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NOVEL DYNAMIC SPLINT DESIGN FOR ANKLE SPRAINS AND LIGAMENTOUS INJURIES

A Major Qualifying Project

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Dynamic
Ankle
Splint

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Abstract

One out of every ten thousand people in the United States experience an ankle sprain each day, but many of the available devices do not have the correct level of support for the injured ligaments. The goal of this project was to design a device that would permit inversion at a range of 20 to 30 degrees while minimally hindering range of motion in the sagittal plane by mimicking natural ligament behavior through material orientation and selection. This was achieved by utilizing biomechanical simulation software and uniaxial load testing to determine materials; tests of gait, passive muscle movement, and rapid inversion were completed. Results indicate that the splint slowed the rate of ankle inversion and allowed fluid plantar flexion and dorsiflexion. The device provided a balance of inversion restriction while still allowing sagittal plane motion, which provides the user optimal healing options for injured lateral ankle ligaments.

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Glossary

The following terms are commonly used words throughout the report that might be helpful to the reader to better understand the project. All anatomical definitions were obtained from MedlinePlus Medical Dictionary (National Institutes of Health, 2012).

Anatomical Terms	
Term	**Definition**
Dorsiflexion	Flexion of the foot in an upward direction.
Eversion	The condition of being turned or rotated outward.
Inversion	The condition of being turned or rotated inward.
Plantar Flexion	Movement of the foot that flexes the foot or toes downward toward the sole.
Pronation	Rotation of the medial bones in the mid-tarsal region of the foot inward and downward so that in walking the foot tends to come down on its inner margin.
Subluxation	Partial dislocation.
Supination	A corresponding movement of the foot and leg in which the foot rolls outward with an elevated arch so that in walking the foot tends to come down on its outer edge.
Varus	Deformity in which an anatomical part is turned inward toward the midline of the body to an abnormal degree.
Common Terms of the Report	
Brace and splint	The group have used these words interchangeably, referring to a device that partially immobilizes a joint after ligamentous injury.
Client and sponsor	UMass Memorial Hospital plastic surgeons presented the project, and also have an invested interest as the clients that could use the device. The team use these words interchangeably because they apply to the same part.
Dynamic	Allowing for motion of the ankle.
Mobility	Permissive movement of particular anatomical components.
Stability	Restrictive movement so that particular anatomical components cannot move.

1.0 Introduction

The most prevalent type of ankle injury is acute ankle sprain due to inversion of the ankle. One out of every ten thousand people in the United States experience an ankle sprain each day, and an estimated two million individuals suffer from an ankle injury annually (Waterman et al., 2014). People who have previously suffered from an ankle sprain have a higher likelihood of an additional ankle injury, especially if the initial sprain does not heal properly. If treated incorrectly or neglected, acute ankle injuries can develop into chronic conditions. Current brace devices that are designed for ankle sprain recovery are not ideal because they excessively restrict ankle movement or permit over-rotation of the ankle joint. These devices are undesirable because they are cumbersome, heavy, odorous, unattractive, and do not conform to the patient's unique anatomy. The cost of devices and surgery present a financial burden for the patient; over two billion dollars are spent annually on associated medical costs (Waterman et al., 2014).

Eighty-five percent of all ankle sprains are a result of ankle inversion, leading to damage of the supporting lateral ligaments and muscles (Pellow et al., 2001). Lateral ankle sprains can result in weakness, stiffness, and instability of the lateral ligaments, thus prohibiting normal function. Typically, sprained ankle ligaments can recover in a period of four to six weeks, allowing the patient to return to normal levels of activity (Hubbard et al., 2008). The ligament healing process is essential for proper repair and remodeling of the damaged injury site. During healing, there must be restrictions on ankle joint-mobility, in the plane of inversion, while still allowing stress to be applied to the ligaments in the sagittal plane of motion. This results in ideal length ligaments and produces healthy scar tissue. Lack of ankle mobility will result in compromised tissue repair and compensation by the surrounding structures (Denegar et al., 2003). Untreated acute ankle instability can result in chronic ankle instability and recurrent injuries (Hubbard et al., 2008).

Many physicians currently treat mild to moderate ankle sprains by taping or bracing the ankle to secure the joint and prevent reinjury. These practices act as protective devices that externally support the ankle and prevent the ankle from experiencing harmful movement. Studies have demonstrated that braces are more beneficial than taping; however, either is more preferable than no stabilization (Tiemstra, 2012). Ankle braces are manufactured in different materials and designs, offering various levels of ankle support and ranges of ankle motion. Brace categories include: soft braces, semi-rigid braces, and rigid braces.

Mild to moderate acute ankle sprains are treated using a series of ankle braces that vary in level of support. Patients typically wear a high support, rigid brace immediately following injury and are weaned onto a lower support, soft brace as they regain ankle function (Tiemstra, 2012). In some cases, ligaments fail to heal properly and can become weak or lax. Lax ligaments do not stabilize the ankle efficiently, allowing the ankle to move in harmful degrees of motion. Since reinjury can easily occur, treatment for ankle sprains must provide a balance of proper ligament motion and protection against damaging inversion so that the ligaments can heal properly.

A treatment that aims to ameliorate mechanical and functional instability in the ankle is necessary for proper healing because the ankle is prone to reinjury after an initial sprain (Denegar et al., 2003). Remedies that allow early ankle mobilization reduce inflammation and pain, and heal ligaments more effectively than those that completely immobilize the ankle (Dettori et al., 1994). Standard treatments are inadequate because they do not restrict inversion enough or excessively hinder ankle dorsiflexion and plantar flexion.

This project aimed to develop a splint for ankle sprains and to improve upon existing methods by reducing the risk of reinjury. The novel dynamic ankle splint needed to be protective, adjustable, comfortable, and inexpensive. The splint was designed to treat ankle injuries by effectively restricting strain on the ankle joint while also allowing enough mobilization for proper ligament healing.

2.0 Literature Review

This section provides an overview about the ankle anatomy, the healing process, and currently available treatments to provide the reader background knowledge for the field of focus of this project.

2.1 Significance

2.1.1 Medical Significance of Ankle Sprains

Ankle sprains are one of the most common musculoskeletal injuries worldwide. Over 23,000 ankle sprains occur in the U.S. each day (Van Rijn et al., 2008). Currently two billion dollars are spent annually on medical costs attempting to treat ankle injuries (Waterman et al., 2010). Lateral ligament sprains are the most common type of acute ankle sprains ("Fact sheet: Ankle Sprain", 2013). These injuries are often sustained during physical activity, such as sports and recreation. Severity of sprains can range from minor ligament stretching to complete tearing, and can affect the lateral, deltoid, and syndesmotic portions of the ankle.

Young, active individuals between the ages of 15 to 24 are most at-risk for ankle injuries (Waterman et al., 2010). High levels of physical activity are contributing factors to this trend; nearly half of all ankle sprains are caused by athletics (Waterman et al., 2010). A study conducted from 1977 to 2005 analyzed the prevalence of ankle injuries in 70 different sports. Ten to thirty percent of all injuries in the study were ankle sprains (Chan et al., 2007).

Despite the commonplace nature of sprains, only 5.2 million patients sought treatment for ankle and lower leg injuries in 2005 (Mabee et al., 2009). Reinjury is a common trend after lateral ankle sprains. Thirty percent of patients with acute ankle instability will suffer another sprained ankle after their initial injury and may develop chronic ankle instability (Murphy et al., 2003). People with chronic ankle instability have a greater chance for ankle injury due to permanent damage to the ligaments.

2.1.2 Anatomy of the Ankle

Ankle Joint

Since the novel splint design aims to conform to each patient's individual anatomy, the structure of the ankle, as seen in Figure 1, must be taken into consideration during the design process. The ankle is composed of two primary joints which allow movement of the ankle: the talocrural (TC) joint in the upper ankle and the talocalcaneonavicular (TCN), or subtalar joint, in the lower ankle (Procter et al., 1982). The TC joint is a uniaxial modified-hinge joint and is comprised of the talus, the tibia, and the fibula. The position and shape of the three bones enhance ankle stability; damage to the ligaments in the TC joint can lead to instability. In particular, the close fit between the dome-shaped talus and the concave tibial undersurface provide a significant amount of stability to the TC joint. The TCN, a second gliding joint, lies beneath the talocrural joint and holds together the talus and the calcaneus (Procter et al., 1982, Norkus et al., 2001). The TC and TCN work in conjunction with two further joints that exist solely between the tibia and the fibula: the proximal tibiofibular joint and the distal tibiofibular joint. The proximal tibiofibular joint is a syndesmotic joint which upholds structural ankle integrity between the tibia and the fibula. The syndesmosis joint, the distal or inferior tibiofibular joint, is integral for stability between the tibia and fibula and thus stability of the whole ankle joint. Due to synergistic interactions between each joint in the ankle, injury to one joint can negatively impact other joint functions (Norkus et al., 2001).

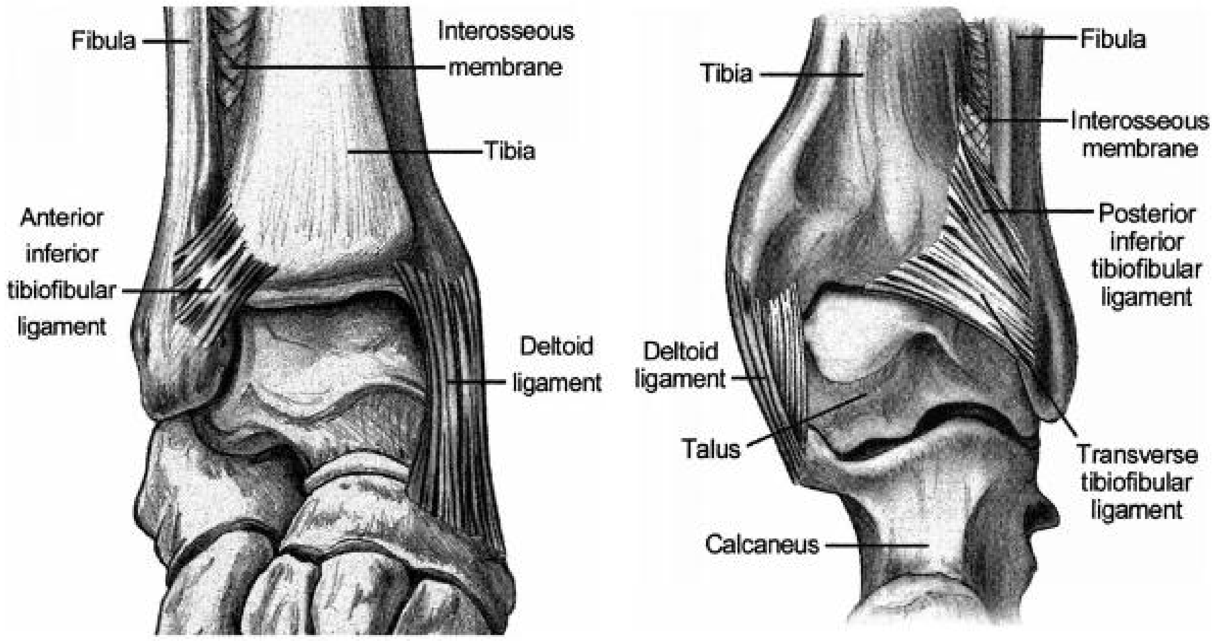

Figure 1: Anterior and Posterior Inferior Tibiofibular Joints (Norkus et al., 2001). The ankle is composed of two primary joints, the anterior and posterior inferior tibiofibular joints.

Ligaments

Ligaments, fibrous bands that bind bones together, are anatomically positioned to guide normal movement and to prevent abnormal movement of joints. Ligaments function by restricting excessive ligament elongation, and the microstructure of ligaments facilitates their functionality. Skeletal ligaments are composed of tightly bundled, parallel, collagen fiber bands made up of many smaller fibers (Woo et al., 1993). Fibrils are credited for creating a crimp pattern in ligaments. Crimping is believed to influence the biomechanical behavior of ligaments by either acting as a shock absorber/recoiling system when tensile forces are applied in parallel to the ligaments, or as a resisting force when rotational forces are applied within the ligament. Ligaments are strong and efficient in resisting tensile loads due to crimping, and therefore are able to resist ligament elongation and prevent harmful movement (Franchi, 2010).

