March 28th, 2019
Dr. Andrew H. Rawicz
School of Engineering Science
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RE: ENSC 405W/440 Project Proposal for the TechBrace by FlexTech

Dear Dr. Rawicz,

Please find attached the proposal for the FlexTech TechBrace. This product is a soft shell knee brace that will help the injured user maintain proper positioning of their knee to avoid further injury and facilitate faster recovery.

This document outlines the goal of the project, anticipated risks, intended market, plans, and financial considerations of the team as we endeavour to help people who suffer from Anterior Cruciate Ligament injuries.

FlexTech consists of five passionate engineering students: Jason Fevang, Lauren Fridman, Jack Guo, Andrea Manjarres, and Nic Klassen. These students come from different backgrounds in the hopes of combining their expertise to create an innovative solution to a painful problem.

Thank you for your consideration of our product. If you have any questions or concerns please contact our CCO, Jack Guo, at yupengg@sfu.ca.

Sincerely,

Lauren Fridman
Chief Science Officer
FlexTech

Enclosure: Design Specification for FlexTech TechBrace

Design Specification

For FlexTech TechBrace

"The results will shock you!"

March 28th 2019

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Executive Summary

Knee injuries, specifically ACL injuries, are the most common form of injury [1] over a variety of sports, including skiing, basketball, and soccer, and can remove athletes from training for over a year. Severity of these injuries may require different treatments, ranging from rest to surgery, but in all cases there is a resulting instability in the knee joint. This instability can lead to compromised knee positions, which can result in further injury. Currently, the most prevalent solution is strengthening exercises that build up the supporting muscles, which help train those muscles over the short period of time that the person is consciously engaged in a rehabilitation program. However, in the average person's daily life, proper knee position is not at the forefront of focus, which can lead to greater risk of improper movement.

The FlexTech TechBrace aims to minimize this risk by helping the user engage stabilizing muscles when the knee goes into these dangerous positions without direct user input, thereby strengthening the muscles and the subconscious neural pathway. The system we propose consists of three main subsystems: the angle deviation sensor, muscle activation system, and mobile app. The separation of these systems allows for easy replacement of worn out parts and recycled use. Each user calibrates the device to their custom measurements and needs, and the brace can be used to simultaneously avoid potential reinjury while rebuilding the biological knee support system.

The current market for prophylactic knee braces is broad and multi-faceted. Depending on the user's needs, there are soft, generic braces all the way up to hard custom braces, with prices ranging from tens of dollars to thousands [2]. The market for braces is heavily influenced by the rehabilitation/physiotherapy industry, for which quantitative data would help in decision making and rehab program development. To our knowledge, there are no instrumented knee braces with electrical stimulation, so this innovative product would be unique. It's expected price tag of $150 also provides a cheaper alternative to custom hard braces, while still accounting for the individuality of each user's natural body angles.

The total development costs are expected to be $495.63, which will be funded by the Wighton Fund, ESSEF, or by the FlexTech team members. Over the course of the project, the goal is to create a Proof of Concept by April 15th, 2019, which will serve as

a base for the subsequent Prototype and Production Ready versions of the device. With each iteration we aim to make a better, safer, and more effective solution for athletes with ACL injuries.

Each member of FlexTech brings different insight and experience to the project, which is reflected in the complexity of each subsystem of the TechBrace. But, like the components of the TechBrace, the members of FlexTech come together as a cohesive unit to help athletes recover and return to their sport.

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1 Introduction

Every year, a quarter of a million athletes in Canada and the United States suffer ACL injuries that leave them unable to train for up to a year, depending on the severity of the injury [3],[4]. This is not only a year of lost training, but also a year without the other healthy advantages of sport, such as stress relief, a sense of social bonding and community, and the physical benefits. This can be very damaging for an athlete to suddenly lose, particularly for professional athletes, whose livelihood depends on their performance.

Much of the recovery time is focused on rehabilitation to regain stability in the knee joint to avoid further injury and allow the athlete to return to their sport safely. This rehabilitation is designed to help the injured athletes redevelop the muscles that have atrophied from disuse and retrain the neural pathways that control those muscles. Often, a physiotherapist will prescribe the athlete a set of exercises to consciously train the body, but as the person is going about their daily lives, they may not be consciously focused on contracting the proper muscles and maintaining stability. Thus, the risk of reinjury or prolonged recovery time would be lessened if there were a way to consistently train those muscles throughout the day to protect the knee subconsciously.

