Construction of a Post-Injury Medicated Ankle Brace

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A Major Qualifying Project Report Submitted to the Faculty of Worcester Polytechnic Institute in partial fulfillment of the requirements for the Degree of Bachelor Science

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LIST OF ABBREVIATIONS

ASTM -	American Society for Testing Material
ATFL -	Anterior Talofibular Ligament
CAD -	Computer Aided Design
CAI -	Chronic Ankle Instability
CFL -	Calaneofibular Ligament
CI -	Confidence Interval
CIR -	Cosmetic Ingredient Review
CS -	Collegiate School
DDP -	Drug Delivery Patch
DDR -	Drug Delivery Reservoir
DDS -	Drug Delivery System
ECM -	Extracellular Matric
ED -	Emergency Department
FAI -	Functional Ankle Instability
Frescolat MGA -	Frescolat Laevo-Methone Glycerin Acetal
Frescolat ML -	Frescolat Laevo-Methyl Lactate
HS -	High School
MAI -	Mechanical Ankle Instability
MQP -	Major Qualifying Project
NSAIDs -	Non-Steroidal Anti-Inflammatory Drugs
OTC -	Over the Counter
PDMS -	Polydimethylsiloxane
PLA -	Polylactic Acid
PMD38 -	Trans p-methane-3,8 Diols
POC -	Proof of Concept
PTFL -	Posterior Talofibular Ligament
RICE -	Rest, Ice, Compression, Elevate
ROM -	Range of Motion
ST Joint -	Subtalar Joint
TDDS -	Transdermal Drug Delivery System
WS-3 -	Wilkinson - Sword
3D -	Three Dimensional

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ABSTRACT

The intent of this Major Qualifying Project (MQP) was to develop an ankle brace with medicinal properties to promote wound healing by providing a mechanism to deliver pain relief drugs through topical administration while maintaining ankle stability. The ankle joint is one of the most common location of orthopedic injury. Ankle braces currently available in the market target specific stages of rehabilitation. This project seeks to fill in current gaps that exist in the market through the construction of a medicated ankle brace that can be used during the inflammatory and proliferative phases of wound healing. The brace is designed in such a way that allows effective, localized, and specific drug delivery to various sites of the human ankle in addition to a topical drug delivery system as the skin is the largest and one of the most readily available organs of the human body.[1] The constructed medicated ankle brace is a rehabilitation system designed to help individuals stabilize, improve, and overall enhance the healing of the ankle. A computer aided design model of the prototype brace was developed using Solid works, a CAD software. Human test subjects were used to test the constructed medicated ankle brace against an unbraced ankle. Data collection validation testing was achieved through various tests – goniometer test, Polhemous G4™ Wireless Motion Tracker (Colchester, Vermont) ROM test, and the Talar tilt test to quantify the ROM of the ankle with and without the brace. A student's t-test ($p<0.05$) showed a statistically significant reduction in ankle range of motion indicating effective post-injury ankle rehabilitation by increasing ankle stability and an enhanced the wound healing process of the ankle through a regulated drug delivery system (DDS).

1. INTRODUCTION

An ankle sprain is a common and acute injury as a result of a disrupt ligament of the ankle joint. Ankle sprains are reported as a common problem in acute medical care, occurring at a rate of approximately one injury per 10,00 people per day, accounting up to twenty percent of all sports related injuries.[2] Therefore, ankle sprains are most common among athletes and physically active individuals. Recent epidemiology studies revealed that lateral ankle sprains remain a dominant sports injury.[3] Lateral ankle sprains are commonly overlooked with no medical intervention sought by the injured individual. This course of action is problematic as appropriate precautions and management greatly contribute to proper healing and a successful recovery. Without the proper diagnosis, identification of injury, assessment, and intervention plan, the risk of ankle instability and reinjury increases. Risks associated with ankle instability and reinjury will be further discussed in Section 2.5.

Ankle sprains in the foot and ankle can lead to the potential development of ankle instability as time progresses. It is reported that approximately twenty percent of acute ankle sprains develop into chronic ankle instability.[4] Ankle instability is a prevalent condition characterized by recurrent ankle sprains and persistent pain. To combat ankle instability, functional rehabilitation is crucial. Failure to reduce the risk of injury to the ankle tends to result in the development of chronic instability. Ankle sprains often occur due to the combination of inversion, internal rotation, and plantar flexion (will be further discussed in Section 2.2). The excessive motions in these directions can be restricted by braces. Ankle braces are commonly used for treatment and rehabilitation of acute ankle injuries. These braces are also used by individuals with chronic ankle instability to prevent recurrent injuries and reduce ankle sprains in high risk activities. There are a variety of different ankle braces on the market, each equipped with different ways to rehabilitate the ankle. In general, the major function of the ankle braces should be focused on stabilizing against inversion sprains.

The device we designed provides a more ideal wound-healing environment than current ankle braces on the market, while still allowing the user to be relatively mobile. Our design will be ergonomically favorable compared to current devices on the market, because we eliminate the need for the user to unstrap the ankle brace to apply medication and combine the strongest aspects of ankle braces currently on the market.

The purpose of this project was to develop an ankle brace exhibiting optimal mechanical support while expediting the healing process of the injured ankle. Although the market for ankle and foot related injuries cost Americans $3.65 billion a year for medical and psychotherapeutic treatments, there exists a disconnect between the mechanical aspect of healing and the pharmaceutical side.[5] The device designed provides a more ideal wound-healing environment than current ankle braces on the market, while still allowing the user to be relatively mobile. In other words, the design will be ergonomically favorable compared to current devices on the market as it will provide mechanical support with an integrated drug delivery system to reduce inflammation and promote healing.

The sleeve designed creates an ideal compressive environment. Our compressive material is made of neoprene or nylon which is used by ankle braces currently on the market. The reusable ankle sleeve contains removable biomaterials to best deliver the drug. A controlled release drug delivery system will adhere to the skin with a cooling patch. In addition to the reusability of the drug delivery system, the cooling element of the design is also removable and reusable. The cooling element is contained in a compartment of the ankle sleeve and enclosed with magnets.

The three primary objectives of our design are: to provide the mechanical support for optimal healing of the ankle, to have a mechanism to topically deliver drugs to aid with pain and inflammation localized to the ankle region, and to have a cooling agent with a simple delivery system to further alleviate pain and inflammation. In terms of mechanics, ankles in normal static conditions will face rotations from about 7 to 48 degrees of inversion. The device we design will aim to allow movement within this range restrictively as to not impede on function. With increased ankle degree of inversion, the brace will provide more resistance, not allowing movement above 48 degrees. For the drug delivery system, the developed ankle brace permits usage time of at least 8 hours. The rate of drug released is dependent on the drug selected and therefore, the size of the delivery system used. For the cooling element we aim to have a cooling temperature of 5±1.7°C over the course of two hours.[6]

2. LITERATURE REVIEW

2.1 Ankle Anatomy

The ankle is a joint formed by three bones. The three bones are the tibia, fibula, and talus. The point where the three bones meet creates a hinge forming the human ankle. According to the encyclopedia, the human ankle has a deceptively simple construction.[7] Therefore, understanding the ankle's anatomy and forces acting upon the joint are critical to injury prevention.

Classified as one of various synovial joints of the human body, the ankle is formed at the point where the tibia, fibula, and talus meet. The tibia is one of two bones that forms the lower leg of the human body and is commonly known as the shin.[8] The tibia is the larger of two bones that form the lower half of the human leg. The tibia functions as the main weight-bearing bone of the lower leg and is the second largest bone of the body (as shown in Figure 1).[9] Although the tibia plays a critical role in forming the knee joint, this section will focus on its significance and role of the ankle. Located at the lower/inferior end of the tibia is the medial malleolus. This inner projection of the bone forms part of the ankle joint. Located laterally of the tibia is the fibula and the fibular notch, where the tibia connects to the fibula forming the Tibiofibularjoint.

Figure 1: Human Tibia [1]

Conversely, the fibula is characterized as the thin, longer, and lateral bone of the leg located adjacent to the tibia (as shown in Figure 2). Although the fibula is parallel to the tibia, the fibula is smaller in diameter and has distinct roles independent from those of the tibia (displayed in Figure 2). Due to its slender-like structure, the fibula does not bear weight and moves very little relative to the tibia. The fibula forms the proximal Tibiofibularjoint with the lateral side of the tibia. From the proximal Tibiofibularjoint, the fibula extends downward, medially, and anteriorly towards the ankle where it forms the lateral malleolus. At the medial malleolus, the fibula forms the inferior Tibiofibularjoint with the tibial condyle. Additionally, the fibula also forms the Talocrural joint with the tibia and talus.

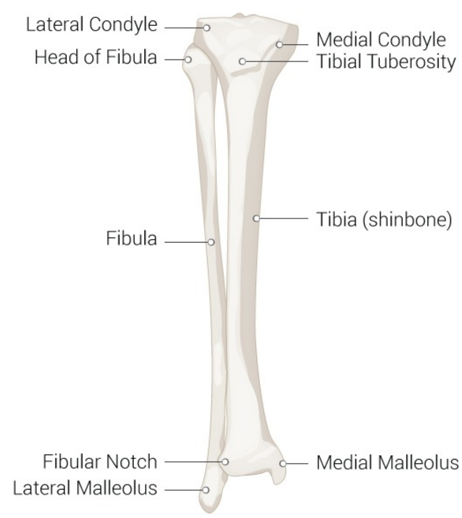

Figure 2: Human Lower Leg (Tibia and Fibula) [2]

The foot is composed of twenty-six bones which are divided into three functional groups/segments: hind foot, mid foot, and forefoot. The hind foot is the posterior segment which is composed of the talus and calcaneus. The posterior half of the human foot is comprised of seven tarsal bones with the talus bone as the most superior (as shown in Figure 3). The mid foot is composed of the navicular, the cuboid, and three cuneiforms (as shown in Figure 3). The forefoot is the anterior segment composed of the metatarsals and the phalanges. There exist three areas of articulation that form the ankle joint. As described by the textbook, Anatomy and Physiology by Rice University, the superomedial surface of the talus bone articulates with the medial malleolus of the tibia, the top of the talus articulates with the distal end of the tibia , and the lateral side of the talus articulates with the lateral malleolus of the fibula.[9] The formed joints significantly contribute to the functions of the ankle. The ankle complex is comprised of three joints: the Talocrural joint, the subtalar joint, and the distal Tibiofibular Syndesmosis.[10]

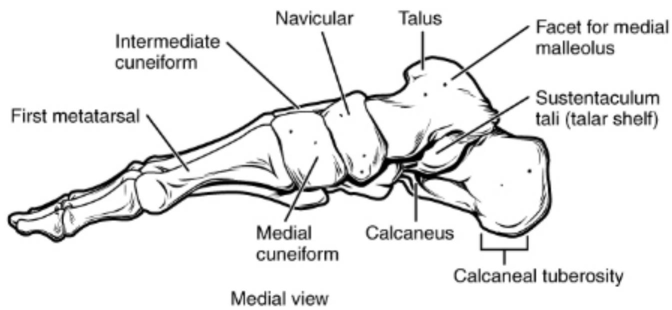

Figure 3: Medial View of the Human Foot [3]

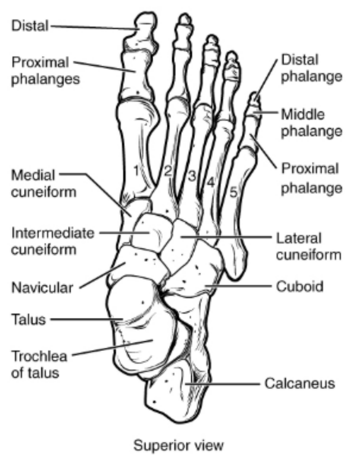

Figure 4: Superior View of Human Foot [4]

2.2 Epidemiology - Ankle Injury

Ankle sprains account for approximately twenty percent of reported sports injuries (previously mentioned in Chapter 1).[2] Among all ankle injuries reported, ankle sprains are the most common and account for eighty percent of which seventy seven percent are lateral sprains due to rupture or tear of the Anterior Talofibular Ligament (ATFL).[11] In a 2009 – 2014 study on ankle injuries in the United States, ankle injury data from three national surveillance datasets were collected – United States emergency department (ED), high school (HS), and collegiate school (CS). The study analyzed patients ages fourteen to twenty-two who participated in twelve sports. The results of the study were determined with a ninety-five percent confidence interval (CI). During the study period, the surveillance systems captured over twenty thousand ankle injuries presenting in the ED, approximately five-thousand five hundred forty-six ankle injuries in HS, and two-thousand seven hundred twenty-five ankle injuries in CS.[11] Additionally, a total of 227 epidemiological studies were conducted from 1977 to 2005 involving seventy sports in thirty-eight countries. The outstanding results of this study were as follows – over thirty-two thousand ankle injuries were reported, of which over eleven thousand were ankle sprains.[12]

Injuries to the lateral ligaments of the ankle joint are experienced by men and women at approximately the same rates.[11] Lateral sprains occur when the rearfoot undergoes excessive supination on an externally rotated lower leg causing inversion of the ankle.[11] Lateral sprains are often acute and therefore, are inadequately treated and thus, frequent recurrence of ankle sprains are resulted. Appropriate management of lateral sprains is critical to a successful recovery. However, it has been reported that approximately fifty percent of those who sustain an ankle sprain fail to seek medical attention. Therefore, they typically rely on conservative forms of treatment and functional rehabilitation failure which ultimately leads to ankle instability, injury recurrence, increased risk of osteoarthritis, and articular damage and degeneration of the ankle.[11]

Ankle injuries are defined when a bone, ligament, or tendon is damaged. The most common injury mechanism for acute ankle injury is a combination of inversion and adduction of the foot in the plantar-fixed position.[11] This form of injury mechanism may cause and result in damage to the lateral ankle ligament. On the lateral side (outside) of the ankle, the joint is stabilized by three smaller ligaments: the anterior talofibular, the calcaneofibular, and the posterior talofibular. Injuries these ligaments account for more than 80% of all ankle injuries.[11] There are two main categories of ankle sprains: acute ankle sprains and chronic ankle instability. Acute ankle sprains are categorized into three grades depending on the severity of the injury. The classification of the injury helps identify and diagnose the level of damage to provide the correct treatment. An ankle injury can be classified on a basis of severity. Ankle sprains are classified from grade I to III (as shown in Figure 5). Ankle injuries categorized as Grade I are low risk with mild damage. Grade I ankle sprains include no loss of function, little to no hemorrhaging, no point tenderness, decreased total ankle motion of ≤5°, and swelling of ≤0.5 cm.[15] An example of grade I ankle sprain include stretching of the ligaments without joint instability and macroscopic ligament rupture. For this grade of sprain, patients have minimal swelling and soreness. A talar tilter test and anterior drawer may be performed by the patient to diagnosis the severity of the injury. Injuries categorized as Grade II are moderate injuries resulting in pain, swelling, bruising, decreased in range of motion, and partial ligament rupture. Functional and mobility limitations are used to further diagnose the severity of injury. Grade II ankle sprains include some loss of function, hemorrhaging, point tenderness, decreased total ankle motion >5° but >10°, and swelling >0.5 cm but <2.0 cm. The positive anterior drawer test (ATFL involvement) and talar tilt test (no CFL involvement) could be performed for a more accurate diagnosis.[15] Grade III injuries are the most severe type of ankle injury which include complete ligament rupture, pain, swelling, bruising, hematoma, and marked pain, resulting in function impairment and severe instability with decreased total ankle motion >10°, and swelling >2.0 cm.[11,15] Inadequate treatment of ankle sprains can lead to chronic problems such as decreased range of motion, pain, and joint instability. Patients with

Grade III ankle injuries cannot walk on the ankle and often require maximum immobilization. In some cases, this grade of injury can require long-term physical therapy in order to correctly heal the joint.[11]

Table I.

Classification of acute ankle sprain according to its grade, severity, pathophysiology and clinical findings

Grade	Severity	Pathophysiology	Clinical findings
Grade 1	Mild	Stretch of the ATFL, causing tear of the ligament fibres.	Mild swelling, no laxity, little ecchymosis, and difficulty in full weight bearing.
Grade 2	Moderate	Moderate injury to the lateral ligamentous complex with a complete tear of the ATFL ± Partial tear of the CFL.	Localised swelling, hemorrhage ecchymosis, and anterolateral tenderness. Abnormal laxity may be mild or absent.
Grade 3	Severe	Complete disruption of the ATFL along with CFL and PTFL.	Tenderness, swelling and ecchymosis on the lateral ankle and heel side with marked laxity.

Figure 5: Classification of Ankle Sprains [6]

2.3 Ankle Pathoanatomical Features of the Human Foot and Ankle

An in-depth understanding of the ankle anatomy is imperative for diagnosis and treatment. This section of the paper aims to highlight key anatomical soft issues that form the ankle joint complex. Anatomically, the ankle consists of three major articulations – Tibiotalar joint, Subtalar joint, and the Distal Syndesmosis (previously mentioned in Section 2.1). These three articulations work cohesively providing hind-foot movement occurring in the sagittal plane, frontal pane, and transverse plane.[11] Further assessment of the anatomy of the ankle reveals its complexity. Ligaments and tendons play critical roles in the human body, particularly the ankle. They are similar in structure with different functions. Both ligaments and tendons are made up of collagen type I molecules that are arranged as fibrils, fiber, fiber bundles, and fascicles.[13] Tendons and ligaments have low cellularity which explains their collagenous nature. Additionally, they both have low vascularity and are nourished by peripheral vessels and exhibit low metabolic activity compared to cartilage and bone. However, because of these traits, tendons and ligament are more tolerable and resistant when high energy forces are transmitted as they can maintain long-standing tension forces.[12] Conversely, due to this challenges and slow injury recovery rates are resulted.

The tendons anchor every muscle within the human body to bone. Therefore, the tendons are responsible for transmitting forces from the muscles to bones and allow for joint movement. The ligaments are responsible for connecting bone to bone in the human body and therefore, are crucial in providing joint stability. The anatomy and functions of the tendons and ligaments of the ankle complex are discussed in the next two paragraphs.

The ankle joint is supported by groups of muscles and tendons. As mentioned above, tendons are low vascularized tissues and have low healing capacity and capability; therefore, management of the tendons is technically demanding.[12] The basic structure of tendons is collagen type I. There are various tendons that make up the ankle – Achilles tendon, Flexor Hallicus Longus, Flexor Digitorum, Peroneal tendons, Posterior tibialis tendon, and the Anterior Tibialis tendon.[14] As described by the Arthritis Foundation, the Achilles tendon attaches the calf muscle to the calcaneus. The Flexor Hallicus Longus runs along the inside of the ankle and attaches to the big toe. The Flexor Digitorum runs along the inside of the ankle and attaches to the other toes. The Peroneal tendons are a set of three tendons that extend along the outside of the ankle and attach at the fifth metatarsal and the bottom of the foot. The Posterior Tibilias tendon attaches at the mid-foot and helps maintains the foot's arch and the Anterior Tibilialis tendon runs down the front of the leg and attaches to the bones of the midfoot.[13] Tendon injuries have become a common clinical problem due to overuse of age-related degeneration.[15] Damage to the Achilles tendon is the most common form of tendon injury. The Achilles tendon has a "false sheath" called the Paratenon: a loose areolar connective tissue composed of collagen fibrils, some elastic fibrils, an inner lining of synovial cells, blood vessels, and nerves. The Paratenon provides vascularization, reduces friction, and permits free tendon movement against surrounding tissues.[14] Injury to the Achilles tendon is referred to as Achilles tendonitis. Several factors next to sport injuries are responsible for tendon injuries. This includes body weight, age, diabetes, obesity, and genetics.

The most common form of ankle injury is termed lateral ankle sprains (further discussed in Chapter 2.2). Therefore, the following lateral ligaments of the Talocrural joint are discussed – Anterior Talofibular Ligament (ATFL), Calaneofibular Ligament (CFL), and the Posterior Talofibular Ligament. The most common mechanism of injury for a lateral ankle sprain is forefoot adduction, hindfoot inversion, and tibial external rotation in plantar flexion.[16] Stabilizers prevent the occurrence of excessive talar rotation and translation. Of these stabilizers are the articular surfaces and the ligamentous support from a joint capsule and several ligaments among which include the Anterior Talofibular Ligament (ATFL), the Posterior Talofibular Ligament (PTFL), the Calaneofibular Ligament (CFL) and the Deltoid ligament.[17] The ATFL, PTFL, and CFL provide support for lateral aspects of the ankle while the deltoid ligament provides medial support.[18] The three ligaments – ATFL, CFL, and PTFL at the lateral aspect – provide support for the Tibiotalar joint, which is a hinge joint that allows dorsiflexion and plantarflexion.[11]

According to Healthline, the Anterior Talofibular Ligament (ATFL) is the weakest and most commonly injured ligament in the ankle.[17] Approximately seventy percent of all lateral ankle sprains involve isolated ATFL injuries.[15] The ATFL originates from the Fibular Malleolus, an area at the end of the fibula (calf bone). It measures approximately two millimeters thick, ten to twelve millimeters wide, and about twenty millimeters in length.[18] As displayed in Figure 6, the ligament connects the talus (ankle) bone to the anterior of the fibula. The ATFL is a lateral ligament consisting of a band of a connective tissue. The ligament is located near the Posterior Talofibular Ligament (dorsolateral of foot). The ligament is approximately forty-five degrees from the frontal plane and extends from the lateral Malleolus (anterior) and medially towards the Talus.[18]According to the article, *Functional Anatomy, Pathomechanics, and Pathophysiology of Lateral Ankle Instability,* in vitro kinematics studies have shown that that the ATFL prevents anterior displacement of the talus and excessive inversion and internal rotation of the Talus on the tibia.[19] Additionally, the strain in the ATFL further increases as the ankle moves from dorsiflexion to plantar flexion. Studies have also revealed that under tensile stress, the ATFL demonstrates lower maximal load and energy as compared with the PTFL, CFL, and Deltoid ligament. The data collected can thus, be used to explain why the ATFL is the most frequently injured of the lateral ligaments.