While collagen fibers are responsible for responding to forces in ligaments, water and proteoglycans provide lubrication and spacing, lending ligaments their viscoelastic properties.

Since ligaments are viscoelastic, the shape of their stress-strain curve, shown in Figure 2, depends on the strain rate at which a load is applied (Weis et al., 2001). The stress-strain curve of a ligament can therefore be classified as nonlinear (Woo et al., 1993). Loads are typically carried along the direction of fiber bundles (Weis et al., 2001). When a load is applied, ligaments straighten, resulting in a concave upward stress-strain curve, referred to as the "toe" region of the curve. The toe region typically has a strain of 2 percent. When the load becomes higher, the curve transitions from the toe region to a linear region. The ligament then remains linear until it reaches its tensile stress and corresponding ultimate strain. Ligaments are able to handle high loads with little to no permanent deformation until ultimate strain is reached. Applying further stress to the ligament results in failure of the ligament and ligamentous injuries (Weis et al., 2001).

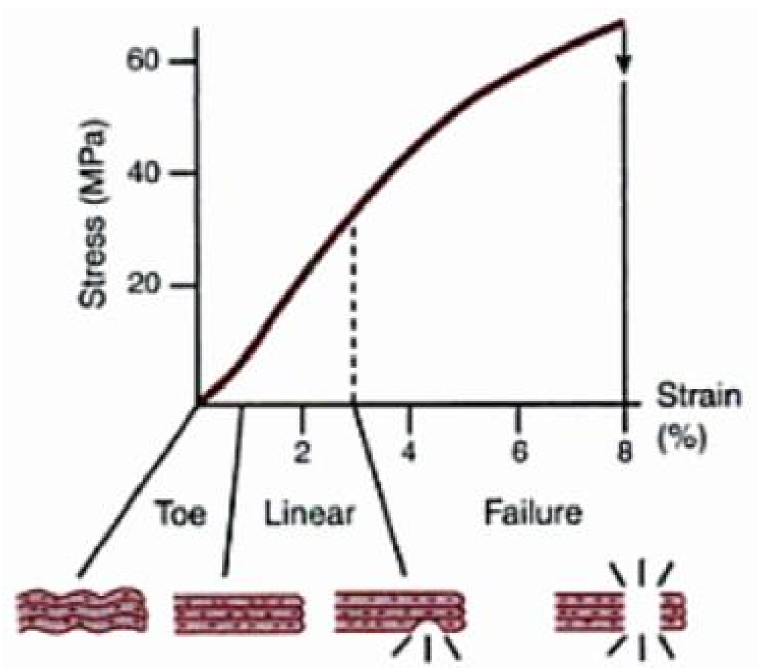

Figure 2: Ligament Stress-Strain Curve (Hamill et al 2004). The shape of the ligament's stress-strain curve depends on the strain rate at which a load is applied.

Ligaments in the ankle are categorized as medial, lateral and syndesmosis (Norkus et al., 2001).

Medial Ligaments

The deltoid ligament, located on the medial part of the ankle, is made of four bands known as the anterior tibiotalar, posterior tibiotalar, tibiocalcaneal, and the tibionavicular bands. Essentially a flat triangular ligament, the deltoid is the strongest ligament in the entire ankle and prevents excess eversion of the foot and external rotation of the talar (Norkus et al., 2001).

Lateral Ligaments

While the deltoid ligament prevents eversion, the three lateral ligaments in the ankle prevent excess inversion of the foot and are highly susceptible to injury (Norkus et al., 2001). The calcaneofibular ligament (CFL) originates at the anterior distal surface of the fibula and extends to the mid-lateral part of the calcaneus. The CFL plays no individual role in ankle stability; it works with the other two lateral ligaments to stabilize the ankle in all directions and movements (Leardini et al., 2000). The CFL also prevents lateral talar tilt, working primarily to prevent external rotation and supination (Norkus et al., 2001, Leardini et al., 2000).

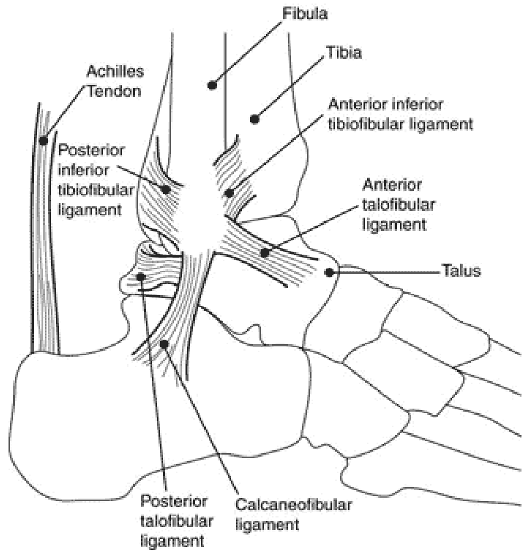

Figure 3: Lateral Ligaments (National Institutes of Health, November 2013). The three lateral ligaments in the ankle (ATFL, CFL, and PTFL) prevent excess inversion of the foot and are at high risk of injury.

The anterior talofibular ligament (ATFL) is an average 7 mm wide and 25 mm long and extends from the lateral malleolus to the lateral talar neck (Leardini et al., 2000). Considered the most significant ligament for ankle stabilization, the ATLF limits the lateral rotation of the tibia and fibula during flexion and lateral talar tilt (Norkus et al., 2001, Leardini et al., 2000). The ATFL is involved in approximately 85 percent of all inversion injuries (Leardini et al., 2000)

Finally, the posterior talofibular ligament (PTFL) acts as a posterior brace for the talus and limits external talar rotation. The PTFL is the strongest of the three lateral ligaments (Norkus et al., 2001).

Syndesmosis Ligaments

The anterior inferior tibiofibular ligament and the interosseous ligament stabilize the syndesmosis joint. The anterior inferior tibiofibular ligament is flat and stronger than other ligaments in the in the ankle. This ligament extends between the fibula and tibia, and prevents excessive fibular movement and talar rotation. The posterior inferior tibiofibular ligament, which runs from the tibia to the malleolus, has twisting fibers which prevent posterior talar translation. The interosseous ligament acts as a spring which allows for separation between the medial and lateral malleolus at the ankle joint (Norkus et al., 2001).

2.1.3 Ankle Sprain Injury and Healing

Lateral Acute Ankle Sprains

For this project, the ligaments of interest during the healing process are the ATFL, PTFL, and the CFL. Of the three lateral ligaments, the ATFL and CFL are the most commonly injured during an ankle sprain because they are the weakest of the three ligaments (Dirsci et al., 2012). Eighty-five percent of all ankle sprains are a result of inversion of the foot, causing damage to the ATFL and the CFL. In addition, other parts of the ankle system can be damaged as well, including muscles, cartilage, and tendons (Hubbard et al., 2008). Lateral ankle sprains occur when the foot is flexed and inverted, such as when a person is jumping or stepping (Pellow et al., 2001). These sprains can lead to instability, weakness, and stiffness of the ankle joint (Hubbard et al., 2008).

Ankle Sprain Grades

Ankle sprains are categorized based on severity of the injury, as illustrated in Figure 4. Grade I sprains are defined by slightly torn or stretched ligaments, and are mild sprains in which the ankle is still relatively stable. Grade I sprains have minimal swelling and no hemorrhages. Grade II sprains are defined by partially torn ligaments, and are moderate sprains. Localized swelling and hemorrhaging occurs. Grade III sprains are defined by completely torn ligaments, and are severely unstable. Grade III sprains lead to excessive swelling, extreme ligament laxity, and require surgery (Pellow et al., 2001). Therefore, this project focused on Grade I and II sprains that do not require surgery.

The severity of a sprain depends on the stress applied to the ligament. When no stress is applied, the ligament becomes lax. After reaching its yield stress, the ligament becomes inelastic, resulting in Grade I and II sprains. After the tensile stress is applied to the ligament, the ligament fails completely and a Grade III sprain occurs.

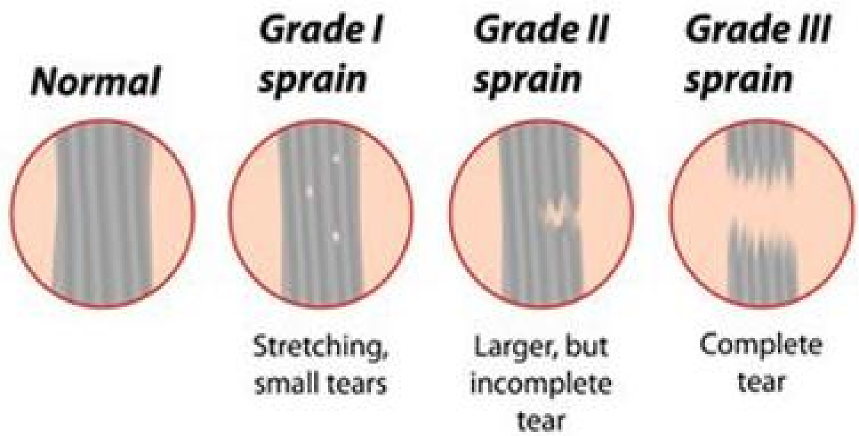

Figure 4: Ankle Sprain Grades (Center for Orthopaedics and Sports Medicine 2013). Ankle sprains are categorized based on severity of the injury into Grades I, II, and III.

Ligament Repair

Often rehabilitation does not provide proper healing for patients with chronic ankle instability and surgery needs to be performed. A study using a rabbit MCL model proved that cut ligaments that are connected and loaded are much stronger than ligaments with a gap two years after surgery (Hildebrand et al., 1998). Motion of the stable joint encourages the ligament scar to elongate and grow. Therefore, loading the ligament and encouraging motion is beneficial for ligament repair.

Normal Healing Process for Ligaments and Musculoskeletal Injury

The typical recovery period for sprained ankle ligaments is four to six weeks. At the end of this period, the patient can then begin normal levels of activity (Hubbard et al., 2008). Following injury, ligaments prompt a healing response that leads to scarring. Scar tissue is much weaker, larger in size, and creeps more than the original ligament. The healing response involves scar tissue formation that conjoins the torn ends of the ligament, ultimately leading to stable ligaments (Hildebrand et al., 1998). Overall, the healing process for ligaments is comprised of three phases: inflammatory, repair, and remodeling. This time is vital for ligament rehabilitation.

Phases for Ligament Healing Process

Reaction – Inflammatory Phase

The inflammatory phase occurs immediately following a ligament injury, lasting approximately three to five days. The injury to the ligament causes hemostasis, and a fibrin clot forms (Hildebrand et al., 1998). Debris is removed within the ligament, and angiogenic cells and fibroblasts are recruited to the injury site (Hildebrand et al., 1998). As inflammation decreases over time, a matrix is formed and produces new tissue (Hildebrand et al., 1998).

Tissue injury leads to pain, inflammation, and joint dysfunction (Denegar et al., 2003). Lack of symptoms does not indicate faster tissue growth. Therefore, the functionality of the ankle does not reflect the state of the damaged ligaments. However, people do not realize this so they immediately go back to their daily activities and do not take proper care of their injury, possibly leading in reinjury. Pain and inflammation decrease over short periods of time whereas joint dysfunction may take months to years to heal (Denegar et al., 2003).

Typical effective treatment during the inflammatory response is the RICE system: rest, ice, compression, elevation and oral medication to alleviate pain. A patient with a more serious injury will use crutches to lessen weight on the injury site, and will immobilize the ankle for two to three days (Hubbard et al., 2008).

Repairing Phase

During the repair phase, the types of collagen within the ligament are altered for repair (Hildebrand et al., 1998). Collagen levels increase rapidly and reach normal levels around week six (Hildebrand et al., 1998). The repair process has been estimated to require up to three weeks to maximize collagen content in the wound and allow for fibroblast proliferation (Hertel, 2002). Once collagen formation is complete, stress and strain can be induced to yield optimal alignment of the ligament fibers and overall ligament strength (Madden et al., 1971).

Remodeling Phase

During the remodeling phase, the injured ligament continues to heal for months to years after the initial injury (Hertel, 2002). The number of cells and vessels decrease over time, and the collagen becomes mature and more aligned (Hildebrand et al., 1998).

The most healing occurs in the first 12 months post-injury regarding stiffness, stress, strength, and tissue quality (Hildebrand et al., 1998). After 12 months, very little progress and improvements are achieved (Hildebrand et al., 1998). Scar tissue returns back to normal properties two years after the injury (Hildebrand et al., 1998). Return of joint function does not mean the injury is completely healed, and this is very misleading (Hildebrand et al., 1998).