Figure 1: Soft Knee Brace [5]

The TechBrace developed by FlexTech is a means to that end. The TechBrace is a soft, instrumented knee brace that detects when the user's knee is in a critical valgus angle that may be dangerous and interfaces with a set of electrodes that contract muscles in the quadriceps muscle band to stabilize the knee back into a safe position. The TechBrace also incorporates an interactive mobile app that enables the user to calibrate the brace to their own specific body and track the deviations that occur throughout the day. This mobile app thus also helps the user and their physiotherapist track progress to help them determine when it is safe to return to play.

2 Project Overview

2.1 Background

The TechBrace system is composed of three main subsystems: an angle deviation sensor, muscle activation system, and mobile app. The angle deviation sensor uses the Madgwick method to calculate relative orientations based on a quaternion reference frame. This will monitor the medial position of the knee as it deviates from the baseline of the user. This angle is measured because the knee is a hinge-type joint that is designed for flexion in the coronal plane [6]. A healthy knee would ideally be able to avoid movement in the saggital plane, but for people with compromised ACLs, this can be difficult due to disuse atrophy.

When a critical angle is detected, the TechBrace will use the system of electrodes to help the user engage the supporting muscles, specifically the vastus medialis (VMO) and vastus lateralis, to bring the knee out of danger. This will be accomplished through the use of Neuromuscular Electrical Stimulation (NMES); a system that has been increasing in popularity since 1961 [7].

NMES works by sending electrical impulses to peripheral motor nerves through the skin that incite an action potential, leading to the contraction of the muscle [8]. NMES is commonly used to retrain muscles and recover lost strength [9]. More specific to the case of ACL reconstruction, NMES has been repeatedly shown to prevent muscle atrophy linked to the months of immobilization after surgery [10]. This disuse atrophy also applies to the neurons that control the muscles in a similar way.

Plasticity in the brain allows humans to reinforce and optimize the pathways that are used more often, so by contracting the muscles that have atrophied, more receptors for neurotransmitters are delivered to the synaptic location. This causes increased input sensitivity, which helps facilitate muscle contraction [11],[12]. There also is evidence demonstrating that electrostimulating strength training, such as with NMES, can increase the force of a maximal voluntary contraction due to modification of the excitability of specific neural paths [13]. Thus, the use of NMES increases maximal force production in the quadriceps and the excitability of the associated neural pathways.

2.2 Scope

The goal of the TechBrace is to speed up recovery from ACL injury by providing a means of correcting dangerous positions of the knee while training the user's body to make those corrections themselves. Throughout this Capstone project, we hope to develop a Proof of Concept, Prototype, and Production Ready version of the device as we fine tune the capabilities of the system. Each stage will have augmented features from the previous one, which allows us to focus on different parts of the system. The ultimate goal is to have a comfortable, soft knee brace that has all technical components mounted on the knee sleeve except for the electrodes, which will be on the quadriceps. The electrodes will be mounted with a reusable adhesive and a strap to ensure that they remain in the correct position. The data collected on the knee brace will be transmitted to a mobile app so the user can track their recovery progress. Below is a high level overview of the system.

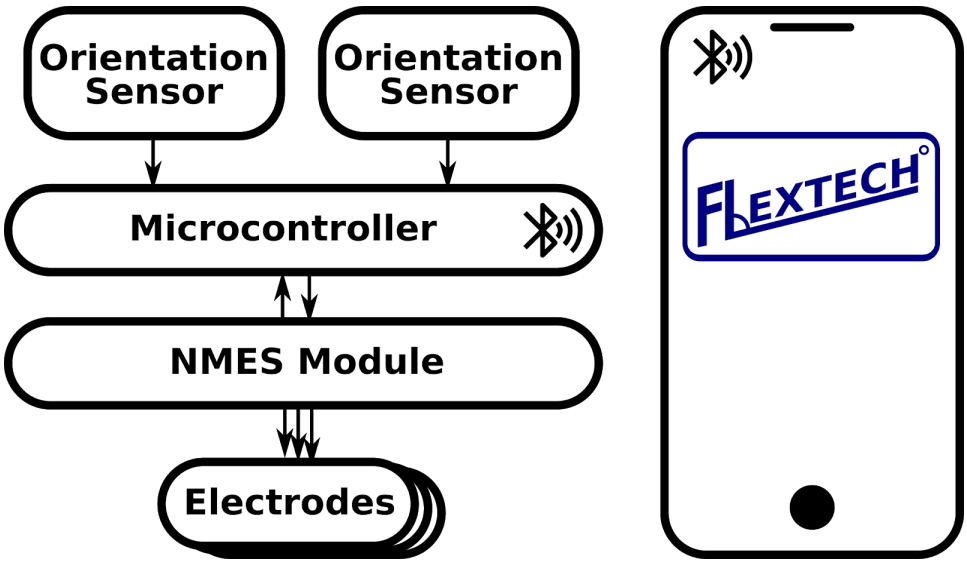

Figure 2: System Overview

The testing component of the project will be critical, so a detailed acceptance test plan has been addressed in the design requirements document [14] with the goal of individually testing each subsystem as well as the system as a whole to ensure safety and efficacy.