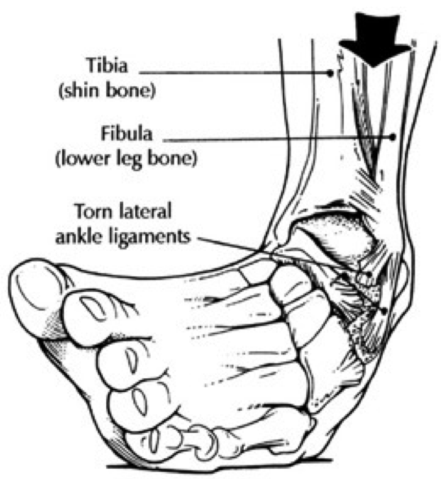

Figure 6: Anterior Talofibular Ligament [5]

The Posterior Talofibular Ligament (PTFL) is the least sprained of the lateral ankle ligaments and usually occur in severe ankle sprains.[18] The PTFL is comprised of the inferior transverse ligament that lies in the deeper portion of the ligament. The PTFL extends from the Lateral Malleolus (posterior) to the posterolateral location of the talus. Its origin is on the posterior border of the fibula extending perpendicular to the longitudinal axis of the tibia, as displayed in Figure 7. The ligament plays a supplementary role in maintaining ankle stability when weight-bearing loads are applied to the foot and ankle. The PTFL has the greatest strain in ankle dorsiflexion and limits the posterior talar displacement in the mortise as well as prevents excessive talar external rotation. It provides restraint to both inversion and internal rotation of the loaded Talocrural joint.[16] The PTFL acts as the secondary defense mechanism of the ankle as the short fibers of the PTFL restrict the internal and external rotation, talar tilt, and dorsiflexion.[18]

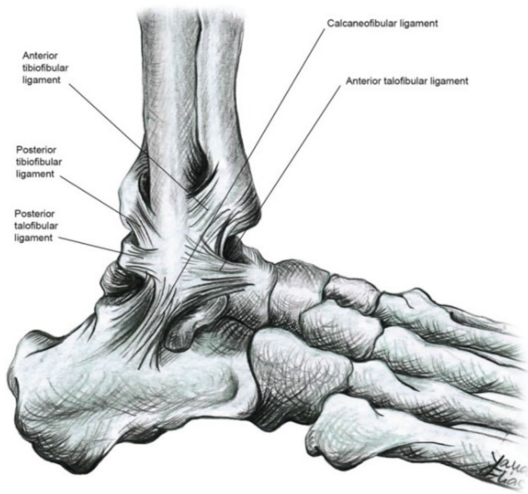

Figure 7: Ligaments of the Ankle [7]

The Calcaneal Fibular ligament (CFL) is the second most often injured of the lateral Talocrural ligaments. Displayed in Figure 7, the CFL extends from the lateral malleolus (posterior and inferior) to the calcaneus (lateral) at an angle of approximately one-hundred thirty-three degrees from the long axis of the fibula. It borders the fibula, approximately nine millimeters to the distal tip, and inserts on the calcaneus thirteen millimeters distal to the subtalar joint.[17] The CFL restricts the excessive supination of the Talocrural and subtalar joints. In vitro kinematic experiments reveal the ligaments crucial role in restricting excessive inversion and internal rotation of the rearfoot and this most stressed when the ankle is dorsiflexed.

Unlike the ATFL, PTFL, and CFL which supports the lateral aspects of the ankle, the Deltoid ligament, also known as the Medial Collateral ligament [MCL], provides medial support.[11] The Deltoid ligament is considered a superficial layer that extends across both the Talocrural and subtalar joints.[11] Displayed in Figure 8, the deltoid ligament is located on the anterior colliculus and extends and inserts into the navicular neck of the talus, Sustenaculum Tali (strongest component, resists calcaneal eversion), and the Posteromedial Talar Tubercle.[16] The deltoid ligament functions as a primary stabilizer of the medial ankle, preventing lateral displacement, external rotation of talus, restraint to valgus tilting of talus, resist eversion of hindfoot, and stabilizes against plantar flexion, external rotation, and pronation.

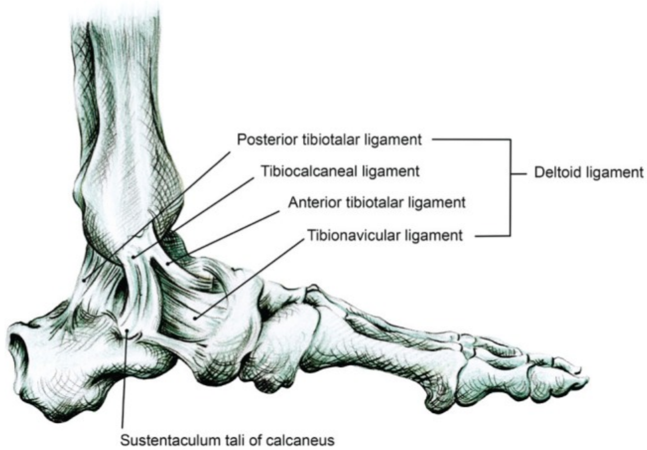

Figure 8: Medial Ligament of the Human Ankle (Deltoid Ligament) [7]

2.4 Biomechanics of the Ankle

As previously mentioned in Section 2.1, three articulations work together to facilitate coordinated movements of the foot – Talocrural joint, the Subtalar joint and the Distal Tibiofibular Syndesmosismosis. The movements of the foot occur in the sagittal-plane motion, the frontal-plane motion, and the transverse-plane motion. The motions of the foot do not simply occur in one specific plane rather, it is the product of coordinated movements of all three joints. The foot experiences coupled motion – pronation and supination.[18] The angulation of the foot and ankle is commonly known as the pronation and supination; where the coupled motions permit the foot to rotate, extend, and move in various directions. Three major contributors to the stability of the ankle joints are the congruity of the articular surfaces, the static ligamentous restraints, and the musculotendinous units.[18] The three components mentioned are crucial to the dynamic stabilization of the joints. There are various functional demands of the ankle. These include dampening of rotations which are imposed by the proximal joints, flexibility, shock distribution and absorbance, and conformation to changes. The human ankle is a complex structure with intricate components that play critical roles in the biomechanics of the ankle. The complexity of the ankle significantly influences the biomechanical performance of the joint. This section of the paper aims to analyze the motions of the ankle joint complex, highlight the critical role of the ligaments to the stability and function of the ankle, and describe movements involved in a normal gait cycle.

The ankle complex is comprised of three primary joints, the lower leg, and the foot. The coordinated motions of the aforementioned components interact in such a way that form kinetic linkages that promote movement of the lower limb. Key movement of the ankle joint complex are plantar-and dorsiflexion, abduction, adduction, and inversion-eversion.[20] The coordinated motions across the subtalar and Talocrural joint allow for the ankle to preform three-dimensional motions called supination and pronation.[19] As seen in Figure 9, the ankle displays hinge-like characteristics as it can move in multiple directions. Movements of the ankle do not occur in one specific plane, but rather across multiple planes.

The motion about the axes cannot occur simultaneously. Therefore, the transition is estimated to occur close to the neutral position of the joint.[19]

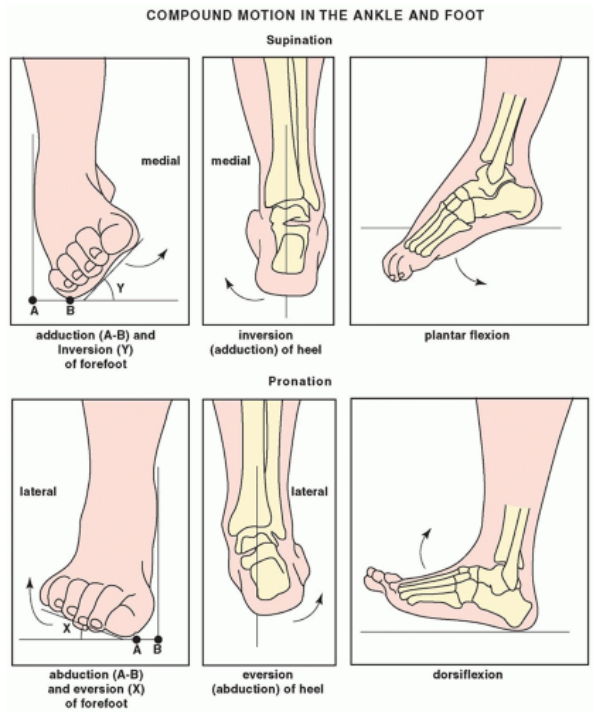

Figure 9: Relative Motions of Ankle Joint Complex [8]

To fully understand the motions of the ankle, it is important to note the planes in which these motions occur about (as shown below in Figure 10). The plantar-and dorsiflexion motions occur in the sagittal plane, the abduction and adduction motions occur primarily in the transverse plane, and the inversion-eversion motions occur in the frontal plane. Supination movements are resulted through the combination of plantarflexion, inversion, and adduction allowing the foot to face medially. Pronation movements are resulted through a combination of dorsiflexion, eversion, and abduction motions allowing the foot to face laterally.[19] The axis of the ankle joint complex in the sagittal plane occurs around the line hat passes through the medial and lateral malleoli (represented as the dotted line below in Figure 11). The frontal plane axis of rotation occurs around the intersecting point between the malleoli and the long axis of the tibia (as shown below in Figure 10). The transverse plane axis of rotation occurs around the long axis of the tibia intersecting the midline of the foot (as shown below in Figure 10).

The primary motions of the ankle occur within the sagittal plane. Common motions in this plane include dorsiflexion and plantar flexion. In other words, ankle flexion and ankle extension. Dorsiflexion is described as movement of the top of the ankle and foot towards the tibia. Conversely, the plantar flexion is movement of the ankle and foot away from the tibia. The normal ankle allows approximately fifteen to twenty degrees of active dorsiflexion and between forty five degrees to fifty five degrees of active plantar flexion.[9] It is also reported about twenty four of sagittal plane motion at the ankle during the stance phase of gait, maximal dorsiflexion is approximately ten degrees during the stance phase of normal running and fourteen degrees for plantar flexion.[21]

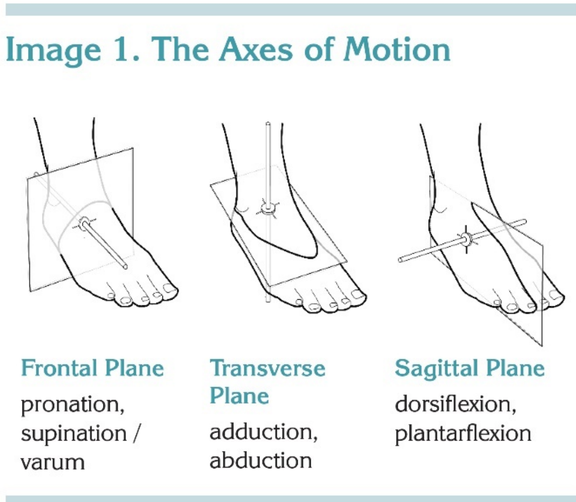

Figure 10: The Axes of Ankle Motion [9]

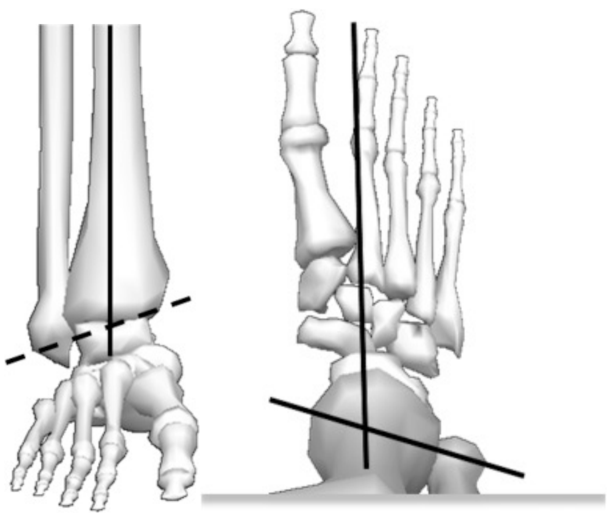

Figure 11: Sagittal Plane & Frontal Plane Axis of Rotation vs. Transverse Axis of Rotation [10]

To understand the mechanisms that permit stability and the motions of the joints that make up the ankle complex, it is crucial to visit the concept of planar and triplanar motion. General principles of planar motion include the concept of joint motion. Assessing the concept of joint motion allows for a greater understanding of planar motion. There exist three cardinal planes in the foot and ankle: frontal, sagittal, and transverse. Generally, joint motion is described by the cardinal plane in which the motion occurs and is typically perpendicular to an axis. An axis between two planes will give rise to a single plane motion in the third plane.[22] To relate this idea to the motions and stability foot and ankle, various examples are given. An axis that lies in the frontal and transverse plane result in plantar flexion and dorsiflexion in the sagittal plane. An axis formed by the sagittal and transverse planes will give rise to the inversion and eversion motions in the frontal plane. An axis formed by the frontal and sagittal plane results in abduction and adduction in the transverse plane.[23]

This section of the report seeks to analyze the biomechanics of the ankle during range of motion and the general principles of the triplanar motion. Triplanar motion occurs around the axis of rotation oblique.[21] The motion can either be referred to as pronation or supination with coupled movements of the talus and calcaneus segments moving together on the navicular and cuboid bones. Triplanar motion at the foot and ankle is described by the component motions from each cardinal plane. The amount of each component motion is determined through the concept of angulation or pitch. Therefore, a triplane axis that is pitched evenly across the three planes result in motion with equal components from each plane. The axis of each joint differs in angulation, also called pitch. Therefore, varying degrees of motions from the cardinal planes are resulted. This is critical because the arches of the foot provide various functions which include force absorption, base of support, and acts as a rigid lever during gait propulsion.[21]

The first joint is the Talocrural joint, also referred to as the tibiotalar joint. The Talocrural joint is formed by joining the dome of the talus, the medial malleolus, the tibial plafond, and the lateral malleolus.[19] The Talocrural joint, also commonly referred to as the Synovial Hinge, connects the tibia and fibula to the proximal end of the talus and is located between the lateral and medial malleolus. The talus moves within the mortise during dorsiflexion and plantarflexion allowing for the ankle to move up-and-down in the vertical direction. Due to its shape, the Talocrural joint permits the forces exerted to be transmitted from the lower leg to the foot, internal and external rotation to pronation and supination. The Talocrural joint has an axis of rotation which passes through the medial (tibia) and lateral malleoli (fibula). The axis is located anterior to the frontal plane in relation to the tibia and posterior to the frontal plane in relation to the fibula.[19] The axis of rotation is approximately thirteen to eighteen degrees laterally from the sagittal plane and at an angle of eight to ten degrees from the transverse plane. The TC joint permits movement of the sagittal plane and thus, is responsible for dorsiflexion and plantarflexion motions of the ankle.

Generally, the movements of the joint occur in the sagittal plane, but small amounts of transverse and frontal plane motion occur about the oblique axis of rotation. Motions of the ankle predominantly occurs at the Talocrural joint which encompasses the movements in the sagittal, plantar, and dorsiflexion planes. The dorsiflexion, plantar flexion, and abduction and adduction components predominate over inversion and eversion motions.[22] Several studies indicate the overall ROM in the sagittal plane is between sixty five to seventy five degrees moving from ten to twenty degrees in the dorsiflexion through forty to fifty five degree of the plantarflexion plane.[19] The total ROM in the frontal plane is approximately thirty five degrees (twenty three degrees inversion and twelve degrees eversion).[19] However, in everyday activities the ROM required in the sagittal plane is reduced, with a maximum of thirty degrees for walking and between thirty seven and fifty six degrees for ascending and descending the stairs.[19]

The subtalar joint, also known as the talocalcaneal joint, is formed by the talus and calcaneus. The axis of rotation of the subtalar joint lied approximately forty-two degrees superiorly to the sagittal plane and about sixteen to twenty three medial to the transverse plane. According to a study conducted in 1989 on the kinematics of the ankle/foot complex, the motion of the subtalar ranges from five to sixty-five degrees.[9] The average ROM for pronation and supination is reported to be five to twenty degrees. The inversion and eversion ROM were identified as thirty degrees and eighteen degrees.[9] The ST joint is the condyloid joint of the ankle, allowing for movement of the transverse plane and limiting movements of sagittal plane. Due to its anatomy and structure, the ST joint allows for the inversion and eversion and flexion and extension motions of the ankle.

The Tibiofibular Syndesmosis limits motion between the tibia and fibula. Its function is to maintain stability between the bone ends. The Syndesmosis is composed of three parts – the anterior Tibiofibular ligament, the posterior Tibiofibular ligament and the interosseous Tibiofibular joint. The Syndesmosis permits the gliding motion of the fibula while maintaining the integrity between the tibia and fibula. The ankle Syndesmosis widens during dorsiflexion and external rotation of the fibula. The Syndesmosis resists axial, rotational, and translational forces.[24]

2.5 Ankle Instability

This section of the report highlights the mechanism of ankle instability. To understand the potential causes of ankle instability, it is important to define ankle stability. According to the article, *Functional Anatomy, Pathomechanics, and Pathophysiology of the Lateral Ankle Instability,* the three major contributors to stability of the ankle joints are listed below:[18]

1. The congruity of the articular surfaces when the joints are loaded
2. The static ligamentous restraints
3. The musculotendinous units, which allow for dynamic stabilization of the joints

Lateral ankle sprains most commonly occur due to excessive supination of the rearfoot about an externally rotated lower leg soon after initial contact of the rearfoot during gait or landing from a jump.[25-26] This is due to excessive inversion and internal rotation of the rearfoot. This coupled with external rotation of the lower leg, results in strain to the lateral ankle ligaments.[18] Ligamentous damage occurs when the strain in any of the ligaments exceeds the tensile strength of the tissues. It is often observed that the ATFL is the first ligament damaged during a lateral sprain and is followed by the CFL. Ankle instability is a prevalent condition characterized by recurrent ankle sprains and persistent pain.[27] Ankle instability is defined either mechanical or functional instability, or both.[6] To combat ankle instability, functional rehabilitation is crucial. Failure to reduce the risk of injury to the ankle tends to result in the development of chronic instability. Ankle instability is typically the result of recurrent ankle sprains. The complex anatomy and mechanics of the ankle joint in addition to the biomechanics and physiology related to acute and chronic ankle instability are crucial factors when evaluating, diagnosing, and treating ankle injuries.

Chronic Ankle Instability

The term chronic ankle instability (CAI) encompasses both mechanical ankle instability (MAI) and functional ankle instability (FAI). CAI is the most commonly used term to describe subjects reported to have ongoing symptoms after an initial sprain. CAI denotes the repetitive occurrence of lateral ankle instability which result in numerous ankle sprains.[18] Pathologic laxity of the injured joints is the result of ligamentous damage. The severity and extent of the pathologic laxity is dependent on the degree of damage done to the lateral ligaments. Pathologic laxity greatly contributes to joint instability and subsequent injuries to joint structures. To fully understand the cause of CAI, it is important to understand the dichotomy of function and mechanical instability.

Mechanical Ankle Instability

Mechanical ankle instability (MAI) may occur due to the following anatomical defects - ligamentous tear, synovial irritation, arthrokinematics changes, or degenerative pathological laxity.[18] MAI occurs due to anatomical changes of the ankle after the initial ankle sprain. The initial injuries expose the ankle to insufficiencies that predispose the ankle to future episodes of instability. Injury to the ATFL and CFL is primarily due to Talocrural instability. Injury to the AFTL is assessed using the anterior drawer test. This test determines the amount of anterior displacement of the talus from the Tibiofibular mortise. The integrity of the CFL is best assessed using the talar tilt test when inverting the rearfoot with the Talocrural joint in the dorsiflexed position.[18] Another potential insufficiency contributing to mechanical instability of the ankle is impaired arthrokinematics at any of the three joints of the ankle complex.[18] Hypomobility, or diminished range of motion (ROM), is a mechanical insufficiency. Restricted dorsiflexion ROM is thought to be a predisposition of lateral ankle sprains.[28]

Functional Ankle Instability

Functional Ankle Instability (FAI) is due to lateral ligamentous injury which result in adverse changes to the neuromuscular system. The neuromuscular system provides dynamic support to the ankle. Therefore, impaired balance as a direct result of lateral ankle sprains is attributed to damaged articular mechanoreceptors in the lateral ankle ligaments.[18] A direct correlation between proprioception and neuromuscular control of joint stability (as shown below in Figure 12). Functional insufficiencies among individuals with either ankle sprains or CAI have been demonstrated by quantifying deficits in ankle proprioception, cutaneous sensation, nerve-conduction velocity, neuromuscular response times, postural control, and strength.[18] Many studies have been conducted to investigate the relationship of impaired neuromuscular control and lateral ankle sprains. The studies report of similar results -neuromuscular recruitment patterns have been demonstrated in individuals with a history of repetitive lateral ankle sprains. The individual symptoms of functional ankle instability do not occur in isolation, but are likely a combination of components of a complex paradigm (as shown below in Figure 12).

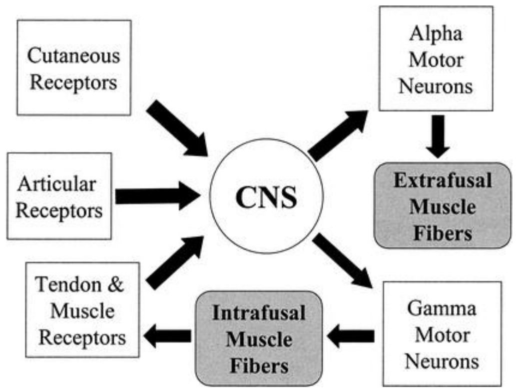

Figure 12: Feedback Loop
Proprioception and Neuromuscular Control [11]

2.6 Overview of the Healing Processes

The actual amount of healing time needed for ligament healing after an ankle sprain is unknown as healing is dependent on various extrinsic and intrinsic factors. However, it is estimated that the recovery rate of the ligaments, during an acute lateral ankle sprain, is reported to be anywhere from six weeks to three months.[29] While the recovery rates of the ligaments are known, the surrounding muscle, range of motion, proprioception, and return of function varies. Nonetheless, improved mechanical stability of the ankle is a preliminary indicator of healing. Therefore, it is suggested that ligament damage and mechanical laxity of the ankle joint are related.[30] The physiological stages of the healing process is discussed in this section of the report (as shown in Figure 13).