Once a ligament is damaged, other structures in the joint may compensate for the injured ligament. Below in Table 1 there is a summary of the biomechanical, biochemical, and histologic changes that the ligament experiences about one year post injury (Hildebrand et al., 1998).

Table 1: Changes to Ligament Post Injury (Hildebrand et al., 1998). Changes that occur to a ligament post injury. Biomechanical, biochemical, and histologic changes to ligaments one year post injury.

Biomechanical changes	Weaker
	Inferior material quality

	Larger
	Greater creep
Biochemical changes	Increased type V collagen
	Decreased hydroxypyridinium cross-links
	Increased glycosaminoglycans
Histologic changes	“Flaws” in matrix
	Abnormal collagen fibril diameter distributions

After collagen formation, subluxation needs to be corrected and the joint needs to be mobilized to correct motion restrictions. By moving the ligaments, they can heal at the ideal length and normal joint motion can be restored (Denegar et al., 2003). Studies by Dr. Tricia Hubbard have shown that there is no known time when ligament healing is complete. In her studies, ligament healing started to occur six weeks to three months after the injury (Hubbard et al., 2008). At this point, biomechanical improvements involving mechanical stability and laxity began to occur (Hubbard et al., 2008). Bearing excessive weight on the ligaments too early will result in continual tear or lengthening of the ligament over time, leading to residual mechanical instability (Denegar et al., 2003). Over time, if these ankle instabilities remain, other structures within the ankle behave abnormally to compensate (Denegar et al., 2003).

2.1.4 Ankle Instability

Acute

For acute ankle sprains, mobilization of the ankle should be incorporated early in the rehabilitation process if accessory joint motion is inadequate. Exercising the muscle early in the healing process while minimizing tissue stretching will enable the ligament to heal at an optimal length (Denegar et al., 2003). As healing progresses, more strain can be applied to the ligaments to maximize the stress applied and function of the muscles. For acute ankle injuries, resistance applied to the injury site should be low and occur during the first three to four weeks post-injury (Hubbard et al., 2008). Through observation of subtalar laxity after a lateral ankle sprain, it has been reported that the ankle joint functions more properly if pronation is inhibited by an orthotic device (Denegar et al., 2003).

Subluxation in the ankle should be corrected and stress to the injured ligaments should be avoided so they do not tear (Hubbard et al., 2008). The joint-mobility restrictions need to be corrected for the ankle, and then increased stress applied to the tissues without abruptly straining them.

Following an inversion ankle sprain, unaddressed lack of mobility at the injured point may result in compromised tissue repair and movement of other joints. For example, an inversion ankle sprain may produce a displacement of the talus. The talus has a restricted range of motion due to its incorrect location. Consequentially, motion of the ankle is limited. Ligaments and structures within the ankle will move and bear weight to compensate for this injury. Torn ligaments will often elongate during the healing process and will adapt to compromise joint stability and function (Denegar et al., 2003). These healing processes can also occur laterally in the knee as well. When the ankle complex cannot completely bear weight or stabilize the leg, the deficiency is compromised by the knee (Denegar et al., 2003). Therefore, if the injury is not attended to, compensation will move up the leg and other joints will perform incorrectly.

Chronic

If left untreated, acute ankle instability injuries can develop into chronic ankle instability (CAI). Chronic instability patients suffer persistent pain and repeated episodes of instability, resulting in recurrent ankle sprains. During healing if the patient returns to full weight bearing too early and the ligaments receive too much stress, subtalar joint laxity with chronic instability will result. Although the ATFL and CFL are not overstressed when first returning to weight bearing, this potential issue must be addressed (Hubbard et al., 2008). Studies have proved that reducing and restricting pronation can help with the healing process (Hubbard et al., 2008).

2.2 Universal Treatment Methods

2.2.1 Current Splint Designs

Sprain Treatments

Lateral ankle sprains are a common type of ankle injury, particularly in athletes. Methods of ankle sprain treatment range from bracing or taping the ankle to surgery, depending on the severity of the sprain and ligament damage. The scope of this project focuses on ankle injuries that require bracing. Despite the plethora of treatments available, reinjury is common amongst patients with previous sprains and can eventually lead to ankle instability (Papadopoulos et al., 2005). Several studies have been performed to evaluate the effectiveness of ankle sprain rehabilitation methods. These studies concluded that for full restoration of a sprained ankle, the ankle joint should be loaded with an applied force in order to improve joint function and stability (Eils, 2002). Additionally, orthotic devices should be accurately fitted to protect proprioceptive neuromuscular function in order to allow for active muscular stabilization (Scheuffelen, 1993).

Functions of Braces

Bracing the ankle is a popular rehabilitation method following an acute ankle sprain, especially in sporting activities. The goal of bracing is to act as a protective device and prevent further ankle injury (Eils, 2002). The primary function of a brace is to stabilize the ankle and to limit motion at the ankle joint. The most crucial directions of ankle brace movement are inversion, plantar flexion, and internal rotation (Eils, 2002). Ideally, braces should be comfortable for the patient and easy to put on.

2.2.2. Evaluation of Current Designs

Previously, ankle injuries were thought to be best healed through immediate immobilization, usually either by casting or splinting. Bracing or taping would be used as a follow up immobilization method (Backx, 2011). Evidence now indicates that mobile treatment, such as bracing or taping, result in more efficient recovery of ligamentous ankle injuries (Backx, 2011). Current methods that utilize partial immobilization include taping, soft braces, semi-rigid braces, and rigid braces.

Taping

A study has found that taping is less effective in treating ankle sprains than semi-rigid braces. While there was no substantial evidence to support reduced pain, swelling or instability between taping and ankle braces, taping received lower scores on functional ankle movement tests (Backx, 2011). Current materials used in taping include elastic taping, taping with pre-wrap, and taping directly applied to the skin (Boye, 2005; Ricard, 2014). An example of ankle taping is seen below in Figure 5.

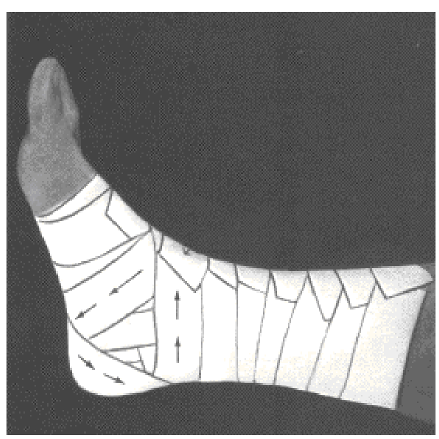

Figure 5: Ankle Taping (Orthopedic Surgery). Ankle Taping includes elastic taping, taping with pre-wrap, and taping directly applied to the skin.

Soft Braces

Soft braces allow for more plantar flexion than in immobilized treatments (Eils, 2002). However, soft braces do not restrict passive inversion or rapidly induced inversion as well as other braces (Eils, 2002). Currently, available braces include Kalassy, Fibulo Tape, and Dynastab (Eils, 2002). Common materials used for soft braces include an elastic support bandage, wool and crepe wrap, canvas, nylon and neoprene (Boye, 2005; Callagha, 1997). An example of a nylon brace is seen below in

Figure 6.

Figure 6: Nylon Ankle Brace (Easy Comforts, 2014). Common materials used for soft braces include an elastic support bandage, wool and crepe wrap, canvas, nylon and neoprene.

Semi-Rigid Braces

Semi-rigid braces include various designs of lace up braces and hinged braces. Semi-rigid braces have more stability for eversion and plantar flexion than soft braces, however, they have less stability than rigid braces (Eils, 2002). Semi-rigid braces limit passive plantar flexion, supination, and adduction (Papadopoulos et al., 2005). Commonly used semi-rigid braces include the Aircast, Air Gel, Air Brace, Ligacast Anatomic, and Malleoloc (Eils, 2002). Lace up braces are boot-shaped with laces on the front brace face for added support. They are covered in vinyl with nylon webbing material that surrounds the instep over the ankle (Peters, 1985). The Aircast AirLift has padding under the foot and on each side of the ankle to prevent inversion and eversion, as seen below in Figure 7. Velcro strips are used to attach the brace to the ankle (Callagha, 1997).

Figure 7: Aircast AirLift PTTD Ankle Brace (The Brace Shop, 2014). Aircast AirLift PTTD Ankle Braces are made of inflatable air bags or other forms of padding.

Rigid Braces

Rigid braces have plastic stirrup panels lateral to the ankle to restrict inversion (Eils, 2002). Rigid braces are composed of two exterior injection molded plastic shells known as stirrups. The interior of the stirrups are made of inflatable air bags or other form of padding. The stirrups are joined with Velcro straps located over the ankle and below the heel (Bowman, 2004). This type of brace may not fit into all shoe types, particularly high top shoes (Peters, 1997). A study comparing ten different ankle braces proved that rigid braces composed of stirrups and plastic reinforcements restrict ankle inversion more efficiently than the other models (Eils, 2002).

Figure 8: Aircast Stirrup Brace (Better Braces, 2014). Aircast Stirrup Braces have plastic stirrup panels lateral to the ankle to restrict inversion.

2.2.3 Patent Review

In addition to the current, commercially available ankle braces mentioned above, other devices aimed at protecting the ankle have been developed and patented, as shown in Appendix H. Many braces that focus on healing injury-prone ligaments have been developed. In 1998 a patent was awarded to Smith & Nephew for a custom-fitted ankle splint, shown in Figure 9. This device focuses on healing injuries to the ATFL by protecting against excessive eversion and inversion and allows for plantar flexion and dorsiflexion. The brace is custom fit to the patient's anatomy using a cast mold and resin to conform to the patient (US 5980474 A, 1998).

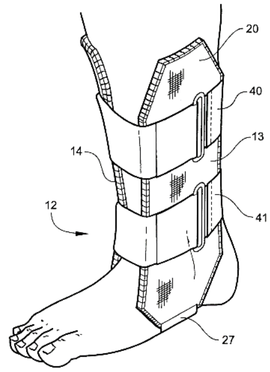

Figure 9: Smith & Nephew Custom-Fitted Brace. Focuses on healing injuries to the ATFL by protecting against excessive eversion and inversion and allows for plantar flexion and dorsiflexion.

A patent was awarded to Shane D. Draper in 2011 for protective ankle braces for joints and associated methods, shown in Figure 10. The brace focuses on stabilizing joints in the body to prevent injury while allowing for close to full range of motion of the joint. The design, specifically for ankle injuries, is comprised of an engagement element that secures the brace to the ankle. At least one supporting strap, which extends from one part of the engagement element to another, mimics the function of a fibrous connective tissue in the ankle, such as a ligament, tendon, or fascia (US 20110034846 A1, 2011).

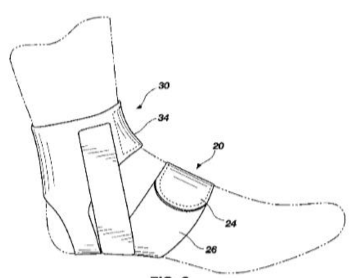

FIG. 3

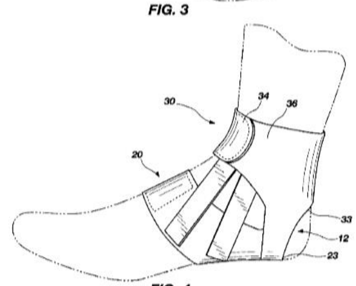

FIG. 4

Figure 10: Draper Protective Brace for Joints & Associated Methods. Focuses on stabilizing joints in the body to prevent injury while allowing for close to full range of motion of the joint.

A 2003 patent was granted to Leonard Janis for a removably mounted ankle brace that is comprised of a main body and support straps, shown in Figure 13. The main body is made of a flexible, non-elastic material. It contains separate side sections, a rear section, and a bottom section. Two pairs of support straps serve to provide support for the ankle and the internal ligaments. The two pairs of straps hold the ankle in a correct anatomical position to stabilize the joint. Restricting movement in both the horizontal and vertical directions provides positive support for the ATFL and CFL by restricting any forces that strain the ligaments (US6663583 B1, 2003).