3 Product Justification

In this section, the justification of the product will be provided, potential risks, benefits of the product, market analysis, and competitors in current market environment will be discussed.

3.1 Risks

Safety

Since the TechBrace can be considered as a biomedical instrument, the core priority is the concern for the safety of its users, therapists, and any related personnel to the design, production, and transportation of the product. Currently in development, we do not foresee significant safety concerns related to the primary use of the product, although several measures have been taken into consideration to guarantee the safety of the product. As a wearable biomedical device, the TechBrace will also be exposed to various weather conditions. Water resistance is an important factor to keep the electrical system function properly and for the safety of its users. Electrical components of the TechBrace will be encapsulated in a waterproof polymer protective cover to mitigate the risk. Secondly, since a NMES device is incorporated in the product, the circuit is designed to have sufficient current to stimulate the muscle area of the user in a researched and approved range for safety (less than 95 mA), using a current limiting circuit.

Product Performance

The TechBrace is designed to measure and correct excessive valgus angles of the user's knee. A major challenge of the project is accurately measuring this angle and determining critical angles for each user. To find the angle, quaternions will be used to determine the orientation in 3-D space by calculating the relative angle between the two inertial measurement units (IMUs) embedded in the TechBrace. Critical angle will be determined from initial calibration by each user and physiotherapist input.

3.2 Benefits

Benefit to the Users

TechBrace provides a new solution for patients recovering from an ACL related injury with two major benefits: comfort and affordability. With automatic correction and performance tracking functionality implemented in the TechBrace, users will experience

a less restrictive range of motion than the traditional ACL knee brace, while providing reliable protection to the users. The TechBrace incorporates the revolutionary functionality of auto correcting the joint angle of the users' knee position, which provides users with a more comfortable experience of a soft knee brace while helping the user protect themselves. Additionally, the TechBrace includes mobile platform support and functionality for monitoring and visualization of the rehabilitation process.

Additionally, the TechBrace will also be cheaper than most functional ACL knee braces on the market. This is important since Medical Service Plans (MSP) has a limited coverage on medical devices. The average post injury functional ACL knee brace typically falls into the price range of two hundred to potentially a thousand dollars (CAD) [15], and can be more expensive for custom knee braces. For the majority of ACL injury patients, a more affordable solution is needed. FlexTech's TechBrace is able to reduce the cost by using a soft brace and electronic components. The cost of a single TechBrace is roughly around $150, and in manufacturing, the cost will be reduced even further. In conclusion, the TechBrace will be a more affordable option for ACL injury patients.

Benefit to the Therapists

Therapists will also benefit from the data acquired by the TechBrace, which can help them address specific patient needs as it allows them to observe progress over time. Concrete data will be acquired by the TechBrace, and easily accessible on the user's cell phone, it will enable the therapists to have a better understanding of when the patient is able to return to their sport based on their everyday movements.

3.3 Market Analysis

The global market for orthopedic braces and supports is anticipated to surpass $5.0 Billion USD within the next six years [16]. This market considers braces and supports for foot and ankle, spinal, upper extremity, wrist and hand, shoulder and knee supports, as well as pain management and post-op braces, so the TechBrace fits well into this category. With 100,000 ACL reconstruction surgeries performed each year in the United States [17], there is certainly demand for pre-operative and post-operative knee braces.

Custom knee braces vary greatly in price, quality, and purpose, and different braces may be better for different patients. Custom-fit products range from $750 to $2200 CAD [15], and often medical insurance companies pay for braces, but they cannot be reused since they are designed for exactly one patient. The TechBrace is compatible with many

leg sizes and shapes, allowing one brace to be used many times, greatly lowering price per patient. The largest brace manufacturers are listed in table 1.