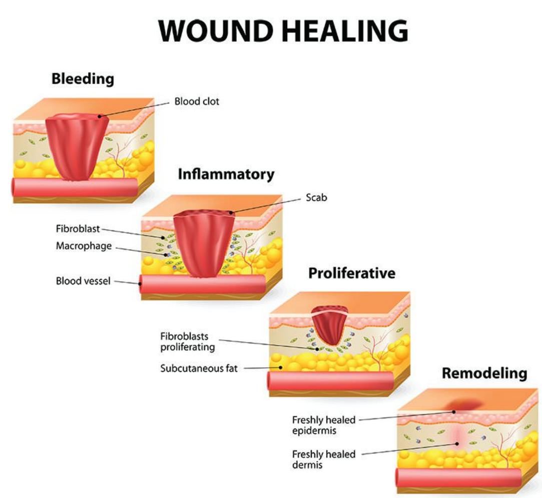

Figure 13: Wound Healing [12]

The process of recovery from a traumatic physical injury is dependent on several factors including the type of injury, severity, and location.[30] When an area of the body experiences trauma, the balance of normal cellular function is disrupted, triggering a cascade of responses and marking the beginning of complex physiological repair processes. Extrinsic and intrinsic factors contribute to the causation of ankle sprains and the healing processes. Extrinsic factors contributing to the ankle sprains include the magnitude of the load, the rate of the load, and the direction of the load. Intrinsic factors are unique to each individual. They include the anatomical characteristics of the ligaments and surrounding tissue which are significant contributors to the healing processes of a sprained ankle. To understand the healing process and manage pain or discomfort, it is critical to analyze the processes following an ankle injury. These processes are as follows – inflammation phase (hemostasis phase), the reparative phase, and the remodeling and maturation phase.[30]

The first phase of the healing process is initial inflammation. The inflammatory response is a defense mechanism of the body. During the inflammatory phase, cells are sent to the injury site to both dispose of damaged cells, and to fight possible infection. Almost immediately after an ankle sprain occurs, the body initiates the process to form blood clots in the injured area, causing acute inflammation. To reduce blood loss, the body releases chemicals near the site of injury to tighten the vessels through the process of vasoconstriction. Platelets then adhere and clump together at the site of injury, creating a plug. The plug, which later forms a clot, is reinforced through the formation of protein fibers. However, following this transient event, the body can experience increased blood flow a process called vasodilation, lasting an upwards of several hours.[31] During this response, the body experiences four cardinal signs: redness, swelling, warmth, and pain. Many of these responses are directly due to the increase blood flow.

The inflammatory phase can last several days. During this period a cascade of events occur one of which involves the gathering of white blood cells and red blood cells at the injured site. The WBC and RBC, medically termed leukocytes and monocytes, are attracted to the injured site and begin to engulf foreign particles and dead cells. Additionally, depending on the injury, other immune cells may be triggered, leading to other symptoms, such as fever.[31] During this phase, the tissues are extremely fragile. The tissues at this point are not strong enough to carry on its previous weight bearing properties. This is one of the reasons why rest is important during this period of an ankle sprain. Further damage in this phase can cause the inflammatory phase to last longer and become a chronic wound. The inflammatory phase of wound healing can last from fifteen minutes to several hours.[32]

The rebuild and repair phase of the healing process involves the influx of collagen and cells responsible for the extracellular matrix (ECM). The platelets in the blood release chemicals to initiate long-term processes of healing during the reparative phase.[31] The ability and rate of cell regeneration is dependent on the type of cell. During this phase, the endothelial cells give rise to new blood vessels and fibroblasts that can form loose frameworks for the injured tissues. The influx of collagen allows for scar tissue to form. This phase lasts about four to twenty-one days after the initial injury. It is here that fibroblast cells create a collagen framework. After the framework is assembled, it will contract, causing injured tissue to form a scar to provide stability. This phase corresponds with the rehabilitation on a macroscopic level in that this is the time when the injured party starts to gradually add more weight on the sprain, working to regain their full range of motion.

The remodeling and strength training phase are the final phase of the healing process. This phase can last several weeks or even years. During this phase, it is crucial that the muscles around the injured are exposed to interfragmentary strain. Stressing the muscles and connective tissues stimulates growth and improved function and is therefore, pivotal to recovery. Remodeling of the injured site, for example the ligament, requires a stronger scar tissue to be formed. The stronger scar formation, derived from the fibrous framework formed in the repair phase, occurs during the final remodeling. Here the body will trim away at the base of the collagen framework and allow for restricted tension created by bodily movement. If proper wound care was not followed in the aforementioned phases then scarring may occur, causing instability and/or pain. In this phase more active exercises can be reintroduced like jumping, running, etc. Increasing the intensity of exercise in this phase will direct the body to build more collagen where there is more stress, making it stronger. However, if the exercises are too strenuous, the body could return to the inflammatory phase.

2.6.1 RICE

As mentioned in the previous section, an indirect outcome of an ankle sprain is an edema, swelling. According to various sources, application of ice immediately after the injury is necessary in limiting the swelling of the ankle. The method, RICE, is a popular and highly recommended initial form of immediate treatment after injury. Ice is used to reduce swelling. When applied to the injured site, the ice or any cold substance/material causes the blood vessels to constrict a phenomenon commonly known as vasoconstriction. Swelling is one sign/indication of inflammation. Inflammation is an immune response due to injury or infection. Typically, pain, redness, and heat are resulted. A sequence of complex chemical reactions occurs to defend the body. Histamine is released by the cells in the tissues in response to the injury causing the smooth muscles to contract and the capillaries to dilate to increase permeability and lowers blood pressure. Therefore, ice or any cold substance is used to counteract the body's response to reduce inflammation. From this, the swelling/inflammation is reduced, pain relief is resulted, and exchange of heat is reduced. It has been reported that cell and enzymes of the body function best at approximately thirty-seven degrees C (approximately ninety-eight degrees F). Although initial cooling is good for wound healing, when temperatures decrease as little as two degrees C, vasoconstriction causes an increase in the hemoglobin's need for oxygen and thus, insufficient oxygenated blood supply is delivered to the white blood cells and therefore, inhibits its roles in wound healing. Wound healing can slow or even cease.[33]

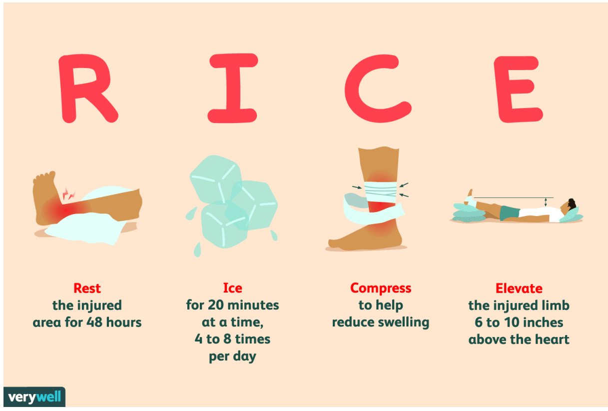

Figure 14: RICE Treatment for Acute Musculoskeletal Injury [13]

2.6.2 Post Injury Rehabilitation and Drugs

There are two main types of OTC (over the counter) pain medicines: acetaminophen (Tylenol) and nonsteroidal anti-inflammatory drugs.[34] Acetaminophen is used to treat aches and is conveniently an over-the-counter medicine. One disadvantage to Acetaminophen is that it does treat inflammation. Nonsteroidal anti-inflammatory drugs are used primarily bought as pain relievers. Specific drugs in the categories of NSAIDs require a prescription which is a limitation. NSAIDs relieve pain by reducing the production of prostaglandins, which are hormone-like substances that cause pain. Acetaminophen works on the parts of the brain that receive the "pain messages."[35] Some considerations that will be involved while outlining out design criteria for the drug delivery system is the compatibility of the drug container/patch to the body, the skin to drug interface and transmission rate, stability of the drug, and proper mechanical structure to deliver drugs. One of the goals of our project is to make it as mobile as possible, but still firm enough to provide optimal support to the injury.

2.7 Background on Human Dermis- skin

The skin is a complex organ that plays a major role in protecting the body. Thus, a deep understanding the anatomy and physiology of the human skin is crucial in developing an effective system for drug delivery to promote wound healing. As the largest organ of the human body, the skin covers a total area of approximately twenty square feet accounting for fifteen percent of the total adult body weight. [36-37] The skin is a continuous with mucous membranes lining the body's surface.[38] It preforms various vital functions which includes providing an external, physical, and chemical layer against microbes. Additionally, the skin plays a major role in thermoregulation of the human body and prevents excess water loss from the body. There are three primary layers that make up the skin – epidermis, dermis, and the subcutaneous tissue. In general, the skin is formed via the integumentary system.

2.8 Current Treatment

According to *WebMD*, in the United States, over one million people visit the emergency rooms each year because of ankle injuries. Ankle injuries have been studied in athletic cohorts, however, not much is known of its epidemiology in the general population. Many patients with ankle injuries fail to seek medical attention, regarding the injury as trivial. According to an epidemiological study conducted on athletes in Hong Kong, it was concluded that over 73% of athletes had recurrent ankle sprains and 59% of the athletes had significant disability and residual symptoms that further led to impairment of their performance.[38] The main cause for the recurrent ankle injury is due to improper treatment and recovery. Ankle sprains are more serious than commonly perceived by the patient because if the injury is not properly healed or treated, chronic problems are resulted. In addition, the likelihood of another ankle injury nearly doubles.[39] Therefore, it becomes even more crucial to differentiate between an ankle sprains vs. ankle fractures as it is possible to diagnose the injury without getting X-rays.

2.9 Material Research

The material we use to make the ankle brace is important not only so that it can achieve our objectives for optimal healing, but also so that it is comfortable enough for consumers to want to use. One aspect of this is encapsulated within the customizable, thin, wrap model we used to offer support during movement while maintaining stability of the ankle. Our focus on the design was primarily optimal mobility. The two most common materials for ankle braces currently are neoprene and nylon. Although both may satisfy the mechanical requirements based on how we design and manufacture the product. The distinguishing material we ultimately decide on will depend on how comfortable the material is, the breathability of the material, the degree to which it will provide sufficient compressive strength, and ultimately cost. With all considerations, various types of common materials will be tested: neoprene and nylon.

According to the ASTM D-2000 Classification, neoprene is classified as a synthetic rubber. Its chemical definition is polychloroprene as it is produced by the polymerization of chloroprene. The material is chemically stable and is widely used due to its broad range of applications and can be easily fabricated through various mechanisms such as hand fabrication, fabricated using a laser, die, and water-jet cut. Neoprene is used where moderate oil, petroleum, ozone, and weathering-resistance is needed. Characteristics of neoprene also include its excellent resistance to Hydrogen gas, Natural Gas, Salt/Sea Water, Butanol, Acetic Acids (up to twenty percent), Ammonium Salts, Mineral Oils, Silicone Oils and Greases, etc.[40] In addition, neoprene exemplifies excellent abrasion resistance and operated well under both low (-12 to - 46°C) and high temperatures upwards of 121°C. Neoprene has a durometer range (Shore A) from 20 - 95, offering moderate flexibility and pliability. It has a tensile range is from 500 - 3000 PSI and an elongation range of 300 (minimum) - 600% (maximum).[42]

Another commonly used material is Nylon. Nylon is classified as a synthetic polymer, more specifically the aliphatic or semi-aromatic polyamide.[41] Nylon fibers are light in weight, yet stronger than most polyester fibers. Nylon is exceptionally tough, abrasion resistant and has a low absorbance rate. Durable, nylon is commonly used for more demanding applications which include tire cords, ropes, seat belts, hoses, conveyor belts, sleeping bags, and civil engineering material.

We looked to Polydimethylsiloxane (PDMS) as a material to use for the drug delivery device. In addition to being accepted as generally safe for skin contact.[42] It's ability to be crosslinked to desired stiffnesses makes it an attractive material for its mechanical properties. The shear modulus range from 100 kPa to 3 MPa depending on manufacturing.[43] Moreover, the hydrophobicity of this material makes it ideal for comfort, similar to the hydrophobicity of many of the ankle brace components. Hydrophobicity is important to quantify the moisture wicking capabilities improving the user experience via comfort. PDMS is categorized as a kind of silicone and is the most widely used silicon-based organic polymer. PDMS is transparent, generally inert, non-toxic and non-flammable. Its commercial application ranges from medical devices to cosmetics and even to the food industry as an anti-foaming agent in food.[44]To speak to the commercial acceptance, the Cosmetic Ingredient Review's (CIR) panel has concluded PDMS and other dimethicone polymers to be "safe as used" in cosmetic formulations.[45] Furthermore, the European Union has allowed it to be used as a food additive, listing it under E900.[46] Environmentally

PDMS is marked as toxic to aquatic life if not properly disposed and although it is nonbiodegradable, its degradation can be catalyzed by certain kinds of clay.[47]

A critical element to the design of the reconstruction of a medicative ankle brace is the medicative holder. The holder was 3D printed on the Makerbot (Brooklyn, NY) using Elastic Resin purchase for the Form 3 machine. This resin was selected for its material properties which includes a 80 percent elongation at break. The flexibility of this material allows the holder to form around the ankle of each individual patient. In addition to its flexibility, the resin has a high tear strength which allows for repetitive use cycles. According to literature, the elastic resin is ideal for prototyping of wearable and consumer goods.[48]

Figure 15: Elastic Resin [14]

Elastic Resin Form 2 Material was used to create final DDS accessory due to its high elongation and ability to hold up repeated cycles without tearing.[49] Based on research and reviewing the technical spreadsheet data, it was most beneficial to select Elastic Resin as our resin choice. Not only did the elastic resin have the most reasonable elongation to failure, but also due to a lack of resources it was the only resin we would be able to print with given our lack of 3D printer variation. In determining a flexible material for the medicative holder it is important that it is flexible enough to move with the ankle joint, but hard enough to maintain shape to deliver drugs correctly. The elastic resin can also withstand repeated cyclic loads without tearing. The elastic resin was the best selection to provide a form fitting, yet structured material.

	Elastic Resin	Flexible Resin	PhotoCentric LCD FLexible Resin	NinjaFlex
Type of Printer	Form2	Form2	LCD Printer	FDM Printer
Ultimate Tensile Strength	1.61 MPa	3.3-3.4MPa	1.5 Mpa	26Mpa
Elongation at Failure	100%	60%	60%	660%
Tear Strength	8.9kN/m	9.5-9.6 kN/m		------
Shore Hardness	40A	70-75 A	85D	85A
Price	$199/L	$199/L	$77/L	$55/spool

Table 1: Resin Selection for Final Prototype[50]

Tensile Strength	**Tear Strength**	**Elongation (%)**
8.5 MPa	14.1 MPa	80

Table 2: Elastic Resin Information[50]

	Type of Printer	Ultimate Tensile Strength	Elongation at Failure	Tear Strength	Shore Hardness	Price	Score
Elastic Resin	1	1	1	1	1	0	5
Flexible Resin	1	1	0	1	1	0	4
PhotoCentric LCD Flexible Resin	0	0	0	----	0	1	1
NinjaFlex	0	1	1	-----	1	1	4

Table 3: Material Selection Pairwise Comparison

2.10 Current Ankle Braces on the Market

2.10.1 Ankle Sleeve

To reduce ankle swelling and foot pain, a compression or foot sleeve is typically used as a form of treatment. Commonly used is the Orthosleeve FS6 Compression Foot Sleeve. The sleeve provides medical grade orthopedic support of the foot structure and claims to help relieve swelling and foot pain with targeted compression. With six targeted support zones and three levels of compression, the sleeve aims to support the foot's natural structure and boost blood circulation. By doing so, the sleeve provides the proper amount of support for relieving pain and swelling caused by plantar fasciitis, heel spurs, calcaneal bursitis, and arch pain.[50] Specifications of the sleeve includes 24% spandex and 76% micro-nylon.[50] It is lightweight, can be slipped on easily, and can stretch to fit and hug the foot. The sleeve provides a gradual to firm support and can be worn underneath regular socks. This sleeve uses a patent pending Compression Zone Technology® which is depicted in the figure below (Figure 16).

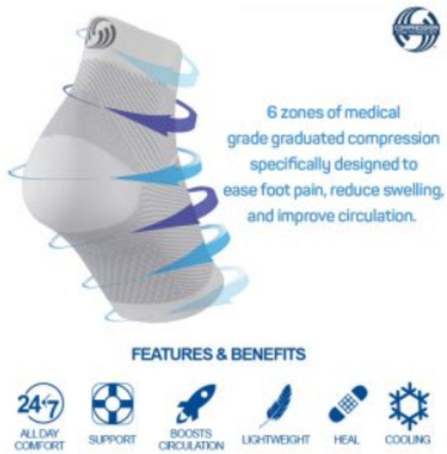

Figure 16: Compression Sleeve [15]

Another commonly used sleeve is the copper joint sleeve. The copper-infused compression ankle sleeve is used for joint support and pain relief and is filed as patent number US6171606B1. It is comfortable, durable, and has a breathable component due to the high-performance fabric, preventing moisture and thus, bacteria build up. The high-performance fabric keeps the joints at optimal temperatures. The sleeve is made from 88% copper infused nylon and 12% spandex.[51] The sleeve aids joint and muscle recovery while providing relief from arthritis, joint pain, and inflammation. It compresses the pain-points to enhance oxygen delivery and augment airflow.[52]

2.10.2 Wrap-around/Lace-up brace

An alternative design to the typical sleeve and the aircast brace is the wrap around/lace up design. This is favorable to some because it allows a wider range of motion, while also exhibiting very thin behavior. Depending on the intention of the brace, this type of brace can have a rigid and semi-rigid portion to help maintain proper structure and form. The braces typically involve element of elastic stretchable fabric that surrounds the ankle to provide proper structure and support. The material is often designed to be breathable so that it is comfortable to wear and to prevent excess hydration surrounding the ankle and foot. Many designs also incorporate an element to provide support to the arches of the feet for an additional ergonomic element. Two brands of ankle braces seen below exemplify many of these elements.[53-54]

Figure 17: Example Braces from EZ-ON Wrap [16]

Figure 18: FUTURO Wrap Around Ankle Support [17]

In the case of an ankle injury, preventative measures are significantly more effective than rehabilitative measures. Common preventative measures regarding ankle injury are taping and ankle braces. The preventative brace is the best device for prevention of injury in that they allow a larger range of motion than both sleeves and air casts, however these preventative braces are not without fault. Studies have found that there are no effects on muscle activation with prolonged use.[55] In fact, long-term use of the brace has shown no effect on performance, speed, or agility.[56,57,58] Preventative ankle braces decrease the likelihood of injury but not severity.[59]

In the event of an injury, an ankle brace can be used to help stabilize the area to help with the healing process. Wrap-around and lace-up braces create tension around the ankle to prevent additional rotations that may lead to worsening or additional injuries, much like the sleeve and aircast. In a rehabilitative context, this type of prevention has strengths and weaknesses. This design may allow more motion than the sleeve (dependent on sleeve design) while not as much as an aircast (due to the seizing up to restrict motion only when a critical rotation is attempted). The largest benefit of the lace-up/wrap-around brace is that it is much more aesthetically pleasing and much less bulky.

2.11 Patent Research

2.11.1 Gel and Air Cushion Ankle Brace

This patented design contains a highly viscous gel intended to prevent hasty movements and incorrectly distributed pressure. It also contains an air pocket feature to provide compressive force to the injury. The brace contains a hard-outer shell and is to be worn under the shoe and adjustments can be made to fit the ankle adding a personalized medical element. Straps are added to secure the brace to the lower extremity and may be adjusted to fit the ankle accordingly.

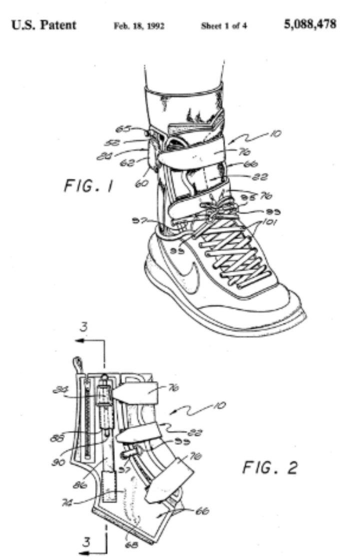

Figure 19: Gel and Cushion Patented Ankle Brace [21]

2.11.2 Inflatable Ankle Brace with Porous Compressible Filler

This ankle brace is constructed with the standard hard-shell outer casing in a U-shape base. Within the casing is a cushion of air pocket lining. The brace contains straps to adjust for form fitting structure. The air pockets pre-inflate to the stirrup to provide a cushion member which serves the dual purpose of comfort and compression. The amount of air compression is versatile and can be reduced at different altitudes.

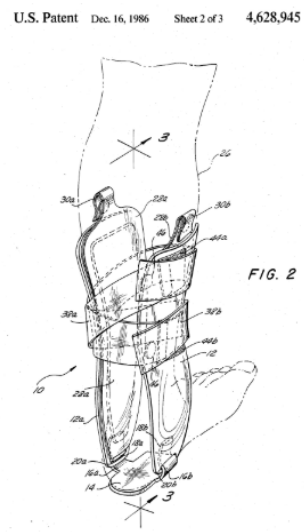

Figure 20: Inflatable Ankle Brace with Porous Compressible Filler [22]

2.11.3 Non-bulky Ankle Brace for Use with Footwear

This brace prioritizes mobility of the ankle to the stability of the ankle. The goal of this design was to provide optimal comfort. The material used to create the brace is moisture-wicking and the strap provides opportunities for adjustment. The straps are cut from the same material as the body of the brace which eliminates the typical metal fasteners found in other braces.