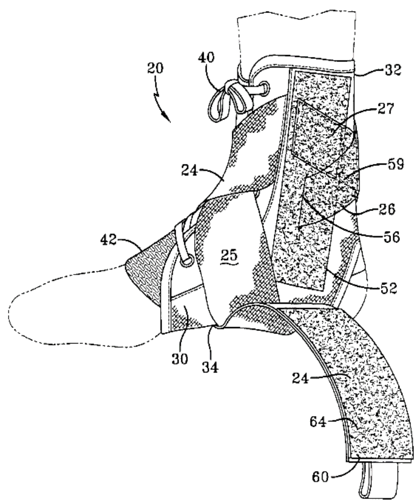

Figure 11: Janis Removably Mounted Brace. Comprised of a main body and support straps that Restrict movement in both the horizontal and vertical directions.

2.3 Ankle Mechanics

2.3.1 Internal Forces on the Ankle

A complex analysis of the ankle can be conducted by breaking it up into its components to view the internal forces. There are two main joint systems in the ankle, the TC and the TCN. The TC joint is the upper joint in the ankle. Its primary responsibility is to provide the movement for the flexion and extension of the talus relative to the shank. This allows for ankle dorsiflexion and plantar flexion. Typically this movement has about 20 to 30 degrees of motion (Paul, 1982). The TCN joint, also known as the subtalar joint, is another uniaxial joint. It provides the inversion and eversion of the hindfoot relative to the talus. Usually, the inversion-eversion of the ankle has about 10 degrees of motion, and exceeding this in inversion is the leading cause of lateral ankle sprains (Paul, 1982). The pronation and supination of the ankle is caused from a combination of these movements, which have about 30 degrees of motion (Wei, 2011).

There are noticeable differences between a healthy and unstable ankle in internal analysis. The severity of these differences depends on the orientation of the joint. Dorsiflexion provides stability for both joints; at 20 degrees of dorsiflexion there are no noticeable differences between a healthy and injured TC or TCN joint. However, plantar flexion does not provide the same stability. At 20 degrees of plantar flexion there is a significant anterior TC translation seen in the injured ankle. There is also reduced TC internal rotation. The TCN does not exhibit translation, but it does have a larger internal rotation in this position. This significantly increases the risk for additional sprains or injury (Atsushi, 2014).

2.3.2 Gait Analysis

Gait, also known as walking, is the most common physical activity (Punt et al., 2015). Due to its regularity, it is the predominant cause of forces and movements on the ankle. The design of any weight-bearing orthotic not only accounts for these kinetics and their impact on the ankle, but also for the effect the orthotic may have on natural gait. These topics can be examined by looking at the ankle as a single system on the sagittal plane. This simplifies the analysis by providing a model that ignores the complex system of bones and ligaments, and instead focuses on the overall kinematics of the joint. The dorsiflexion and plantar flexion of the ankle during walking can be measured by observing fixed points around the joint. These points can be tracked in 3D space using electromagnetic tracking (EMT) software, such as Polhemus™ G4 Electromagnetic Tracking System. The dorsiflexion angle can then be easily calculated using vector analysis.

Natural gait is described as a series of stages, shown in Figure 12 below. Although each stage can be viewed as a static system, the dorsiflexion angle changes continuously throughout the cycle due to the dorsiflexor and plantarflexor muscles. This serves to propel the body forward. During initial contact the ankle dorsiflexors are engaged to keep the foot upward. As weight is then shifted anterior to the joint in the mid-stance, the plantar flexors in the ankle fire eccentrically. This continues during the terminal stance to lift the foot off of the ground. During pre-swing the plantar flexors keep the ankle at about 20 degrees. The dorsiflexors are then needed to ensure toe-clearance during the swing stages until ground contact. During the entire cycle, sufficient dorsiflexion is required to propel the body forward (Ueda et al., 2014). This usually means a dorsiflexion value of approximately 10 degrees (Punt et al., 2015).

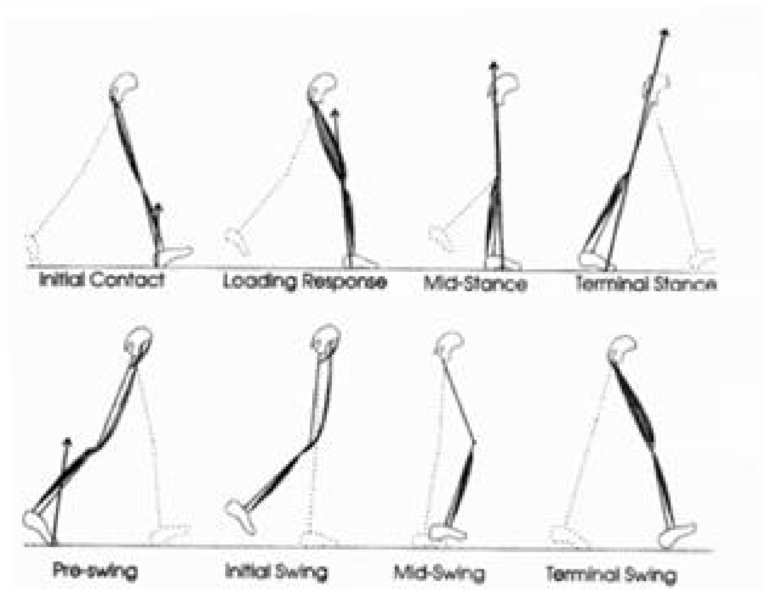

Figure 12: Stages of the gait cycle with the resulting ground reaction forces (Winter 2009.) Stages of the gait cycle with the resulting ground reaction forces. The dorsiflexion angle changes continuously throughout the cycle due to the dorsiflexor and plantarflexor muscles.

Bracing the ankle after injury has many benefits, but it also causes irregular movement patterns that adversely affect gait. Specifically, ankle orthotics restrict the natural dorsiflexion/plantar flexion of the ankle (Ueda et al., 2014). A study comparing the maximum range of motion with and without a brace found clear differences. Natural dorsiflexion and plantar flexion angles averaged 18.3 ± 7.5 degrees. However, this number was reduced to 9.6 ± 7.5 degrees with a brace. The study concluded that semi-rigid and rigid braces limit both peak hindfoot dorsiflexion and plantarflexion (Kitaoka et al.,2006). Although this limitation may be useful in reducing pain after a sprain, it may also limit gait efficiency. It interferes with rocker mechanisms in the ankle, and leads to a less dynamic gait (Kitaoka et al., 2006). Dorsiflexion reduced under eight degrees also affects temporal and sagittal gait, leading to “slower walking speed, shorter step length, shorter single support time, and less symmetrical support time” (Punt et al., 2015). It also directly interferes with the kinematics of the knee; less dorsiflexion leads to a varus angle, which can lead to knee osteoarthritis (Ueda et al., 2014). Plantar flexion resistance leads to increased knee flexion, which results in unstable gait (Kobayashi et al., 2013). There is even evidence that suggests that limited sagittal motion is a risk factor for ankle reinjury (Punt et al., 2015).

3.0 Project Strategy

This section explains the process the group utilized to complete the project.

3.1 Client Statement

3.1.1 Initial Client Statement

To begin a design project, a problem is identified by a client so that a solution can be designed to meet their needs. During the "pre-processing phase of design," the client gives a statement explaining the characteristics they are looking for in a new product (Dym et al., 2009). Once this statement is received, the project team analyzes the statement and works to solve the problem.

Initially a brief statement was provided by the client, University of Massachusetts Hospital (UMass). The client stated (Dowlatshahi et al., 2014):

> The ankle joints provide a delicate balance between stability and laxity. Ankle injuries in form of sprains, ligamentous injuries, fractures, are common in sports and pose a particularly difficult problem to treat because of activity restrictions and the bulkiness [of] splints and casts on the one hand, and inadequate stability offered by less bulky alternatives such as taping. This MQP will look into the currently available device designs and define an improved device that allows for dynamic splinting with the necessary stability as well as convenience.

Using this statement, the team completed background research on ankle and ligamentous injuries to provide a solid foundation for a design plan. After performing initial research, the team developed questions to ask the sponsors in a follow-up meeting to form a revised client statement, shown in section 3.1.2.

3.1.2 Final Client Statement

The ankle joints provide a delicate balance between stability and laxity. Acute ankle instability is the most frequent form of ankle injuries (Witt et al., 2013). Specifically concerning the ligaments, ankle injuries pose a particularly difficult problem to treat because of activity restrictions, bulkiness of splints, and inadequate stability offered by less secure alternatives.

The focus of this project was to research the currently available devices and create a specific, inexpensive design that allows for dynamic splinting with necessary protection, stability, and comfort. Due to its dynamic nature, the goal of this device was to provide a balance between ligament support and joint mobility to aid healing.

The sponsors specified that the device needed to specifically target the injured ligaments rather than immobilizing the entire foot. The device needed to stabilize and protect the ankle, acting as a protective device. The sponsor wanted the device to be comfortable, lightweight, and washable to increase customr satisfaction. The device needed to be inexpensive so it could be available and enticing for consumers. Current devices either overly restrict movement or permit excessive motion; therefore, this novel dynamic ankle splint needed to provide a balance of stability and mobility for the ankle.

3.2 Objectives and Constraints

3.2.1 Objectives

To achieve the goal of designing a dynamic ankle splint for lateral ligamentous injuries, the group determined multiple objectives. Objectives are primary attributes and behaviors that the client would like to see in the final product. Both primary and secondary objectives were determined after researching the disadvantages of current braces on the market. After outlining primary objectives, secondary objectives were determined to bolster the achievement of the primary objectives. These objectives are ranked by the team and depicted below in Figure 13.

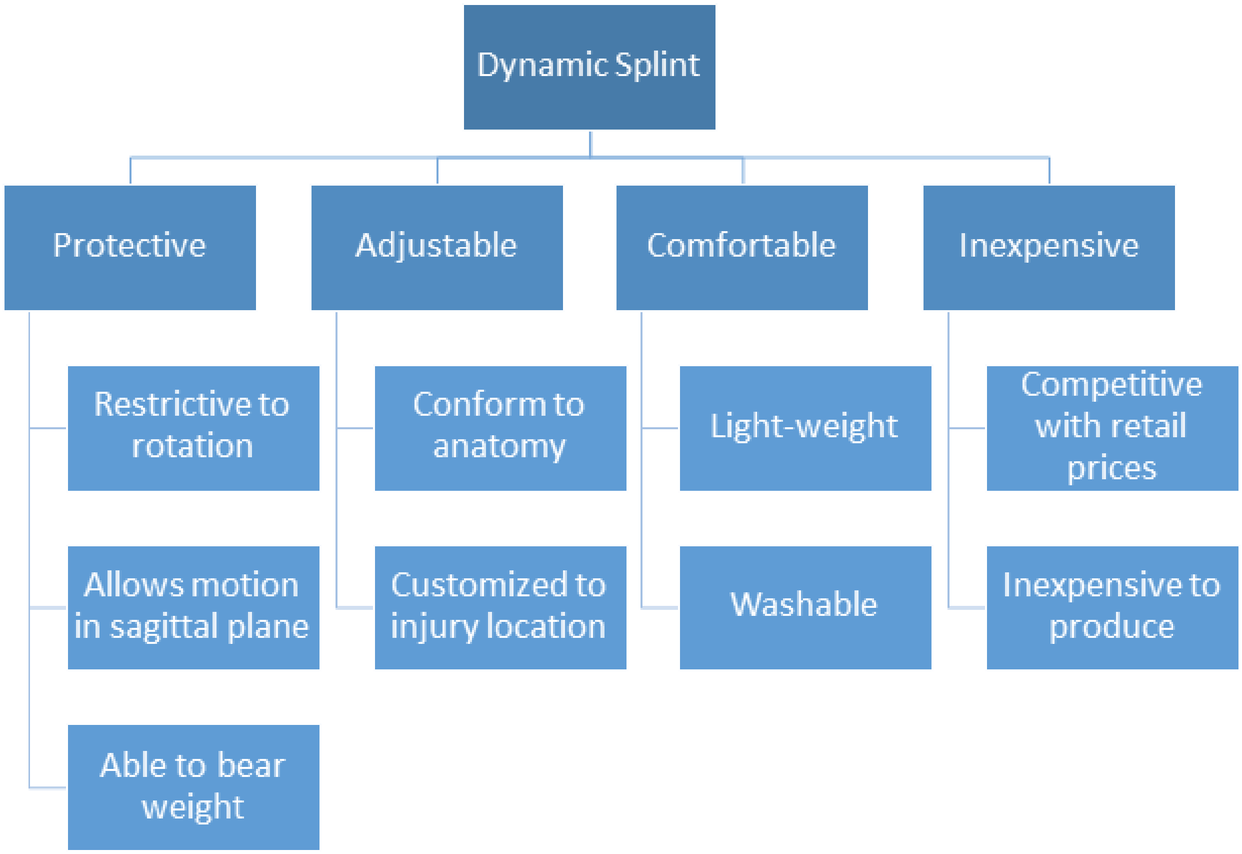

Figure 13: Objectives Tree of Primary and Secondary Objectives. Both primary and secondary objectives were determined after researching the disadvantages of current braces on the market. After outlining primary objectives, secondary objectives were determined to bolster the achievement of the primary objectives.

