The Design and Fabrication of a Rehabilitative Device for Medial Tibial Stress Syndrome

A Major Qualifying Project

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Abstract

There is currently no device on the market today that mimics the rehabilitative benefits of professionally applied athletic tape to rehabilitate the symptoms of medial tibial stress syndrome (MTSS) and is available to the average consumer. The goal of this project was to address this need by designing and fabricating a device to give the user similar rehabilitative benefits as professionally applied athletic tape, whilst being accessible and affordable to the common injured person. The scope of this project includes individuals who need relief from the symptoms of MTSS but do not have regular access to professional care. Those within that population include, but are not limited to, hobby runners, military personnel and active persons. The device also aimed to be customizable to meet individual user needs, cost-effective, and easily applicable. The final device resembled a sock and incorporated two different athletic fabrics and Velcro to mimic athletic tape by pulling the muscle in specific directions. Various testing and statistical analyses were performed to ensure that the materials used in making the device could withstand the many forces and conditions.

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1. Introduction

Medial tibial stress syndrome (MTSS) is a common injury of the lower extremity and one of the most common causes of exertional leg pain, making up 10-15% of running injuries and 60% of leg pain syndromes [1]. The injury is not seen as disabling, but there are different reactions by the tibia and surrounding musculature that occur when the body is unable to heal properly and effectively. This can be due to the shins experiencing repetitive muscular contractions and tibial strain while the injury is still present. The pain can be severe enough to affect performance or even keep individuals from participating or competing in events [2].

Although athletes and military personnel are more commonly affected by MTSS, it is a nondiscriminatory syndrome that can affect any active individual. For those who have access to professional care, MTSS can be treated by individualized rehabilitation routines to increase lower extremity musculature. One of the more effective treatments is the strategic placement of athletic tape, which helps rehabilitate the affected individual by relaxing associated muscles, relieving pressure on tissue to reduce pain, and increasing circulation. The primary benefit of using athletic tape for MTSS is that it provides a custom fit to the athlete's body. For the best effect, the taping should only be done by a professional, as improper taping can lead to the injury becoming worse instead of allowing it to heal. Those experiencing symptoms of MTSS that do not have access to an athletic trainer or other types of professional health care have limited options for treatment. Most resort to self-treatments such as ice packs applied to the affected area, stretching of the lower-leg musculature, or use of over-the-counter painkillers [2]. However, such treatments only provide temporary relief. Other forms of treatment for the non-athletic and non-military populations include utilizing current technology such as braces that resemble compression sleeves. Although these devices can be found conveniently at a local pharmacy or athletic store, they do not have the same effectiveness as professionally applied athletic tape and can give the illusion that the individual is ready to go back to regular activity before proficient healing has taken place. This results in a prolonged experience of symptoms and the potential development of stress fractures.

The contrast in rehabilitative success between professional care and self-treatment of MTSS contributes to the need for an effective and accessible rehabilitative device. As a result, the goal for this project was to design and fabricate such a device that achieves similar rehabilitative

benefits of professionally applied athletic tape accessible to the general population. The device aimed to be customizable to meet individual user needs, cost-effective, and easily applicable. The scope of our project includes individuals who need relief from the symptoms of MTSS but do not have regular access to professional care. Those within that population include, but are not limited to, hobby runners, military personnel and active persons.

In order to ensure that our device meets the objectives of our project, the device must be long-lasting. Several tests were performed to verify that the material used in making the device could withstand various forces and conditions. An Instron 5544 was used to perform 50 cycles of tensile testing as well as tensile testing to failure on each material. Data was recorded using BlueHill and force gauge testing was used to predict the average force applied to the straps of our device. The predicted average force was then used as the maximum load applied to each material during cyclical testing. Failure testing was performed on each material until the material ripped or the Instron reached its maximum extension. Statistical analysis was carried out on all data collected.

More details on the methodology used for testing will be described in the following chapters. Topics such as the physiology and pathophysiology of MTSS, population affected by MTSS, and the current rehabilitation methods currently being used to treat MTSS will all be discussed in the literature review and will be followed by a discussion with WPI athletic trainer Shannah Dalton. The project strategy section will discuss the client statement as well as the objectives and constraints of this product. Then, the current standards and regulations pertaining to our product will be examined as well as our project approach, including our project and budget management strategies. Chapter four will discuss the stakeholder and needs analyses as well the specifications that will help determine if our objectives are met. Additionally, this chapter will go over the conceptual designs determined by the team and the alternative prototypes that were designed prior to final product design which is discussed in the following chapter. Validation designs will also be considered in this chapter. Lastly, we will go into the discussion which will include the project considerations and impact as well as an examination of the results and data collected.

2. Literature Review

This chapter provides background on important facets of the project which helped to provide the team with a solid foundation of knowledge. Topics discussed in this chapter include the physiology and pathophysiology of MTSS, prevalence of MTSS, and current rehabilitation devices and methods.

2.1 Physiology and Pathophysiology of MTSS

2.1.1 Introduction

Medial Tibial Stress Syndrome (MTSS) can be defined as the resulting effects of the tibial bone remodeling process as it adapts inadequately to repetitive or unnatural stress [3]. It is one of the most common causes of exertional leg pain amongst active individuals. Before MTSS is diagnosed and in its the early stages, pain can occur at the beginning of exercise, with a higher intensity of pain at the beginning and a gradual subsidization as the exercise continues. The danger of this symptom is the misinterpretation that the pain in the shin-area is temporary pain that dissipates after a certain length of exercise. As the injury progresses with overuse, the onset of pain can present itself in lower-intensity activity or even at rest. Other commonly experienced symptoms may include vague, diffuse pain along the middle-distal tibia in the lower extremity. Within this section of the chapter, the topics that will be discussed include the pathophysiology and physiology of MTSS, potential common causes of injury, and when and how to distinguish between MTSS and stress fractures.

2.1.2 Pathophysiology and Physiology of MTSS

An individual with MTSS is most likely to experience pain along the tibia, periosteum, posterior tibialis, anterior tibialis, and/or the soleus. The tibial bone is located on the medial side of the lower extremity and its main purpose it to provide structure and stability for the leg. Figure 1 illustrates the relationship between the tibia and its outermost layer, the periosteum. The periosteum is composed of collagen fibers and connects to the fascia between the lower extremity muscles.

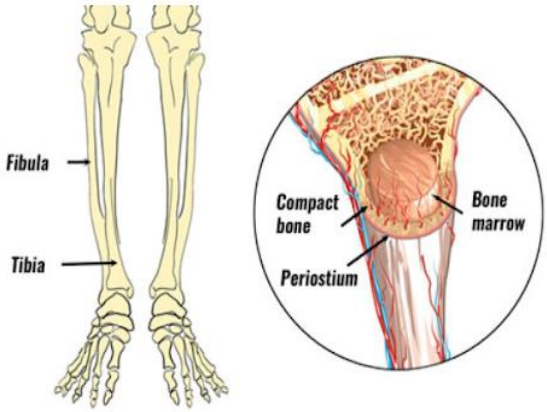


Figure 1: The Tibia and Periosteum. The periosteum is the collagen-rich outer layer of the bone that meets the lower extremity-fascia. [4]

The tibial bone is designed to thrive under compressive forces along its neutral axis, though there is a maximum material tensile strength of 150 MPa [5]. When experienced forces exceed this maximum force or begin to shift away from the tibial neutral axis, the bone is placed under unnatural and undue stress, resulting in the surrounding muscles pulling in an attempt to compensate in prevention of bone fatigue and failure. As a result of the inappropriate overuse and pulling of the surrounding muscles, the periosteum can become inflamed and produce pain.

Knowledge of the pathophysiology of the injury aids in the understanding of the impact it has on the surrounding affected muscles. As stated previously, the most commonly affected muscles in those who have MTSS are the posterior tibialis, anterior tibialis, and the soleus. Injury, pain, or swelling of the three muscles previously listed have a profound impact on the individual's ability to walk, let alone continue exercises such as running or jumping.

The *posterior tibialis* is the most central of the leg muscles located in the deep posterior compartment of the leg, as shown in Figure 2. The muscle borders the inner posterior of the tibia and fibula, proving to be one of the key muscles that aid in the stabilization of the body. The muscle attaches to the bones that form the arch of the foot, and when it contracts, it produces an inversion of the foot at the subtalar joint and assists with plantar flexion of the foot at the ankle [6]. The posterior tibialis originates from the proximal posterior surfaces of the tibia and fibula and inserts at the navicular, tarsals, calcaneus, and metatarsals 2-4 [6].

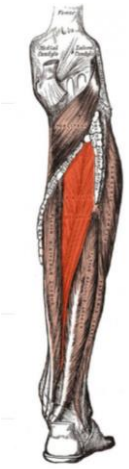


Figure 2: Tibialis Posterior. The posterior tibialis is denoted in red and is in the deep posterior of the lower extremities. [39]

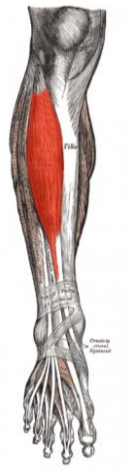


Figure 4: Anterior Tibialis. The anterior tibialis is denoted in red and is located anteriorly in the lower extremity. [8]

Figure 3: Soleus. The soleus muscle is denoted in red and is located posteriorly in the lower extremity. [9]

The *anterior tibialis* is located along the lateral side of the tibia and is easy to locate by palpation on the anterior section of the shin [7]. The exact location of this muscle in respect to the anatomy of the lower extremity can be found in Figure 3. When this muscle contracts, it allows for adduction of the foot, moving it upwards (dorsi flexion). For an individual that is active, an impairment of the anterior tibialis is quite apparent, as something as simple as picking up their foot can cause extreme pain. The anterior tibialis originates from the lateral condyle and lateral surface of the tibia and inserts at the medial surface of the first cuneiform bone and at the base of the first metatarsal bone [8].

The largest muscle that can be affected by MTSS is the *soleus*, which is a powerful lower limb muscle that runs from the back of the knee to the ankle, as shown in Figure 4. This muscle aids in the plantar flexion of the foot at the ankle and stabilizes the tibia on the calcaneus, limiting forward swaying [7]. It is one of two calf muscles that has major contributions in running, walking, and other active movements. The soleus originates from the head and shaft of the fibula and medial border of the tibia and inserts at the calcaneus by way of the Achilles tendon [9]. When the *soleus* experiences symptoms of MTSS, there tends to be pain when activating the calf muscles in activities such as running or jumping and walking on tiptoe can aggravate the pain [10].

2.1.3 Potential Causes of MTSS

Though there are numerous reasons that this may occur, most causes of MTSS can be placed within the categories of alterations of tibial loading, overtraining, overpronation (the inward rolling of the foot during exercise), oversupination (the outward rolling of the foot during exercise), inadequate footwear, or poor flexibility [11]. When an individual increases their running mileage too quickly, chronic and repetitive loads can cause abnormal strain and bending of the tibia, resulting the periosteum and surrounding muscles to inflame and to radiate pain [12]. Similarly, with overpronation and oversupination of the ankle joint, the tibia is forced to operate under unnatural circumstances, which increases the stress on the soft tissues of the lower leg. Inadequate footwear such as wearing unsupportive or inappropriate shoes can contribute to both the over-pronation/supination as well as excessive tibial loading. Finally, poor flexibility of the gastrocnemius muscle, soleus or tibialis posterior muscles can cause an increased amount of stress on the soft tissues, muscles, and tendons of the lower leg during exercise.

2.1.4 MTSS Versus Stress Fractures

With musculo-tibial stress injuries, there are many potential causes and each case has a unique effect on the individual in how it presents itself, making the prevention and diagnosis of MTSS more challenging. This syndrome is not seen as disabling; however, unanticipated reactions by the tibia and surrounding musculature can occur when the body is unable to heal properly and effectively due to repetitive muscular contractions and tibial strain. This could possibly lead to the development of stress fractures.

Stress fractures can be defined as small cracks or severe bruising in the bone. The most common locations for stress fractures to develop are the second and third metatarsals of the foot, which is the greatest impact area of the foot as one pushes off whilst walking or running [13]. Additionally, stress fractures can develop in the calcaneus, talus, fibula and/or tibia, and the locations of these bones can be found in Figure 5.

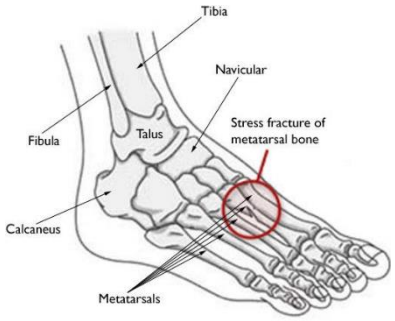


Figure 5: Potential Locations for Development of Stress Fractures in Active [38].

Typical signs that an individual has graduated from medial tibial stress pain to the development of stress fractures are as follows; pain that worsens upon weight-bearing activities, pain which is very well-localized on palpation of the shin area, and pain which is present at night with no initiation of activity [13]. It is important to determine the distinction between symptoms experienced by MTSS and the development of stress fractures. MTSS symptoms can be treated using rehabilitative methods from health care professionals, such as athletic trainers, or on-the-market medical devices, whereas stress fractures require medical attention and intervention.

2.2 MTSS Population

Though MTSS can affect anyone, it tends to target a few specific groups of people. MTSS is a condition of the lower leg and affects active people who are at risk of overuse of the lower leg. Those that are especially at risk for MTSS are runners, athletes, military personnel, females, and people with anatomical deformities and other issues.