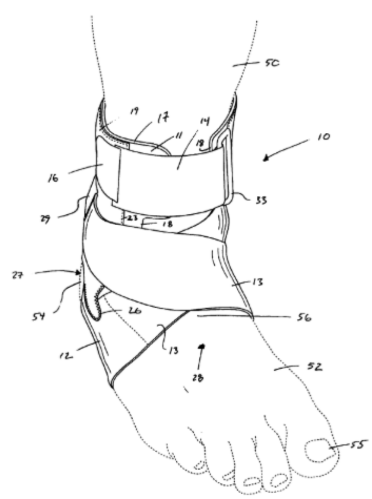

Figure 21: Non-bulky Ankle Brace to Use with Footwear [23]

2.11.4 Self-Contained Heating and Cooling Orthopedic Brace

There currently exists an orthopedic brace with self-contained heating and cooling elements. The brace has a main body which contains the straps used to support the brace on the desired area. The areas suggested for use are the back, knee, and shoulder. The temperature elements are in an inner pocket, heating and cooling pads are connected to a temperature controller so that they can be easily adjusted. The pads function utilizing the Peltier Effect. The temperature controller is manually adjustable and can include a rechargeable battery for extended use. The material for the brace itself has temperature retaining properties. Users of this brace have their own body moisture retained if a moist heat application is desired.

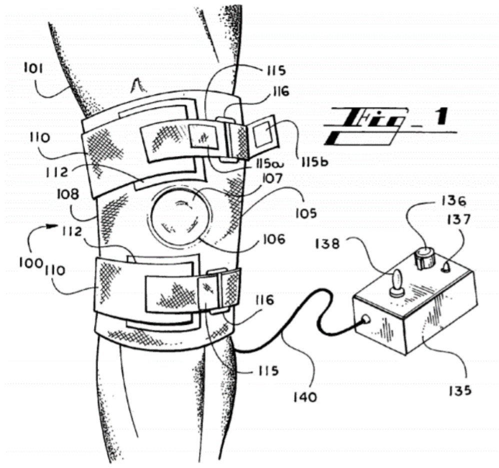

Figure 22: Self Contained Heating and Cooling Orthopedic Brace [24]

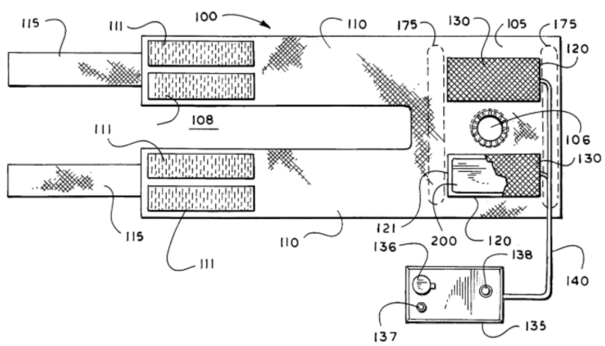

Figure 23: Component of SH&C Orthopedic Brace [24]

2.11.5 Transdermal Drug Delivery Patch (Reservoir)

A medicated patch that works through diffusion of the drug of choice through skin via a reservoir system. There is an adhesive component to stabilize the location in which the drug is placed and a regulatory mechanism to ensure that an initial burst of the drug does not occur (as it can cause irritation). The drug itself has a delay in release and therapeutic effects so prolonged use can be achieved. The main agent to control the drug release is moisture. The primary form of the drug stored will not be able to be absorbed through the skin as it is meant for an anhydrous environment. Exposure to moisture via skin contact will create an acidic or basic solution that is able to be absorbed through the skin or mucous.

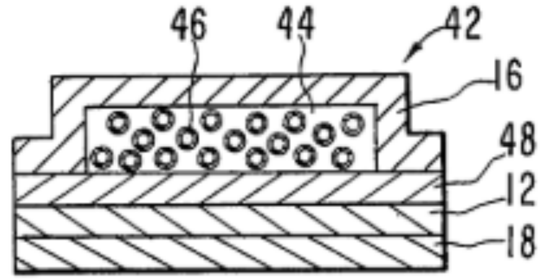

Figure 24: DDR [25]

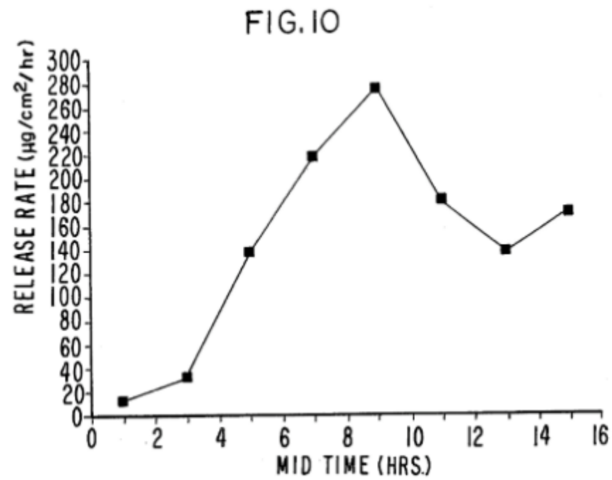

Figure 25: Drug Release Rate [25]

2.11.6 Transdermal Drug Delivery Patch (Matrix)

A medicated patch that works through diffusion of the drug of choice through skin. The patent is specific to the hydrophilic salt form of a drug. The matrix in which the drug is woven into contains a water based, pressure sensitive hydrophobic adhesive in which the drug is contained in. A permeation enhancer may be included but is not a requirement for this patent. The reason for the specificity of the salt form of a drug is that the drugs have to be hydrophobic to be incorporated into this kind of adhesive (organic solvent based and hydrophobic) to make the matrix. The salt forms are not typically compatible with these types of adhesive and must be converted to a hydrophobic acid or base first. The main advantage of keeping the salt in the hydrophilic form is that it can be incorporated into a water-based hydrophobic pressure sensitive adhesive in addition to being readily permeable across skin and mucous from a dry adhesive film.

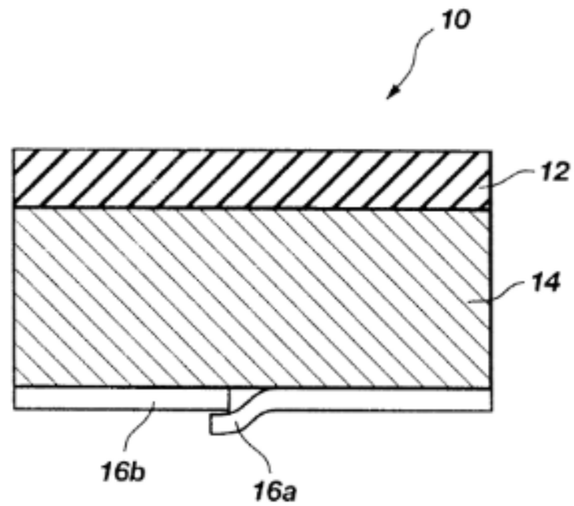

Figure 26: Medicative Patch [26]

2.11.7 Matrix Material Composition for TDDS

In regards specifically to the matrix model of TDDS, the drug is woven into or incorporated into another material. This patent is for the specific composition that can be used for the matrix system. The mixture consists of mineral oil (MO), polyisobutylene (PIB), and colloidal silicon mixtures (CDS). A model system using this contains 6% CSD, a MO/PIB ratio of at least 1.0, and a viscosity of at least 1.5×10^{7} poises. The specific figure used contains an example with multiple drugs in different layers but the patent covers a variety of layers that can be used with this type of composition.

FIG.1

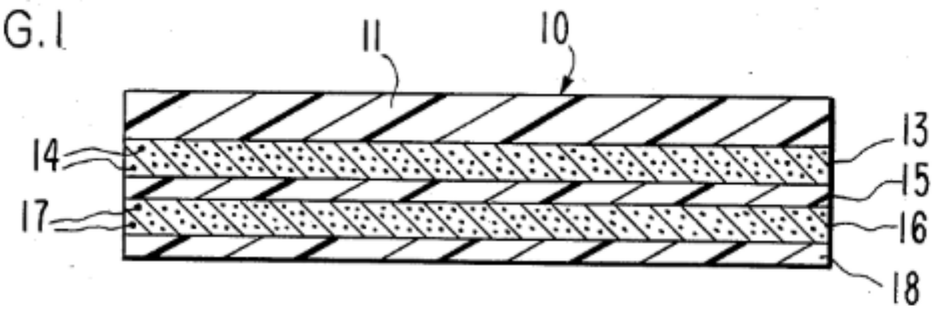

Figure 37: Multiple Drug Layer Patch [27]

2.11.8 Topical Patch for Pain Relief Using Cooling agent

The topical cooling patch described has an adhesive gel component for support. The gel itself contains an odorless cooling agent, a water-soluble poltergel, water, and an agent to store the water. The application of the patch is to apply it the skin after removal from the original packaging. Some of the chemicals that could be used in the cooling agent include but are not limited to: linalool, geraniol, hydroxycitronellal, WS-3, Flescolat MGA(Haarman & Reimer), Frescolat ML, PMD38, Coolact P and Cooling Agent 10. It should be noted that Frescolat ML which does have a faintly minty odor.

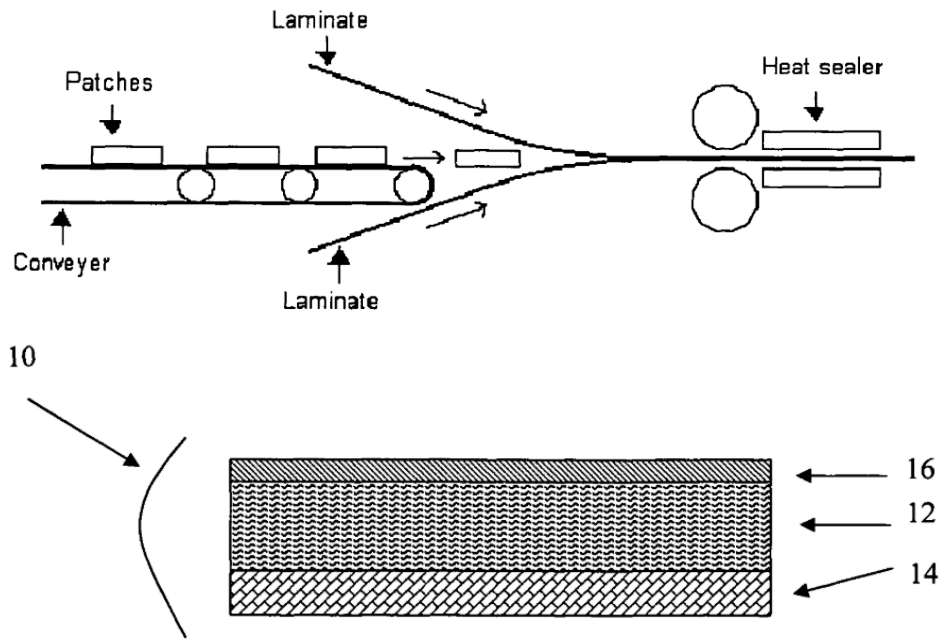

Figure 28: Cooling Patch [28]

3. Project Strategy

3.1 Initial Client Statement

Ankle ligament injury is a common orthopedic injury experienced by many athletes in a variety of sports and populations. Ankle braces are used in conjunction with other treatment modalities to support and provide an optimal healing environment for rehabilitation. Although many devices exist on the market, no device has been created that incorporates mechanical support and a place to introduce a variety of therapeutic modalities to meet the needs of an injured athlete at several stages of the healing process. The hope is for a full design and fabrication of a device that is catered towards rehabilitating and supporting an individual post ankle injury at a variety of stages in the recovery process.

3.2 Project Strategy

The strategy constructed to outline this project started with the creation of a survey. The survey was created in an attempt to collect information on the gaps present in the current ankle brace market. The goal of this survey is to collect information from professionals to establish a problem in the ankle brace market and then create a solution. Our team aims to establish this problem and create the most optimal conditions for ankle healing. After the survey was created it was sent out to several local physical therapists and feedback was obtained to construct a device that fulfills the objectives and creates a client statement. Next, we obtained the major requirements needed to manufacture the design. We created a transdermal drug delivery patch holder using Creoparametric, a 3-D CAD (computer aided design) software. After fabricated, several tests were performed on the brace to ensure successful healing conditions, mechanical stability. Finally, the brace was tested on human subjects and determined to be a successful brace.

3.2.1 Objectives and Constraints

The objective of this project is to create an optimal wound healing environment for ankle injuries through the use of an ankle brace. This objective will be achieved with three goals of our design: providing mechanical stability to the ankle; having a mechanism to allow the delivery of a topical drug; and incorporating a cooling element to further aid in pain and the wound healing process.

To quantify all of our goals, in terms of mechanics: ankles in normal static conditions ankles will face rotations from about 7° to 48° of inversion. The flexibility and mechanical stability of the ankle will be tested via the goniometer test, the talar tilt test, and through the use of the Polhemus device. The constructed ankle brace aims to allow movement within this range restrictively as to not impede on function. With increased ankle degree of inversion, the brace will provide more resistance, not allowing movement above 48°. In terms of the drug delivery system we aim for a usage time of at least 8 hours. The amount of drug released will be dependent on the drug we select, but will be refillable based on drugs of choice. The instructions on dosage will be supplied by the drug of choice. For the cooling element we aim to have a cooling effect of 2° C for at least 1 hour, while having a cooling effect to a lesser degree for about the same duration as the TDDS.

Quantifying the mechanical strength of the ankle permits analysis of treatment effectiveness and quantification. Mechanical ankle instability is induced by ligament laxity; while functional ankle instability is caused by postural control deficits, neuromuscular deficits, muscle weakness, and proprioceptive deficit.[1] The most common approach to manage ankle instability is a more conservative approach. This non-invasive approach includes the use of bracing and taping to provide support for the ankle and potentially prevent initial and recurrent ankle sprains. The purpose is to restrict joint motion without limiting performance. Therefore, to assess the mechanical ankle instability and quantify the effectiveness of the ankle brace, it is important to compare the differences in laxity at the ankle under three conditions: taped vs. braced vs. no post-injury application. Ankle laxity is the anterior displacement and inversion-eversion rotation. To measure ankle laxity, an ankle arthrometer is used under the conditions.

Ankle sprains often occur due to the combinations of inversion, internal rotation, and plantar flexion. The excessive motions in these directions can be restricted by braces. The Anterior Talofibular Ligament (ATFL) is the weakest ligament in the ankle. Having the lowest ultimate load, the ATFL is the most commonly injured in a lateral sprain. In general, the major function of the ankle braces should be focused on stabilizing against inversion sprains. To further quantify and evaluate the effectiveness of the stabilizing effects of ankle braces, several mechanical tests and studies are required. Studies conducted must evaluate the stabilizing effect of the ankle brace in conditions: passive and rapidly induced. Passive conditions refers to situations where the ankle joint complex is unloaded and moved in various directions. Advantages of this test include stability characteristics in different directions: inversion-eversion, plantar-dorsiflexion. The disadvantage is that it is not a realistic representation of the potentially traumatizing situation due to the lack of dynamics in the application of the torques and the neglected potential influence of the muscles that stabilize the ankle joint. Rapidly induced stability is when subjects are subjected to a fast inversion event on a tilting platform. The tilting platform simulates an ankle sprain. The foot is loaded with bodyweight and the inversion instant is unknown to the subjects, therefore emulating a more realistic condition/instance. The disadvantage of this test, however is that it is mainly limited to inversion. Both the passive and rapidly-induced tests provide objective information about the stabilizing effects of the ankle braces either under laboratory or more realistic conditions allowing for quantification. The results of the tests will provide information to what extent the braces stabilize the ankle joint complex against passively induced inversion and eversion, plantar and dorsiflexion, and internal and external rotation as well as against rapidly induced inversion movements on a tilting platform. In addition, the correlation between passive and rapidly induced inversion and amount of restriction for both tests are of interest to understand relation between test conditions.[2]

An indirect outcome of an ankle sprain is edema, swelling. According to various sources, application of ice immediately after the injury occurs. The method, RICE, is also one of great popularity as an initial form of immediate treatment after injury. Ice is used to reduce swelling. When applied to the injured site, the ice or any cold substance/material causes the the blood vessels to constrict a phenomenon commonly known as vasoconstriction. Swelling is one sign/indication of inflammation. Inflammation is an immune response due to injury or infection. Typically, pain, redness, and heat is resulted. A sequence of complex chemical reactions occur to defend the body. Histamine is released by the cells in the tissues in response to the injury causing the smooth muscles to contract and the capillaries to dilate to increase permeability and lowers blood pressure. Therefore, ice or any cold substance is used to counteract the body's response to reduce inflammation. From this, the swelling/inflammation is reduced, pain relief is resulted, and exchange of heat is reduced. It has been reported that cell and enzymes of the body function best at approximately 37° C (98.6° F). Although initial cooling is good for wound healing, when temperatures decrease as little as 2° C, vasoconstriction causes an increase in the hemoglobin's need for oxygen and thus, insufficient oxygenated blood supply is delivered to the white blood cells and therefore, inhibits its roles in wound healing. Wound healing can slow or even cease.

3.2.2 Revised Client Statement

To design and fabricate a post-injury, protective ankle brace to support the rehabilitation process of the ankle. The brace will provide the most optimal conditions for healing of the ankle, including: a reusable medicative feature, cooling element, and compressive features. The brace will be moisture absorbent to combat foul odor and flexible to keep the ankle at proper walking and resting angles. The hard-outer shell will prevent re-injury from forces up to twice the body weight. Also, this device should be adjustable and able to meet the needs of individuals of different sizes as well as different ankle ligament injuries. The brace will incorporate the following:

1. Reusable medicative feature, cooling element, and compressive features

2. Moisture absorbance to combat foul odor
3. Mechanical stability

3.3 Project Approach

Ankle braces are commonly used for treatment and rehabilitation of acute ankle injuries.[60] Ankle braces are also used by individuals with chronic ankle instability to prevent recurrent injuries and reduce ankle sprains in high risk activities.

While there are plenty of different ankle braces currently on the market, all of them lack a connective element to best address wound healing beyond mechanical support. Some of the more successful designs on the market include: ankle sleeves, wrap-around/lace-up braces, and air-cast braces to name a few. The niche goals of these designs range from comfort to heavy protection. Typically, the more comfortable the current markets brace are less protective and do not provide sufficient mechanical stability. To combat this, the project design will be a combination of elements that provide both ample protection, comfort, and a wide range of motion. The current ankle brace market is not primitive, there are various designs that take into consideration the degree at which your ankle can roll without injury which is an advanced research element. Nevertheless, there is a disconnect between design elements and the healing objective, which causes the patient to choose one over the other. In addition to the unique design of this project's brace, the compression and cooling elements will be integrated into the design which allows the user to remove and reuse the cooling element based on user need. The design aims to provide an optimal healing environment while minimizing the thickness of current ankle braces available on the market. The goal of this project is to close the gaps in the current market.

3.3.1 Medicated Orthopedic Support Structures for Treatment of Damaged Musculoskeletal Tissue

For the healing of damaged musculoskeletal tissue, a method and system that has been developed is an orthopedic support structure with a nitroglycerin incorporated composition. The orthopedic support structure provides mechanical support to the damaged tissue and maintains skin contact with the nitroglycerin-containing composition. The design is open to have the nitroglycerin element integrated in the support structure or within a removable dosage mechanism. The goal of the medicated device is to provide pain relief and improved function of musculoskeletal tissue.

3.3.2 Cooling Element

One of the four cardinal signs of injury is inflammation. Although this occurs through natural processes and is an important function of the healing process, it is commonly accepted to cool the area of injury to help with the inflammation soon after injury. This is so that tissue damage can be minimized and limitations can be made on secondary hypoxic damage while also reducing the risk of edema and muscle damage. During the rehabilitation process, however, cooling the injured area carries a different effect. Colder temperatures can have an analgesic effect while also causing vasoconstriction to restrict blood flow and thus swelling. This can drastically reduce nerve conduction velocity which aids in the relief of pain. For this aforementioned reason, a cooling element was one of the three priorities of the design (mechanical viability, drug delivery, and cooling). This is achieved through both the selection of material of the cast and through a cooling patch localized to the afflicted sprain.

A common application of cooling patches is specifically designed for fevers. The cooling elements of a typical generic patch is composed of a polymer hydrogel with a mixture of water, glycerine, polyacrylic acid, aluminum hydroxide, and dimethyloldimethyl hydantoin. This is all placed on a non-woven cloth sheet, covered with a polyethylene terephthalate laminate poly film and sealed within an laminate film outer bag comprised of either a vinylidene chloride coated polyethylene/polypropylene, ethylene-vinyl acetate copolymer mixture or polypropylene/alumina deposited polyester/polyethylene, ethylene-vinyl acetate copolymer mixture. These components all work through an exothermic process in which the water within the cooling patch evaporates from the heat of the skin resulting in the cooling sensation felt from the gel.

