletes were chosen based on gender and size. The largest male athlete, Jon McNemar, is roughly 6 foot 6 inches and 300 pounds. There needs to be an understanding of how different sized people can have different issues with their specific knee braces. The next set of customers are the Athletic Trainers. The reason they are chosen as customers is because they are the people who deal with the injuries immediately after the injuries occur, and also after the rehabilitation process has begun. They are also the ones we hear all of the complaining when it comes to how the knee brace fits and the speed at which the player returns to play. The 2 that were chosen for questions were 2 that deal with different athletes every day. Blas Ruelas, is an athletic trainer for Jacksonville University; and he deals with athletes who are the bigger and larger scale. Dr. Dewayne DuBose is a professor/athletic trainer for Bethune Cookman University; but he spends a lot more time dealing with athletes on the younger side, because he spends his weekends being an athletic trainer at youth sporting events. Having these 2 as our customers make them great candidates, because, like the athletes, they deal with different sports, gender, and size.

Customers' needs

- Stable and effective
- Decreased recovery time and help preventing reinjury
- Comfortable/light and wont adversely affect the person's competitive ability while wearing the brace
- Smooth movement of the brace that doesn't fight with the person's desired movements.
- Waterproof/corrosion resistant

Criteria for success

In the criteria for success we have collected the most important aspects that we think would define our future product and set them with different importance in order to know better what we are looking for in the final design.

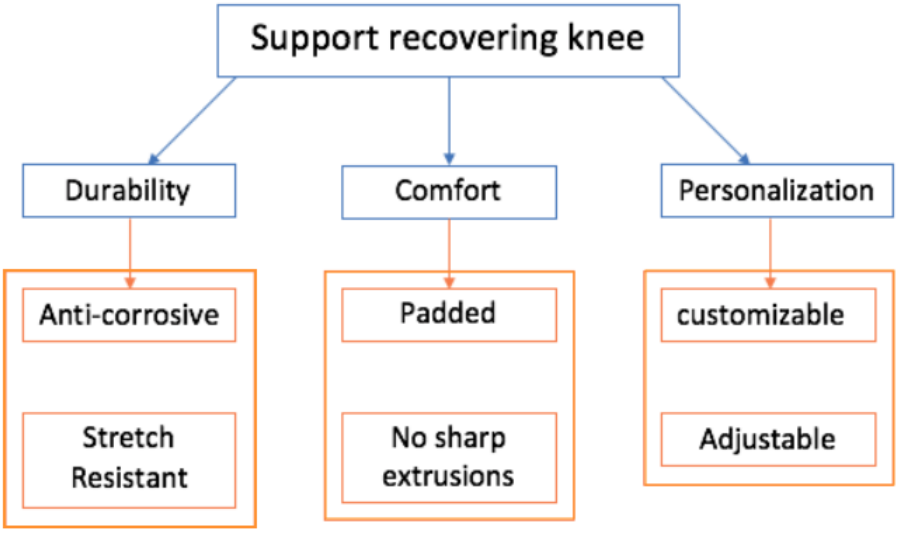
Criteria	Importance	Description
Durable	High	The materials for the brace should be water resistant and resistant to constant stretch and constant hits applied to it. Also, should not suffer from corrosion.
Personalized	High	The knee brace should be able to fit every single customer perfectly. There should be different sizes according to the individual who is wearing it, and also it should have a system that allows each customer to loosen or tighten the fit of the brace depending the activity he/she is performing.
Comfortable	High	The feeling of the materials on the skin should be pleasant and not produce any bruises or cuts.
Easy to acquire	Medium	The knee brace should be available to get through any doctor or pharmacy with no

		restrictions.
Price friendly	Medium	The knee brace should have a reasonable price that is attractive to doctors, insurances, physician assistants to recommend to any school athlete with any kind of monetary background.

Table 1 [Criteria for success]

Functional Block Diagram

The functional block diagram serves the purpose of presenting the functions and features of the knee brace design in a hierarchical manner. As you can see in the figure below there are three tiers to the diagram, the first tier is the primary function of the product, in this case the knee braces main purpose is to support a recovering knee. The next tier discusses how that is accomplished with specific functions in this case these functions/ characteristics are comfort, durability, and personalization. The final tier which is signified by an orange box, is what these secondary traits or functions are made up of or executed, in the block diagram these are all traits that allow the secondary traits to actually function and influence the design.



Block Diagram 1.0

Concepts of knee braces

The knee is formed by the articulation of the femur (thigh bone), the tibia (bone of the lower leg) and patella (kneecap) that are stabilized by numerous muscles and ligaments and provide the structural framework for the joint. The knee is under constant stress from supporting 80% of body weight and absorbing the impact of walking, running, etc. This puts it at high risk for injury, especially in individuals who participate in sports and other vigorous activities. Knee braces can be used to provide support and stability to the joint.