2.2.1 Runners

One group that MTSS affects is runners. MTSS is non-discriminatory in that it can affect the casual runner trying to get some exercise, or the seasoned marathon runner. Running properly is a skill that is learned overtime and it is of utmost importance to run with proper biomechanics. The body is an intricate system and when a motion is done improperly, an array of health issues could arise. There are approximately 700 skeletal muscles in the human body, and many are used in running. Most muscles used are in the legs and some include the hamstring, quadriceps, hip flexors, gastrocnemius and soleus of the calf, and the tibialis anterior. Some muscles that are used by not located in the legs include the muscles of the core, deltoids of the upper arm, and latissimus dorsi of the back [14]. The act of running repeatedly puts a great deal of force on the lower leg. There is simply no way around avoiding the load, but there are ways to alleviate it such as running with proper biomechanics and wearing shoes with good shock absorption capabilities. MTSS has been reported as the most or second most frequently diagnosed injury among runners [15]. Runners put themselves at risk by running on hard or uneven surfaces, wearing shoes with poor shock absorption, hill training, and running more than twenty miles per week [1]. Additionally, runners are more prone to experience symptoms of MTSS at the start of a new season or from a significant hike in the amount of distance ran [16].

2.2.2 Athletes

Another group prone to MTSS is athletes. Other than running, MTSS is common in sports such as football, basketball, soccer, and dancing [12]. These sports all require similar motions such as running and jumping. MTSS is the most common leg injury in athletes [17]. In two separate prospective studies of high school cross-country runners, 12 percent of 125 runners and 15.2 percent of 130 runners developed MTSS [18]. In another prospective study of 146 collegiate athletes who participated in running and jumping sports, 19.9 percent developed MTSS during their competitive seasons [18]. Aerobic dancers are among the worst affected and have MTSS rates of up to 22 percent [19].

2.2.3 Sex

Sex also plays a role in the prevalence of MTSS. The incident rate for MTSS in females is 16.8% while in males it is 10.7% [15]. In a study of military recruits during basic training, researchers found female recruits developed MTSS at a rate that was 10 times greater than their male counterparts. In another prospective military study, females were only twice as likely to develop MTSS. In two prospective studies of high school cross-country runners, female runners were 2.5 to 6.5 times more likely to develop MTSS than their male counterparts [18]. Additionally, females are at a 1.5 to 3.5 times increased risk for progression to stress fractures [12]. The main reason for this difference in sex is because females have a lower bone density and thus are more prone to MTSS.

2.2.4 Military

Entry level military training has been notorious for causing many injured recruits. Military training is very intense and involves a great deal of running for distance and speed, running with added weight, marching, and other strenuous activities and exercises. In some cases, 60 to 70 percent of trainees have been injured over the course of the 8-week training regiment, with the majority of these injuries related to overuse of the lower limb such as MTSS [20]. In the military, MTSS is believed to be the overuse injury with the largest impact on recruits during basic military training [21]. According to a recent study of British Army recruits, it is estimated that MTSS affects 7.9-35% of recruits and accounts for 20% of all time spent in rehabilitation [22]. In another study, a total of 124 naval recruits (84 men and 40 women) were monitored during training for MTSS using several biomechanical examinations. At the end of the study, 40 of the 124 recruits (22 men and

18 women) developed MTSS. This equated to an incidence rate of 35% [23]. Another study looked at the prevalence of musculoskeletal injuries in marine corps recruit training. During the Initial Strength Test (IST), MTSS was the fifth most frequent injury behind sprain, strain, iliotibial band syndrome (ITBS), and patellofemoral pain syndrome (PFPS). The IST is the initial strength test performed on the first day of training and consists of pull-ups, crunches, and a 1.5 mile run for time [24]. The high number of MTSS could be due to recruits trying to run the 1.5 mile run too fast without proper training leading up to it. This is referred to as "too much, too fast." It is also possible that the recruits did not run with proper biomechanics, causing excessive strain on their lower leg which resulted in the MTSS.

2.2.5 Anatomical Issues

People with anatomical deformities and other issues are also susceptible to MTSS. Since MTSS is an issue involving bone, people with low bone density and osteoporosis are at a higher risk for MTSS. Females have a higher incidence of diminished bone density and osteoporosis, as seen in the female athlete triad (osteoporosis, amenorrhea, and disordered eating) [12]. This could be a reason as to why females have a higher incident rate than males. Muscle weakness in the triceps surae, core, thighs and glutes could lead to MTSS [16]. Additionally, muscle exhaustion and a lack of flexibility could also lead to MTSS. There is also a study that shows a relationship between BMI, internal hip rotation angle, and MTSS in females [25]. Lastly, in another study, excessive navicular drop measurements correctly identified 64% of MTSS cases in high school cross country runners [15].

2.3 Current Rehabilitation Devices and Methods

Currently, there are a few rehabilitation devices on the market; however, studies have shown that these devices have not been effective in treating the symptoms of MTSS, or they require professional application for effective treatment. The most common rehabilitative treatments recommended for MTSS include elastic bandages, compression sleeves, and taping.

2.3.1 Elastic Bandages

An elastic bandage, or compression bandage, is a stretchy strip of material that can be wrapped around a limb to apply pressure to the injured area [26]. Although these bandages provide compression which may help eliminate swelling, they do not provide a lot of support. Additionally,

these bandages must be wrapped correctly around the injured area to be effective and provide the right amount of pressure needed. Wrapping the area too loosely will not provide enough compression to get rid of swelling while wrapping the area too tightly can cut off blood flow to the area [27].

2.3.2 Compression Sleeves

Similarly, compression sleeves are used to apply pressure or compression to a body part. Compression sleeves come in many different sizes and can be slipped onto the lower leg rather than wrapped around the area, decreasing the chance of incorrect application. It is vital that the sleeves fit properly to achieve graduated pressure where the most amount of compression is exerted at the ankle and less compression is exerted at the calf or shin [28]. Proper fit of the compression sleeves would help deoxygenated blood flow back to the heart; meanwhile, constricting the veins of the body part, increasing the flow of oxygenated blood to the injured area and resulting in decreased inflammation and pain. One drawback of compressions sleeves, however, is that the sleeve applies pressure to the entire lower leg rather than the affected area. As a result, compression around the calf area can lead to increased risk of muscle cramps.

2.3.3 Taping

Lastly, taping is often used to alleviate the symptoms of shin splints and is typically the most effective method. For the tape to properly work, however, it is crucial that it is applied correctly. Proper taping for MTSS often requires professional application and consists of two main types of methods: shin taping and foot taping. The type of taping used to alleviate MTSS depends on the preferences of the injured person as well as the professional applying the tape.

2.3.3.1 Shin Taping

Taping of the shin includes the use of kinesiology tape (KT tape) or athletic tape to pull the muscle closer to the shin as seen below in Figure 6 and 7. The main difference between KT tape and athletic tape is that KT tape is more flexible allowing for better range of motion compared to normal athletic tape. Both types of tape, however, aim to provide compression to the injured area while also minimizing unnecessary movement to promote healing. Furthermore, some studies show that proper use of KT tape can result in pain relief due to increased blood flow as a result of macroscopic lifting of the skin [29].

Figures 6 and 7 show an example of a common shin taping method using athletic tape. Non-adhesive pre-wrap was used to prevent the athletic tape from having direct contact with the skin to avoid irritation or painful removal of the tape. The white athletic tape was used over the pre-wrap to apply an appropriate amount of compression to the shin. It is vital that the athletic tape was placed below the calf to avoid muscle cramps. Since MTSS symptoms are typically caused by slight detachment of the muscle from the bone, this type of taping is believed to be more beneficial than other types of taping because it forces the muscle up against the tibia.

Figure 6: Side view of shin splint taping using athletic tape

Figure 7: Top view of shin splint taping using athletic tape

2.3.3.2 Foot Taping

Foot taping typically utilizes athletic tape to provide support to the arch of the foot, resulting in a decrease of medial plantar pressure and an increase of pressure towards the outside of the foot.

Figures 8 and 9 demonstrate a common foot taping method. Pre-wrap was used first again to avoid direct contact with the skin and athletic tape was used over the pre-wrap. It is important to note that the athletic tape was pulled tightly on the medial portion of the foot to apply pressure on the inside of the foot. On the other hand, the tape was applied loosely on the lateral portion of the foot. This taping method develops a theoretical arch on the bottom of the foot which allows MTSS pain to be alleviated but does not necessarily aid in treating the condition.

Figure 8: Side view of foot taping using athletic tape

Figure 9: Top view of foot taping using athletic tape

2.3.3 Previous Patents

Currently, assistive devices in orthopedics are a popular topic of research. Over the years, there have been numerous patent searches conducted for various musculoskeletal illnesses including MTSS. In fact, in April 2017, the patent for a Device for the Treatment of Medial Tibial Stress

Syndrome and Other Conditions of the Lower Leg was published by the Patent Cooperation Treaty (PTC) [30]. It was invented by three researchers from Ossyx Pty Ltd and aimed to target certain zones of the lower leg to promote release of the user's calf muscle to alleviate the symptoms of MTSS. The device was designed as a calf brace that can be slipped on by the user with straps attached to the sleeve allowing for adjustability of the device.

2.4 Interview with Shannah Dalton

The team interviewed WPI Athletic Trainer Shannah Dalton to gather more information as to how MTSS is rehabilitated. Prior to the start of the interview, Shannah Dalton granted the team permission to record the meeting. The team started off by explaining that the current problem is that there are effective no MTSS devices on the market. The team continued by describing their intentions of developing a device under Professor Tiffiny Butler that is adjustable and simple to use while also providing similar rehabilitative benefits to athletic taping. The team asked Shannah for advice to help determine how our final device is successful. She responded by saying that athletic taping is typically a "most fit everyone" approach and broke down some taping methods that are typically used to treat MTSS. Arch taping is often used to support the bottom of the foot by taping from the toes and around the ankle. A teardrop or low-die arch tape method is then used followed by a supporting piece of tape that is placed and pushed against the arch. This taping is performed using multiple layers of tape that overlap one another. Shin taping, on the other hand, consists of wrapping the shin with tape and finishing it off by placing a X pattern of tape. Shannah mentioned that the type of taping method used for shin splints typically depends on the individual; however, for patients experiencing MTSS, it is better to use the arch taping method as it doesn't apply additional pressure to an already tight area or the calf muscle. Additionally, Shannah justified our idea of incorporating both taping methods into our final design by stating that athletic trainers sometimes combine the methods and "create a loop that goes from the arch straight into a shin tape job." Shannah also said that compression sleeves can often also help alleviate pain from MTSS as they push the muscle back against the bone and prevent the fascia from experiencing additional stress. Shannah added that these compression sleeves are usually made of material such as nylon or neoprene which can wick away sweat. A full transcript of the interview can be found in Appendix A.

3. Project Strategy

3.1 Initial Client Statement

In athletic populations, MTSS is a common exercise induced injury. Currently on the market, there are many orthotic or assistive devices available for the rehabilitation of MTSS, but few studies have shown any of these devices to be particularly effective in relieving of symptoms when athletes return to play. Athletes exhibiting symptoms of MTSS are treated in combination with rest, ice, compression, a support brace or assistive device, and a range of therapeutic modalities. There is a need for a new assistive device that can reduce or eliminate symptoms related to MTSS.

3.2 Technical Design Requirements

With the information gathered from the initial client statement and literature reviews, the team was able to determine the objectives and constraints of their project. The established objectives and constraints are detailed in the following sections.

3.2.1 Objectives

To keep track of goals and ensure progress was made, the team identified several objectives for the prototype, separated them into primary, secondary, and tertiary objectives, and created a pairwise table to rank the objectives and determine their importance.

Table 1: Project Objectives. The table displays the established objectives of the project and a description explaining what each objective entails.

Objective	Description
Simple	• Device should require little time to put on and remove • Device should be able to be put on with little effort
Customizable	• Device should be adjustable to fit people of different size
Affordable	• Device should be able to be reused to reduce costs to the consumer • Device should be <$50
Comfortable	• Device should not slip or cause abrasion • User should enjoy wearing the device
Effective	• Device should ultimately aid in rehabilitation MTSS
Safe	• Device should be antimicrobial and allergen free • Further complications should not arise from wearing device
Washable	• Device should be machine-washable and easy to clean

Once the objectives were identified and organized into a chart, the team created a pairwise table to rank the importance of each objective. This process entailed comparing entities in pairs to determine which entity was preferred or had greater significance. The purpose of creating a pairwise table was to objectively analyze each objective and assign them into primary, secondary, or tertiary objectives.

Table 2: Pairwise Comparison Chart.

	Simple	Customizable	Affordable	Comfortable	Effective	Safe	Washable	**TOTALS**
Simple	x	0.5	0	0	0	0	0.5	1
Customizable	0.5	x	0	0	0	0	0	0.5
Affordable	0.5	1	x	0.5	0	0	1	3
Comfortable	0.5	1	0.5	x	0	0	1	2
Effective	1	1	1	1	x	0.5	1	5.5
Safe	1	1	1	1	0.5	x	1	5.5
Washable	0.5	1	0.5	0	0	0	x	2

3.2.1.1 Primary Objectives

Based on the pairwise table (Table 2), the primary objectives of the prototype were established. They included effectiveness, safety, and affordable. Since the purpose of designing this device is to aid in relieving the symptoms of MTSS, it is evident that the main objective of the prototype should be for it to effectively achieve its purpose. Additionally, medical devices are required to follow the standards established by the FDA and ISO to ensure safety of the product. Therefore, the prototype should not cause harm to the user and should not worsen the symptoms of the condition. The prototype is meant to serve the general population so it should be relatively cheap to manufacture and purchase. In other words, all persons should be able to afford the device.

3.2.1.2 Secondary Objectives

The secondary objectives established by the team were comfortable, washable. simple and customizable. The device may be used during physical activity and will aid in relieving pain symptoms, so the device should be made of a material that will be comfortable for the user to wear for a long duration of time. Additionally, the device may be used along with a shoe, so it is vital that it is not bulky to ensure proper fit. Lastly, the material used for the making of the device should be washable to avoid bacteria buildup and allow for reuse of the device.