The team used a pairwise comparison chart to rank the project's objectives. As seen in Table 2, objectives were organized into a matrix of rows and columns to compare them on a pair-by-pair basis. The objectives were compared and evaluated respectively. Moving across the rows, the objective that was considered more important was scored one, while the less important objective was scored zero. If two objectives were considered equally important, both were scored 0.5. For example, as seen in Table 2, "comfortable" received a zero when compared to "protective" because comfort is not as important as preventing injury. Once all objectives were evaluated and the total score was calculated for each. Higher scores represent a higher rank and thus more important objective.

Table 2: Pairwise Comparison Chart of Primary Objectives. Pairwise Comparison Chart of Primary Objectives ranked the project's objectives. Higher scores represent a higher rank and thus a more important objective.

PAIRWISE COMPARISON CHART OF PRIMARY OBJECTIVES					
	Protective	Adjustable	Comfortable	Inexpensive	TOTALS
Protective		0.5	1	1	2.5
Adjustable	0.5		1	1	2.5
Comfortable	0	0		1	1
Inexpensive	0	0	0		0

Protective and adjustable were the top two objectives that ranked equally. The main objective of the splint was to prevent further injury of the ankle after an acute lateral ankle sprain has occurred. If the brace cannot protect the ankle, patients could injure themselves more severely, inhibiting the healing process rather than assisting it. The team determined if the objective had been met using three sub-objectives. The brace needed to be resistant to excessive inversional rotation past a range of 20 to 30 degrees to prevent rolling of the ankle that may stretch or tear damaged ligaments further. When the ankle is inverted to 20 degrees, pain can be felt, and when the ankle is inverted past 30 degrees serious injury can occur. The brace needed to prevent the patient from reinjury while allowing the patient to stand and walk in their normal gait in order to allow the ankle to move and regain ligament function. Instability could lead to failure of the unprotected ankle during patient mobility. At the same time, the brace should allow for motion in dorsiflexion and plantar flexion directions. The brace should bear weight and protect the injured ankle, allowing the patient to be mobile.

In addition to being protective, the brace needed to be adjustable. The brace had to be effective regardless of patient anatomy. The team determined if the objective had been met by using two sub-objectives. The brace had to conform to the patient's anatomy, providing customized support to the sprained ankle so the patient could achieve a balance of ankle protection and movement. A customizable splint required the brace to target the specific location of the ankle that needs to be immobilized. As a result, normal movement is promoted in the ankles and legs.

Thirdly, the ankle splint had to be comfortable so that consumers could wear the brace without it interfering with their normal daily activities. Ideally, the brace needed to be comfortable enough that the consumer does not notice its existence. A comfortable brace could be more marketable to both patients and hospitals looking for braces that are not intrusive. Currently, patients prefer not to wear braces longer than necessary because available braces are uncomfortable and impinging. Since current devices are cumbersome and odorous, the device should be light-weight and washable. These two objectives were secondary, meaning they were derived from the primary objectives, but they were not the most important. A washable design could limit brace odor, allowing patients to wear it more often and for longer periods of time. Patients can wear light-weight braces with their shoes on a daily basis.

Finally the ankle brace had to be inexpensive and competitively priced with currently available braces so that the average consumer can buy the brace from a local pharmacy or department store. Ideally, the device would cost less than $40, the average price of similar braces sold in retail stores. An inexpensive final product could allow hospitals to recommend the brace to patients. Sometimes a brace is prescribed that is paid for by insurance, resulting in increased hospital costs. It was hoped that this problem would be avoided with a low-price product. In order to maintain a low-cost brace, the brace had to be inexpensive to mass produce.

3.2.2 Constraints

The design process was limited by the following constraints: budget, materials, time, limited test subjects, and Grade of ankle sprain. The project had a developmental budget of $780. These funds were applied to prototype fabrication and testing. The final product had to be sold for under $40. These restrictions impacted the material choice for the prototype, as well as testing capabilities. This constraint was to ensure the product was competitive with other braces currently on the market. The scope of this project was limited to one academic year, limiting the number of revisions to the prototype. The product was intended to offer the support and protection necessary for subjects suffering Grades I or II ankle sprains. Therefore, the product design was not intended to stabilize Grade III sprains immediately post-surgery. Testing of the prototype was limited to the number of group participants, because the group did not apply for approval by the Institutional Review Board. In addition, testing was also limited to the equipment available to the team via Worcester Polytechnic Institute's Biomedical Engineering Department. Prototyping was limited by the skill, experience, and equipment available to the group.

3.3 Project Approach

3.3.1 Research Phase

The group completed background research, as presented in Chapter 2. Objectives and constraints were identified and ranked using a pairwise comparison chart. Several design options were evaluated and presented to the sponsors.

3.3.2 Design and Prototyping

Different design alternatives were evaluated using a weighted objectives tree. Several conceptual models were created to visualize different designs. Two tangible designs were created through prototyping. The prototypes needed to remain within the group's design budget, and needed to be easy to manufacture as industrial manufacturing equipment was unavailable to the group. The prototypes were tested against current braces available on the market, and against each other to determine how to improve the prototypes and how to consolidate them into a final design.

Various tests were outlined and used for proof-of-concept testing to determine if the anatomy-inspired, ligament design was functional. Gait analysis using electromagnetic tracking sensors gave insight on flexion of the ankle during the gait cycle. The process was repeated with currently available ankle splints to understand how these ankle devices impacted the gait cycle. A drop plate device was used to determine how the ankle responds to dynamic inversion movement with and without braces. A goniometer was used to passively measure range of motion ankle with different devices compared to barefoot. In addition, virtual testing in OpenSim® was used to ascertain how the brace band orientation and material properties influenced the effectiveness of the design.

3.3.3 Testing and Validation

Iterative testing of prototypes along with OpenSim® evaluation led to a final design. Once the final prototype was created, the group applied the same testing methods used on the preliminary two prototypes to the final design. Each group member acted as a test subject for the passive measurement, gait, and drop plate testing. The group members represented different body sizes, types, and ankle condition

3.3.4 Statistics

The mean and standard deviation of each data set were taken to determine average outcome of testing and how far spread the data was. This allowed the team to determine general trends in the data. Results were also analyzed using Analysis of Variance (ANOVA) in Microsoft Excel to test for significant differences between averages. A 95 percent confidence interval test was used to determine if data was statistically significant ($p<0.05$). ANOVA can also detect interactions between variables. For instance, ANOVA can determine if two sets of independent variables affect outcomes separately. ANOVA was useful in determining if certain braces led to significant differences in range of motion versus barefoot and if the individual test subject was a cause of significant variance in the data.

3.3.6 Analysis Approach

Different mathematical approaches were used to help aid in the design and to validate the prototypes. First, a simplified, 2D static analysis was used to give the group a starting-off point for the materials search. It worked by modeling the brace band as a spring, and using the strain and force values to estimate a needed modulus range. After construction, the prototypes were validated be looking at the location of the ankle. Two planes of motion were analyzed, and in each case the results were compared to other braces as well as a barefoot trial. In the sagittal plane, the ankle flexion angle was measured using electromagnetic sensors that tracked in 3D space. Joint angles were calculated by analyzing the two vectors that were drawn between the three points. The angle was found through the dot product of the vectors, governed by the following equation:

Equation 1: $$\vec{a} \cdot \vec{b} = a_x b_x + a_y b_y + a_z b_z = |\vec{a}||\vec{b}| \cos\theta$$

Data was further analyzed by finding the allowed range of motion by subtracting the minimum angle from the maximum. In the coronal plane, the inversion angle was found through a similar method. Three sensors were placed to track markers that were located on the rear of the ankle. This allowed the inversion angle to be calculated using the three vectors. The maximum value found during an inversion test was used to see how each brace restricted inversion. Additional analysis calculated the average inversion rate by dividing the maximum measured angle by the time it took to reach that angle. This was used to see how each brace slowed the inversion of the angle during the fall, rather than the maximum allowed angle.

3.3.5 Conclusions and Recommendations

Upon completing the testing and validation process, the group analyzed the effectiveness of the chosen design. The group then created a list of recommendations and conclusions for the sponsors.

4.0 Alternative Designs

This section outlines the different alternatives the group considered, and the preliminary data and testing conducted to ultimately choose a final prototype.

4.1 Needs Analysis

4.1.1 Required Characteristics

Currently ankle splints on the market do not accommodate a patient's normal ankle movement and do not conform to the patient's anatomy. Many splints excessively restrict ankle movement in all axes or permit over-rotation of the ankle joint. There is a need for a brace that is both stiff and flexible, and allows for appropriate restriction and movement of the ankle to aid in ligament healing. Specifically, there is a need for a splint that resists inversion because this is the primary motion that injures lateral ligaments. There are limitations in both rigid and soft devices. The goal of this project was to develop a splint that can span this range. The ankle splint had to begin restricting inversion at approximately 20 degrees; this is the angle of inversion in the ankle that can be tolerated before the initiation of pain (Markolf et al., 1989). A maximum of 30 degrees was used for permitted range-of-motion in calculations because this is the farthest point at which the ankle can naturally invert prior to injury (Paul, 1982). Defining an inversion range of 20 to 30 degrees assisted in calculating the device's ideal specifications. Specifically, a range of Young's moduli was calculated to define ideal material properties. Based on calculations (see Appendix C), the group determined which materials could be purchase for use in prototyping. Furthermore, the brace needed to be adjustable so that the device is universal for different patient's individual anatomy. The device must have had a retail value of $40 to be competitive within the market.

4.1.2 Wants & Desired Characteristics

It was desired that the brace should be comfortable, fit in a shoe, washable, and light-weight. It was intended that the device would permit strain the ligaments by allowing minimal inversion of the ankle. Healing would be improved by targeting the injured ligaments using biomimicry in the design.

4.2 Functions & Specifications

The team's dynamic ankle brace was intended to prevent further injury of Grade I and II lateral ankle sprains. Thus, the team determined that the device must meet the following functions in order to be competitive with and improve upon current braces: balance restriction of ankle inversion and mobility of ligaments, conform to ankle anatomy, bear weight, be comfortable, and be washable. The team identified an ideal range of 20 to 30 degrees inversion for balancing harmful with beneficial movement.

The brace had to conform to ankle anatomy to provide comfort to the user. By conforming to the anatomy, the brace was intended to cause less discomfort whilst wearing the brace in typical shoes. The brace had to bear the user's weight during normal functions such as standing and walking. The brace was not intended to be used during extensive activity such as running or during sporting activities, because this would require higher restriction requirements than identified as the team's goal. The user needed to be able to wear the brace for long periods of time without experiencing discomfort. Thus, the brace had to be made of a material that was not abrasive to the skin and that would not cause pain to the user. The brace needed to be washable to reduce order to further motivate patient compliance with wearing the brace. Additionally, the brace needed to fit users of different size feet.

4.3 Initial Designs

4.3.1 Angle Controlled Boot

One of the first alternative designs considered was a angle controlled boot. It would be designed for mild acute ankle injuries. Patients can benefit from this design by controlling range-of-motion of the ankle to aid in healing and rehabilitation. As seen in Figure 14, below, the foot would be lined with foam for comfort and cushion. A gel lining within the foam was also considered for maximum comfort. An external frame would be formed by plastic plates on the internal and external sides of the ankle to give rigid support, as well as around the instep and arch of the foot. Each of the two dials controls uniaxial motion in their respective plane. The dial on the malleolus controls the degree of motion for plantar flexion and dorsiflexion. The dial on the instep of the foot controls the degree of motion for eversion and inversion. The maximum angle for the ankle to move would be determined for both planes, and the dials would be used to lock the maximum angle. This is the point at which the ankle motion stops. As ligament healing continues, the range-of-motion would increase and the maximum angles would be set higher.