There are many causes of knee injuries, including bursitis, tendonitis, ligament tears, worn-out cartilages, arthritis, muscle sprains, muscle strains and a host of other problems. Postural misalignment such as knock-knees or bowlegs may also predispose a person to future knee injuries. Many people, from athletes to people with arthritis and other knee problems, turn to knee braces for support or pain relief

Knee braces support the knee joints to prevent further injury, while also reducing pain and swelling. Knee supports are great for surgery recovery and rehabilitation of the knee joints as well. Knee

braces fall into four general categories, these including Prophylactic, Functional, Rehabilitative, and Unloader/Offloader knee braces. Each class has its own advantages and disadvantages, and proper care must be taken to choose the appropriate one. Regardless of the choice, the knee brace must not interfere with the activities of daily living and the functionality of the joint. Here are a few concepts that will help us fulfill all the functionalities of a knee brace.

Prophylactic braces

Prophylactic knee braces are designed to prevent and reduce the severity of ligamentous injuries to the knee. This type of knee brace is mostly used by athletes who play contact sports such as football. Prophylactic knee braces protect the MCL (medial collateral ligament) against valgus knee stresses, while at the same time protects the knee joints from getting injured again. These knee braces are great for athletes of contact sports at high risk for MCL injury, or who previously suffered an MCL injury.

Functional braces

A functional knee brace is used to provide support to knees that are already injured, either from playing a sport or a fall. Functional knee braces are also great for reducing rotation following an ACL injury or tear, and for those who need additional support after ACL repair surgery. In some cases, they can also be used to support mild to moderate PCL or MCL instability. This kind of knee brace may be prescribed as part of physical therapy. There are some patients that find them uncomfortable, but they have been shown to improve stability and reduce the risk of injury to the other ligaments and tissues.

Rehabilitative braces

This type of braces is designed to allow the joints to heal. In order to do so, it limits potential harmful knee movements to protect injured ligaments and regulate movements during the rehabilitation process. They are built from foam liners on an adjustable metal frame around the knee and are usually kept in place for several weeks before being replaced by another, more mobile, kind of knee brace.

Unloader braces

This type of knee brace is designed for people who suffer from osteoarthritis in the medical inner knee compartment or basically provide relief to people who have arthritis in their knees. They are also helpful for people who are waiting for a knee replacement surgery. They work by transferring the biomechanical stress from the affected joint onto the thigh bone, forcing the knee to bend away from the affected area.

Best concept to fulfill options based on criteria

The concept that is the best based on the others is a combination of both Functional and Rehabilitation. This does as previously stated help speed up the process of getting back to the field as soon as possible. Also, it reduces the cost that people will have to spend on the purchase of 2 different knee braces. The cost of a rehabilitation brace can go upwards of $1,000 from some doctors; and it will only be worn for a certain number of months since it is only for rehab (picture to the left). The functional brace is also expensive with the price going towards $900. With that also comes its negatives like the rehabilitation brace. One being the soft straps and the must to wear something under the brace as the top strap will rub on the skin causing irritation (see picture to the right). With that being said the new concept is a way to bridge the gap between the 2 braces as said before. A brace that is both usable for rehabilitation and it will allow for the person to move back into their sport. This allows for less time in rehabilitation as the person will be more comfortable moving in the brace as it is a functional brace as well.

Design Concepts

The design of the knee brace is based off of the functional block diagram seen on page 14, these criteria are used to determine how the design is put together and what aspects are prioritized. First of all, the design needs to be lightweight, durable, customizable/adjustable, and comfortable, these are achieved by using the most modern and high-tech materials, such as carbon fiber and titanium, and sampling design ques from current designs. One of the key design features is the ability to fit a wide range of patients effectively, this will be achieved by obtaining a 3D scan of the patient's knee in order to get a model of the patient's knee in a CAD software, where the brace will then be built around the patient's knee with precision and comfort in mind. With a 3D model of the patient's knee a mold will be made in order to make a carbon fiber shell that will fit the patient's knee and leg with precise fit. carbon fiber is being used for both its lightweight, stiff characteristics, as well as anti-corrosive properties. Carbon fiber also has the ability to be molded into any shape that the patient requires, this allows the for small dimensional adjustments to be made depending on the patient. With the shell made, the rest of the hard components will be made of aluminum. Aluminum is used for its lightweight qualities, ease of manufacturing as it is one of the easiest metals to work with, and cost effectiveness. When contrasted to stainless steel which is stronger, and anti-corrosive, but harder to manufacture and more expensive to obtain and manufacture, the main drawback of aluminum which is the galvanization process that it undergoes when exposed to the elements, can be simply circumvented by a simple and cost effective clear coat. The final main component that is part of the design is the padding, this padding will strategically be placed inside of the carbon fiber shell in order to promote comfort for the patient. The pads will be placed using the 3D model of the knee obtained from the scan, the patient will also be able to choose how dense they would like the padding to be, and request adjustments to the precise locations of the padding.

Discussion and ethical bearing

This product requires a very diligent and caring oversight as it directly impacts the user's health and wellbeing. When a customer allows us to design and build their brace, they are putting their health and happiness as well as even their prosperity in some cases. Along with this as we develop a new technology that is being used to help people heal and improve lives it is key that we work diligently and think about what it means to be a company on the leading edge of product development, while it is key that we work for the success of our company it is a necessity that we take time to think about ways that we can help everyone develop new technologies that help improve lives.

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