3.2.1.3 Tertiary Objectives

Simplicity and customizability were found to have the least impact on the success of the overall system. If these objectives were not met, it would have little to no effect on the outcome of system validation. In order to make the device simple, it should take little time to put on and remove and have very few complex components. The prototype should also be customizable to ensure proper fit for people of all sizes. Proper fit of the product is vital to guarantee effectiveness in relieving MTSS symptoms.

3.2.2 Constraints

The main constraints for this project were time, cost, customer satisfaction, adhering to the medical device manufacturing and safety regulations. There were only 14 weeks to complete the fabrication, testing, and finalization of the device, only allowing for a certain level of excellence in product development. Additionally, the budget for the project was $750 ($250 per team member) which prevented the use of quality materials and advanced testing. The interaction between customer and developer was theoretical, as there were no physical stakeholders involved in this project, but rather the device served as a solution to a general population. Lastly, the fact that the device was meant for human use required the testing to be completed on human test subjects. This indicated that we would need to go through the proper procedures for human testing, manufacturing of the device, and adhering to the medical device regulatory standards and testing protocols. This includes receiving WPI Institutional Review Board (IRB) approval for human studies, which can be a vert lengthy process.

3.3 Design Standards

In order to ensure the safety and quality of medical devices, a set of standards and regulations have been established by several organizations to control the development, manufacturing, and material criteria of medical devices as well as the testing methodologies used during the initial design process [31]. The regulatory organization and the accepted standards necessary for compliance of a device vary depending on the type of device. The following sections discuss the standards that our fabricated device will need to follow to ensure its safety and efficacy.

3.3.1 International Organization for Standardization (ISO)

The International Organization for Standardization (ISO) is an agency made of 164 members, each representing a different country. ISO members are responsible for the development of national standards, regulations and specifications of products and services in various industries from "technology, to food safety, to agriculture and healthcare" [32].

ISO 13845 is the established standard for the regulation of medical devices developed by the organization [31]. Although this standard does not have specific requirements that must be met, its intent is to encourage medical device industry workers to organize a quality management system, or a system of procedures, for the design and production of their product. The goal of this standard is to ensure that customer needs are met in the development of the product [33]. Additionally, compliance with this standard guarantees the safety and efficacy of the medical device. Since our medical device will require some type of manufacturing, it is vital that it meets these ISO standards.

3.3.2 Food and Drug Administration (FDA)

The Food and Drug Administration (FDA) is a United States federal organization that ensures the safety and quality of drug products, food products, medical equipment and many more. The FDA classifies medical devices as "*an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes*" [34]. Additionally, medical devices are classified into three categories by the FDA depending on the risks the device comes with. Class I devices are those with the lowest probability of harm to the patient. According to the FDA, elastic bandages are an example of Class I devices and, therefore, our fabricated design will fall under this category.

For medical devices to be put on the market, Premarket Notification [510(K)], Premarket Approval (PMA) and Humanitarian Device Exemption (HDE) information must be approved by the FDA or the device must be exempt from 510(k). 510(k) exemption is typically achieved for Class I devices

and does not require a Premarket Notification [510(K)] to be submitted prior to listing the device to the market.

3.4 Revised Client Statement

There are few orthotic devices on the market today that aid in the rehabilitation of active individuals with MTSS; however, those on the market have not been effective in reducing the symptoms of MTSS or have required professional advisement and application. The most effective products available utilize therapeutic athletic tape to strategically pull the tibialis posterior muscles, creating a sling that allows for the user to resume regular activity whilst protecting the injured muscle. In order for this type of rehabilitation to be effective, one must have the knowledge of how to align the tape to ensure proper support, yet most who are affected by MTSS do not have access to a health professional such as an athletic trainer on a daily basis.

There is a need for a device that accomplishes similar rehabilitative benefits of professional application that has a simple application process, is customizable to meet the individual needs of the user and is affordable for the consumer. MTSS is a common injury experienced by athletes, military personnel, and non-professional active individuals, making the need for a more accessible and effective device for the rehabilitation of MTSS symptoms imperative.

3.5 Project Approach

Once the client statement and objectives of the project were confirmed, the team outlined an approach to achieve the objectives of the project and address the need. A timeline and budget of the project were established and are further discussed in the following sections.

3.5.1 Project Process Flow

Table 3: Project Flow for Design and Fabrication of a Rehabilitative Device for MTSS

Term	Highlights
A	• Background research • Meet with athletic trainer • Identify project objectives and constraints • Research standards of medical devices/manufacturing • Research materials that prototypes could be made of • Brainstorm ways to incorporate taping method into device
B	• Design/manufacture prototype • Repeat and improve design/manufacture/test method until final prototype is achieved
C	• Test prototype

	• Complete report • Present final presentation

Table 3 above shows the details for the flow of the project. During the first seven weeks of the project (A-term), mainly introductory tasks were performed. After meeting as a team and with the advisor, the team had a much better grasp of the project and began right away. Background research was performed on a variety of topics including the physiology, prevalence, and current rehabilitation methods of MTSS. A meeting with a certified athletic trainer was also conducted so that the team could see how they treat MTSS, ask questions, and get taped as if the trainer was to tape them to rehabilitate MTSS. Additionally, project objectives and constraints were identified. Once a deep knowledge of several different constituents of MTSS and the scope of the project was achieved, the team began to formulate initial conceptual designs.

In the first few weeks of the following term (B-term), the team edited the report to reflect comments from the advisor and met with the lab administrator to go over the basics of ordering materials and lab etiquette. To test and receive feedback on the device, the team created a survey and consent form to be used in C-term when validation testing of the device is conducted. The survey and consent form were submitted to the WPI IRB Board for approval. Additionally, materials for prototyping were ordered and prototyping began. The team was able to complete their first prototype and have a physical device at the end of the term, which was one of the main goals of the term. The team continued to document their work in the report and were able to complete Chapter 4 and most of Chapter 5.

The team made great progress throughout the next seven weeks of the project (B-term). In the first few weeks of the term, edits to the report to reflect comments from the advisor were made and a meeting with the lab administrator to go over the basics of ordering materials and lab etiquette was had. To test and receive feedback on the device, the team created a survey and consent form to be used in C-term when validation testing of the device is conducted. The survey and consent form were submitted to the WPI IRB Board for approval. Materials for prototyping were ordered and prototyping began. The team was able to complete their first prototype and have a physical device at the end of the term, which was one of the team's goals of the term. The team continued to document their work in the report and were able to complete Chapter 4 and most of Chapter 5.

During the last seven weeks of the project (C-term), the team was very busy tying up loose ends and preparing for the final stretch of the project. Some small edits were made to the report based on the advisor's feedback from the B-term submittal. The main highlight of C-term was performing the testing of the device and materials. Most of the testing was mechanical and utilized the Instron 4000. Statistical analysis of the results was performed and communicated later in the report. Unfortunately, IRB approval of the team's study on humans was not granted in time, so the study was aborted. However, the team retained their protocol for the study so that in the future, if this project was to be continued, the human study could be carried out. Lastly, throughout the term, the team added to their final report and created their final presentation.

3.5.2 Project Management Strategy

To keep the team on track and ensure that deadlines were met, a Gantt Chart was created. The Gantt Chart served as the team's outline for the entire project. It was broken up by term, week, and day. As the project developed, objectives and dates were changed as needed. This tool worked well to give the team an idea of the progress made and what still needed to be done. The Gantt Chart can be seen in the Appendix. In addition to the Gantt Chart, the team had weekly meetings with the advisor of the project to ensure progress was made in a timely manner and to troubleshoot any issues that arose. The team also had meetings throughout the week to collaborate. Communication with the advisor was conducted via an email alias while the team communicated with each other via text messaging and email.

3.5.3 Budget Management Strategy

To conduct this project, the team received a budget from the Biomedical Engineering Department at Worcester Polytechnic Institute. The budget was $250 per person, and with a three-person team, our total budget was $750. Below in Table 4 is a detailed record of the price and purpose of each material purchased.

Table 4: Budget Management Chart for Keeping Track of Finances

Material Name	Quantity/Per Unit	Purpose	Cost
Black Tricot Fabric	2 yards/$9.95	Fabric material option for the compression aspect of the device	$19.90
Athletic Knit Mesh Fabric	2 yards/$4.19	Fabric material option for the compression aspect of the device	$8.38
European Cotton Blend Fabric	1 yard/$7.46	Fabric material for supportive straps	$7.46

Velcro	1 order/$8.10	Method used for securing the supportive straps to compression aspect of device	$8.10
Sock Stop Paint	1 order/$10.28	Used for creating friction between the device and the wearer.	$10.28
Mannequin Foot	1 order/$30.38	For displaying the prototype for final presentation	$30.38
		TOTAL	**$84.50**

4. Design Process

The following chapter outlines the entire design process for the MTSS device. The team initially started with a stakeholder and needs analysis to determine how the device should incorporate the needs of the various stakeholders. Next, based on the stakeholder and needs analysis the team conceptualized several design specifications that the final design should ultimately adhere to. Lastly, this chapter discussed how the team came up with several conceptual designs and ultimately moved forward into the prototyping process with one design.

4.1 Stakeholder and Needs Analysis

4.1.1 Introduction

In order to understand how this rehabilitative device will be conceptualized and fabricated, it is important to discuss the stakeholders involved. The two sections involved in this chapter are the stakeholder and needs analyses, illustrating how these tools can be used to describe the influences that exist on the project. Finally, the section ends with a general summary.

4.1.2 Stakeholder Analysis

Below in Table 5 is a detailed list of the stakeholders involved, their influence on the fabrication of the device, and at what priority they operate at.

Table 5: Stakeholder Analysis for The Rehabilitative Medial Tibial Stress Syndrome Device

ID	Title	Description	Role/Influence	Support	Needs	Priority
SH.01	Prof Butler	Introduced the need for a new rehabilitative device for MTSS cases – primary project contact. Wants to design something that has the simplicity of a compression sleeve for application but the benefits of professionally applied athletic tape.	Advisor / Project Manager Direct Influence	Positive	Strong	1
SH.02	Patient	Those experiencing MTSS in need of a more accessible rehabilitative device.	User Indirect Influence	Positive	Strong	2
SH.03	FDA's CDRH	The FDA's Center for Devices and Radiological Health – in charge of regulating devices and creating specifications that devices are to uphold to	Regulators Direct Influence	Positive + Negative	Strong	1
SH.04	Patent Lawyers	Those who will ensure that integrity of the device does not	Regulators Direct Influence	Positive + Negative	Medium	2

		impede the integrity of pre-existing devices				
SH.05	Pharmacies + Doctor's Offices	Those who will be marketing and providing access to the product we create	Marketers Indirect Influence	Positive + Negative	Weak	3

The most important stakeholders in this project are SH.01 and SH.03, though the stakeholder that is most accessible and directly influences how the processes and design aspects of the projects will be handled is SH.01. This stakeholder was the first to introduce the need for a new rehabilitative device for those who have MTSS and serves as the primary project contact. Their vision helped to shape the goals and objectives to this project, which include the need for a simplistic yet effective device that is accessible to the general population. SH.03 holds important testing and usage regulations in order to promote a safe product. Though this stakeholder is not actively involved, their regulations heavily impact how we will be proceeding with the conceptualizing and testing of the product. The second level priority stakeholders involved include SH.02 and SH.04, both of which are silent stakeholders. Since this device will be a new concept and the fabricated design will be unique to the market, the influence of SH.04 allows for the assurance that the integrity of the device does not impede the integrity of pre-existing devices. The role of SH.02 in this project is silent in that there is no true patient that this device is being marketed to, but rather the device will be made to serve the general population of those affected by MTSS. Therefore, this stakeholder is not necessarily a specific individual, but rather a theoretical individual representing those who are affected by MTSS in need of a more accessible rehabilitative treatment option that is available to the general public. Finally, the stakeholder with the lowest priority is SH.05. This stakeholder serves as the main form of marketing for the potential product, which determines the level of accessibility for the device to the general population.

4.1.3 Needs Analysis

Along with the identification of the stakeholders comes their appropriate needs as far as how the system will operate. Below in Table 6 is the detailed outline of each need and the corresponding stakeholder it can be traced back to.

Table 6: Needs Analysis for the Rehabilitative Medial Tibial Stress Syndrome Device.

ID	Title	Description	Traceability	Priority	Complexity (1-5)
N.01	Affordability	Product is both affordable to manufacture and sell for user convenience	SH.01	Medium	2

N.02	Effectiveness	Accomplishes similar rehabilitative benefits of professionally applied athletic tape	SH.01 SH.02	High	5
N.03	Simplicity	Does not require the assistance of a professional to use the device	SH.02	High	4
N.04	Accessibility	Can be used by most of the population (accounts for different sizing, and ability to be reused and reapplied)	SH.02 SH.01 SH.05	High	5
N.05	Safety	Product follows the medical device guidelines and ensures safety for users	SH.03 SH.04	High	2
N.06	Originality	Product developed is innovative and original – fills the gap in the market	SH.01 SH.04	Medium	3

Rows denoted in blue are the high priority needs linked to high priority stakeholders

The following statements below are the needs this project will abide by in order of priority:

1. The system should effectively accomplish similar rehabilitative benefits of professionally applied athletic tape.
2. The system should be simplistic in application, not requiring professional assistance.
3. The system should be accessible to the general population by means of sizing, usability, and convenience.
4. The system should promote the highest level of safety, following the medical device guidelines for testing and usage.
5. The system should be affordable to manufacture so that the device can be affordable for the user.
6. The system should be an original product that is innovative and fills the gap in the market.

4.1.4 Summary

In summary, the stakeholder that is most essential to the success of this project is SH.01, who is also most involved in the development of the MTSS rehabilitative device and gives the essential guidelines as to how the flow of the project will be implemented. The needs are separated into levels of priority, with Table 2 showing the high priority needs linked to the highly influential stakeholders. The needs are presented in order of highest priority to least priority.