Four Largest Brace Manufacturers			
Breg	Bauerfeind	DonJoy	Ossur

Table 1: Largest Brace Manufacturers

For an example of finances, the Bracing and Vascular sector of DonJoy had $129 million USD of net sales and a growth of 1.2% in the third quarter of 2018 [18]. This serves to show that bracing is a significant and profitable industry that is still growing, so there is a lot of opportunity for FlexTech to enter the industry with an innovative product.

3.4 Competition

FlexTech is positioning itself as a preoperative and postoperative custom hard brace replacement. Current hard brace designs are expensive and limiting. By developing a more robust injury prevention system, FlexTech braces can use more affordable materials, and not require custom fitting.

Existing custom fit, hard brace solutions are dependable and effective at preventing injury, however there are downsides to custom fit hard braces, namely price and convenience. The TechBrace intends to replace hard braces used in post-op and pre-op by providing an equivalent quality brace in injury prevention at a lower price. Table 2 outlines the comparison points between the FlexTech TechBrace and existing custom fit hard braces.

FlexTech TechBrace	**Custom Fit Hard Braces**
Pros	
• Less Expensive • Reusable on different people • More effective (trains muscles) • More comfortable (hard brace limits range of motion)	• Established industry and rapport in medical community • Backed by medical studies

• Digital tracking of correction events to track progress	
Cons	
• Needs to be charged • Needs daily calibration	• Expensive • Custom fit often required

Table 2: Comparison between the FlexTech TechBrace and existing custom fit hard braces

There is also a limited selection of electronic IoT knee braces on the market. While not a direct competitor, these braces function with a mobile app in a similar way and collect user data from the brace. An example of such braces is the DONJOY global smart brace that enables the user to monitor real time range of motion, changes in pain level, and exercise compliance using a phone app. DONJOY has also developed a platform to allow physicians to monitor their patients' activity and recovery [19]. While both braces have an accompanying app, the TechBrace monitors only the deviations, rather than total activity, and also interfaces with the electrode system that activates the main muscles that stabilize the knee. No other smart braces on the market offer this feature.

4 Finances

Below is a breakdown of the expenses required for the whole execution of the program, including Proof of Concept, Prototype, and Production Ready stages. The table will be divided in the 3 main components that make up the TechBrace.

Function	Part Name		Quantity	Unit Price ($CAD)	Total ($CAD)
Angle Sensing	IMU		2	21.21	42.42
	Strain Gauge		1	29.79	29.79
	Load Cell Amplifier		1	14.11	14.11
Muscle Activation System	Electrodes		10	2.00	20.00
	Proof of Concept:	Vibration Motor	1	4.35	4.35
		Transducer	1	3.66	3.66
		Diode	1	0.16	0.16

		Capacitor	1	0.15	0.15
	Prototype:	Op-amp	4	3.04	12.16
		High Power Amplifier	1	32.14	32.14
		DC-DC converters	2	10.50	21.00
		Low Dropout Regulator	2	4.38	8.76
App	N/A			0.00	0
General	Wire (4.56 meters)		3	1.84	5.52
	PCB board		8	1.15	9.2
	Microcontroller		1	19.95	19.95
	Knee Brace		1	50	50
				Total:	273.37

Table 3: Projected Expenses

These expenses are not fixed and may be subject to change as the design of the TechBrace evolves. In the event that there are unexpected expenses, the team members at FlexTech have agreed to split the expenses in equal parts. Ideally the funding described below will be enough to cover small, unexpected expenses.

4.1 Funding

After analyzing the expenses presented above, the FlexTech team came to the decision that funding would be necessary to realize a functioning prototype. There are a couple of funding opportunities for engineering students who are in the process of completing their capstone project.

1. **Wighton Engineering Development Fund**, administered by Dr. Andrew Rawicz. Projects that benefit society, such as a biomedical project, are to be treated preferentially. The TechBrace by FlexTech will benefit society by

improving the recovering and prognosis of persons that have suffered an ACL injury. We will be applying for this grant early in the Summer 2019 semester.

2. **The Engineering Science Student Endowment Fund (ESSEF)**, administered by the Engineering Science Student Society (ESSS) of SFU. The TechBrace would qualify into Category C, a project that originated from an engineering class. We will be applying for this grant early in the Summer 2019 semester.

Finally if none of the funding options materialize, each executive member of FlexTech has agreed to contribute $100 dollars, which will be enough to allow us to construct a working prototype of the TechBrace.