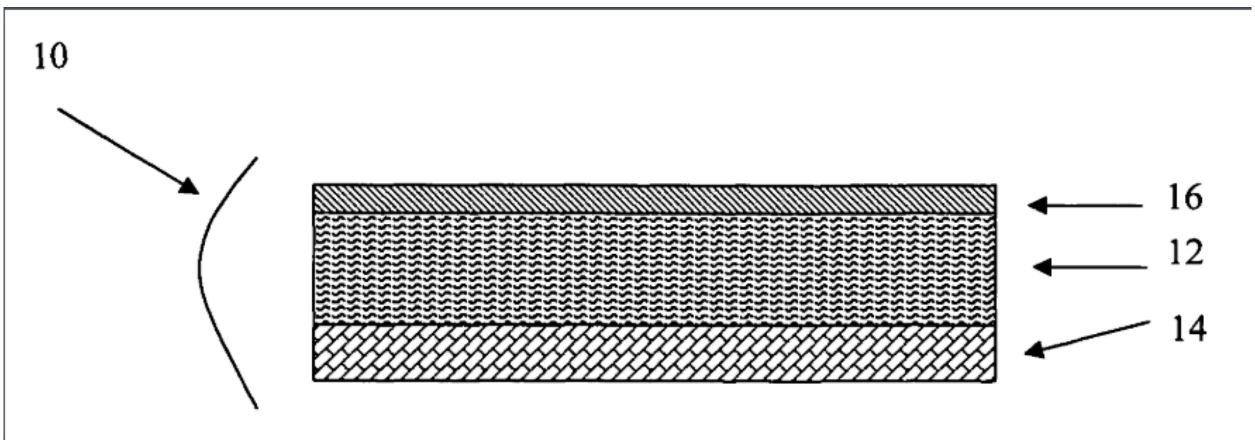

Figure 29: Image taken from a patent showing the layers of the sheet, hydrogel mixture, and outerbag [29]

3.3.3 Topical Medication Overview

Topical analgesic medication offers a necessary alternative to oral medications. Nonsteroidal anti-inflammatory drugs (NSAIDs) work by blocking enzymes that affect pain and swelling. If taken orally they are safe for the short term but in the long term, they can lead to stomach ulcers and bleeding, liver damage, kidney damage, and increase the risk of a heart attack.[61] Topical medications on the other hand, have been proven to provide pain relief to the same effectiveness as oral medication for both acute and chronic injuries and cause significantly less gastrointestinal adverse effects than oral medication.[62] This is corroborated by several studies including one looking at a similar application as our device, lateral elbow pain (tennis elbow).[63] Topical analgesics target pain relief locally based on where it is applied rather than systematically as with oral medications. The localized pain relief targets peripheral receptors and neural pathways to deliver the desired effect. This means that the drug may not reach the concentration that systemic ingestion may induce and the side effects are lessened.[64]

4. Alternative Designs

4.1 Needs Analysis

After research on the current market advantages and gaps in ankle braces, our team found it essential to bridge the gap between an adequately designed performance based brace and a fair price for the product. Often times those who have an ankle injury tend to go to the pharmacy to purchase an ankle brace. However, it is human nature to buy the cheapest ankle brace, especially if the price is a consideration in the purchase of a brace. The chart below describes the current gaps between price and performance.

Design	Price	Advantage	Gaps	Picture
Ankle Bandage Wraps	$1+	Cheap, minimal mechanical support	No analgesic element except compression, hard to put on	
Compression Sleeves	$15+	Decreases edema, thin	Limited mechanical support	
Medicative designs	$30+	Pain relief, compression, thin	Limited mechanical support, reusable	
Cooling braces	$35+	Pain relief, compression, thin	Bulky, limiter to no mechanical support	
Air Casts	$75+	Great mechanical supp	Expensive, bulky, no analgesic element	

Table 4: Current Ankle Braces on the Market

4.2 Function Specifications

Our brace will function as a compressive, medicative, and cooling brace. While there are a couple layers to the design, it is still thinner than most braces on the market. The spandex sleeve serves as a preventative layer against the cooling agent. A side of the spandex was cut and sewed to serve as a unique horseshoe designed transdermal drug delivery holder, located around the lateral and medial malleoli. The object of this design is to serve two purposes, the first purpose is to administer the medication directly to the skin and the second is to prevent a buildup of fluid in the ankle bone. On top of the spandex sleeve is a figure eight brace composed of neoprene and nylon. The object of the figure eight design is to limit joint movement and prevent further injury. A thin layer of cooling beads lined in an ace bandage are contained in a layer above the brace structure to reduce swelling and provide ample compression.

The brace claims to be a fully reusable ankle brace that is able to cool the injury where the customized ice pack lays. In addition to cooling, the brace contains a horseshoe transdermal drug delivery holder. The holder is composed of a flexible resin that was 3D printed. The part was created with the intention of direct contact between the part and the contact surface at the skin. Lastly, our figure eight wrap around will provide a compressive feature.

4.3 Conceptual Designs

4.3.1 Designs

The goal of this portion of the project is to create a tangible proof of concept (POC) that encompasses the following components to fill the gaps of the ankle braces currently on the market – medicinal application, cooling element, mechanical support, compression, and minimized thickness. Our first conceptual design (as shown in Figure 30) aimed to achieve the three main elements that set aside our brace from the market: cooling element, medicative element, and compressive element. To achieve this our brace started with a sock as the first layer. The sock was stuffed to reflect the thickness of a foot and ankle. On the first layer a rubber support was hot glued. This rubber was wrapped starting around the heel on the foot and crossed over the top of the foot, then attached to the top of the sock. The DDR was held via Velcro and the figure 8 provided stability and ankle support. This was our first attempt at mimicking the figure eight design, however we soon found that this is not the case.

Figure 30: Preliminary POC Design 1

The second design (as shown in Figure 31) was a simple ankle sleeve that slipped on like a sock. The advantages to this design was its slender build, compressive, and minimized thickness that was less than the average thickness of an ankle brace.[65] However, this design did not provide a cooling element or a medicative element. In addition, there was minimal support of the ankle in the brace.

Figure 31: Preliminary POC Design 2

The third design concept (as shown in Figure 32) incorporated the figure eight method to reduce joint swelling. This design was much simpler than the first design concept. It consisted of a felt strap that wrapped in a figure eight motion around the ankle. This was very much a preliminary design as we used felt to wrap the in a figure eight. Additionally, the goal of this Preliminary POC was to minimize thickness without compromising the provided ankle stability.

Figure 32: Preliminary POC Design 3

The fourth design (as shown in Figure 33) was a combination of the simple figure eight design that was initiated in the second conceptual design. Expanding upon the previous design, a spandex sleeve was sewed to fit a small foot. This layer was slipped directly onto the ankle and adjusted to form around the ankle. POC Design 4 aims to address the following:

1) Compression
2) Limited thickness
3) Mechanical Stability
4) Ice Component

Figure 33: Preliminary POC Design 4

At this point of the project, incorporating the transdermal holder and the cooling element became a priority. For this particular POC, the cooling element was integrated into the pocket of the wrapping portion of the brace. The cooling agent would be Orbeez saturated in 10% Isopropyl alcohol and water for 3 hours to maintain ideal saturation for cooling in addition to a size that would not make the brace too bulky as displayed in Figure 34 below:

Figure 34: Cooling Element

4.4 Feasibility Study

The cotton straps in the form of the figure 8 allows for effective stabilization of the human ankle based on previous studies conducted.[66] The Cotton Straps are attached via Velcro and thus, allow for limited movements of the ankle in the eversion, inversion, plantarflexion, and dorsiflexion directions. The incorporation of the PDMS Horseshoe provides mechanical stability and reduces edema of the ankle. Therefore, promoting an optimal healing environment. The accessories of the ankle braces are held together by magnets which are easier to manufacture and are more durable than velcro straps based on preliminary research and testing in WPI facilities, GH 006.

4.5 Modeling

Ankle Brace Insert Accessory – Design 1

Displayed is a CAD drawing of an ankle brace insert accessory made for the constructed ankle brace. Accessory 1 is an insert for the lateral and medial parts of the ankle for mechanical support. This design will provide protection and mechanical stability for the ankle. Additionally, the design allows for the containment of the drug delivery system. The user will have the option to use or not use the drug delivery system depending on the status of the ankle healing. Nonetheless, the supports are designed to be rigid to limit inversion and eversion movements of ankle sprains while simultaneously allow for constant and controlled application of topical medication.

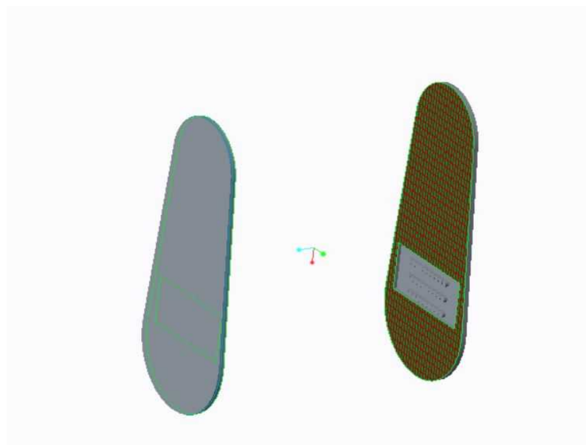

Figure 35: Lateral and Medial Ankle Supports

PLA Horseshoe Insert and Drug Delivery System (DDS) Accessory – Design 2

This design aims to build upon Design 1 and reduce edema of the ankle sprain while simultaneously provide stability and allow for medicinal application. The “horseshoe” design will be integrated into the ankle brace to provide both medial and lateral ankle support. This design encompasses the structural integrity and the mechanical support provided by conceptual design 1. Conceptual design 2 includes the drug delivery system that directly fits into the horseshoe designed for stability, unlike the objective of conceptual design 1. As displayed, the DDS consists of a simplistic reservoir and mesh on the outer surface of the system which allows for ease of use for the user. Similarly, to conceptual design 1, the user has the option to use or remove the DDS. However, in this design, it is via a “snapping” mechanism. This accessory is recommended to be applied during the Inflammation Phase of Wound Healing.

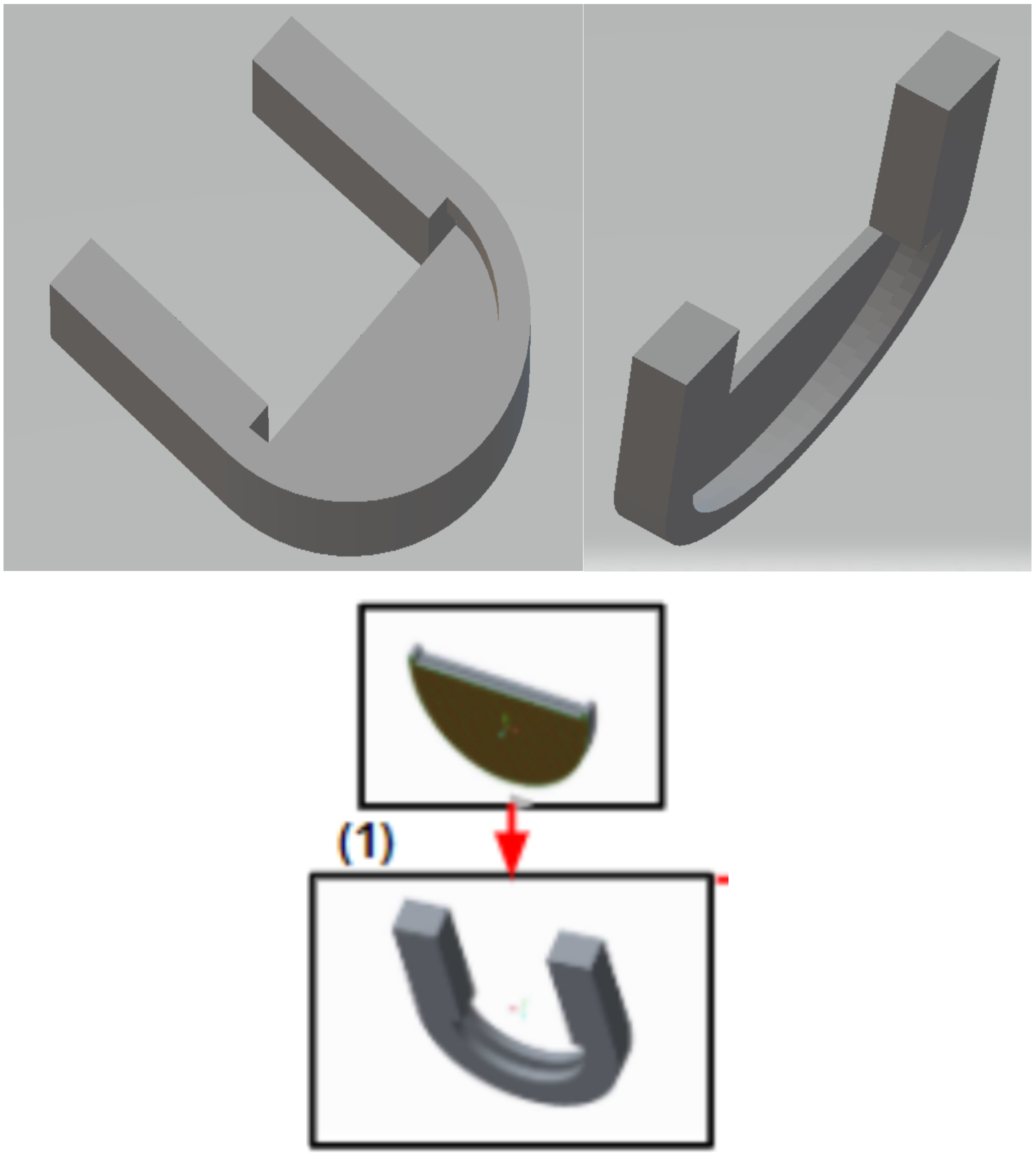

Figure 36: PLA Horseshoe Insert and DDS Accessory

PDMS Horseshoe and DDS – Design 3

Design 3 incorporates all the components of the previously described designs. It is designed to provide mechanical support and constant and controlled application of topical medication. This design serves to improve the user experience by changing the mesh to patterned 0.1mm pores and allowing for the user to include/integrate an additional mesh layer for a more controlled drug release. Additionally, Design 3 includes a holder for both the horseshoe and the DDS which allows the patient to store the device without risk of losing components and reduce exposure to bacterial build-up. Unlike Design 2, the Horseshoe will be made of PDMS to provide mechanical stability without irritating the surrounding skin.

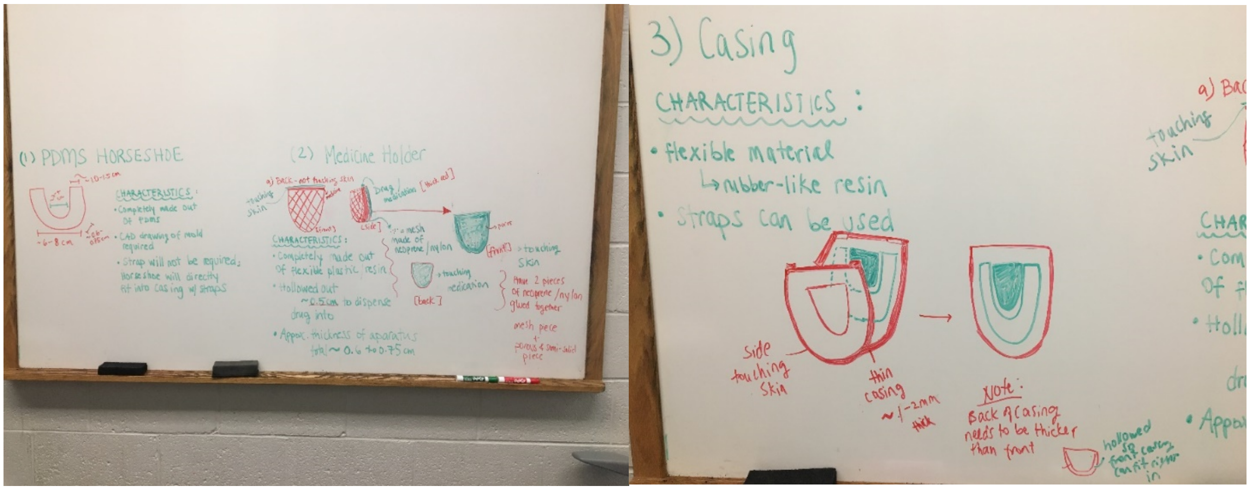

Figure 37A: PDMS Horseshoe and DDS Design 3 Group Sketch

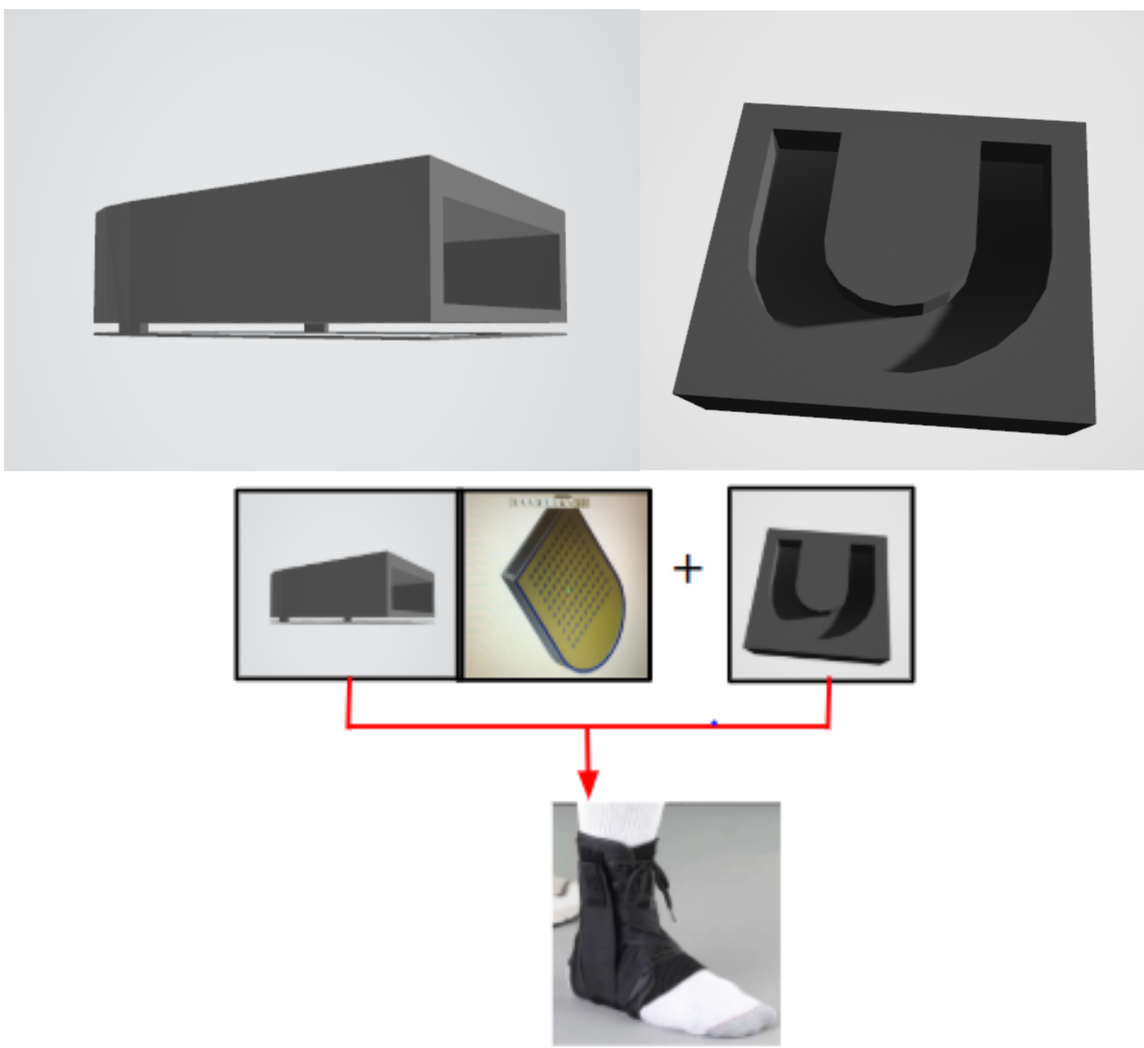

Figure 37B: PDMS Horseshoe and DDS Design 3 CAD

4.6 Preliminary Data

Our preliminary data was obtained through the goniometer which was used to measure the ROM of one human subjects with ankle sprains and two without ankle sprains. The results are also displayed below. For Dorsiflexion and Plantar flexion the following landmark were used as reference to create a triangle and obtain the degree change in the ankle: Fifth metatarsal, Calcaneus, and Malleolus. Likewise, the landmarks used to obtain the degree change in the ankle are: inner Calcaneus, Inner Malleolus, Fifth Metatarsal, Outer Malleolus, and the Outer Calcaneus.

Typical Values
(Firm) dorsiflexion value – 20 degrees
(Firm)Plantar flexion- 50 degrees
sagittal plane
(Firm)Inversion- 35 degrees
(Hard) eversion- 15 degrees

Placement for Dorsiflexion/Plantarflexion	Sensor
Malleolus	3
Calcaneus	2
Fifth Metatarsal	1

Placement for Inversion/Eversion	Sensor	Hub
Inner Calcaneus	1	1
Inner Malleolus	2	1
Fifth Metatarsal	3	1
Outer Malleolus	1	2
Outer Calcaneus	2	2

Patient sits or lays with leg dangling from patient table. The fulcrum is applied over the lateral malleolus while the station arm is linked to the fibula head. the patient flexes and the moving arm stays parallel with the fifth metatarsal. The measurements are taken in dorsiflexion and plantar flexion.

Inversion and eversion calculations are determined by placing the fulcrum between the medial and lateral malleoli and the stationary arm is in line with the tibia crest. The patient moves their toes inward and outward then calculated.

Ind. 1 (no ankle sprain)	Test subject (without braces)	Test Subject (with brace)	Percent Decrease
dorsiflexion	20	5	75%
Plantar flexion	49	33	32.65%
Inversion	25	18	28%
Eversion	15	11	26.67%

Table 5: Test Subject 1 with no ankle sprain

Ind. 3 (without ankle sprain)	Test subject (without braces)	Test Subject (with brace)	Percent Decrease
dorsiflexion	23	9	60.87%
Plantar flexion	50	37	26%
Inversion	30	23	23.33%
Eversion	16	11	31.25%

Table 6: Test Subject 2 with no ankle sprain

Ind. 4 (with ankle sprain)	Test subject (without braces)	Test Subject (with brace)	Percent Decrease
dorsiflexion	17	3	83.4%
Plantar flexion	52	22	58.7%
Inversion	23	21	8.7%
Eversion	13	8	38.43%

Table 7: Test Subject 1 with ankle sprain

5. Design Verification

5.1 Design Summaries

Provided below is a table summarizing each Preliminary POC which was used to monitor the progress of the project and provide a framework for the subsequent measures of the project. With the compression, stability, and cooling elements addressed, the project proceeds to develop accessories to address the following gaps:

1. Drug Delivery System
    - Optimize healing process
2. Mechanical Support
    - Inhibit ankle motion and reduce swelling

Components	Objective	POC 1	POC 2	POC 3	POC 4
Cooling	Integrated into ankle brace without exceeding brace thickness of 2 inch				✓
Material	Thin and flexible		✓	✓	✓
Drug Delivery	Contacting skin, counter noncompliance, and allow for easy application & clean up	✓			

Table 8: Summary of Preliminary POC

5.2 Final Horseshoe and DDS CAD Design

PDMS Horseshoe and DDS – Final Design

The Final Design builds off the previous conceptual designs. The design provides mechanical stability, a DDS that is easy to use and sanitize, is thin in size, has 0.08 in sized pores, and allows user to insert an additional layer to enhance the control of drug release. It is recommended that this accessory is used during the Inflammatory and Proliferative Phases of Wound Healing.