4.2 Functions (Specifications)

Measures of Performance for the MTSS Device:

- Does the device withstand up to 3 hours of exercise without need of adjustment? And support the lower extremity muscles? [SH.02, N.02, N.03]
- Does the device maintain structural and functional integrity for up to 3 weeks, the typical duration of MTSS symptoms during rehabilitation? [N.02, SH.01, SH.03]

Technical Performance Measures for the MTSS Device:

- Lifecycle must be longer than three weeks—the average rehabilitation period for individuals with MTSS. [SH.05, SH.03, SH.01, N.02]

Key Performance Parameters for the MTSS Device:

- The device functions at the same efficiency as professionally applied athletic tape by relieving pain from the affected area by at least 50% (measured using a medical pain scale from 1-10) in comparison to no device at all. [N.02, SH.02, SH.03, SH.01]
- The device functions at the same safety as professionally applied athletic tape—wicking sweat away as quickly as 15 minutes after exercise has begun, as well as possessing antimicrobial fabrics to promote clean usage. [N.05, N.02, SH.03, SH.02]
- The device is wearable for up to 8 hours comfortably without causing numbness of the toes or cramping of the lower extremity muscles. [SH.03, SH.01, SH.02, N.05]
- It must be reusable for up to 312 uses where the MTSS-affected individual can apply the device and receive instant relief from symptoms such as medial tibial pain and swelling. [N.04, N.02, N.05, SH.02, SH.04]

4.3 Conceptual Designs

Through our research and interviews, we found that the most effective treatment for MTSS is athletic taping of the shin or the arch of the foot. Taping of the shin and arch requires pulling the tape in certain directions to apply pressure to a specific area in order to alleviate the symptoms associated with the condition. When crafting potential designs for the rehabilitative device, these taping techniques were taken into consideration and attempted to incorporate them into our final prototype.

4.3.1 Compression Sleeve

Although compression sleeves don't necessarily treat MTSS itself, they often alleviate the pain associated with the condition. As a result, the team determined that a compression sleeve may be beneficial to incorporate in our design as it might encourage the user to continue using the device if their pain is alleviated. Additionally, in order to prevent calf cramping, it was made sure the compression sleeve did not surpass the bottom of the calf muscle.

4.3.2 Arch Support

Arch taping requires a tear drop taping technique. This technique ensures the tape wraps around the heel and bottom of the foot, only applying pressure at the arch of the foot. Additionally, arch taping requires small pieces of tape to be applied at only the bottom of the foot up against the arch support to apply additional pressure.

The team made sure to incorporate this taping technique into the design by having a piece of fabric wrap around the middle of the foot. Furthermore, the team made sure to consider that the fabric could not be loose around the user's foot and that it must apply a certain amount of pressure to provide arch support. As a result, the system was adjustable using Velcro.

4.3.3 Pressure at the Shin

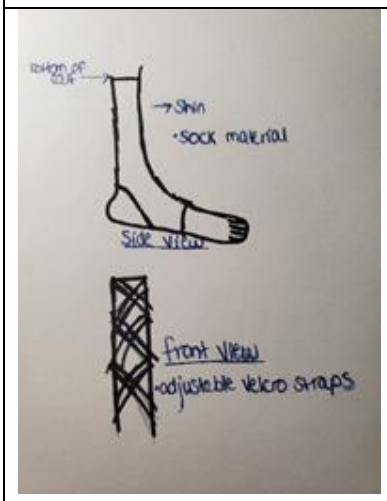
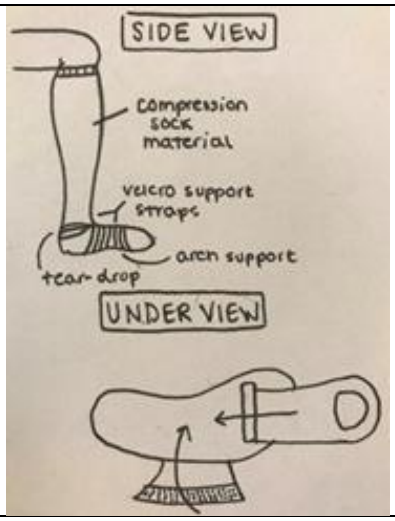
When shin taping is utilized, the tape is applied from the top of the ankle to just below the calf to ensure there is no pressure applied at the calf to prevent cramping. Additionally, it is vital that the tape is only applied at the medial side of the lower extremity where the condition is located as taping around the entire lower extremity would cause too much compression.

The team incorporated this method of taping into the design by ensuring there was a piece of fabric on the device that could wrap around the shin area. Since the pressure should only be applied on the medial portion of the leg, it was made sure that the fabric started from the medial side and ended at the lateral side where it would be able to be adjusted using the Velcro attached.

4.4 Alternative Designs

The three design alternatives that were created and are further analyzed in the trade study in the following section are shown in Table 7, along with their individual descriptions as to their specific attributes and functions.

Table 7: Description of the Three Design Alternatives

Design 1 – Shin-Guard Model	Design 2 – Arch/Shin Support Model	Design 3 – Compression Sock with Arch Support Model
		
• Slides over the foot • Incorporates an adjustable Velcro crisscross strapping method over the shin area to promote targeted compression of the affected muscles	• Focuses on arch support and lower shin compression • Based upon the successful taping methods used by athletic trainers	• Compression sock for distributed compression over the shin to promotes targeted compression of the affected muscles • Utilizes the arch support taping method used by athletic trainers

The three alternative designs were conceptualized with the knowledge of the taping methods and compression sleeve properties that have been successful in other devices. From here, the trade factors, ranges and weights need to be established to continue with the trade study in order to determine which of these designs will best accomplish the goals and objectives of the project. Table 8 shows the trade factors and their details.

Table 8: Trade Factors for Determining the Ranges and Weights

	Factor Description	Range	Scale Analytics	Weight	Comments
1	Device Cost	$10-100	10-1	.15	Cost of materials
2	Percentage of Pain Reduction based off pain scale	0-100%	0-10	.30	Efficiency Measure
3	Number of Complex Components (negative)	1-5	1-5	.15	Simplicity Measure
4	Device Weight	0-5lb	5-0	.10	-

5	Lifespan	0-700 days	10-0	.20	Efficiency Measure
6	Percentage of the Body that is Covered	0-100	10-0	.10	Simplicity Measure

The following categories were chosen in order to analyze the efficiency of each design; device cost, percentage of pain reduction based off pain scale, number of complex components, device weight, lifespan, and percentage of body that is covered. These categories are somewhat related to the objectives stated in Table 1 but differ in the fact that the factors above allow for a quantitative analysis of each design. The intention behind this is to establish a method of choosing a design that fulfills the desired requirements without the inclination of bias. The "range" column of the table indicates the projected range of values for the given factor, and the scale analytics help to quantify the scale by which these ranges will be analyzed. Depending upon the importance of the factor, the weighted column denotes a certain percentage to each factor.

Following the identification of the factors used in this trade study, a trade matrix was used in order to assign values to each alternative design. This aided in selecting the design that best fits the needs and objectives of the project. Table 9 below lists the results of the weighted trade factor analysis and the design that proved to have the highest score post analysis. For the factors that require physical measurements such as the weight, lifespan, and percentage of pain reduction, estimates were made based upon previous research on devices that have similar structures and goals.

Table 9: Trade Matrix for Determining the Best Design for the System

	Device Cost	Percentage of Pain Reduction	Number of Complex Components	Device Weight	Lifespan	Percentage of Body Covered	**Total Weight**
Design 1	8/15	3/30	4/15	3/10	5/20	4/10	**1.85**
Design 2	6/15	5/30	2/15	2/10	7.5/20	6/10	**1.875**
Design 3	6/15	4/30	2/15	3/10	5/20	2/10	1.42

Based upon the trade matrix above, Design 2 ranked the most likely to achieve the design goals and objectives for the system. This makes sense, as it targets less area of the patient, allowing for it to work in targeted areas. It also showed to have a higher life span, and it utilizes both successful taping method patterns using Velcro straps, proving to have a high level of pain reduction. However, the margin of success between Design 2 and Design 1 are extremely close, only a difference of 0.025 points, which is a cause of concern when determining one design over the other.

5. Final Design Verification

5.1 Final Design

After analyzing the results from the Trade Matrix, the decision to move forward with a final design was based upon the fact that Design 1 and Design 2 had very similar scores. The team thought it would be best to consult with Shannah Dalton, an athletic trainer for Worcester Polytechnic Institute, to aid in the decision of the final design. From the interview, Shannah had mentioned that if an individual is "having symptoms more aligned with MTSS, you would try more for the arch tape job. The reason being is that if you use the shin tape job, then you are adding compression to an already tight area and muscle so all that compression can irritate it even more" (Appendix A). This reinforced our concept of having a supportive strap from the underneath of the foot pressing upwards and strapping to the top of the foot, creating a supportive hold without cutting of circulation. Shannah had also mentioned that the incorporation of the technology used in compression sleeves are also useful "because they go over the whole [affected area] whereas tape is a lot of compression on one spot and that can sometimes be too much for people" (Appendix A). Gaining the insight from a professional athletic trainer and considering the results from the trade study from section 4.5, a decision was made to incorporate the arch support from arch taping, the compression aspect of a compression sleeve as well as supportive straps along the shin for the final design. Images of the fabricated device can be found below in Figures 10 and 11.

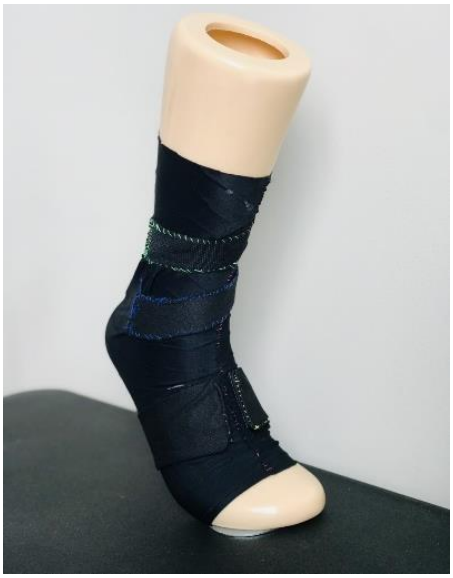


Figure 11: Final Design of Medial Tibial Stress Syndrome Rehabilitation Device. Front View

Figure 10: Final Design of Medial Tibial Stress Syndrome Rehabilitation Device. Side View

Each component was stitched using a bright colored thread so that during testing, if there were any tears or device malfunctions, the location and area of the issue could be easily located. The sock was sewn with magenta colored thread, the arch strap with yellow, the first shin strap with blue and the second shin strap with green.

The compression aspect of the device is made of Athletic Mesh Knit Black Fabric. This material will be now be referred to as "sock material." The shape of the device was based upon a sample sock with an average size of a Woman's 8.5 US and cutting two identical pieces of fabric that represented the side profile of the sock. The device was first sewn using a whip stitch to secure the two identical pieces together and followed by a straight stitch to increase the strength of the stitch when the compression sock expands with use. The strap around the arch of the foot was made of European Linen Cotton Blend Black Fabric and consists of one singular strap that was double layered with fabric to ensure strength during application and longevity of the material. This material will now be referred to as 'strap material.' It was sewn to the sole of the compression sock in the middle, allowing for uniform support of the arch. Velcro was attached to the strap as well as the area of the compression sock that is over the top of the foot to secure the strap in place. Additionally, two more straps made of the same double-layered fabric were attached to the right side of the portion of the compression sock that is over the shin. Velcro was attached to the end of the straps as well as to the opposite side of the compression sleeve to secure the straps over the shin area. A similar sewing strategy of whip stitch followed by straight stitch was used for all straps. This final prototype was designed to lay against the skin while the individual wears socks and appropriate footwear over the prototype.

In order to secure the device to the individual whilst the compression straps are laid into place, Abs Sock Stop paint was used as silicone-alternative to create a thin layer of friction between the device and the user. An image of what this Sock Stop adhesive looks like on the inside of the device can be seen below in Figure 12.

Figure 12: Inside of the Device for the Final Design

5.2 Establishment of Validation Requirements

In order to determine if the fabricated device is adequate for accomplishing the goals and objectives of the system, specific validation processes must be established. For this project, since most of the feedback that will be received from testing is qualitative or subject to participant's opinion, the most applicable process for validation would be surveying the satisfaction of the system in accordance to the overall objectives of the design. Below in Table 10 is a reference of the objectives established in section 3.2.1 and how each will be determined to have passed or failed the validation test.

Table 10: Establishment of Validation Requirements for Medial Tibial Stress Syndrome

Objective	Priority Level	Description	Determination of Validation
Effective	Primary	Device should ultimately aid in rehabilitation MTSS	Pain relief scale Does not improve / declines - not effective Improves by 1-2 - moderately effective Improves by 3+ - extremely effective
Safe	Primary	Device should be antimicrobial and allergen free Further complications should not arise from wearing device	Does the device fall within the classification of a Class 1 Medical Device? Does the user retain motor, circulation, and sensory when device is applied?
Affordable	Primary	Material cost of the device should be reasonable enough to attribute low market costs Device should be no more than <$50	Final cost per unit of material $1-10 - affordable $11-25 - moderately affordable $25-40 - moderately expensive $40+ - expensive
Comfortable	Secondary	Device should not slip or cause abrasion User should enjoy wearing the device	Does the test subject's sensory, motor, and circulation retain before, during, and after application of the device? Is there pain when applying the device?
Washable	Secondary	Device should be machine-washable and easy to clean	Does the fabric lose its elasticity, strength, or stitching after; hand washing or machine washing
Simple	Tertiary	Device should require little time to put on and remove Device should be able to be put on with little effort	Timing the duration of application / removal 1-10 sec - very simple 11-20 sec - moderately simple 21-30 sec - moderately difficult 31-40 sec - difficult 40+ sec - very difficult
Customizable	Tertiary	Device should be adjustable to fit people of different size	Average men's shoe size - 10.5 Average woman's shoe size - 9 Can one size fit all?