5 Project Scheduling

5.1 Milestones

5.1.1 Proof of Concept (Alpha) Prototype

The Proof of Concept (PoC) Prototype will include a minimal working subset of the features of the TechBrace. This will be the first testable version of the product. The purpose of the PoC is to illustrate the viability of the core ideas of the product, as well as to demonstrate the progress that has already been made. Our PoC prototype will also function as an Appearance Prototype for the TechBrace, as we expect it to closely resemble the final look of the product. The PoC Prototype has a hard deadline of April 15th, 2019 for our ENSC 405 project demonstration.

5.1.2 Engineering (Beta) Prototype

The Engineering Prototype will be completed mid-semester during ENSC 440, and will be a further refined version of our PoC Prototype. The Engineering Prototype will incorporate improvements that are discovered while making and testing the PoC, as well as features that were not included in the PoC. The goal is for TechBrace to satisfy most of the testing requirements at this stage.

5.1.3 Production Ready (Pilot) Prototype

The Production Ready (PR) Prototype will be completed by the end of ENSC 440, and will be the final iteration of the TechBrace. The PR Prototype will include all of the

promised features, and will specifically be designed with production and manufacturing in mind. This version will also be designed so that it could actually be given to users, so usability will be a major consideration. This final iteration will also be the most thoroughly tested.