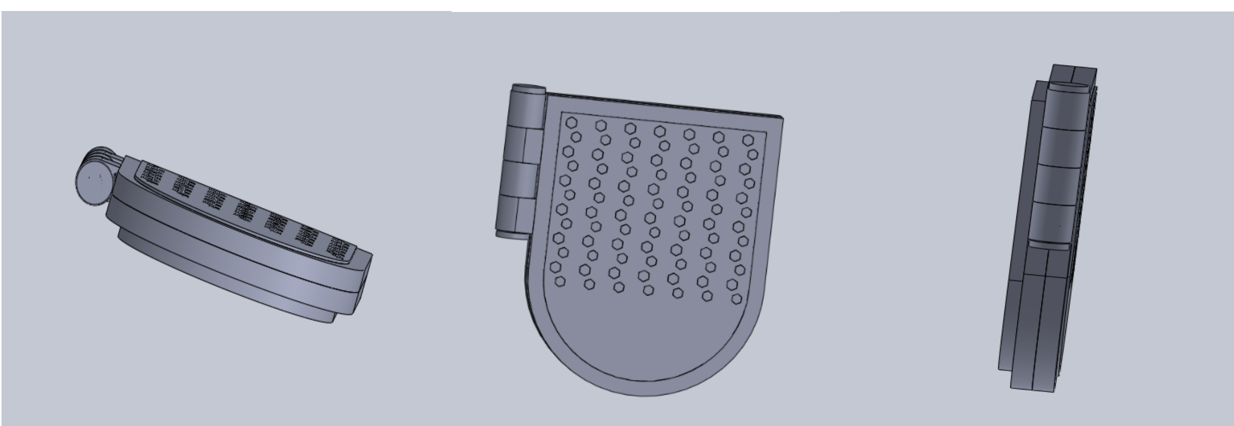

Figure 38: DDS Design 4 – Final Design

Breakdown of Conceptual Design 4 – Final Prototype

1. <u>Front of the DDS:</u>

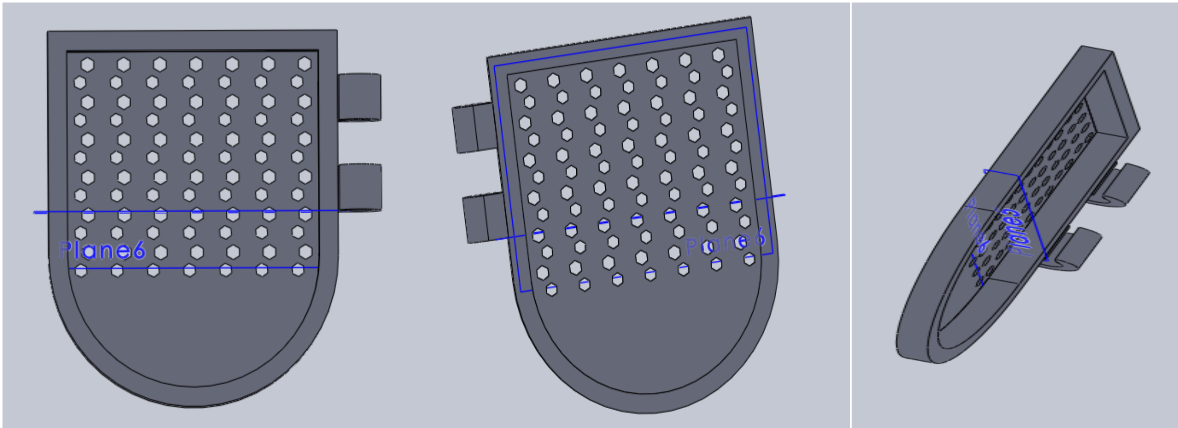

Figure 39: Final Design Breakdown (Front)

2. Back of DDS:

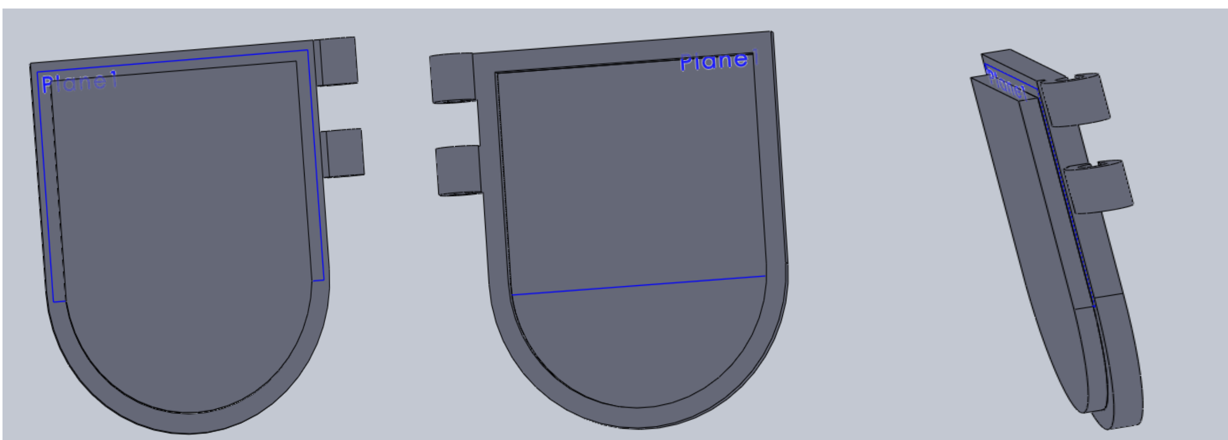

Figure 40: Final Design Breakdown (Back)

3. Screw 1:

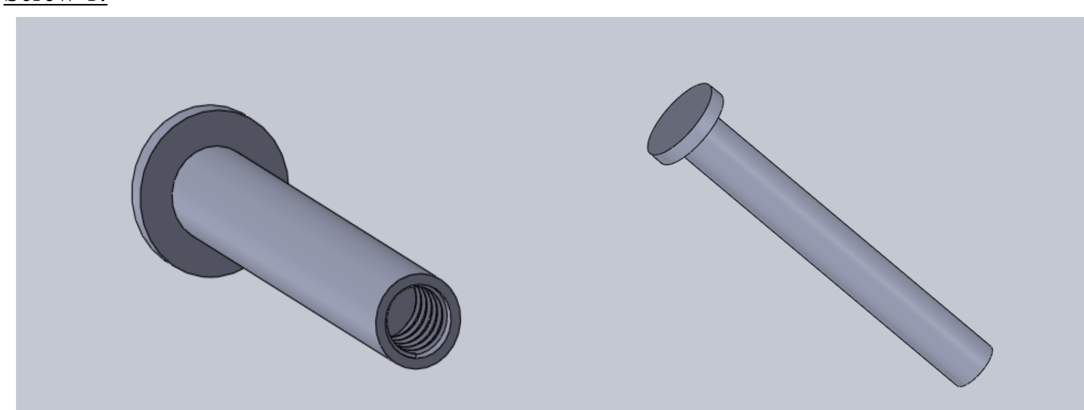

Figure 41: Final Design Breakdown (Screw 1)

4. Screw 2:

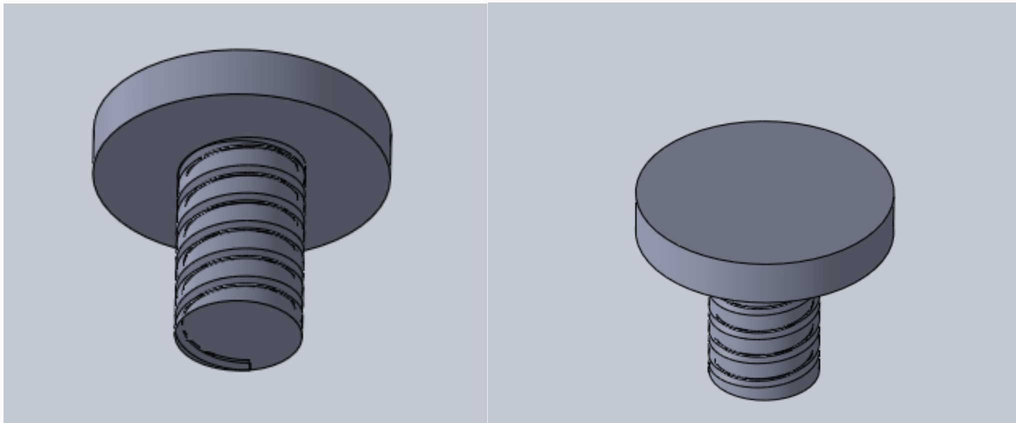

Figure 42: Final Design Breakdown (Screw 2)

Below is a table summarizing the features included in the final Horseshoe and DDS Accessory.

Accessory	Objective	Objective Met
Horseshoe	1. Provides support 2. Reduces ankle edema	✓
DDS	1. Flexible, thin, and conforms to skin 2. Regulated Drug Release	✓

Table 9: Final Horseshoe and DDS Accessory

6. DISCUSSION

The progress of our preliminary designs and development of our drug delivery element at this point satisfy most of our goals and objectives. At this point 3D the design itself remained to be done to assess the design and the brace needs to be resewn in a more cohesive manner. The cooling device was ultimately decided to be good as is. For the final design, the material drug delivery system, mechanical stability, compression, and cooling element must be tested to validate whether or not our device successfully accomplishes all of the goals. The table below explains the testing that needs to be done to validate our final design.

Type of Test	Objective	How it is Performed	Hypothesis
Cooling	To test how much the ankle is cooled through the brace	The cooling packet was placed in the pocket through the layers of the brace recording the starting temp and the temp after 10 min	The brace will allow a minimum cooling of 2 ℃ while not being so cold it burns
Material	To test the moisture wicking capabilities through hydrophobicity	A drop of water was applied to the brace in direct skin contact and the angle was measured with Image J	The angle measured will be between 45° & 90° for hydrophobicity
Drug Delivery	To test the rate of drug release	The medication was applied to a cotton round and the surface area of saturation was compared to a control	The drug release will be between 0.25 mL (pores too small) & 2 mL (pores too big)
Goniometer	To measure the range of motion through angle change	Flexions were performed before and after wearing the brace and the angle was measured with a goniometer	The angle measured will be smaller with the brace than without
Polhemus	To measure the range of motion through sensor movement	Flexions were performed before and after wearing the brace and the angle was measured with sensors via Z-position [pixels]	The angle measured and the max Z-positions will be smaller will be smaller with the brace than without

Table 10: Summary of Testing to be done to validate the final design based on the point of the design thus far

7. FINAL DESIGN AND VALIDATION

7.1 Final Design

Our Final Prototype constructed encompasses the following components that fulfills the goals for this project as shown in Table 11 below. Various trials and iterations, as illustrated in Chapter 4 of the report, were required for the completion of the final prototype. The final prototype is versatile and can be applied by users of different ages and shoe sizes. The constructed medicated ankle brace encompasses a drug delivery system for topical medication via the user's preference or choice, mechanical stability, compression, and a cooling element. Additionally, the ankle brace is thin, compacted, and can be worn comfortably with shoe for long periods of time.

Nylon Sleeve for compression

Horseshoe

Drug Delivery System

Cooling Element

Figure 43A: Final Prototype Tangible Components

Approx. 1.5 inches thick

Figure 8

Ability to sit on flat surface

Figure 43B: Final Prototype Tangible Components 2

Components	Objective	Final Prototype
Material	Thin and flexible (approx. 1.5 inches)	✓
Drug Delivery	Contacting skin, counter noncompliance, and allow for easy application & clean up	✓
Mechanical Stability	1. Provides support 2. Reduces ankle edema	✓
Compressive	Reduces edema, keeps swelling under control	✓
Cooling	Integrated into ankle brace without exceeding brace thickness of 2 inch	✓

Table 11: Summary of the Final Prototype

	Affordable	Thin/Able to fit in a shoe	Compressive	Horseshoe Edema Reducer	Medicative Element	Cooling Element	Mechanic Stability	Moisture wicking	Reusable	Aesthetic	Score
	1	0	0	0	1	0	1	0	0	0	3
	1	1	1	0	0	0	0	1	1	1	6
	1	1	1	0	0	1	1	0	1	0	6
	1	1	1	0	0	1	1	1	1	1	8
	1	1	1	1	1	1	1	1	1	1	10

Table 12: Pairwise Comparison of our final design

7.2 Mechanical Testing Literature Review

To combat the risk of ankle instability and injuries various testing has been performed to obtain the natural biomechanics of the human ankle. These tests strive to better understand the mechanics of the ankle by obtaining maximum and minimum rotation, flexion values, and other values to provide the most optimal rotational environment for the ankle to heal. The main function of the ankle joint is to perform its natural range of motion.

Prior to performing the special testing on the ankle, it is important to examine the ankle and possible mechanisms of injury. Gait observations and analysis are made to check for discrepancies. Palpating the ankle and fibula upon examination allows for determination of tenderness or existence of fracture. Additionally, the distal pulses must be checked to ensure the pedal pulses are present. Finally, Girth measurements in other words, the circumference of the narrowest point of the ankle, is taken to determine the extent of the ankle swelling.[67]

Based on literature the primary form of motion in the ankle occurs on the sagittal plane. The sagittal plane has been evaluated to have an overall range of motion between 65 and 75 degrees.[68] The frontal plane of the ankle has a total range of motion of 35 degrees. These ranges change depending on daily activities such as walking, running, and jumping. In order to create the most optimal healing environment for our brace design it is necessary to review previous methods to evaluate range of motion in the ankle.

There are several exams that can test the stability of the ligaments and tendons in the ankle such as the Talar tilt test (Figure 44), the anterior drawer test, the squeeze test, and the Thompson test. The first test mentioned involves positioning one hand on the patient's leg and the other hand cupping the heal then performing inversion on the ankle joint. If a reaction is made or pain is felt in the ankle, then the test may prove instability.[69] The same test can be performed while wearing the braces to determine the prevention of instability while wearing the brace. The talar tilt test can determine biomechanical compatibility of the braces to the ankle is the Talar tilt test. Further specifics into performing this test is to first position a patient's foot 10-20 degrees of plantarflexion, then the distal lower leg is held proximal to the malleoli and the hindfoot is inverted with the other hand.[70] To determine tilting palpitations are performed to the lateral part of the talus.

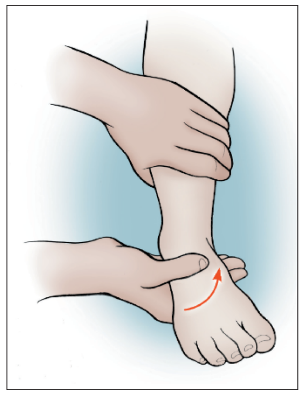

Figure 44: Talar Tilt Test [18]

The anterior drawer test (Figure 45) is used to evaluate hypermobility in the sagittal plane of the Talocrural joint.[71] To perform this test the patient’s knee joint is positioned at a 20 degree angle of flexion with the heel cupped in the examiners hand. The tibia and fibula are pushed posteriorly. As time proceeds during this test, the posterior translation weakens as the ligaments weaken. If greater than 1 cm posterior translation, then there is a presence of ligament weakening. The degree of bending of the test is categorized on a 4-point scale, 0 being the laxest and 4 the most.

Figure 45: Anterior Drawer of the Ankle [19]

The third test that can be performed on the ankle is what we call the Polhemus Test (as shown in Figure 21) This test involves identifying and placing sensors on the human body, in our case the ankle, and measuring range of motion based on the magnetic tracking system. This test can be performed with the ankle brace and without the ankle brace on a healthy ankle. The results from these two tests will be compared to determine the baseline range of motion in a healthy ankle compared to the range of motion of ankle injured using our brace.

Figure 45: Polhemus Test [20]

7.3 Mechanical Testing

To quantify and evaluate the effectiveness of the stabilizing effects of ankle braces, further mechanical analysis is required. Studies conducted must evaluate the stabilizing effect of the ankle brace in conditions: passive and rapidly induced.[72] Passive conditions refer to situations where the ankle joint complex is unloaded and moved in various directions. Advantages of this test include stability characteristics in different directions: inversion-eversion, plantar-dorsiflexion. The disadvantage is that it is not a realistic representation of the potentially traumatizing situation due to the lack of dynamic analysis in the application of torques and the neglected potential influence of the muscles that stabilize the ankle joint.[73] Rapidly induced stability is when subjects are subjected to a fast inversion event on a tilting platform. The tilting platform simulates an ankle sprain. The foot is loaded with bodyweight and the inversion instant is unknown to the subjects, therefore emulating a more realistic condition/instance. The disadvantage of this test, however, is that it is mainly limited to inversion.[74] Both the passive and rapidly induced tests provide objective information about the stabilizing effects of the ankle braces either under laboratory or more realistic conditions allowing for quantification. The results of the tests will provide information to the extent that the braces stabilize the ankle joint complex against passively induced inversion and eversion, plantar and dorsiflexion, and internal and external rotation as well as against rapidly induced inversion movements on a tilting platform.[75]

Quantifying the mechanical strength of the ankle permits analysis of treatment effectiveness and quantification. Mechanical ankle instability is induced by ligament laxity; while functional ankle instability is caused by postural control deficits, neuromuscular deficits, muscle weakness, and proprioceptive deficit.[76] The most common approach to manage ankle instability is a more conservative approach. This approach includes the use of bracing and taping to provide support for the ankle and potentially prevent initial and recurrent ankle sprains. The purpose is to restrict joint motion without limiting performance. Therefore, to assess the mechanical ankle instability and quantify the effectiveness of the ankle brace, it is important to compare the differences in laxity at the ankle under three conditions: taped vs. braced vs. no post-injury application.

7.4 Summary of Mechanical Testing

7.4.1 Polhemus Test

The Polhemus is an electromagnetic motion tracking device. It is used in many cases to determine biomechanical behavior of a certain area on the body. In this case, the objective in using the Polhemus was to track the orientation and position of an object (the ankle) relative to a global coordinate system. The G^4 source contained in the dongle produces the electromagnetic field needed to collect the data along with the use of these coordinates and by matching the data with the frame time, an angle can be obtained. It was performed by establishing a positive global coordinate system that contains strategically placed markers with sensors attached to wires connected to a sensor hub. A dongle is inserted into a computer that will allow wireless communication with the sensor hubs this will in turn aggregate the raw tracking data from the movement of the ankle relative to the global coordinates.[77] In our case, three different sensor ports were used to obtain accurate data in dorsiflexion and plantarflexion motions: sensor number one was located at the fifth metatarsal of the ankle, number two was located at the calcaneus of the ankle, and sensor three was at the malleolus of the ankle. The sensors will become the determinate position to calculate the range of motion. Past the setup of this experiment, the team hypothesized that during the performance of each flexion, the angle measured, and the max Z-positions will be smaller with the brace than without the brace. The Polhemus test was performed from rest to dorsiflexion, and from rest to plantarflexion. In each of the two flexions the test was performed with and without the ankle brace. The results are shown in Figures 47 – 58.

Placement	**Sensor Number**
Malleolus	3
Calcaneus	2
Fifth metatarsal	1

Table 13: Dorsiflexion/Plantarflexion Set-Up

Displayed below are the results of the ROM Testing of the dorsiflexion motion without wearing the constructed ankle brace at various locations – malleolus, calcaneus, and the fifth metatarsal. The average maximum and minimum values for each set of data was determined based on the minimum and maximum macros generated in excel. The units of the values are in pixels.