Figure 14: Angle Controlled Boot Alternate Design. The angle controlled boot alternate design controls range-of-motion of the ankle to aid in healing and rehabilitation.

Advantages of this design would be: maximum support and comfort for the ankle, complete control of ankle movement, and the restriction for range-of-motion could be changed over time. The disadvantages of this design would be that it is difficult to wear under a shoe, it is potentially heavy, and overall would be an expensive design. An additional design alteration may include use of antimicrobial fabric in the layer of the brace directly in contact with the skin. This design was not implemented because it did not best align with the desired objectives and functions for the final design. The boot would be unable to fit under a typical shoe, be cumbersome, and likely retail for more than $40.

4.3.2 Orthopedic Shoe

An orthopedic shoe design was proposed as an alternative to heavy and bulky devices such as the angle-controlled boot. While other designs would ideally fit inside the patient's regular shoes, this design option would eliminate the need to fit inside the shoe because a custom fit shoe is part of the device. The orthopedic shoe was designed to provide support for a severe injury in the early stages of ligament healing. The design consists of two main components: a lightweight shoe and a stiff external harness to prevent rotation of the ankle. The shoe would ideally be made of a lightweight material to allow for user mobility. Much like running sneakers, the shoe would have meshing in the front top area, making the brace breathable and thus, more comfortable for the user. The external harness would consist of two semi-stiff, metal rectangular plates, which would encase the ankle and the lower shin on either side. An adjustable band would wrap around the two metal plates at the shin to secure the harness to the foot. Both plates would be attached by a thin flexible strap, which would wrap around the arch of the foot. The double plate model was inspired by the design of the Aircast stirrup brace. A second strap, connected at the top of the two plates, would wrap around the foot immediately below the ball of the foot. The second strap would be made out of elastic material with a low modulus of elasticity to inhibit harmful ranges of motion.

The most significant advantage of the orthopedic shoe design is its ability to limit ankle inversion and eversion, and protect the ankle from harmful motions that may lead to further ligamentous damage. The orthopedic shoe is comfortable and breathable, which can help limit odors. The shoe component of the design can be customized for the patient's foot, which is particularly advantageous for patients who need extra support. A major disadvantage to this design is the rigidity of the two plates, which may make the brace uncomfortable and may excessively limit movement of the foot. Additionally, the shin wrap could rub against the skin, causing redness and chaffing. Furthermore, the design would be expensive to manufacture due to the variety of materials and manufacturing methods needed to construct both the shoe and the harness. Due to the complicated manufacturing process of the brace, the design was not implemented.

4.3.3 Minimalist/Adjustable Strap Design

The minimalist/adjustable strap brace was designed to be customizable for each user while remaining as unobtrusive as possible. A minimalist design would allow patients to wear the device for long periods of time without discomfort. Straps on the design attempt to mirror the natural ligament anatomy and provide resistance to movement in the same directions. This is to protect the ligaments and ankle while providing the maximum amount of ankle joint mobility in other directions. In the design the straps are anchored to the foot using a webbed system of bands that wrap around the upper ankle and arch of the foot. The resistance bands are able to be moved along this system so they can be repositioned to mirror a specific patient's ankle anatomy. The bands could also be replaced so stiffness can be customized based on the needs of the user.

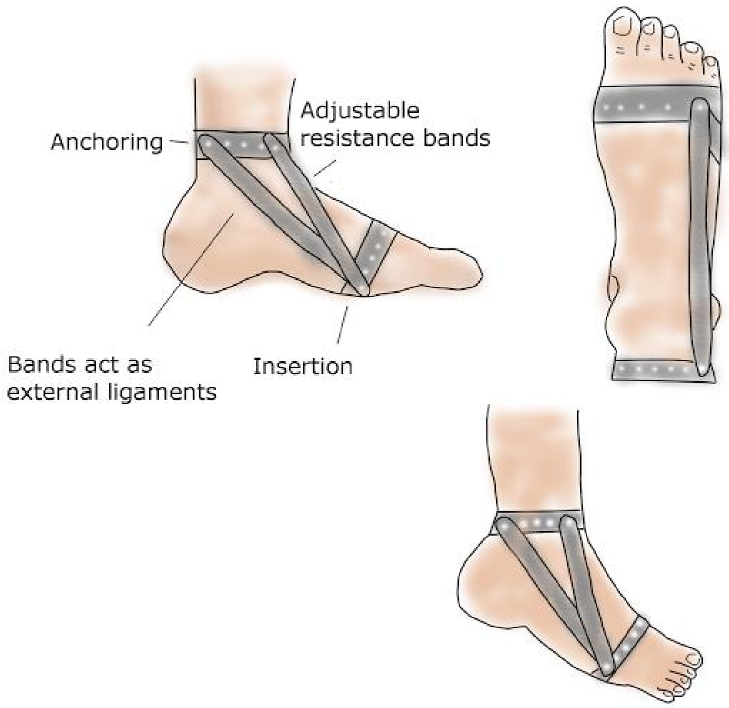

Figure 15: Minimalist/Adjustable Strap Alternate Design. Design consists of customizable straps that mirror the natural ligament anatomy that provide resistance to movement.

Although a good idea in theory, there were several issues with this brace that rendered it an unsuitable choice for a final design. The two anchoring bands must provide enough stability for the entire brace. Any inverting movement will distribute the forces to these bands, and this introduces the risk of slippage or fracture. It also could irritate the skin where the anchoring bands are attached due to the pulling motion it would produce. A truly customizable brace introduces additional problems. User error could be presented if a patient does not position the resistance bands correctly. The bands are also less secured if they are able to slide along the webbing, or if they are removable from the brace.

4.3.4 Reinforced External Ligament Sleeve

The reinforced external ligament sleeve design consists of a neoprene sleeve with elastic components intended to mimic the function of ankle ligaments, as illustrated in Figure 16. The sleeve concept was chosen for its ability to conform to patient anatomy, comfort, ease of use, comparable market cost, and be washable to reduce odor. However, the sleeve alone does not prevent inversion of the ankle that would result in a lateral ankle sprain. Therefore, external ligament pieces were added to provide further restriction. The team identified the three main ligaments typically injured during a lateral ankle sprain as the ATFL, CFL, and PTFL. The external ligaments would be located in the same position as these three ligaments and anchored to the sleeve to mimic their anatomy. The material would have a similar stiffness to that of a healthy ligament in order to restrict ankle mobility. This method would have the advantage of allowing for some mobility of the ligaments, while also limiting inversion to prevent further injury. This design also has an adjustable component because the external ligaments are removable from the sleeve and allow for the insertion of bands with varying levels of stiffness. The user could exchange stiffer bands for more elastic bands as the ligaments heal and need less restriction. A limitation to this design would be preventing the external ligaments from distorting the sleeve. The sleeve would be more compliant than the bands and therefore be pulled by its stiffer counterpart. The adjustable bands would have to be easily attached to the sleeve in order to be exchangeable to the user. For these reasons the team concluded that the reinforced external ligament sleeve would be unable to meet the design goals of restricting harmful inversion and ease of use.

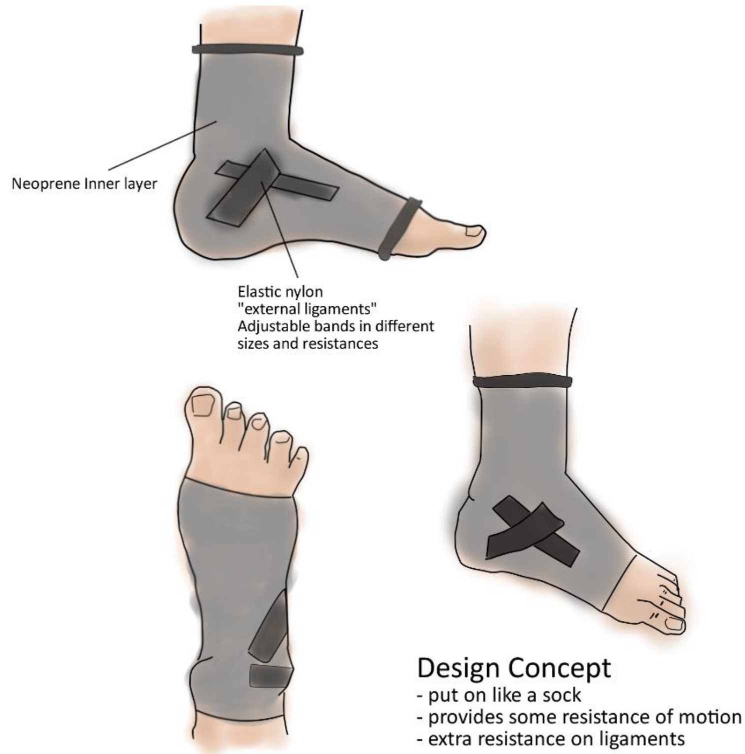

Figure 16: Reinforced External Ligament Sleeve Alternate Design. Reinforced External Ligament Sleeve Alternate Design consists of a neoprene sleeve with elastic components anchored to the sleeve intended to mimic the function of the ATFL, CFL, and PTFL.

4.3.5 Double Ring Brace Design

After considering several designs, the group decided on a double ring brace for the final design. Natural ligament placement is mirrored by the different straps around the ankle, which are color coded according to which ligament they mimic (AFL, CFL, and PTFL). There would be five different levels of stiffness, so that each patient could go through the healing process according to the different levels of stiffness required for each individual case. A ringlet around the malleolus serves as the origin point, and the attached straps insert in various points around the foot to mimic ankle anatomy. The calcaneus area is covered by a second elastic material to allow for structural support to the sleeve to maintain strap stability. The outer ligament layer can be detached from the inner layer, allowing the sleeve to be washed. A top layer of material creates a sleek, streamlined design to improve overall aesthetics of the device.

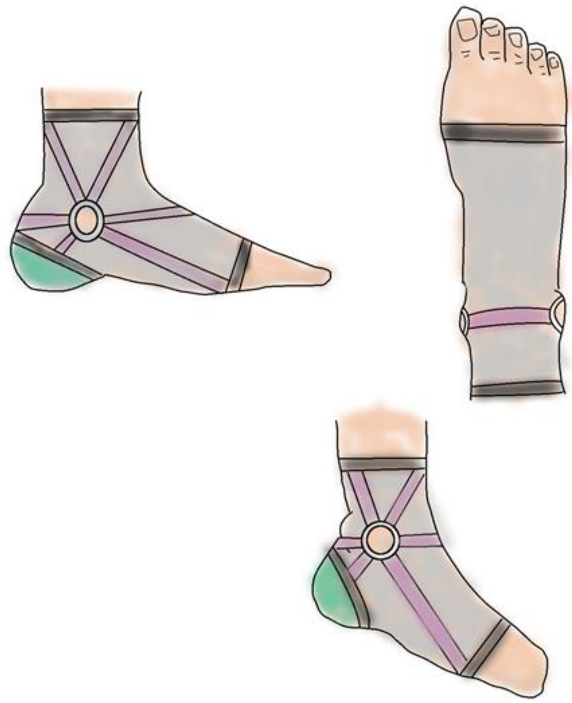

Figure 17: Double Ring Brace Design. Double Ring Brace Design consists of an origin point ringlet around the malleolus and color coded straps to mirror the AFL, CFL, and PTFL.

This design is advantageous because it combines the benefits of the minimalist design with the sleeve design (as described above). The device allows for customization of the healing process of the ligaments using adjustable straps. Depending on how the straps are attached to the malleolus, the mechanical stability of the straps could be impacted. The design also requires additional material on the calcaneus to increase stability of the straps so they do not slide and cause further injury to the ankle. After preliminary testing, it was determined that a second circle of material would be required on both the lateral and medial sides of the ankle to balance forces. This requires more material, which will raise the cost and make the design slightly more bulky.

4.3.6 Weighted Design Matrix

After identifying functions and specifications for the device, the group analyzed specific characteristics for each of the potential designs. This was completed using a weighted design matrix. Ten categories were ranked with a percentage that added up to 100 percent. Then for each device, a ranking of 1 to 10 was assigned. The category weight was multiplied by the assigned rating value, for a total score within each characteristic. The total scores were summed for each device. The highest sum provided a clear choice for which design to pursue. The double ring device scored the highest, followed by the reinforced sleeve and the minimalist design. The matrix can be found in the Appendix A.