The following section goes into more detail about each of the following objectives and how each validation requirement was chosen:

Effective: One of the primary and arguably the most important objective is the device's effectiveness. In order to determine whether the device is effective, the pain scale from the survey will be used during testing. If there is no change, or the pain worsens, the device would be considered ineffective. If the device improves by 1-2 points on the pain scale, it is considered moderately effective. If there is an improvement of 3 points or higher, then the device will be considered extremely effective.

Safe: Another primary objective is the safety of the device. It should have antimicrobial properties, as well as being allergen free. There should not be any further complications that arise from wearing the device. The safety validation is determined on a pass / fail basis. The device should fall under the category of a Class One Medical Device by the FDA, meaning that the device is "not intended for use in supporting or sustaining life or of substantial importance in preventing impairment to human health, and they may not present a potential unreasonable risk of illness or injury" [34]. If the device meets these requirements, it is considered safe for use. Additionally, in conjunction with the comfortability, if the subject's CSMs (circulatory, sensory, and motor function) are maintained through the application and removal of the device, it is considered safe.

Affordability: One of the four primary objectives of the project is affordability. It is important that the material and labor cost of the device be reasonable to attribute to low market costs for consumers. This would make the device more appealing to a greater population of individuals affected by MTSS where finances need not play a role. Validating the affordability of the device will be done similarly to the simplicity validation where the cost is split up into increments of 10 dollars associated with varying degrees of expense, from affordable to expensive. A device is said to have achieved the objective if it costs less than $30.

Washable: Lastly, a secondary objective for this project is the washability of the device. The washability validation is determined on a pass / fail basis — if the stitching of the device and each of the components withstands its integrity and elasticity, it passes the validation test.

Comfortability: A secondary objective for this project is comfortability, which means that the device should not slip, or cause abrasion and the user should feel comfortable wearing the device. This objective is validated by determining if the test subject's CSMs are retained before, during, and after application of the device or if there is any pain when applying the device. If the CSMs are consistent before and during the application of the device, the device will be considered to pass this validation test. If there is any difference between the two, it fails. The device also fails if there is pain when applying the device.

Simple: A non-essential objective for this device is the level of simplicity. The device should require little effort and minimal time to put on and remove, and the most effective way to determine if the prototype accomplishes this objective is through timing the application and removal of the device. The timing is split up into increments of 10 seconds associated with varying degrees of difficulty. A device is said to have achieved the objective if it takes less than 30 seconds to apply and remove, respectively.

Customizable: Another non-essential objective for this device is the level of customizability. Due to time constraints, the ability to fabricate several sizes of MTSS rehabilitation devices is not feasible. This requires for a singular fabricated device that can be utilized by the majority. This objective is determined on a pass or fail basis — if the device fits the individual, it passes and does not require extra customizability, whereas if the device does not fit, it fails and would require extra customizability in order to function properly.

5.2.1 Establishment of Mechanical Property Validation Requirements

In order to determine if the mechanical properties of the fabricated device allow for adequate use of the device, mechanical testing validation processes are required. To test the material's tensile strength and stretch durability, the following requirements in Table 11 below were outlined and established. Outlined are the conditions and how they are to be determined to have passed or failed each validation test.

Table 11: Establishment of Mechanical Testing Validation Requirements for Medial Tibial Stress Syndrome

Validation Objective for Testing	Requirement for Passing Validation Test	Pass / Fail
Stretch Durability	Does the sock or strap fabric fail due to tensile forces?	If no = pass If yes = fail
Strap Tensile Strength	Will the strap material be able to be pulled to 10 N over a period of cycles without permanent deformation? **measurements would be taken in width and length*	If ≤ 5% deformation = pass If > 5% deformation = fail
Strap Cyclic Durability	Will the strap material be able to be pulled to 20% extension over a period of 312 cycles without permanent deformation? **measurements would be taken in width and length*	If ≤ 5%= pass If > 5%= fail
		Whichever material, washed or unwashed, has the least permanent deformation and percentage of force depletion passes.

The following section goes into more detail about each of the following testing objectives and how each validation requirement was chosen:

Stretch Durability: In order to determine if the materials used in the prototyped design can withstand tensile forces, they will be pulled to failure. This will allow for qualitative analysis on if the device can accomplish the goals of the project by being able to stretch over the lower extremity without the material failing.

Strap Cyclic Durability: To determine if the strap material can fulfill the objectives of the prototype in that it can be pulled and support the muscles of the lower extremity, it is important to test the material's ability to withstand forces that represents human use over a period fifty cycles. From here, conclusions can be made about the material's ability to perform adequately within the overall system as the level of deformation experienced is recorded post-testing.

Strap Fatigue Durability: To determine which type of material, washed or unwashed, is preferred and can withstand a higher level of integrity during use, fatigue testing for each population will be done. The parameters tested will be the overall force depletion from first to last cycle as the material is pulled to 20% extension over 312 cycles, as well as the permanent deformation

experienced in width and length. Whichever material has the least force depletion and permanent deformation will be considered to have passed the validation test.

The fabricated device will be measured against these objectives to determine whether the correct device was fabricated for mitigating the symptoms of MTSS.

5.3 Methodology for Testing

This section includes all methods for testing intended for the fabricated device. The following tests were performed in order to validate the design of the prototype: Instron testing, pertaining to force gauge testing, failure testing, cyclic testing and fatigue testing of washed and unwashed materials, as well as washability testing of the device to test its integrity. Also included in this section is methodology for Athlete Testing in section 5.3.2; however, due to complications with IRB approval, these tests were unable to be performed.

5.3.1 Instron Testing

After the prototype of a rehabilitative device for MTSS was finalized, the team performed tensile testing on the materials used. Force gauge and tensile testing using an Instron 5544 was completed to determine durability of the materials. The length, width and thickness of each material was measured before and after each test performed to compare the results.

The materials tested were strap and sock material by inserting the material between two grips. Since two pieces of fabric were used to make a singular strap on the prototype, two pieces of strap material were used at once during testing to ensure accurate results. Prior to the beginning of testing, a BlueHill method was created to collect data as the Instron was performing the 6 tensile tests.

5.3.1.1 Force Gauge Testing

Prior to Instron testing, force gauge testing was performed to determine the average force used when pulling the straps and sock over 50 cycles. Testing was conducted for 20 seconds of pulling, once a second at a frame rate of 50 frames/second. The average peak force was taken between two tests for each material and used as the maximum force value for humans to compare to our cyclical testing.

5.3.1.2 Cyclical Testing

The purpose of cyclical testing was to collect information to help decide whether the materials used would be able to uphold the forces exerted onto them when being used or put on by a patient repeatedly. Each material was tested in the Instron and was pulled 50 times at a rate of 500 mm/min. The strap material was pulled to a maximum load of 10 Newtons and the sock material was pulled to a maximum load of 6.5 Newtons. These maximum load values were determined with force gauge testing, described earlier. Five trials were performed for the straps and one trial was performed for the sock.

5.3.1.3 Failure Testing

The information from failure testing was intended to be used to determine the maximum force that could be applied to the material before it became damaged or ripped. Five trials of failure testing were performed on each material using the Instron. Each material was intended to be pulled until failure; however, the materials never reached failure, so testing stopped when the material slipped from the grips or the Instron reached its maximum.

5.3.1.4 Fatigue and Material Washability Testing

Fatigue testing was also performed on the unwashed strap material. The material was extended at a rate of 500 mm/min up to 20% strain and back down to 0 mm extension. To determine the number of cycles that the materials would undergo, the team replicated Division 1 Indoor and Outdoor Track and Field athletes using the brace during their season for two years. This was done because the team felt that this would be the most extreme end of the activity spectrum, and most people with MTSS would fall below this level of activity. Since every athlete's off-season is different, the team excluded off-season usage. It was decided that these athletes would give us the most extreme case of usage and that most people would not use the device as much as indoor and outdoor track athletes. According to the NCAA Bylaws, a typical indoor and outdoor track and field cannot exceed 156 days [35]. Taking this information into consideration, the team moved forward with determining the number of cycles that the materials would undergo. The team assumed that a typical device would have a two year life span, and assuming that the client would wear the brace every day for the duration of the season, the team came up with 312 uses, thus 312 cycles was used for the cyclical testing.

The strap material was also tested to determine its durability after washing. This was done to simulate the conditions that a rehabilitative device may be put under by a user. The fabric was washed and dried eight times in industrial machines in the WPI Sports and Recreation Center. The fabric was included in loads that also contained other WPI athlete clothing and uniforms. The fabric was then tested in the Instron using the fatigue testing method described above.

5.3.2 Athlete Testing

After the prototype has been tested using the Instron, the team will proceed with testing the efficacy of the device. Testing will require voluntary participation from Worcester Polytechnic Institute (WPI) student-athletes experiencing symptoms of MTSS in order to gather feedback which will be used to further improve the design. All student-athletes participating in the study will be asked to complete a consent form prior to the start of testing (Appendix D) so they are aware of the purpose and requirements of the study.

Testing will occur over a two-day period in a public setting in the WPI Recreation Center. It is vital that during the two days the participant has similar activity levels to ensure that any difference in activity does not skew the accuracy of feedback received. On the first day, there will be an exchange of basic information as well as a physical exercise test without the device and a question and answer period. On the second day, the same physical exercise test will be conducted with the device on and there will also be a question and answer period. The questions that the participants will be asked can be found in Appendix B.

For the physical tests, participants will be asked to complete a set of exercises including walking ⅛ mile, running ⅛ mile, and jumping 10 times. After each physical test, one of the researchers will examine the participants' circulation, feeling, and motor ability after the test by touching the foot and lower leg. This examination will be performed to ensure the device does not negatively affect the participant’s circulation, motor and feeling in the foot or lower leg.

There will be no benefits or incentives given to those participating in the study, but participants will be given the option of stopping the study at any time with no penalty. Additionally, the results of the study will be kept confidential. The paper copies of our collected data will be scanned and uploaded into Microsoft OneDrive. Only the researchers will have access to this information and

the researchers will need to login with their WPI credentials to access the information. Once all of the paper copies are uploaded, the paper copies will be kept in a locked cabinet in Professor Tiffiny Butler's office at the Oasis House.

5.3.3 Device Washability Testing

Since the device will be worn by athletes performing physical activity, it is important that the device be washable for hygienic purposes. It is also important that the device maintains its structural integrity when washed since the device will be washed multiple times throughout its lifetime. Thus, to test this, the team performed a basic test of the washability of the entire rehabilitative device. The team performed this test by washing the device using a standard washing machine. The device was included in one of the team member's normal laundry load and was washed with normal detergent at medium speed for the pre-programmed time of approximately thirty minutes. From the spinning cycle after washing, the device was almost entirely dry and the device was left on a drying rack to finish drying.

6. Final Design Validation

This section includes the testing methods used in order to validate the final prototype design. Most of the tests performed used an Instron 5544 machine to determine the validity of the materials in tension based upon the parameters of fatigue testing, max force cyclic testing and failure testing. All were meant to simulate the effectiveness and lifespan of the prototype relative to realistic forces, uses, and application conditions.

6.1 Experimental Method Results

The details of the experiments performed are outlined in section 5.3 of this report. The following sections record the goal for each test as well as the results gathered.

6.1.1 Results for Failure Testing of Strap and Sock Material

The purpose of the failure testing was to determine whether the material would fail due to a certain level of tensile stresses. This would allow for the speculation of the integrity of the material and if it would rip along the fabric verses the seams of the prototype. The test was performed at a rate of 100 mm/min and a failure protocol of a 20% depletion in force, indicating ripping of the fabric. Five trials of failure testing were completed for the sock material, all of which utilized two strips of fabric to simulate the prototype straps. These tests resulted in either the material slipping out from the grips or the tension grips reaching the upper limits of the Instron 5544 machine. The sock material underwent similar testing where strips of the material were measured before and after testing, pulling the material until failure. Each time, the tension grips reached beyond the upper limits of the Intron 5544 machine. Both materials experienced significant deformation through this testing, with an example shown of the before and after images of the sock material in Figure 13 below.

Figure 13: Before and After Failure testing of the Sock Material

Examples of what the progression of extension experienced by the strap material during testing can be found in Figure 14, and that of the sock material in Figure 15.

Figure 14: Progression of extension for Strap Material during Failure Testing

Figure 15: Progression of Extension for Sock Material during Failure Testing

Though none of the materials were stretched to failure, important information about the max forces experienced by the material were recorded and showed interesting results. Below in Table 12 are the results of the two tests comparing the max forces between the two materials when pulled to machine failure.

Table 12: The comparison between the max loads experienced by the sock and strap materials in failure testing

	Maximum Load (N)	
	Sock	Strap
	33.08675	239.82243
	24.44235	*65.81089*
	18.27406	273.90125
	24.28071	242.05513
	24.74961	*190.20161*
Average	22.9366825	251.9263
STDEV	3.11442962	19.06361
	Removed by the Grubbs Test	

As gathered in the testing, the average forces experienced by the sock and strap material were found to be about 23 N and 250 N respectively, each with relatively high standard deviations. This is most likely explained by the fact that each test failed to rip the materials, so the numbers presented are based upon the max force values experienced before the machine reached its max limit of extension.

Since the materials were never stretched to failure, the qualitative results shown in Figures 13 and 15 prove to be the most valuable results. Through these results, it can be assumed that the material will not fail due to tensile forces, thus the stretch durability test passed; however, as seen in Figure 13, extreme permanent damage can be an unfortunate side effect to extreme tensile forces. This measure of permanent deformation is of concern to the overall integrity of the device, as it is ideal for there to be little to no deformation.

6.1.2 Results for Cyclical Testing Strap Material

The purpose of this test was to determine the material's behavior within specified forces over fifty cycles. Force gauge testing was used in order to determine the average max force that the materials would experience in realistic scenarios. After gathering the information from the failure testing procedure of an average max force of about 250 N that the material could withstand, it was important to determine what conditions the straps would be under in a realistic setting. Each trial

consisted of a peer pulling twenty times in twenty seconds on the material that was attached to the force gauge. The data was collected using LoggerPro software and exported into an excel sheet where the data could be analyzed properly. The results from this test can be found in Table 13, as well as the values that were subsequently used for further testing.