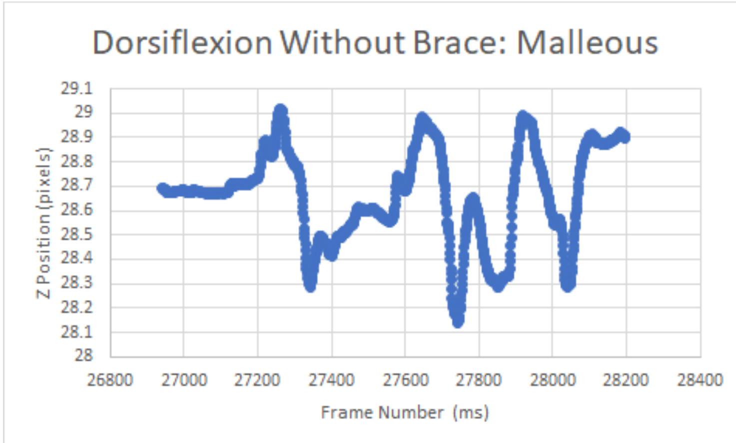

Figure 47: Dorsiflexion without Brace at the Malleolus

Avg max: 31.94 degrees

Avg min: 32.88 degrees

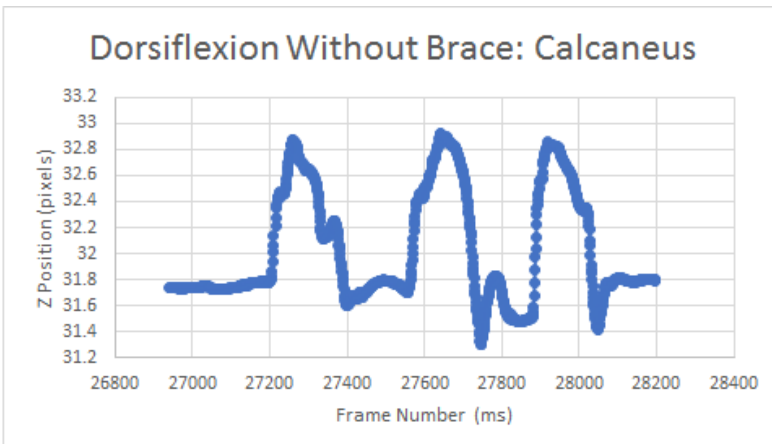

Figure 48: Dorsiflexion without Brace at the Calcaneus

Avg max: 28.88 degrees

Avg min: 28.29 degrees

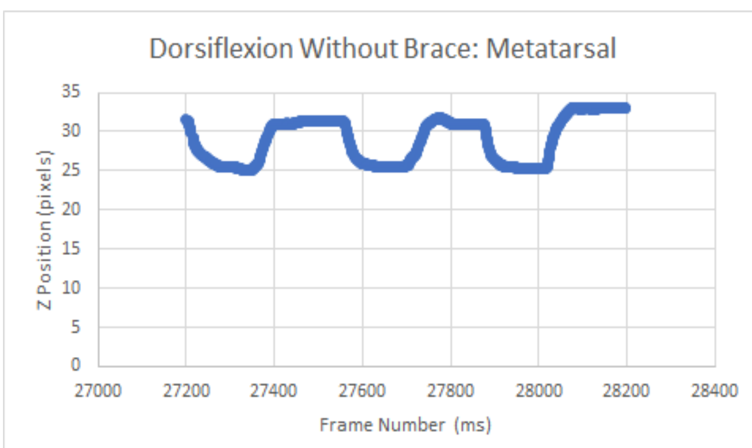

Figure 49: Dorsiflexion without Brace at the Fifth Metatarsal

Avg max: 32.05 degrees

Avg min: 25.25 degrees

Displayed below are the results of the ROM Testing of the dorsiflexion motion with a brace on at various locations – malleolus, calcaneus, and the fifth metatarsal.

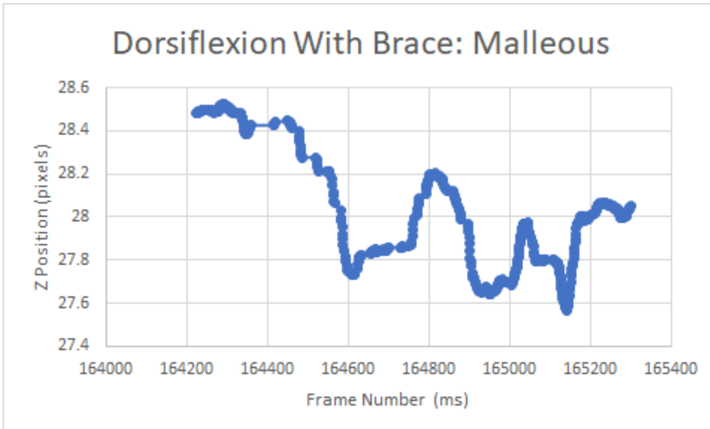

Figure 50: Dorsiflexion with Brace at the Malleolus
Avg max: 30.23 degrees
Avg min: 25.262 degrees

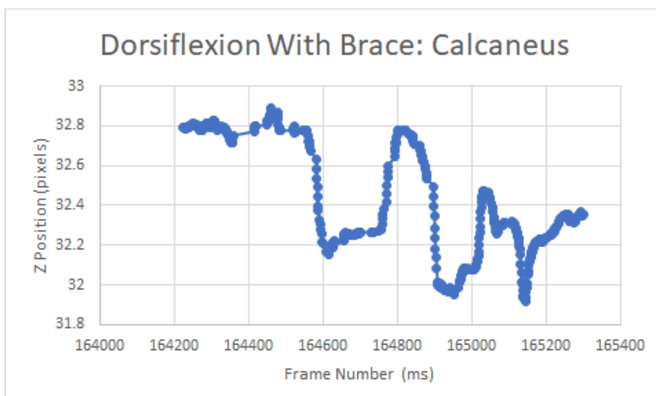

Figure 51: Dorsiflexion with Brace at the Calcaneus
Avg max: 28.08 degrees
Avg min: 27.68 degrees

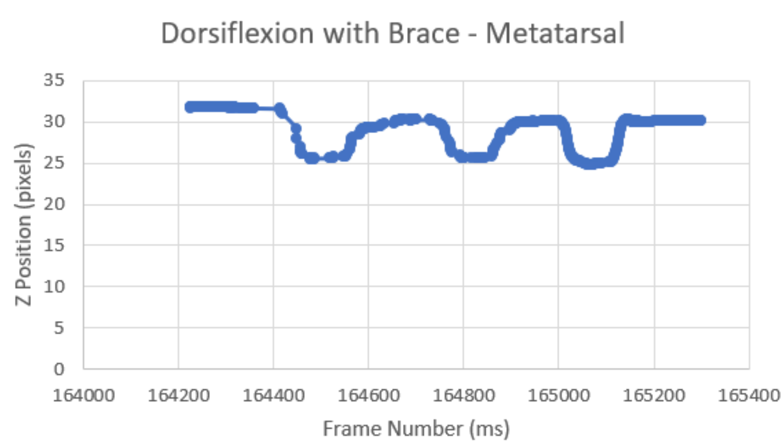

Figure 52: Dorsiflexion with Brace at the Fifth Metatarsal
Avg max: 31.44 degrees

Avg min: 25.26 degrees

Displayed below are the results of the ROM Testing of the plantarflexion motion without a brace on at various locations – malleolus, calcaneus, and the fifth metatarsal.

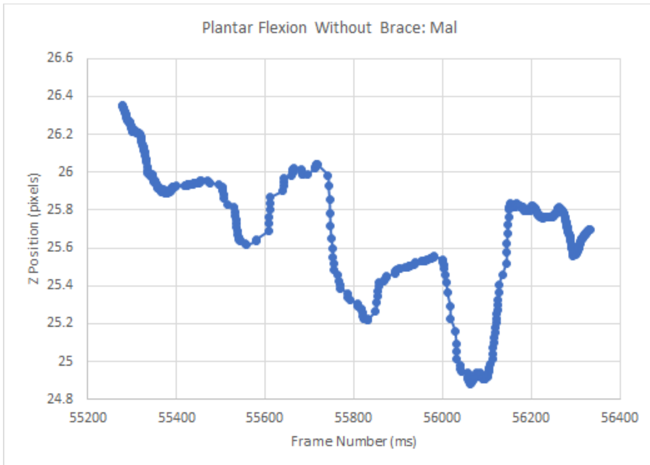

Figure 53: Plantarflexion without Brace at the Malleolus
Avg max: 30.96 degrees
Avg min: 29.77 degrees

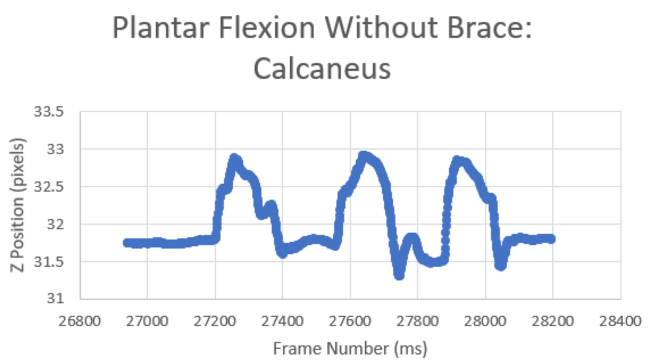

Figure 54: Plantarflexion without Brace at the Calcaneus
Avg max: 28.89 degrees
Avg min: 27.32 degrees

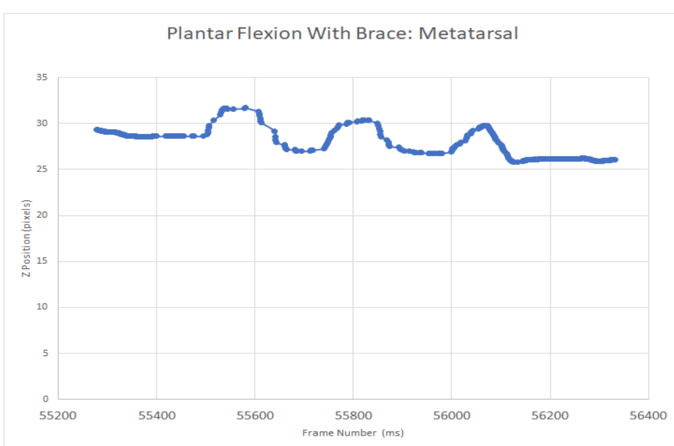

Figure 55: Plantarflexion without Brace at the Fifth Metatarsal
Avg max: 31.7 degrees
Avg min: 25.75 degrees

Displayed below are the results of the ROM Testing of the plantarflexion motion with a brace on at various locations – malleolus, calcaneus, and the fifth metatarsal.

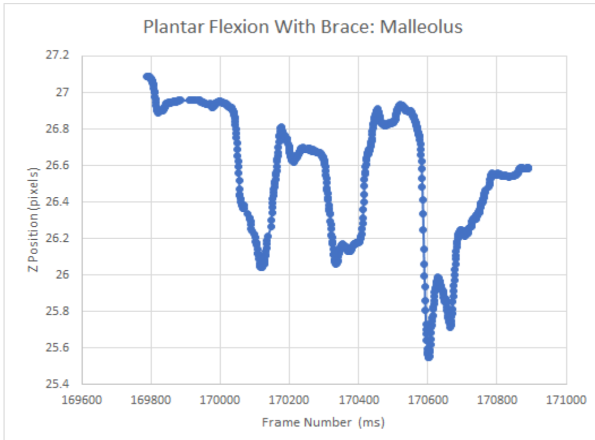

Figure 56: Plantarflexion with Brace at the Malleolus
Avg max: 26.89 degrees
Avg min: 25.88 degrees

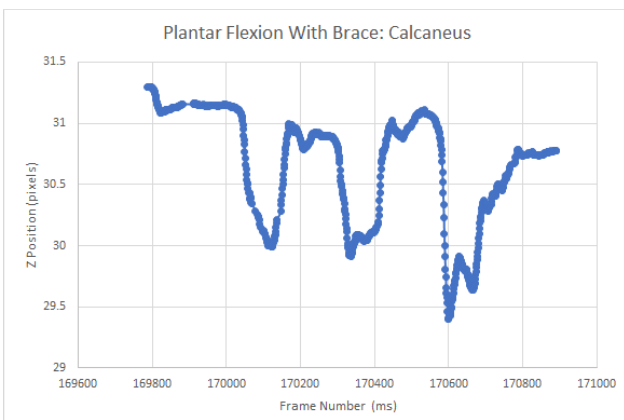

Figure 57: Plantarflexion with Brace at the Calcaneus
Avg max: 25.97 degrees
Avg min: 25.25 degrees

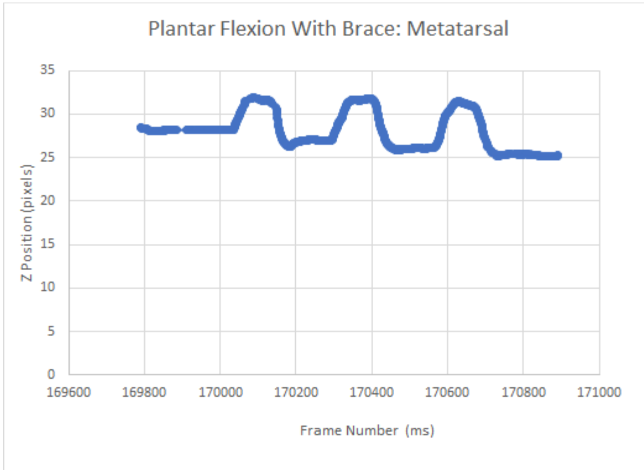

Figure 58: Plantarflexion with Brace at the Fifth Metatarsal
Avg max: 30.63 degrees
Avg min: 26.52 degrees

The overall change in angle was calculated. The equations used to calculate and quantify the results are summarized below. Additionally, a summary of the results is also provided.

$$\tan\theta \frac{(\max distance\ from\ malleolus\ to\ metatarsal)}{(\max distance\ from\ calcaneus\ to\ fifth\ metatarsa} \quad (1)$$

$$Difference = (\theta \text{ without Brace}) - (\theta \text{ with Brace}) \quad (2)$$

Dorsiflexion Calculated Angle Change [degrees]	
Without Ankle Brace	**86.92°**
With Ankle Brace	**73.53°**
Difference	**13.39°**

Table 14: Dorsiflexion Angle Results

Plantarflexion Calculated Angle Change [degrees]	
Without Ankle Brace	**87.75°**
With Ankle Brace	**86.29°**
Difference	**1.46°**

Table 15: Plantarflexion Angle Results

NOTE: The brace limits the movement of the ankle in the plantarflexion motion. The change is not significant as the motions of the ankle are significantly small and difficult to capture. This result may also be due to insufficient contact between skin and sensor.

7.4.2 Goniometer Test

A goniometer is used to quantify even the slightest changes in the range of motion of a part that is being measured, in this case the ankle.[78] This test was performed using the brace and without the brace using four ranges of motion: inversion, eversion, plantarflexion, and dorsiflexion. To perform this test patient sits or lays with leg dangling from patient table. The fulcrum is applied over the lateral malleolus while the station arm is linked to the fibula head. the patient flexes and the moving arm stays parallel with the fifth metatarsal. The measurements are taken in dorsiflexion and plantar flexion. Inversion and eversion calculations are determined by placing the fulcrum between the medial and lateral malleoli and the stationary arm is in line with the tibia crest. The patient moves their toes inward and outward then calculated. Before the test was performed our hypothesis is that the angle measured will be smaller with the brace than without. Our hypothesis was supported with the results obtained. This can be seen in Table 16.

Figure 59: Goniometer Test – Dorsiflexion
The test subject is Gillian Nadeau

Figure 60: Goniometer Test – Plantar Flexion
The test subject is Gillian Nadeau

Figure 63: Goniometer Test – Eversion
The test subject is Gillian Nadeau

Type of flexion	Average ROM Test subject (without braces)	Average ROM Test Subject (with brace)	Average Percent Decrease
Dorsiflexion	19°	5°	75.13%
Plantar flexion	51.5°	33°	36.15%
Inversion	25.75°	18.25°	29.01%
Eversion	14.25°	9.75°	31.78%

Table 16: Goniometer Test Results

7.5 Summary of Hydrophobicity Tests

One of the most important factors for any material that comes in contact with the foot is comfortability in terms of how sweaty their feet will get. The best way to quantify the comfort of the brace against the natural sweat in daily activities is to characterize the moisture wicking capabilities through hydrophobicity. This introduces a new set of parameters to consider because while we want the contact angle to not indicate hydrophilicity, which for our sake we decided to be under 45° because we wanted to set a lower threshold, we also did not want the material to be too hydrophobic because it has been established that those materials can be very uncomfortable.[79] We decided to make the upper limit of hydrophobicity of out hypothesis 90° because that angle is typically indicative of a very hydrophobic surface.[80] Contact angle measurement and analysis with ImageJ software is an ideal test for our situation because it is cheap, easy, and fast. It should be noted there are drawbacks to contact angle measurement like user variability. Three contact angles were taken as seen in table 17 and the average was within 45° and 90° confirming our hypothesis.

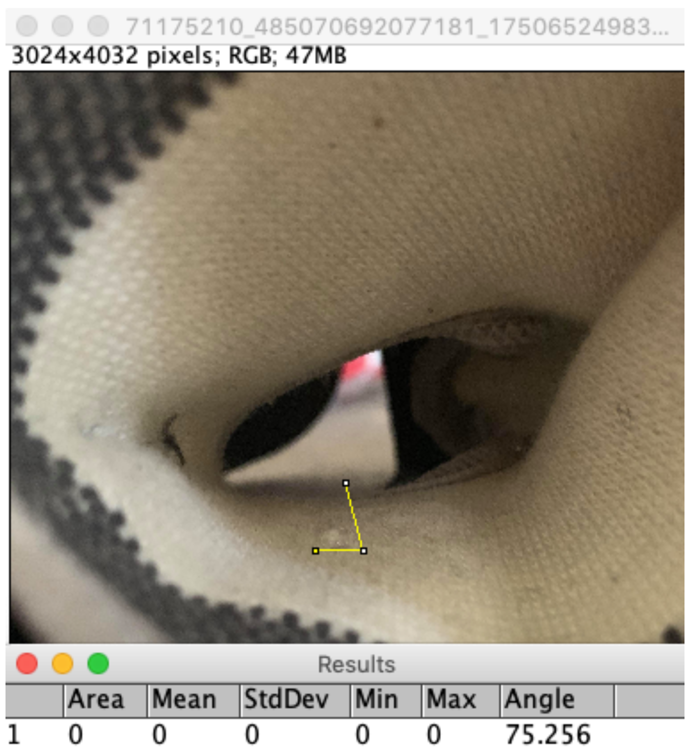

Figure 62: Hydrophobicity Test

Angle 1	78.11
Angle 2	75.26
Angle 3	86.2
Average	79.86

Table 17: Summary of Hydrophobicity Testing

7.6 Summary of Cooling Tests

A cooling effect is important for pain relief and a test was done to confirm the effect. As stated earlier in our background, the bare minimum degree of cooling to have any analgesic effect is 2 ° C. Therefore, we decided to formulate our hypothesis around this minimum. We hypothesized that there would be a cooling effect of at least 2°C while not being so cold that there would be ice burn. To test this the cooling pack was applied to the skin through all the layers of the brace for 10 min. The skin temperature before applying the brace was recorded and compared to the skin temperature after. The results are displayed in Table 18. We had an average cooling effect of 2.6 °C meeting the minimum goal of our hypothesis. None of the users felt that the brace was too cold and the fact that we were so close to the minimum goal makes us confident that this will not be specific just to the trial groups.

Trial Number	Temperature Before [°C]	Temperature After [°C]	Difference [°C]
Trial 1	35.3	33	2.3
Trial 2	33.7	30.9	2.8
Trial 3	34	30.8	3.2
Trial 4	33.7	31.2	2.5
Trial 5	36.2	33.5	2.7
Trial 6	32.9	30.8	2.1

Table 18: Six trails of cooling data monitoring the temperatures before and after.

7.7 Summary of Drug Release Tests

The final device that we designed was able to deliver topical drugs directly to the skin. This was facilitated through the user applying their drug of choice onto their material of choice (we recommend a cotton pad or around) and having the medication seep through the pores which can be seen in Figure 63. The rate of drug delivery is important for both providing pain relief and ensuring the user has a mess-free, comfortable experience. This test was done using a generic oil based analgesic ointment that one can find in any pharmacy. A surface that easily stained with oil was used with the drug delivery device pore side down so that all ointment would absorb into the surface. The surface was suspended to ensure that there was no residual ointment leaking onto the floor that might affect surface absorption. A cotton round was completely saturated with the ointment and compared to a control of 2.46 mL (⅛ tspn packed and leveled), both were applied to the surface for one hour. The resulting surface area was approximated with circles as seen in Figure 64. Table 19 shows the results of the testing. Assuming proportional absorbance throughout the material, a proportion was used to determine the volume that our device released over the course of one hour. The final rate was 1.41 mL/hr release. Keeping in mind that the cotton round was 100% saturated, it should be noted that the user can apply less ointment if they feel that the rate is too high for their preference and can adjust it.

Figure 63: What the loaded device would look like

Figure 64: Image of the stained area after the hour

Group	Surface Area	Volume
Control	6.6 in^2	2.46 mL
Our Device	3.52 in^2	1.41 mL

Table 19: Results of the Drug Delivery Test

7.8 Statistical Results

Statistical analysis of the Polhemus and goniometer test revealed that there was a statistically significant decrease in range of motion as seen in Table 20 and 21. A t-test was used because this kind of analysis is able to provide information on whether or not the null hypothesis, that the ankle brace has no effect can be rejected. A p-value of 0.05 was used and the type of t-test was paired because we are measuring the before and after situations of the same group. Looking at P(T<=t) two-tail in both tables, the Polhemus and goniometer both have values <0.05 indicating that the difference is significant in both situations.[81] Another way to look at the data to determine significance is to see if t Stat < -t Critical two-tail or t Stat > t Critical two-tail.[82] If this is true, in our case it is, then the null hypothesis can be rejected indicating that there is a significant difference with and without the brace.

	Variable 1	Variable 2
Mean	6.801333333	30.23433333
Variance	0.794426333	0.005676333
Observations	3	3
Pearson Correlation	0.735311348	
Hypothesized Mean Difference	0	
df	2	
t Stat	-48.46431158	
P(T<=t) one-tail	0.00021274	
t Critical one-tail	2.91998558	
P(T<=t) two-tail	0.00042548	
t Critical two-tail	4.30265273	

Table 20: Excel analysis of a paired t-Test for polhemus data.
Data used was the difference in measured angle. P(T<=t) two-tail = 0.00042548 < 0.05 and t Stat = -48.46431158 < -t critical two tailed = -4.30265273

	Variable 1	Variable 2
Mean	27.625	16.5
Variance	275.6041667	151.0417
Observations	4	4
Pearson Correlation	0.947783301	
Hypothesized Mean Difference	0	
df	3	
t Stat	3.522623637	
P(T<=t) one-tail	0.019422034	
t Critical one-tail	2.353363435	
P(T<=t) two-tail	0.038844068	
t Critical two-tail	3.182446305	

Table 21: Excel analysis for paired t-Test of goniometer results. Data used were the measured angles. P(T<=t) two-tail = 0.038844068 < 0.05 and t Stat = 3.522623637 > t critical two tailed = 3.182446305

8. CONCLUSIONS AND RECOMMENDATIONS

The objective of reconstructing a medicative ankle brace was to provide relief and promote an optimal healing environment through several goals. Our brace was redesigned help contain two important factors the alleviation of pain and the financial stress of purchasing a temporary brace. Since ankle sprains are the most commonly reported acute injury, our team strived to fill the gap currently on the market for more effectively designed and affordable ankle braces. The ankle brace we redesigned provided efficient mechanical support, as it decreased the range of motion in the ankle joint which was proven through the Goniometer and Polhemus testing. The compressive elements of the brace, mainly from the sleeve and figure-eight straps, add to the positive mechanical nature of the brace. A horseshoe PDMS element was placed around the ankle joint to reduce swelling and prevent edemas. In addition to mechanical favorability, our brace surpassed the threshold of competent cooling as shown in our cooling test. The last essential element that was included in our design was the incorporation of a medicative element. The design for our medicative element was complex involving a complex, continuously reiterated CAD model of the holder. Then the Form2 3D printer was used paired with a biocompatible, inert material called Elastic Resin. After this process came to completion, a soaked cotton pad with medication of your choosing is inserted in the medicative holder. The pore size (controlled by delimitations in the CAD design) of the holder controls the release rate over time. This theory was tested in our drug delivery test and proven effective. All of the elements incorporated in the brace and explained above were designed to be moisture wicking for comfort. The brace can also fit into a shoe easily and all of the elements can be washed, which was another need expressed since most ankle braces on the market were very bulky and a lot of the time non reusable due to: stench, type of injury and what it calls for, and lack of reusable elements. After reconstruction our brace, the total cost of all the materials were under $50, taking into account the bulk purchase. In the future, we expect the price of this product to decrease dramatically through mass manufacturing and production driving prices for materials down. The brace successfully fulfilled all of our objectives and our hypotheses which were validated post experimentation.