5.2 Gantt Chart

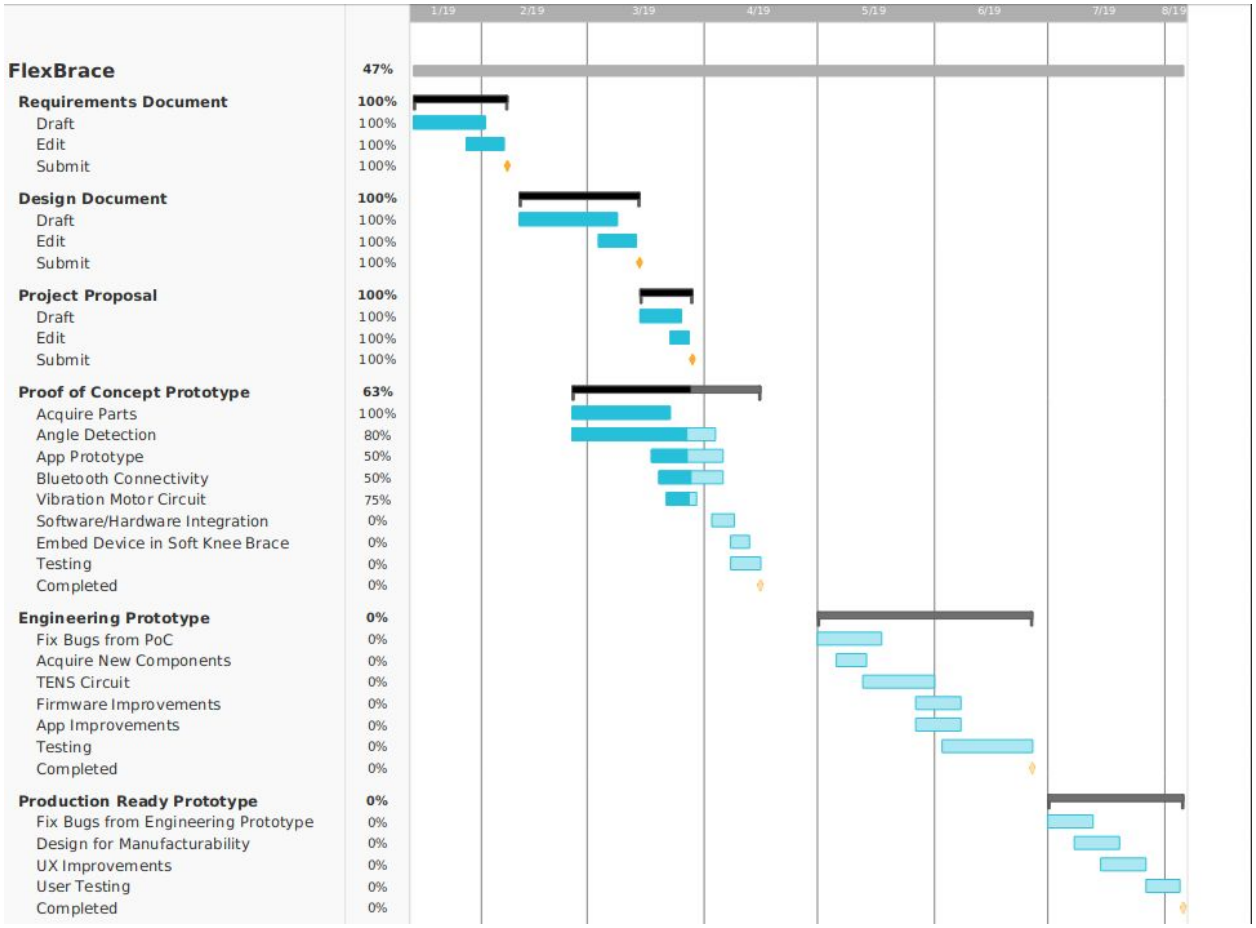

Figure 3: Gantt Chart

6 Company Overview

FlexTech is a group of senior engineering students who have the passion and determination to make knee injury rehabilitation easier. Formed in early 2019, FlexTech has designed a knee brace that will allow for knee support and will accelerate the gaining of muscle force on the affected leg.

6.1 Meet the Team

Andrea Manjarres (CEO)

Andrea is a senior biomedical engineering student that has interests in image processing and machine learning. Her co-op as a researcher at BC Cancer Research center and experience in quality assurance at SKYTRAC, allow her to tackle and apply creative solutions to new problems, such as the TechBrace.

Nic Klaassen (CIO)

Nic is a senior computer engineering student at SFU, with interests in creative software solutions for embedded systems. His co-op experience as a Co-op Instrumentation Engineer at Precision NanoSystems and an Embedded Software Developer at Avigilon gave him the experience to tackle the unique real-time and embedded software challenges of the TechBrace.

Lauren Fridman (CSO)

Lauren is a senior biomedical engineering student and student athlete who is passionate about sports performance and the ways that engineering can contribute to it. Her co-op experience with bracing and orthotics (Braceworks Custom Orthotics) and movement analytics (Plantiga Tech) combine to bring a unique perspective on injury prevention and rehabilitation.

Jason Fevang (CTO)

Jason is a senior computer engineering student who is fascinated by computers. His previous experience includes web development QA and software development at Sierra Wireless working with modems on the software side in Windows. In addition to co-op he has experience with databases and hardware architecture, as well as programming microprocessors. Jason brings an important technical perspective to the team.

Jack Guo (CCO)

Jack is a senior computer engineering student, whose interests are devoted to software development. He has experience in Apache FreeMarker and JSP templates, acquired during his co-op as a junior software developer in E-Hualu and Lexi Tech. His experience in software development allows him to contribute to the software aspect, especially the mobile platform of the project.

7 Conclusion

Most functional knee braces for ACL injury patients in the current market are expensive and only provide limited functions. Considering the prevalence of this type of injury, athletes, and especially student athletes, need a more affordable option.

With that in mind, FlexTech is eager to develop the revolutionary TechBrace. It will incorporate the basic functions of an ordinary knee brace (physical protection and support), while being able to automatically correct harmful valgus knee positions using the user's own muscles. The uniqueness of this type of brace will help athletes, coaches, and physiotherapists be confident in the recovery process and provide specific

data about that process to help make informed decisions. The TechBrace users will be able to spend less time in rehabilitation and more time enjoying life, without consciously worrying about healthy motion of the knee joint.

We are confident that the TechBrace represents a new paradigm in knee brace industry, providing affordable, reliable, and intelligent support to ACL injury patients.

Glossary

ACL: Anterior Cruciate Ligament
Action Potential: the change in electrical potential associated with the passage of an impulse along the membrane of a muscle cell or nerve cell
Coronal plane: an imaginary plane dividing the body into dorsal and ventral parts
Hinge type: a type of joint that facilitates movement in one axis [20]
Madgwick method: computationally efficient gradient descent algorithm for use in a human motion tracking system given measurement from Magnetic, Angular Rate, and Gravity (MARG) sensor arrays [21]
Peripheral motor nerves: nerves that commands skeletal muscles [22]
Prophylactic knee brace: knee brace that is designed to prevent injury
Quaternion: “a four-dimensional complex number that can be used to represent the orientation of a ridged body or coordinate frame in three-dimensional space.” [23]
Saggital plane: the plane dividing a body into right and left portions
Synaptic location: where synapse takes place. Synapse is an information relay between two neurons usually located between the axon terminal of one (the presynaptic element) and the dendrite of another (the postsynaptic element) cell [24]
Valgus Angle: angle of the knee in the saggital plane. See Figure 4
Vastus lateralis: a muscle in the quadricep femoris muscle group
Vastus medialis: a muscle in the quadricep femoris muscle group

Figure 3: Valgus Angle

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