Table 13: Results from Force Gauge Testing to determine the max force required for cyclical testing

Material	Reference Name	Average Force from Data	Force Used for Cyclic Testing
European Linen Cotton Blend Fabric	Strap Material	9.624745591 N	**10 N**

To prep for testing, ten strips of the strap material were cut in varying dimensions. Since on the prototype the straps are comprised of a double layer of strap material, all testing for the strap material included two strips to accurately simulate and model the prototype. Additionally, the strips of material were measured before and after testing to determine the deformation experienced due to loading. In each trial, the straps were subjected to fifty cycles going from 0 N-10 N at a rate of 500 mm/min, for a total of five trials. The results from the test can be found below in Table 14. It is important to note that the material tested was unwashed and freshly cut from the cloth prior to testing, the measurements for length and width were taken from the same location along the fabric, and the beginning length of the first trial was unable to be recorded, therefore the length deformation for trial one is neglected.

Table 14: Results of the Cyclical Testing of the Strap Material

Trial	Max Force Experienced by Material (N)	Initial Measurements (mm) Width	Length	Deformation (mm) Width	Length
1	2.59077	*51.6*	---	*0.85*	---
2	5.05832	61.34	288.925	0.35	0
3	0.7144	66.77	290.5125	0.03	0
4	0.86807	64.45	288.925	-0.02	0
5	1.66817	62.62	*225.425*	0.36	3.175
Average	2.78783	63.795	289.4542	0.18	0.79375
STDEV	2.178654338	2.358481	0.916544	0.3475	1.5875
		Percent Strain Width	**0.282153774**	**Percent Strain Length**	**0.274223035**
				Removed with Grubbs Test	

After testing, it was found that there was a percent strain of 0.28% in width and 0.27% in length, which is considered negligible compared to the failure protocol for the validation testing requirements of 5% strain experienced by a material at its expected max loading force. Therefore, the strap cyclical durability test passed. There were several numbers removed from the statistical

analysis by the Grubbs test that allowed for more accurate conclusions of percent strain. The fact that this material was not washed could contribute to the significant deformation experienced explained by the hysteresis of the material. It was through these results that there was an inherent need to test the fatigue properties of this material washed vs. unwashed.

6.1.3 Results for Fatigue Testing Strap Material – Washed vs Unwashed

When prepping for testing, a similar protocol was followed for cutting the strap material into strips and measuring the initial width and length as in the cyclical testing prep. The protocol for Instron testing was based upon 312 cycles of 20% material extension at a rate of 500 mm/min. Having these parameters allowed for a quantitative analysis of the hysteresis of the material, as well as the overall deformation in length and width after the cycles were complete. There was one trial for each variable, washed and unwashed, and the results from each experiment are recorded in Table 15 below.

Table 15: Comparison of Measures for Washed and Unwashed Strap Material

Unwashed Material											
	Max Force (N)	**Percent of Force Depletion (%)**			**Width Extension of Material (mm)**				**Length Extension of Material (mm)**		
First Cycle	23.42399	21.43511844	over 312 cycles	Trial 1	Initial	46.52	FINAL	Trial 1	Initial	285.75	FINAL
Last Cycle	18.40303				Final	45.3	**1.22**		Final	285.75	**0**
Difference	5.02096					**Percent Deformation**	2.622527945			**Percent Deformation**	0
Washed Material											
	Max Force (N)	**Percent of Force Depletion (%)**			**Width Extension of Material (mm)**				**Length Extension of Material (mm)**		
First Cycle	11.27802	2.895011713	over 312 cycles	Trial 1	Initial	74.43	FINAL	Trial 1	Initial	223.8375	FINAL
Last Cycle	10.95152				Final	73.73	**0.7**		Final	223.25	**0.5875**
Difference	0.3265					**Percent Deformation**	0.940480989			**Percent Deformation**	0.262467192

Before analysis, it was important to conduct a two-sample t-test to determine if the results found from the Fatigue Testing are of any statistical relevance. With an established alpha value of 0.05 and beta value of 0.8, the test used the means, standard deviations, and population size for both the unwashed and washed materials. The results from the t-test can be found in Table 16.

Table 16: T-test for Statistical Significance of Fatigue Testing Results

Null Hypothesis: Unwashed = Washed							
Alternative Hypothesis: Unwashed ≠ Washed							
	Mean	**Standard Deviation**	**Population Size**	**Alpha**	**Power**	**Effect Size**	**P-Value**
Unwashed	20.91351	3.550354864	312	0.05	1	3.898	0
Washed	11.11477	0.230870364	312				

As stated in the table above, the null hypothesis was established to be that the results from the unwashed and washed materials were the same, and therefore, there is no statistical evidence to confirm a difference between the two populations. The alternative hypothesis states that there is statistical evidence to support a difference between the results gathered from testing the unwashed and washed materials. After conducting the t-test, the power was found to be 1, indicating that the probability of making the error of concluding that there is no effect when, in fact, there is one, is negligible. The effect size being at 3.898 concludes that the difference is important and of significance. Finally, the P value calculated from this test was found to be 0, and since $0<0.05$, we reject the null hypothesis and state that there are statistical grounds for the differences in results between the unwashed and washed materials during testing.

Some important information to note from the results of this experiment is the significant difference in the delta of max forces from the first to last cycle between the two groups—the unwashed material having a delta of 5 N, whereas the washed material had that of less than 0.5 N. Additionally, there was little to no deformation in the width and length of both the washed and unwashed material, though the width in the washed material deformed less and the length in the unwashed material was found to not have deformed at all. It is also important to note that the max force of the material washed verses unwashed differed by almost 10N; however, the max force of the strap when washed still achieves adequate results by allowing a desired max force of at least 10N before reaching above 20% extension. Both materials showed very little permanent deformation as a result of the experiment. The percentage of the difference between the width deformation of the two materials is about 1.7%, with the washed material showing much less deformation over time. The length deformation was shown to be negligible for the unwashed material and less than 1% for the washed material; however, the recorded measurements for both materials are subjected to human error since there was very little recognizable difference between the initial and final lengths, and the results were based upon the judgement of the researcher. Based on these results, it was concluded that the strap cyclic durability test passed and that the strap fatigue durability test passed in favor of the washed material.

6.1.4 Results for Device Washability Testing

After finishing the washing and drying process, the device was inspected for any visible signs of wear or loss of structural integrity. It was found that two of the small Velcro pieces that were

adhered to the shin straps used became unstuck from the device and re-stuck to a different part of the device. One piece of Velcro was adhered to the strap sewn in green thread and the other was adhered to the strap sewn in blue thread. Figure 16 below depicts how the two small pieces of Velcro became displaced from their original position. This displacement is understandable as the Velcro pieces were only adhered to the strap and not sewn to the strap.

Figure 16: Photo of the Dislodged Velcro Pieces After Washing

In addition to the velcro, inspection of the device proved that a small amount of thread became frayed. Shown in Figure 17, a small section of green thread from one of the shin straps became frayed in addition to a section of blue thread from the other shin strap. Since this was only a small amount of thread, the team concluded that there were no true signs of wear of the device or extreme weakness of the stitching.

Figure 17: Photo of the Frayed Thread After Washing

7. Discussion

The following sections discuss how the project's objectives were tested as well as the extent that they were able to be fulfilled. Our findings from analyzing the results of mechanical testing of the materials are also talked about. Lastly, this section examines the aspects in which the device makes an impact as well as some concerns that had to be taken into consideration during the completion of this project.

7.1 Objectives

The initial objectives of this project were determined based off human testing; however, during the 21-week timeline, the team had conflicts which resulted in a delay with IRB approval. This delay prevented the team from being able to recruit subjects for the study and human testing was not performed. Instead, the team had to resort to mechanical testing. As a result, not all objectives were able to be tested to determine if the device met our goals. These objectives included effectiveness, comfortability, simplicity and customizability of the device. Additionally, safety was also unable to be tested; however, the materials purchased for the device claimed to be antimicrobial. Additionally, although customizability was unable to be tested on humans, the device included straps that were able to adjust to various size lower extremity sizes. The sock portion of the device, however, was not adjustable so two prototypes were created; one to fit a male foot and the other to fit a female foot. In other words, one size of the device would not fit all, and various sizes may need to be created for different foot or calf sizes.

Mechanical testing was performed to test the durability of the materials and determine if washing and drying the device would influence how it functions. Additionally, a washability test was utilized to verify that the stitching was secure and held the materials together. Lastly, affordability was measured by calculating the cost of materials used in the making of the device. The device came out to cost less than $5; however, market price would likely increase three-fold to ensure a profit can be made. Since the market price is comparable to other devices on the market and the device is expected to last a minimum of two years, the team concluded that the device can be considered affordable.

7.2 Testing Findings

Mechanical testing was performed to determine if the materials were durable and met our objectives. During failure testing, no ripping in the materials were observed, but they did show signs of deformation. Specifically, the unwashed sock and strap materials became elongated, and the width decreased from its original width. This indicated that the materials may not be as effective if stretched to a large extent by the user.

Fatigue testing was used to determine how durable the materials were when stretched to a specific percent of extension several times. This testing was performed to mimic the force that may be applied to each material over a period of time by a user of the device. Results of the strap material showed that there was nearly a 5 Newton difference between the first and last trial when the material was left unwashed. On the other hand, washed strap material showed a 0.3 Newton difference between the first and last trial. Although this material did not experience significant deformation, it showed to have a lot of hysteresis. Additionally, during cyclical testing, the material experienced significant deformation which could be explained by the hysteresis of the material shown by these numbers. Since deformation or hysteresis of a material can greatly affect its function and, therefore, cannot guarantee its effectiveness, washing the materials before manufacturing the device or releasing it to the market may be required.

7.3 Project Considerations and Impact

7.3.1 Economics

The device is predicted to cost less than other similar devices, such as calf braces, that are currently on the market. The product is affordable to manufacture, making it a cost-effective choice for users. Additionally, since the device can be worn multiple times, it will be more cost effective than athletic tape. In comparison to other similar products, the device will function more effectively and will be easier to produce due to the minimal amount of labor and machines needed.

7.3.2 Environmental Impact

Since the only manufacturing machine needed to produce this device is a sewing machine, emissions and gas will not have any negative environmental impact. Though a sewing machine uses electricity, the amount of Watts needed to power a sewing machine to produce a single device is not high enough to create a concern. Although the manufacturing process of the device is not

harmful to the environment, the manufacturing of the sock material that is used to fabricate the device may have some negative environmental impacts. The sock material is made of polyester which requires a lot of energy to be used for production. Additionally, the fabric requires chemicals known as carcinogens to also be used during production [36]. The device is also made of strap material which is made of cotton and linen [37]. Since the device is meant to be worn several times and not disposed of quickly, the team can assume that the device will have minimal harmful environmental impacts.

7.3.3 Societal Influence

MTSS is a common injury among individuals and can often lead to more serious conditions which can disable and greatly affect one's quality of life. The fabrication of a device that could alleviate the symptoms of MTSS may help prevent the worsening of the condition. Additionally, the decrease of these symptoms can improve one's quality of life, allowing people to get back to exercise and doing what they love. This device will especially have a societal influence compared to other products since there are currently no successful devices on the market targeted to alleviate the symptoms of MTSS.

7.3.4 Political Ramifications

There are no known political ramifications of this product. In order to decrease manufacturing costs, the product may be produced outside of the United States which could potentially lead to political ramifications. However, the team projects that the manufacturing costs are low enough to be produced in the United States and, therefore, avoid any potential political ramifications.

7.3.5 Ethical Concern

Since the device was not tested on humans, there were no ethical concerns in the design and testing of the device. Typically, devices intended for human use should be tested on humans at some point in the design and testing phase to give rise to any concerns or to identify any issues. Though the team intended to test the device on humans, the protocol in Appendix B was not carried out due to complications in communication with the IRB. This is something to certainly consider moving forward if the team was to mass produce the device as human testing needs to be done appropriately and ethically to address any potential concerns.

7.3.6 Health and Safety

The overall goal of this device was to provide users with a means of treating and rehabilitating their MTSS symptoms. In using this device, the user would improve their MTSS symptoms, their health, and ultimately have a better quality of life. The user would be able to perform activities that used to cause pain, with the assurance that the device would not cause other medical complications or harm them in anyway. The device is a safe, effective means for those affected by MTSS to live a healthy life.

7.3.7 Manufacturability

This device could be easily replicated and manufactured. The prototype was sewn by hand, but with an industrial sewing machine, many products could be produced quickly. The team used the cheapest, most durable fabric to make the prototype and would expect that the same materials would be used for mass manufacturing of the device. Due to the variety of different foot and ankle sizes of both men and women, the team would predict that multiple different sizes and shapes would need to be made to accommodate anyone who would wear the device. This has the potential to make manufacturing prices rise due to the added need of devices, but the benefit of having a device for every person far outweighs the cost of producing different sizes.

7.3.8 Sustainability

The team does not foresee the production of the device itself greatly affecting biology or ecology in terms of renewable energy. As mentioned above, one of the materials used for the device is made of polyester which uses a great deal of energy to be produced. This material could potentially be sourced from a manufacturer that has clean manufacturing methods and strives to be sustainable. The team would aspire to make the manufacturing process as green and as sustainable as possible by cutting waste and using renewable energy to power the sewing machines. The device would be packaged in some sort of plastic packaging and to be more sustainable, this plastic packaging could be made from recycled plastic and can be recycled again after the user removes the device.