An important consideration for the future of our design is whether or not they comply with ISO standards. ISO 13485:2016 is the most relevant standard we have to make sure we adhere to. This standard involves the quality regulation of medical devices both internal and external which is what our device is classified as. This standard is typically compared to ISO 9001, a key difference between these two is that ISO 9001 requires continual improvement while ISO 13485:2016 only requires that the quality system is effectively implemented and maintained. Additionally customer satisfaction requirements are absent for ISO 13485:2016. ISO standards are in place to ensure we comply with regulatory requirements so that public and company can be protected from possible liabilities caused by poor manufacturing practices.[83]

Although our final design was effective and met the team goals, there are a few limitations involved wearing the brace. Firstly, the CAD model of the medicative holder was without a closing clasp on one side. However, this was not initially a huge concern because the pressure from the brace itself holds the medicative holder closed shut. In the future, a redesigned holder with a clasp on the one side may be more beneficial to deployment of drugs, as well as the ergonomics of the braces. Another limitation was the lack of sensors provided in the lab. More sensors would have allowed for a more accurately calculate of the tests performed in plantar and dorsiflexion. In addition, the inversion and eversion range of motion could be determined, collected, and evaluated to see if the general trend of angles decreasing with the brace proved true for these common flexions of the ankle. Along with the previously mentioned limitations, initially the combination of the medicative holder and PDMS horseshoe was one of the goals of this project. Due to repeated attempts of the PDMS creation for the horseshoe, time was a limiting factor. While the team only tested one medication, it would be beneficial to test more medications and alter pore size of the medicative holder to test different rates of release with different medicative elements. Once again, due to limited resources (in this case variation of 3D printers) there was a lack of 3D printing options which caused the material for the medicative ankle brace to come from a very selective few option. Lastly, we were not able to perform a compression tests, this was due to a time element as well.

We were able to address the various objectives set throughout the course of the project.

Primary Objectives	**Met?**	**Proof**
Reusable Medicative Accessory	✓	Drug release test and we washed the holder
Reusable Cooling Accessory	✓	Cooling test met the minimum threshold
Reusable Compressive Accessory	✓	Compression was noted with all users (shoe size 5.5-11)
Moisture Wicking Material	✓	Contact angle measurement
Mechanical Support	✓	Goniometer and Polhemus tests
Secondary Objectives	**Met?**	**Proof**
Affordability	✓	All material costs were under $50 (taking into account bulk purchases) and future manufacturing would be cheaper given bulk discounts
Thin enough to fit in a shoe	✓	All authors wore the brace (shoe size 5.5-11) & it was able to fit in a shoe

Table 22: Objectives of Project - Discussion

9. Considerations and Impact

9.1 Environmental Impacts

The positive environmental impact of our product would be less waste because our device is reusable. With the inclusion of our transdermal holder, not only can medication waste be conserved but the disposable foam “horseshoes” typically used for edema would be replaced. In addition, the product aims to be washer/dryer safe which conserves water as these cleaning devices tend to be more water efficient. Any negative environmental impact would come from pollution byproduct in manufacturing our device.

9.2 Societal Influence

Our device provides for a gap in the healthcare market that would benefit those without adequate healthcare access the most. Those who may not have access to a medical professional can still be affected by ankle sprains. However, the degree of treatment they receive can differ drastically based on the resources available in one's neighborhood. The device we propose would offer an alternative to society in place of more expensive products while being equally effective. This translates societally because other companies might start to see that their products aren’t competing as well or contribute to this healthcare gap and modify their own products to be cheaper and more accessible. In addition, with an ankle injury, most people would need either some time off work or accommodations (ex. Elevator access, can’t carry heavy loads). By promoting optimal wound care, the injured individual would be able to return to their lives and work with minimal recovery time.

9.3 Political Ramifications

Healthcare, equity, and access. Affordable insurance free device that is available to the entire population. Give people what they need in order to level the playing field. Politically, healthcare and access to healthcare has become a highly debated topic. One way that our device would play into this conversation is through providing an affordable, easily accessible revenue for the consumer. This product can be an off the shelf kind of product that would be affordable even if the consumer’s insurance plan won’t cover the more traditional braces on the market. In addition, the quality of healing won’t be compromised despite being more affordable, leveling the playing field for lower income communities whose political priorities lean more towards affordable healthcare concerns. Our device would have its niche in the equitable healthcare market.

9.4 Ethical Concerns

This brace aims to close the gap in the current ankle brace market. This product was kept relatively inexpensive in manufacturability so that it is a cheaper ankle brace on the market. In addition, the ankle brace is reusable for the consumer. The low price provides more broadly available resources to people who cannot afford to purchase a onetime use ankle brace. The three healing elements incorporated in our design are completely detachable if one of the elements is not necessary later in the healing process. Everyone has the financial ability to obtain this product, in addition the successfulness of the brace in healing the ankle does makes it so unique, versatile.

9.5 Health and Safety Issues

Our responsibility is to provide all of the elements that achieve optimal healing. As engineers we have an ethical responsibility to ensure the safety of our product. The drug delivery element to our brace is a strategic holder design, it is not our responsibility to inform the consumer which drugs to use, the dosage, and when to load the holder. The cooling element of the brace was tested to ensure proper cold exposure to the skin, see Appendix G. We deemed the product to be safe because our tests indicated that it had the bare minimum cooling effect for pain relief and swelling reduction indicating that the device was nowhere near cold enough to cause any ice burns. Since our product is for external use only, we have no concerns about any unintended interactions it may have within the body.

9.6 Manufacturability

Our project will provide design criteria that was incorporated in the engineering of the product. It will include photos and dimensional outlines of the brace to ensure easy reproduction and manufacturability. Along with the design outlines, an instruction manual was created to inform users of the best way to wrap the ankle using our brace. There will also be a guide that outlines the most optimal healing environment for common injuries to the ankle and how our ankle brace can be adjusted at three different stages in the healing, this is referred to in Appendix G.

9.7 Sustainability

The ankle brace was created with the intention of user reusability. Our product includes biodegradable water beads that are saturated with water then frozen. In terms of sustainability, the ankle brace was created with the intention of user reusability. The device was built with machine wash-ability and easy cleaning in mind. This was verified during the drug delivery test wherein the resin was coated with the thick ointment and needed to be cleaned. A rinse under soapy water was able to clean the reservoir without any hassle. Furthermore, we know that the brace itself is machine washable since the materials are common blend materials that are machine washed. PDMS is also very easy to be hand washed and wiped clean. There is no aspect of the brace that is not intended to be reused multiple times across several possible ankle injuries throughout the years. The only aspect of the brace that can be considered waste after use is the cotton ball/round that might be used for medication application but even then, the user can choose to use a small, reusable, washable piece of cloth instead. Our device is not recyclable, but it is intended for long term reuse.

9.7 Economic Impact

The main economic impact of our device is that it provides a cheap alternative to current braces on the market without sacrificing quality. Current ankle braces on the market can be several thousand dollars. Cheap alternatives on the market like ankle wraps offer little to no mechanical support and are not nearly as effective. By creating a design that targets more areas of wound healing to optimize the user experiences, we fill a need in the economy for a cheap alternative. Additionally, our device would be shelf ready. Many American's do not have the luxury of being able to access healthcare for every ailment that occurs. This would save money on costly doctor's visits, in addition to being a cheaper product compared to its competitors. Proper wound care decreases recovery time so that the patient will not have to miss out on wages due to immobility. This impacts economics broadly because there will be more people in the working force sooner optimizing business profits, and the patient's own wages.

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15. APPENDICES

APPENDIX A – STAKEHOLDERS

Below is a lost of potential stakeholders for our MQP:

1. Stakeholders that will have an interest in the project:
    - Worcester Polytechnic Institute
    - Orthopedics Department within a Clinic or Business
2. Stakeholders that will be impacted by the decisions made:
    - Individuals with Grade I and II ankle injuries
    - All franchise or businesses interested in the product
    - Athletes (all levels)

APPENDIX B – PROTOTYPING COMPANIES

As part of the extensive background research component of the project, local prototyping companies were contacted and researched upon to provide further insight and future direction for the project.

Companies	Details	Contact Info
Mack Prototype Inc	Plastic Fabrication 424 Main Street, Gardner, MA 01440 https://www.mackprototype.com/	Ph: 978.632.3700
Lumikha 3D	44 Portland St 4th Floor, Worcester, MA 01609 CONSULTING AVAILABLE	(774) 312-6254
J&J Machine Company	66B Brigham Street Marlborough, MA 01752	(508) 481-8166
Advanced Prototypes and Molding Inc	Plastic Injection Molding 87ervices 21 Howe St Leominster, MA 01453	978-534-0584

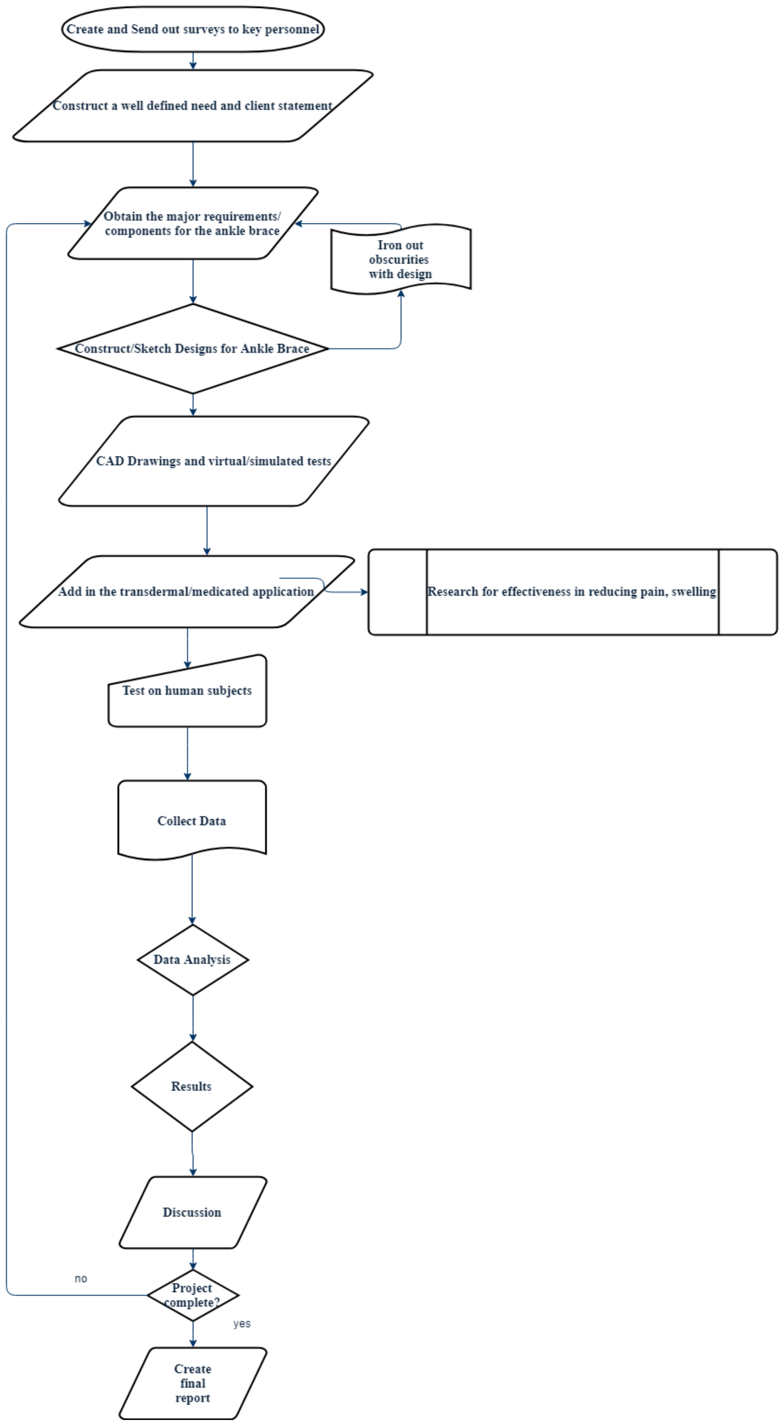
Food for thought:

- What we are looking for in a material?
- Types of materials?

Script:

Hello, we are students from Worcester Polytechnic Institute working on our senior project. We are looking for a company that might be able to manufacture a prototype of our final design. Our device involves a variety of different fabric materials, and polymer fabrication. We have some preliminary prototypes were hoping to have a consultation with someone about the price and feasibility of creating a more cohesive, integrated design.

APPENDIX C – PROJECT APPROACH


Create and Send out surveys to key personnel
Construct a well defined need and client statement
Obtain the major requirements/ components for the ankle brace
Iron out obscurities with design
Construct/Sketch Designs for Ankle Brace
CAD Drawings and virtual/simulated tests
Add in the transdermal/medicated application
Research for effectiveness in reducing pain, swelling
Test on human subjects
Collect Data
Data Analysis
Results
Discussion
no
Project complete?
yes
Create final report

APPENDIX D – CONSTRUCTED SURVEY FOR PROFESSIONALS

Healthcare Professional – Ankle Brace Survey

This form was created in attempt to collect information on the gaps present in the current ankle brace market. The goal of this survey is to collect information from professionals to establish a problem in the ankle brace market and create a solution. Our team aims to establish this problem and create the most optimal conditions for ankle healing.

How long have you been licensed to practice Physical Therapy?

- ◯ Less than 5 years
- ◯ 5 years
- ◯ 5-10 years
- ◯ 10-20 years
- ◯ 20-30 years

What general population do you work with?

- [ ] Pediatric Physical Therapy
- [ ] Geriatric Physical Therapy
- [ ] Vestibular Rehabilitation
- [ ] Neurological Physical Therapy
- [ ] Cardiovascular/Pulmonary Physical Therapy
- [ ] Other: ____________________

What is your area(s) of expertise?

- ○ Sports Injury/Rehabilitation
- ○ Aquatic Therapy
- ○ Joint Conditions/Replacements
- ○ Active Therapeutic Movement
- ○ Stroke Rehabilitation
- ○ Industrial Rehab
- ○ Other: ____________________

How often do manage ankle rehabilitation?

- Never
- Occasionally
- Sometimes
- Often
- Always

How often do you see ankle injuries?

	1	2	3	4	5	6	7	8	9	10	
Never	○	○	○	○	○	○	○	○	○	○	Every patient

What are the braces do you suggestion to a patient for ankle injury management?

Your answer

Do you see any gaps within the current ankle brace market?

- ◯ Yes
- ◯ No

If you think there is anything you could improve on current ankle brace designs what is it?

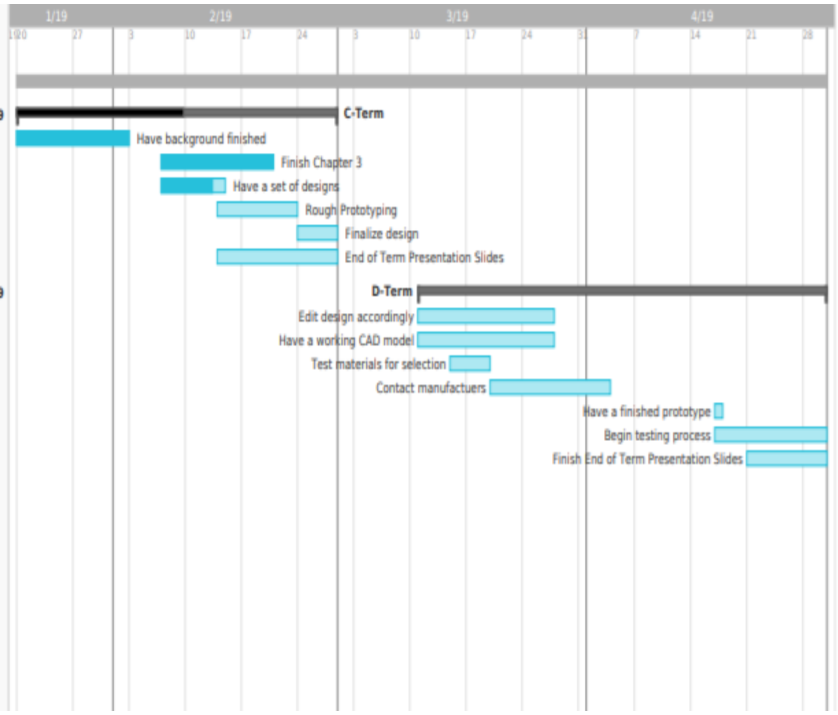
Your answer

Questions, Comments, Concerns?

Your answer

APPENDIX E – MQP GANTT CHART C & D TERMS

MQP	start	end
C-Term	**01/20/19**	**02/28/19**
Have background finished	01/20	02/02
Finish Chapter 3	02/07	02/20
Have a set of designs	02/07	02/14
Rough Prototyping	02/14	02/23
Finalize design	02/24	02/28
End of Term Presentation Slides	02/14	02/28
D-Term	**03/11/19**	**04/30/19**
Edit design accordingly	03/11	03/27
Have a working CAD model	03/11	03/27
Test materials for selection	03/15	03/19
Contact manufactuers	03/20	04/03
Have a finished prototype	04/17	04/17
Begin testing process	04/17	04/30
Finish End of Term Presentation Slid...	04/21	04/30
E/A-Term	-	-



APPENDIX F – PDMS Manufacturing

PDMS was the decided material for a variety of reasons mainly due to the inertness, price, and customizability. Sylgard 184 was chosen because it was what was available on hand. Previously we had a sample of Sylgard 184 manufactured at a ratio of 23.5 g of base and 1.5 g of curing agent that was flexible enough for our needs and decided to copy that. A mold with clamp design was necessary for manufacturing because the 3D printed mold was imperfect and allowed for minor leaks. The filled mold was vacuumed to remove bubbles to aid in the aesthetics and heterogeneity of the PDMS.

Below are the steps to fabricate the PDMS Horseshoe.

1. Obtain a Sylgard 184 kit and weigh 23.5 g of the base and 1.5 g of the curing agent.
2. Attach clamps to the mold to prevent leaks. Vigorously mix the base and curing agent before pouring into the mold.
3. Place in a vacuum until air bubbles are gone
4. Cure for 10 hours in a 60°C oven
5. Carefully remove from mold, use an exacto knife for a cleaner mold

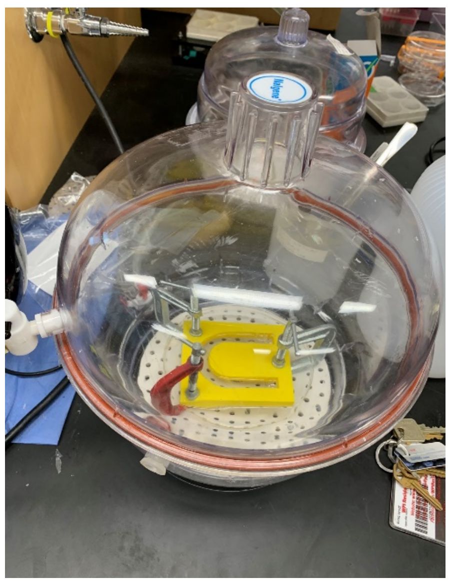


Figure 46: PDMS in Vacuum

Figure 47: PDMS Horseshoe

APPENDIX G – USER GUIDE

How to wrap your ankle:

1. Put on the brace with the straps and appropriate accessories.
2. Wrap your ankle according to a figure 8 configuration. That is starting from the medial side of the foot, above the ankle at an angle, wrap the strap under the base of the foot and bring it back over the top of the foot in the direction of the inner ankle. Wrap it around the Achilles (above the heel on the back of the foot) and back around the other part of the ankle. Secure the end of the wrap on the Velcro.
3. Check your ankle for stability and appropriate tightness by trying to rotate it around a little and adjust the tightness accordingly

Stages of Wound Healing and Our Device:

Inflammatory Phase:
During this phase the injury is still fresh and swollen. During this phase the cooling insertion, drug delivery horseshoe, and figure 8 configuration can all be used to provide pain relief and pressure to the injury. This addresses the issue of pain and swelling.

Proliferative Phase:
This experience of the user may vary at this phase. If pain is still persistent, then the drug delivery horseshoe and the cooling insert should be used to provide relief. Additionally, stability and compression may still be useful to the user at this phase for pain relief and bone/muscle alignment

Remodeling Phase:
During this phase it is important to apply appropriate amounts of strain to the injury site so that the stresses can contribute to the rebuilding process. The horseshoe is no long as necessary for this step because the edema should not reoccur unless additional injury was taken. Instead the wrap should provide enough support so that the impact of walking will not cause an unbalanced load that can regress the healing. The ice can still be used at user discretion.

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