4.4 Conceptual Design of Chosen Solution

4.4.1 Design Specifications

The brace dimensions were determined by first constructing a mock model of the design as seen in Figure 18, above. Ligaments in the initial prototype mirrored the average origin and insertion points of ligaments. Bands 4, 6, and 7 represented the PTFL, the CFL, and the ATFL, respectively, while bands 2, 3, and 5 were used to distribute the load on the brace. Bands, 1, 8, and 9 were anchoring bands for the ligament straps. Specific design dimensions and measurements can be found in Appendix D.

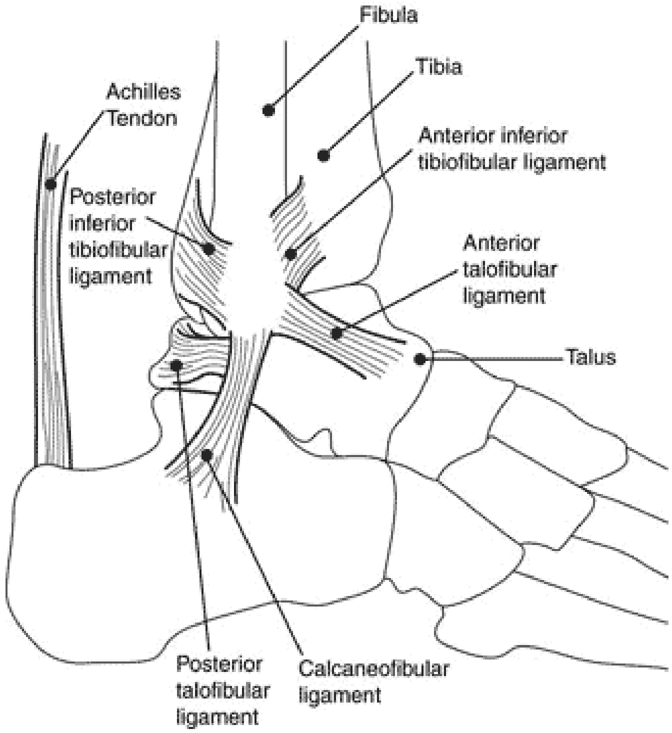

Figure 18: Comparison of natural ligament anatomy with anatomy based design Lateral Ligaments (National Institutes of Health, November 2013). Mock Model of the Ankle Splint Design was based on the orientation of the ATFL, CFL and PTFL.

4.4.2 Adjustability

A unique aspect of the design is the adjustability and personalization available to each patient. The supportive straps are modeled after existing ligament anatomy to provide adequate support to the injured area without causing further harm to uninjured areas. When other devices are especially restrictive to the entire ankle joint, the healthy parts of the ankle are compromised because they become inactive. The design would allow each patient to go through the healing process with graduated levels of straps, so that each personal case is uniquely tailored. This increases comfort levels and effectiveness of the device.

4.4.3 Price

Current braces available on the market have a large price range depending on their intended function. Compression or soft braces are typically the least expensive at around \$10 to \$20, semi-rigid braces cost approximately \$30 to \$40, and rigid braces are sold for about \$45 to \$70. The team identified that the brace will function for Grade I and II ankle sprains during the repair and remodeling phases of the healing process. Therefore it was determined that the brace should be sold at \$40 or less to remain competitive with current braces. This limitation was a key consideration during the design process and specifically had an impact on material selection. The materials chosen to be used for the brace must have the required stiffness and also fall within the specified price range.

4.4.4 Comfort

Braces currently sold on the market utilize a variety of materials ranging from lightweight neoprene to plastic and metals. Neoprene sleeves are lightweight, fit in most types of shoes and are elastic to allow for a wide range of motions. A neoprene sleeve would be extremely comfortable and would be used as a base layer in the final design. The sleeve wraps around the entire foot and ankle with cutouts for the toes and heel. Cutouts would be made of a second material for comfort. In addition to the sleeve, comfort had been considered in the design of the ligament structure. A flat material would be used for the anchoring bands and the ligaments. The anchoring bands would be an elastic that is stiff enough to withstand strain from the ligaments attached to it. The two rings used as insertion points for the ligaments would be made out of thin material similar to the anchoring bands. To limit odor, the team would use a minimal amount of materials and allow the ligament layer and the sleeve layer to separate; the sleeve would be machine washable. All materials used for creating the bulk of the brace would be lightweight and thin as not to hinder motion and to fit in most shoes. In order to keep the brace comfortable the team had decided against the use of any metal fastenings, such as clips, snaps, buttons, or zippers. Instead, the team focused on using materials with adhering properties or Velcro.

4.4.5 Limitations

While the double ring brace was accurate in terms of ligament location and orientation, the brace had many shortcomings. Ligament straps were difficult to anchor securely and were susceptible to slipping. The ring was uncomfortable and prone to plastic deformation. The brace was also difficult to apply and not adjustable to different users. The team decided to explore other design tools to improve upon the design while still meeting the project objectives.

4.5 Modeling & Calculations

4.5.1 OpenSim® Modeling

Although the sample equations provided a starting point for the material research, the ankle is a very complex joint that cannot be fully modeled in two dimensions. Three dimensional analysis is extremely difficult and time consuming, so biomechanical modeling software was utilized to provide simulations of the ankle. OpenSim®, an open-source software system, provided the means for a realistic simulation. The program applied forward kinematics to a pre-existing ankle system to predict the resulting motions and forces.

The software contains pre-fabricated musculoskeletal models of the human body that are ready for simulation. Joints are restricted to natural ranges of motion, and muscle forces can be tuned or disabled depending on the simulation goals. The simulation used for this project was the ToyDropLanding model, available in the standard download files on simtk.org. In this model, the body falls freely and lands on a single foot. The landing platform can be angled to simulate ankle inversion. Although no ligaments are present in the model, this is not an issue because it represents an ankle injury where ligaments no longer function properly. The model was altered through the addition of linear actuators that served to simulate the brace material, shown in Figure 19. They was inserted in the model in various locations to match the different brace prototype designs. This allowed for rapid simulations that measured how each design restricted ankle inversion. The mechanical properties of the actuator were also altered to simulate how different materials behaved in the brace. The force-length curve could also be altered to simulate nonlinear materials that were engineered specifically for this project.

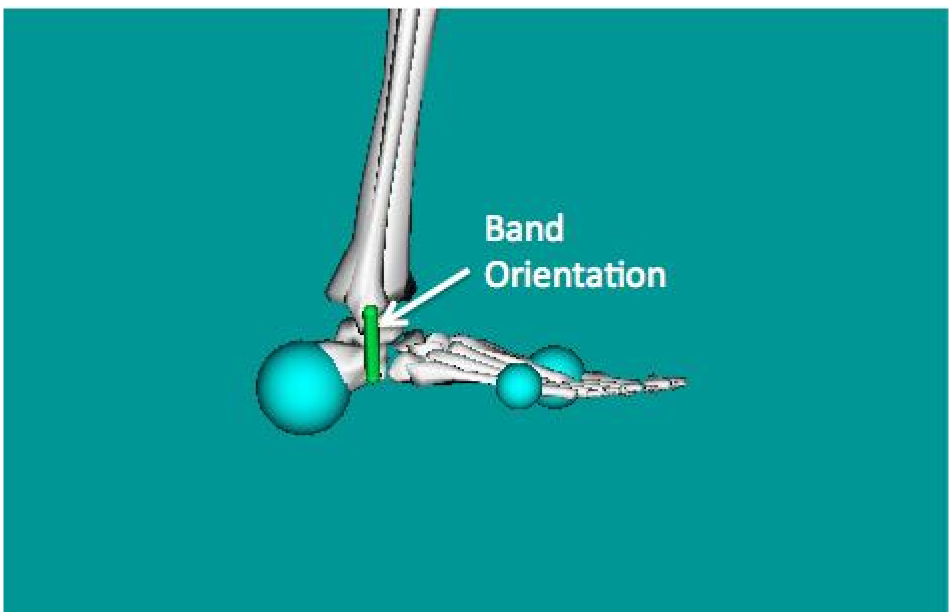

Figure 19: Ligament Band in OpenSim® Model. Linear Actuator was inserted into OpenSim® Model to represent ligament band and simulate brace material.

OpenSim® software was used as a design and verification tool alongside the physical prototyping and testing. Drop plate simulations were completed with different brace designs to see their impact on the subtalar angle during inversion. In the simulations the model was dropped from a very small height onto a plate tilted at 30 degrees, landing on one leg to put an inversion moment on the ankle joint. During the tests, the team altered the brace band orientations as well as band material properties to find a brace that met the project goals.

4.5.2 OpenSim® Prototyping: Band Orientation

A brace was inserted into the OpenSim® model to represent the group's initial anatomically-based design. Three actuator bands represented the generalized locations of the brace bands, minus the ring that covered the malleolus (Figure 20). Band properties in the program included the force-length curve, resting_length, and pcsa_force. The force-length curve represented the elastic properties of the band. In the program, it is displayed as a unitless graph that represents the shape and behavior of the curve. The resting_length simply represented the resting length of the band, and altering it allowed initial tensile forces to be applied on the band prior to the drop. The pcsa_force is a magnitude that scales the force-length curve of the material. This alters the modulus values of the band. Each band was given a standard stiffness of pcsa_force = 1500, a linear force-length curve, and no pre-tension value.

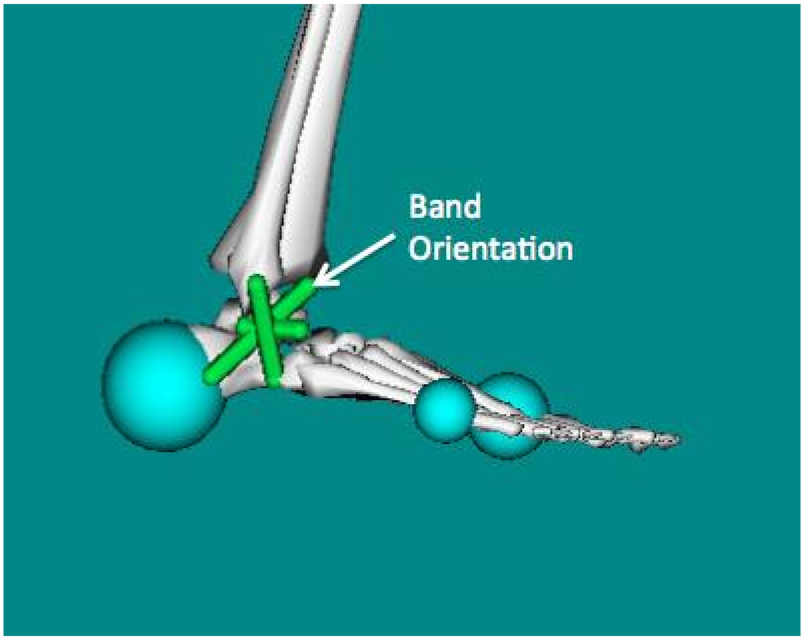

Figure 20: Anatomical Design Band Locations in Model. Band locations were inserted in the model to mirror the bands in the anatomically-based design.

The subtalar ankle angle was used to see the effectiveness of the design. The comparison for the test was a "barefoot" trial that had no active actuator bands. The results of the simulation are displayed below in Figure 21.