8.0 Conclusions and Recommendations

Conclusions

The goal of this 21-week project was to research, design, and fabricate a device to aid in the rehabilitation of MTSS for the general consumer population. The most efficient means of alleviating the symptoms of this condition is by use of athletic tape to strategically pull the muscles of the leg. This puts the average patient of MTSS, such as a hobby runner, at a disadvantage because they would not have the access to a professional trainer to tape them to relieve symptoms. Thus, this project attempted to give the injured individual a way to rehabilitate their symptoms with a device that is comparable in benefits to professionally applied athletic tape.

In order to test the device, several methods to test the mechanical properties of the materials were performed. The team was able to conclude that the materials selected were high quality materials and could certainly be used in a mass-produced device. They also performed a washability test as the device would be used for highly active individuals and the ability to wash the device is incredibly important.

Though the team was not able to accomplish everything that they initially planned to do, the work that they did complete was surely valuable and worthwhile. The team was able to develop a final deliverable that they were proud of and has the potential to make it to the market for consumer use. The final device was a novel design that mimicked professionally applied athletic tape by incorporating adjustable straps both on the shin and on the arch of the foot. Due to the time and WPI IRB constraints, the team was not able to perform their human study. As a result of this, they were not able to measure some of the key objectives. The recommendations section of this chapter goes into more detail of the issues that the team faced, and proposals of how future work can be done on this project.

Recommendations

Due to the lack of time, finances, and equipment, some objectives of this project were left incomplete. Though the team was able to deliver a final prototype for the rehabilitation of MTSS, they were also able to identify some recommendations for further success of the project.

First, the team was on an abbreviated schedule of 21 weeks and though the project was meticulously planned, aspects of the study were left incomplete. Second, the team was not able to perform their study on human subjects. This study would have been used to determine the comfort and efficiency of the device. As a result, the team was not able to analyze three of the objectives: safety, effectiveness, and comfort. The main reason that the team was not able to perform this study was due to the amount of time that the study protocol was in the approval process by the WPI IRB. The protocol ended up being approved, but it was too late to hold the study. Though the team had planned to perform both the human study and mechanical testing, the mechanical testing of the device material was the only true form of testing that the team was able to accomplish. This could have had a great impact on the results and conclusions drawn. Third, the device was originally going to be sewn on a sewing machine. The team had issues with the machine and had to resort to hand stitching. The hand stitching was of good quality, but a sewing machine could have produced stronger, more consistent stitches. Lastly, complications arose since there was no direct client for collaboration throughout the entirety of the project. Because of this, the team had to rely on research and assumptions. It would have been very beneficial to have someone who was diagnosed with MTSS to consult with when it came to design choices and specifications.

Though there were hardships, the team was able to adjust and plan accordingly, making this a very successful project and providing a strong framework for future work.

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Appendix Content

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Appendix A: Interview with Shannah Dalton

Interview with Shannah Dalton, WPI Associate Head Athletic Trainer
9/25/19 @ 12:00pm

Interviewer: Do we have your permission to record you?
Shannah: Yes.

Interviewer: We are creating a device that is going to have the same rehabilitative benefits of athletic taping. Right now, there is no device for MTSS that you can buy on the market besides compression sleeves and ACE bandages, but they don't really work as well as taping. The problem with this is that not everyone knows how to tape themselves or has access to an athletic trainer that can tape them. What we want to do is create a device that normal consumers can buy.
Shannah: Cool!

Interviewer: We want to use the concept of a compression sleeve in that our device would be simple to put on and have the same support that the athletic tape provides to the muscles. Someone can buy KT tape on their own but unless someone is able to show them how to do it, it doesn't work as well. So that is our plan for this term and our hope for next term is to come up with something that we can actually test.
Shannah: Got it, makes sense.

Interviewer: So Tiffiny Butler is our advisor and she was an athletic trainer before she became a professor, and she had mentioned that there is a book to ensure that you meet certain standards for taping.
Shannah: Yes, there is a taping book. I don't believe I have it here, but there is a standard taping book that I can try to look up for you guys. It's at my house, so if you do want the book, I can try to find it.

Interviewer: Yeah, or even if you let us know the name of it, I'm sure we can find it online somewhere.
Shannah: I'm sure it has changed, I wish it was as simple as Athletic Trainer Taping 101, but I'll look on amazon.

Interviewer: Awesome, that way we can use it as a source.
Shannah: Exactly, we all use the same one. Here it is, Athletic Taping and Bracing. It is about $50, so I can look for it at home. I have all my books in storage somewhere. I can try to get that to you soon and I'm pretty sure it's the same one.

Interviewer: One thing we need to come up with is some metrics to determine if our device is actually working. How do you know that you're taping the correct way and that the part of the body is supported adequately?

Shannah: So, taping is pretty universal, so think of it as "most fit everyone." The idea of the arch tape is that it's on the arch so it's very focused on the foot. You go from the base of the toes and do an under-wrap all the way down the foot and go around the ankle a bit. The supporting tape itself goes right on the bottom. You do an anchor tape and do what's called a teardrop or a low-die arch tape. It's named after a teardrop because it resembles a tear-drop. As much as things are universal, athletic trainers do have different names for different things. So, then the actual structural part of it is the tear-drop part that is done afterwards. You do multiple layers of that and each piece of tape you apply if half overlapping the previous one. Then at the end, you push up against the arch with a different size tape. Again, you use multiple layers and half overlapping each time. This is to support the arch, so nothing really goes around the ankle besides a bit on the heel and nothing on the toes, so it's just tape from the base of the toes back to the heel and all the arch space is covered with tape.

Interviewer: So, there is less tape applied to the actual shin area?
Shannah: Correct. It depends which type of taping job you want to do. You can do an arch tape or a shin tape which is the most basic. It's a simple compression wrap over the shin followed by tape in an "X" pattern over the shin wrap. It really depends on the individual and what they prefer.

Interviewer: So, the scope of our project is specifically people that experience Medial Tibial Stress Syndrome as opposed to "shin splints", so we really want to narrow in on MTSS. MTSS seems to have a lot to do with the bigger muscles behind the calf and near the Achilles tendon and that is where a lot of the pain comes from, so would the taping be different?
Shannah: Yes. So, if they are having symptoms more aligned with MTSS, you would try more for the arch tape job. The reason being is that if you use the shin tape job, then you are adding compression to an already tight area and muscle so all that compression can irritate it even more. So, it is hard because you don't always know where the pain is coming from. So people with tight calves don't want that added compression on their calves. The socks disperse it a lot better than the tape does as the tape is more specific and isolated. The compression sleeves are nice because they go over the whole thing whereas tape is a lot of compression on one spot and that can sometimes be too much for people. When people don't like that, that's when we use the arch tape job because arch support can be an issue if they have low arches which can cause a lot of stress and pain on the shin as well. We use those two tape jobs to see where their pain source is coming from and which method would benefit them the most. Were you thinking that there were two different tape jobs when you first came in?

Interviewer: No, but it's really interesting! We envisioned coming up with something that focuses on the shins because that's where the tape usually is when you see people with shin splint taping. Now, I'm thinking of something that resembles a sock with straps on the shins.
Shannah: In the past few years, the arch tape has shown to be more popular because it really takes the pressure off and they don't have additional pressure on their calves.

Interviewer: Yeah, and that's the problem with compression sleeves because people will think "Oh I have shin splints, I'll go down to CVS and buy a compression sleeve" and if what they have is something like MTSS, it's not helping them, it's just more painful.
Shannah: Exactly, and a lot of the times with a syndrome like MTSS, you have to find what's best for you. Some people like the compression sleeve, some people like the tape, some like KT tape, some like arch support tape. So, if you guys did something with a compression on the shin but also gives that arch support, then you would be putting those two tape jobs together.

Interviewer: Do you think having those two combined tape jobs into one would be dangerous or too much?
Shannah: No, I don't think so. Sometimes we do create a loop that goes from the arch straight into a shin tape job. So, sometimes we do put the two together for people who experience symptoms so badly. You just don't want to have something so tight on top if you have arch support as well, but, like with many devices you could have multiple grades. One could be focused more towards compression, one that has arch and compression, and one that has heavy arch and compression. The hard part with MTSS is that people are very individual, and treatment depends a lot on their preferences.

Interviewer: Right, which makes it hard for people like Mr. Johnson down the street who likes to go for runs who doesn't have an athletic trainer who can advise him to try certain devices.
Shannah: Right. There is no negative benefit of adding it, you could say. For example, if you had two things combined, it's not a negative, it's either going to help someone or it's not.

Interviewer: If someone chose to use a compression sleeve, would that just help with the pain or would it actually help heal MTSS too?
Shannah: A lot of times with MTSS, the tight muscles pull the fascia from the bone. So if you have something like a compression sleeve that keeps everything close together, then you're decreasing the stress of pulling the fascia off the bone. So, it is a benefit because it keeps it together. With anything that heals, such as a cut or something, if the two parts that need to be healed are too far apart, then they're not going to heal. So, if you have the parts that are stressed closer together, that's going to help it heal better and faster. With compression socks, people tend to feel better but how many people that start them, take them off? Or do they just keep using them and keep running with them because it makes it feel better? So, I don't know if it would fully heal it, or if it's more just "it makes it feel better temporarily so I'm going to keep using it."

Interviewer: How does taping the arch help heal MTSS?
Shannah: It wouldn't. It's just pain relief. MTSS healing is tough because once it starts, it requires a lot of rest and adjusting to different things such as cross-training. Most tape jobs really provide that healing relief. It's more of a temporary option for the time being.

Interviewer: So, if someone was in off-season and just experienced something like MTSS and were trying to rehabilitate to be able to get back into full health, what would you be doing to help them with that? Would it be doing exercises while they're taped?
Shannah: It's a lot of rest and then gradually working back into it. A lot of strengthening stuff can irritate the muscles that get too tight from MTSS, so if you do too many calf exercises, you're going to bother the injury. So, the rehab would be more focused on making sure that the hip, back, knees are all aligned, and that the musculature is balanced. So rather than looking directly at the shins, you zoom out and look at the bigger picture and make sure that everything is in line and balanced, the musculature is the same on each side, the gait is evenly distributed, etc.

Interviewer: What materials are typical athletic braces made of?
Shannah: Nylon, neoprene, synthetic stuff. Mostly stuff that can absorb sweat and wick it because if the material doesn't, then it won't be supportive. So, definitely something that can absorb sweat and wick it out. Neoprene sleeves are a bit thicker and slide up and stay up due to friction. Ankle braces and other things with the feet tend to be nylon-based.

Interviewer: Is there any brace company that you recommend in general?
Shannah: For MTSS, there isn't really any big brace company or anything like that. ASO's are ankle braces that are most often used. There are also DonJoy and Mueller and those three make up the most common, big name ones.

Appendix B: Survey for Testing

Rehabilitative Device for Medial Tibial Stress Syndrome Survey

The purpose of this survey is to quantify the efficiency of medial tibial stress syndrome rehabilitative device designed as part of a Major Qualifying Project by Sandra Duarte (BME), Madison Stahl (BME), Carly Whittle (BME) advised by Prof. Tiffiny Butler PhD ATC. You will be asked a series of questions and asked to complete a set of exercises, including walking ⅛ mile, running ⅛ mile and 10 jumps, over the course of two days.

1. What is your age? _____

2. What is your sex?

☐ Female ☐ Male ☐ Other _____

3. What sport do you play? _____

3. On average, how many hours do you exercise per week?

☐ 0-3 hours ☐ 4-6 hours ☐ 7-10 hours ☐ 11+ hours

4. How many days per week do you typically exercise?

☐ 0 days ☐ 1-2 days ☐ 3-4 days ☐ 5-7 days

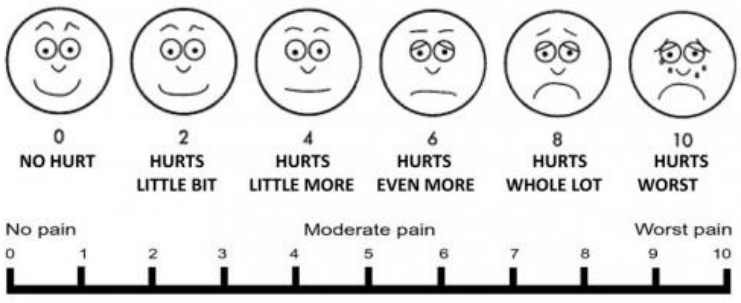
5. What types of exercises do you do?

_____

_____

_____

4. Please refer to the scale below for the following questions:



The following image as sourced from https://www.ortho-neurocenter.com/pain-scale

4a. Based on the pain rating scale, what is your pain <u>before</u> applying the device?

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

4b. Based on the pain rating scale, what is your pain <u>after</u> applying the device?
☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

4c. Based on the pain rating scale, what is your pain <u>after</u> applying the device and <u>after completing the exercises</u>?
☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

5. After a rest period while still wearing the brace, are you experiencing any pain?
☐ Yes ☐ No

6. Are you experiencing any pain after taking the brace off? ☐ Yes ☐ No

---

To be filled out by the researchers

Test Conductor Name: _____

1. Before applying the device: ☐Circulation ☐Feeling ☐Motor
2. After applying the device: ☐Circulation ☐Feeling ☐Motor
3. Comments:

_____
_____
_____
_____
_____
_____
_____

Appendix C: Sample Email for Study Participants

Hello!

We are a group of three students, Sandra Duarte (BME), Madison Stahl (BME), and Carly Whittle (BME), working on an MQP under Prof. Tiffiny Butler PhD, ATC for the design and fabrication of a rehabilitative device for Medial Tibial Stress Syndrome (MTSS), more commonly known as shin splints. As part of our project, we have created a device that incorporates the athletic tape technology for the treatment and rehabilitation of MTSS that regular consumers can use without the need for taping knowledge or access to an athletic trainer.

We are looking for volunteers to participate in a study to quantify the efficiency of our device. In order to participate, we ask that you are currently experiencing MTSS and are available to meet with us for 30 minutes for 2 days. We are conducting this to test and gain feedback on our device for our MQP and to see if users with the diagnosis of Medial Tibial Stress Syndrome will benefit from our device. We are not providing treatment or diagnosis. To complete the study, you will be asked a series of questions related to your injury and pain level. Then, you will be asked to complete a set of exercises including walking ⅛ mile, running ⅛ mile, and jumping 10 times. On the first day, you will not wear the device, and on the second day, you will wear the device. After the physical test on each day, we will ask you questions about your experience. If you are interested in participating in our study, please email **gr-mtssmqp@wpi.edu** and we will send you the sign-up sheet to determine which times you are able to participate. Thank you for your consideration!

Sincerely,

The MTSS Team

Sandra Duarte, Madison Stahl, Carly Whittle

Appendix D: Consent Form for Study

Informed Consent Agreement for Participation in a Research Study for All Participants

Investigators: Sandra Duarte, Madison Stahl, Carly Whittle

Contact Information: gr-MTSSMQP@wpi.edu

Title of Research Study: The Design and Fabrication of a Rehabilitative Device for Medial Tibial Stress Syndrome

Sponsor: Worcester Polytechnic Institute Department of Biomedical Engineering

Introduction:
You are being asked to participate in a research study. Before you agree to this, however, you must be fully informed about the purpose of the study, the procedures to be followed, and any benefits, risks or discomfort that you may experience as a result of their participation. This form presents information about the study so that you may make a fully informed decision regarding your participation.

Purpose of the study: We are a group of senior biomedical engineering students here at Worcester Polytechnic Institute (WPI). We are conducting this to test and gain feedback on our device for our MQP and to see if users with the diagnosis of Medial Tibial Stress Syndrome will benefit from our device. We are not providing treatment or diagnosis. There are few orthotic devices on the market today that aid in the rehabilitation of active individuals with Medial Tibial Stress Syndrome (MTSS); however, those on the market have not been effective in reducing the symptoms of MTSS or have required professional advisement and application. The most effective products available utilize therapeutic athletic tape to strategically pull the tibialis posterior muscles, creating a sling that allows for the user to resume regular activity whilst protecting the injured muscle. We have created a device that incorporates the athletic tape technology for the treatment and rehabilitation of MTSS that regular consumers can use without the need for taping knowledge or access to an athletic trainer.

Procedures to be followed: We have selected you for testing because you identified as someone with MTSS. We will use your feedback to continue to improve our design. Again, we are not providing treatment or diagnosis. We are only asking for your feedback on this device. This test will take place in a public setting in the WPI Recreation Center. The test will be given over a two-day period. On one day, there will be an exchange of basic information, a physical exercise test without the device, and a question and answer period. One the second day, there will be the same physical exercise test with the device, and a question and answer period. The two days will be similar in activity for consistency purposes. For example, we want to avoid having test one on an off-day and test two on a day with a demanding practice. The physical tests will include a walking lap and a running lap around the WPI Recreation Center Indoor Track, followed by jumping in place ten times. If you are comfortable, one of the researchers will examine your circulation, feeling, and motor ability after the test. This examination will be done by touching your foot and lower leg. We ask that you give honest and thoughtful answers to our questions. There are no right or wrong answers. An outlined step by step procedure is shown below.

1.) Day One: You will complete the physical test without the device consisting of walking a lap around the indoor track (1/8th mile), running a lap around the indoor track (1/8th mile), and jumping in place 10 times (5 minutes).
2.) The researcher will ask you some follow-up questions about your experience guided by the survey (3 minutes)
3.) You along with the researchers will then arrange a day and time for Day 2, where the previous steps will be repeated, with the exception that the device will be worn for the entire physical exam.

Risks to study participants: If you are uncomfortable with a question, you do not need to answer it. If you are comfortable, we will take notes as you perform the test. The physical tests require no more than what you would normally do in your sport, but you may stop the test for any reason at any point with no penalty.

Benefits to research participants and others: There are no immediate benefits to the participant. However, this testing will help us understand what improvements need to be made to our device. Our goal is to create a device that incorporates the athletic tape technology for the treatment and rehabilitation of MTSS that regular consumers can use without the need for taping knowledge or access to an athletic trainer. Our primary objectives for the device include being effective, affordable, and safe. Our secondary objectives are for the device to be comfortable, washable, simple, and customizable.

Record keeping and confidentiality: The paper copies of our collected data will be scanned and uploaded into Microsoft OneDrive. Only the researchers will have access to this information and the researchers will need to login with their WPI credentials to access the information. Once all of the paper copies are uploaded, the paper copies will be kept in a locked cabinet in Professor Tiffiny Butler's office at the Oasis House. This information is very valuable to us, and we will also respect your privacy. We will not record your name, however, we will record your age and sex. This means that the age will be connected to your response, but you will not be identifiable. "Records of your participation in this study will be held confidential so far as permitted by law. However, the study investigators, the sponsor or its designee and, under certain circumstances, the Worcester Polytechnic Institute Institutional Review Board (WPI IRB) will be able to inspect and have access to confidential data that identify you by name. Any publication or presentation of the data will not identify you."

Compensation or treatment in the event of injury: This research does not involve more than minimal risk of injury or harm. You do not give up any of your legal rights by signing this statement.

For more information about this research or about the rights of research participants, or in case of research-related injury, contact: gr_MTSSMQP@wpi.edu. The contact information for the IRB Manager; Ruth McKeogh, Tel. 508 8316699, Email: irb@wpi.edu; and Human Protection Administrator; Gabriel Johnson, Tel. 508-831-4989, Email: gjohnson@wpi.edu.

Your participation in this research is voluntary: Your refusal to participate will not result in any penalty. You may decide to stop participating in the research at any time without penalty or loss of benefits. The project researchers retain the right to cancel or postpone the experimental procedures at any time they see fit.

By signing below, you acknowledge that you have been informed about and consent to being a participant in the study described above. Make sure that your questions are answered to your satisfaction before signing. You are entitled to retain a copy of this consent agreement.

_____ Date: _____

Study Participant Signature

_____

Study Participant Name (Please print)

Appendix E: IRB Approval for Study

WORCESTER POLYTECHNIC INSTITUTE

100 INSTITUTE ROAD, WORCESTER MA 01609 USA

Institutional Review Board
FWA #00015024 - HHS #00007374

Notification of IRB Approval

Date :	29-Jan-2020
PI:	Butler, Tiffiny A
Protocol Number:	IRB-20-0224
Protocol Title:	The Design and Fabrication of a Rehabilitative Device for Medial Tibial Stress Syndrome
Approved Study Personnel:	Stahl, Madison~Duarte, Sandra~Whittle, Carly~Butler, Tiffiny A~
Start Date:	29-Jan-2020
Expiration Date:	28-Jan-2021
Review Type:	
Review Method:	Expedited Review
Risk Level:	Minimal Risk
Sponsor*:	

The WPI Institutional Review Board (IRB) approves the above-referenced research activity, having conducted a review according to the Code of Federal Regulations (45 CFR 46).

This approval is valid through 28-Jan-2021 unless terminated sooner (in writing) by yourself or the WPI IRB. Research activities involving human subjects may not continue past the expiration date listed above, unless you have applied for and received a renewal from this IRB.

We remind you to only use the stamped, approved consent form, and to give a copy of the signed consent form to each of your subjects. You are also required to store the signed consent forms in a secure location and retain them for a period of at least three years following the conclusion of your study. You are encouraged to use the InfoEd system for the storage of your consent forms.

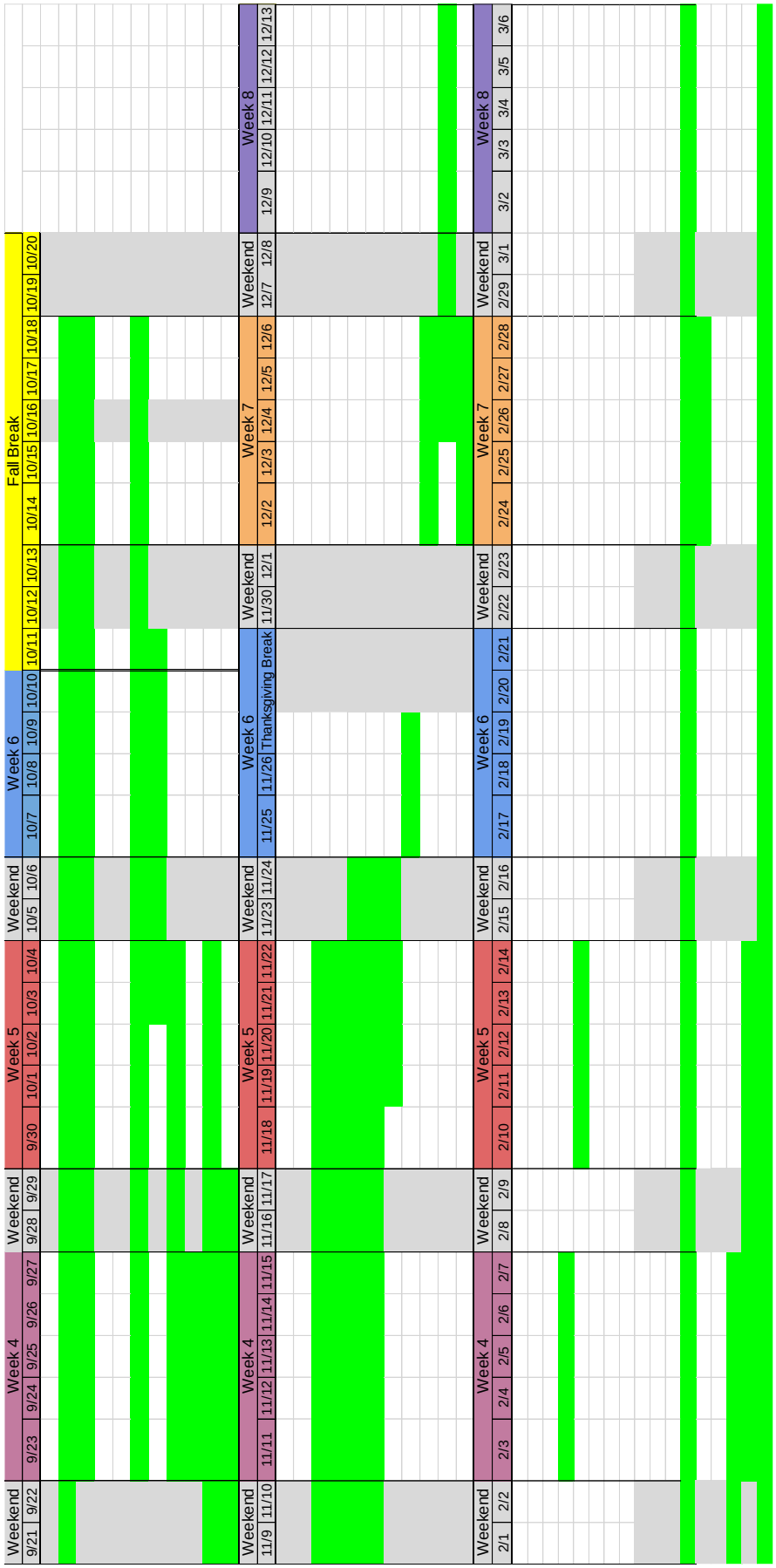
Amendments or changes to the research must be submitted to the WPI IRB for review and approval before such changes are put into practice.

Investigators must immediately report to the IRB any adverse events or unanticipated problems involving risk to human participants.

Please contact the IRB at irb@wpi.edu if you have any questions.

*if blank, the IRB has not reviewed any funding proposal for this protocol

Appendix F: Gantt Chart



			Week 1					Weekend		Week 2					Weekend		Week 3				
Phase	Task No.	Task	09/02	09/03	09/04	09/05	09/06	09/07	09/08	9/9	9/10	9/11	9/12	9/13	9/14	9/15	9/16	9/17	9/18	9/19	9/20
A Term	1	Introduction																			
	2	Literature Review																			
	3	Project Strategy																			
	4	Client Statement																			
	5	Objectives & Constraints																			
	6	Project Approach																			
	7	Create Survey and Submit IRB																			
	8	Alternative Designs																			
	9	Needs Analysis																			
	10	Functions																			
	11	Conceptual Designs																			
			Week 1					Weekend		Week 2					Weekend		Week 3				
Phase	Task No.	Task	xxxxxx	10/22	10/23	10/24	10/25	10/26	10/27	10/28	10/29	10/30	10/31	11/1	11/2	11/3	11/4	11/5	11/6	11/7	11/8
B Term	1	Incorporate Feedback to Report from A-term																			
	4	Prototyping Brainstorm																			
	5	Prototyping																			
	6	Improvements																			
	7	Feasibility Study/Experiments																			
	8	Preliminary Data																			
	9	Complete the Description of Experimental Methods																			
	10	Complete the Results																			
	11	Final Design																			
	12	Test Final Design																			
	13	Complete 1st Draft of Entire Report																			
			Week 1					Weekend		Week 2					Weekend		Week 3				
Phase	Task No.	Task	xxxxxxx	xxxx	1/15	1/16	1/17	1/18	1/19	1/20	1/21	1/22	1/23	1/24	1/25	1/26	1/27	1/28	1/29	1/30	1/31
C Term		Complete final design validation (5)																			
		Complete final design verification (6)																			
		Complete project considerations and impact (part of 7)																			
		Complete discussion (7)																			
		Complete conclusions and recommendations (8)																			
		Incorporate B-term feedback																			
		Set up meeting times																			
		Create the BlueHill Methods for Instron Testing																			
		Complete Instron Testing																			
		Edit and Complete the Solidworks File for Foot Mannequin																			
		Video for how we would have tested on people																			
		Complete the Introduction																			
		Complete the Abstract																			
		Complete the Acknowledgements																			
		Other testing (washability, etc.)																			
		Meet with Shannah for Follow-up Meeting																			
		Format and complete final presentation																			
		Practice final presentation (Wed March 4th @ 5pm in SL105)																			
		Edit report for consistency																			
		Last Edits, Final Submittal, eCDR Submittal																			