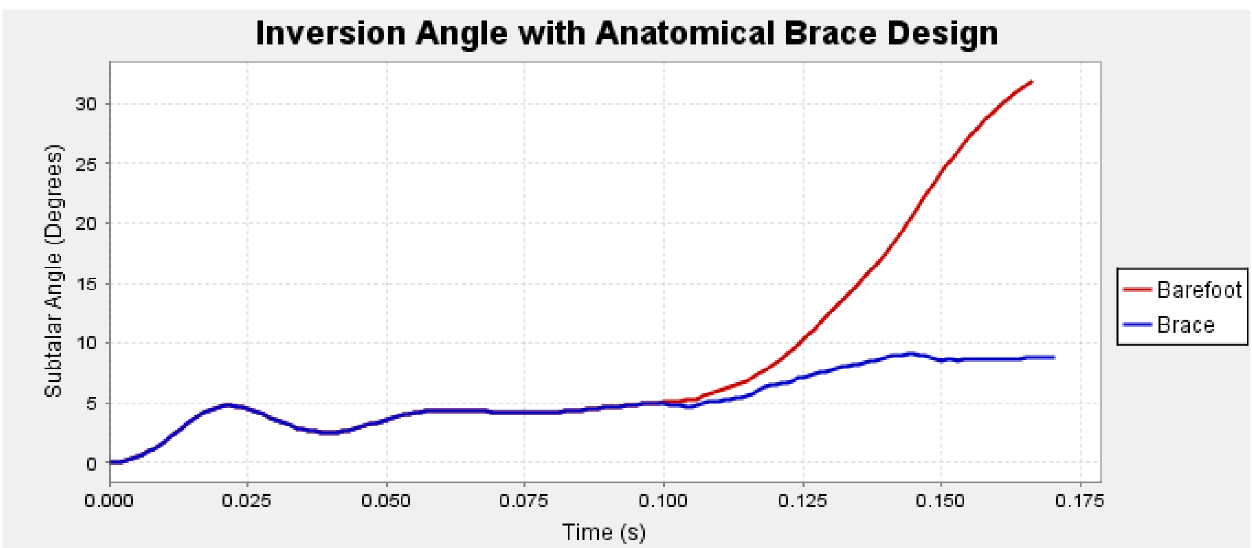

Figure 21: Inversion Simulation Results with Anatomical Orientation. The anatomically-based design restricted ankle inversion when compared to a barefoot trial.

After realizing the prototyping limitations of this design, inversion tests were used to validate a new band orientation. The purpose of these tests was to see if a modified design could have the same level of inversion resistance, while satisfying the prototyping and real-world objectives. The new design used a single, vertical band that ran up the lateral side of the ankle. Again, pre-tension was removed from the band during the simulation and the pcsa_force remained at 1500. The results of the simulation showed inversion resistance, but to a lesser degree. The next simulation had a band with a slight pretension, and this increased its effectiveness to match the first simulation. The results are displayed below in Figure 22.

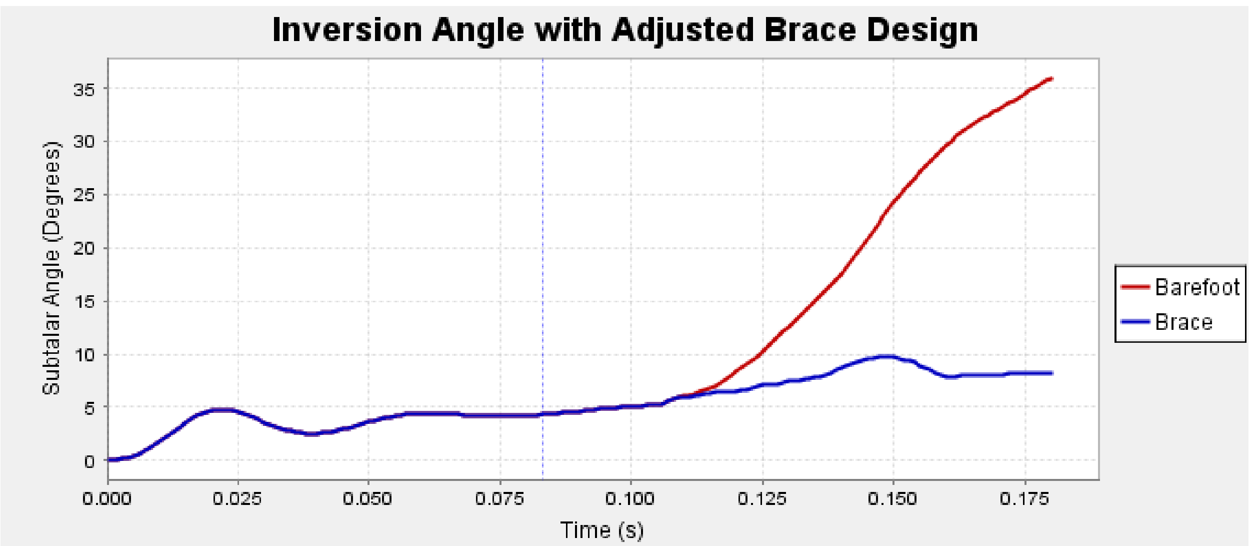

Figure 22: Inversion Simulation Results with Adjusted Band Orientation. The adjusted band orientation was equally as successful in the anatomical design in preventing simulated ankle inversions.

Since the adjusted orientation resisted inversion to the same degree as the anatomical design, the team decided that switching to the lateral band would help better meet the project goals.

4.5.3 Preliminary Testing Calculations

The Model

A simplified model of the ankle was used to create static equilibrium equations for ankle inversion. These equations provided a way to examine the material properties that could be necessary for the brace. This model assumed the ankle as a single joint on the coronal plane. It also assumed two dimensional rotations around the joint to simulate inversion and eversion. Forces on the model were applied as moments based off of values found in literature. In addition, no dynamic analysis was used because ankle rotation frequency does not have a noticeable effect on the failure angle or torque of the ankle (Wei et al., 2010).

Components

Components of the model included the ankle joint, an inverting moment, and resisting everting moments. An inverting moment was included in the ankle with a magnitude high enough to cause ankle joint failure. The peroneus longus and peroneus brevis were applied as two naturally everting muscle moments. The third and final everting force was the device material, which was placed in a vertical position hanging down from the lateral malleolus. This configuration provided the model resistance to inversion via tension in the material. The model assumed injured ligaments, so no ligamentous resistances were included.

Calculations

Two inverting ankle configurations, 20 degrees and 30 degrees, were used in the calculations for material stiffness. Twenty degrees of inversion marks the initiation of pain in the average person (Markolf et al., 1989). Thirty degrees of inversion represents the ankle angle at which ligamentous injury begins to occur (Paul, 1982). A moment of 45.3 Nm was applied directly to the ankle joint, representing a moment high enough to cause ankle failure (Markolf et al., 1989). Muscle everting moments were inserted as 13 Nm and 17 Nm (Lewis, 1984). The moment from the brace material was set equal and opposite to the remaining inverting moment on the ankle.

The moment was then converted into a force by dividing it by the approximated moment arm, which was the distance from the ankle joint to the lateral malleolus. Since the material provides its resistance from tension, Hooke's law was used to calculate the required modulus.

Equation 2: Hooke's law: $F = k\Delta x$

F was the force, k was the spring constant, and Δx was the change in length. The spring constant was set as the constant for a beam under axial load, which is the product of cross sectional area and Young's modulus divided by the material length. The remaining unknowns were the length measurements, the cross sectional area, and the modulus. The cross sectional area was chosen so the material would lay flat and not interfere with any other brace components. The lengths were found by approximating distances on anatomical pictures. The material length was found at resting ankle state, at 20 degrees of inversion, and at 30 degrees of inversion. This allowed the Young's modulus to be calculated at the two ankle configurations. The yield strength at each configuration was also found by using the relationship between modulus, stress, and strain. The calculations aided the material selection process by giving an initial estimated modulus range for potential materials for the brace.

4.6 Preliminary Data

4.6.1 Static Plate

Initial Concepts

A static plate was constructed to determine the effect of ankle braces and elevation on ankle stability and ankle inversion. In order to determine how braces prevent ankle inversion, test subjects purposely inverted their ankles while wearing ankle braces. In the test, subjects stood on a ramp, allowing the team to analyze their ankle inversion without interference from dynamic forces.

Construction

The plate was constructed using two wooden boards, a wooden block and a jack. The wooden block was placed against a wall. The end of one wooden board was placed against the edge of the block and the other end of the board was lain against an unraised jack, as shown in Figure 23. The board acted as a ramp. The other wooden board was pushed against the other end of the jack, acting as a weight to keep the jack from slipping.

Testing

Subjects stood on the equipment with one foot on the jack's platform and the other foot on the wooden ramp with body weight distributed mainly on the ramp. Each subject's ankle was marked with three circles, at, above, and below the ankle's center of rotation. Two sets of independent variables were tested. The marks were used help visualize ankle inversion. First, the experiment tested the effect of different ankle support on ankle inversion. A bare ankle was used as a control, and five store-bought ankle braces were analyzed: Futuro Wrap brace, Neoprene sleeve, Futuro Sports brace, Stromgren Double Strap brace, and Aircast brace. Elevation was varied as the second independent variable. An elevation of 0 degrees was used as a control. Ankle inversion was tested at 13 degrees elevation and 33 degrees, as seen in Figure 23. Subjects wore combinations of all the ankle braces at all elevation levels.

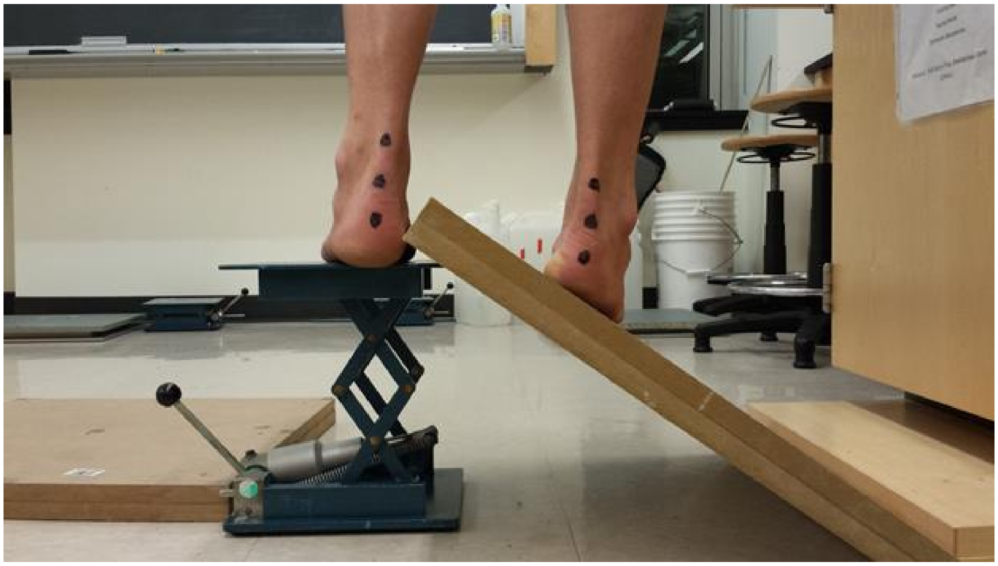

Figure 23: Group member on modified drop plate at 33 degree angle. Each subject stood on modified drop plate at 33 degree angle to measure ankle inversion.

Results & Conclusions

Since each subject's foot rested completely flat against the plate regardless of the brace being tested, all braces were determined to be incapable of preventing the ankle from inverting to 33 degrees. The team determined that fully preventing ankle inversion in a static experiment was not possible and that devices should instead provide resistance by slowing the rate of ankle inversion.

This method of testing also provided insight into which devices were the most comfortable to wear for extended periods of time. The group also determined which devices were difficult to use. In general, rigid braces and semi-rigid braces such as the Aircast were uncomfortable to wear for long periods of time. Braces that had multiple straps were complicated to wear as intended and often did not include clear instructions.

4.6.2 Uniaxial Load Test

Material testing was completed on an Instron 5544 machine using Bluehill testing software. A tensile test pulled the material until failure. This measured for the ultimate tensile strength as well as the Young's modulus of each material. The materials were cut into strips and loaded into the Instron. They were then given a tare load of 5 N before the length, width, and thickness measurements were recorded.

Initial Model Material Testing

The first round of testing involved materials that were possible candidates for a brace design and that were also readily available for immediate testing. The materials tested were polypropylene, cotton, and a silicon skin adhesive. A tensile test pulled the material at a rate of 30 mm/min until failure for each material. A new piece of material was used for each test. Sample Load/Displacement graphs and analysis for each material are shown in Appendix E.

Prototype Material Testing

The second round of tensile testing analyzed materials that were being considered for the first round of prototypes. The materials tested were Fabric Reinforced Oil Resistant Buna N Rubber, Neoprene Rubber, High Strength Multipurpose Neoprene Rubber, Elastic, and Cotton. At least three trials were performed for each material, with a new piece of material being used for each test. Some tests, however, were performed incorrectly so data could not be collected. A tensile test pulled flexible materials such as Neoprene Rubber and High Strength Multipurpose Neoprene Rubber at 200 mm/min due to their elasticity. Other materials were pulled at a rate of 30 mm/min until failure for each material. Sample Load/Displacement graphs for each material are shown below.

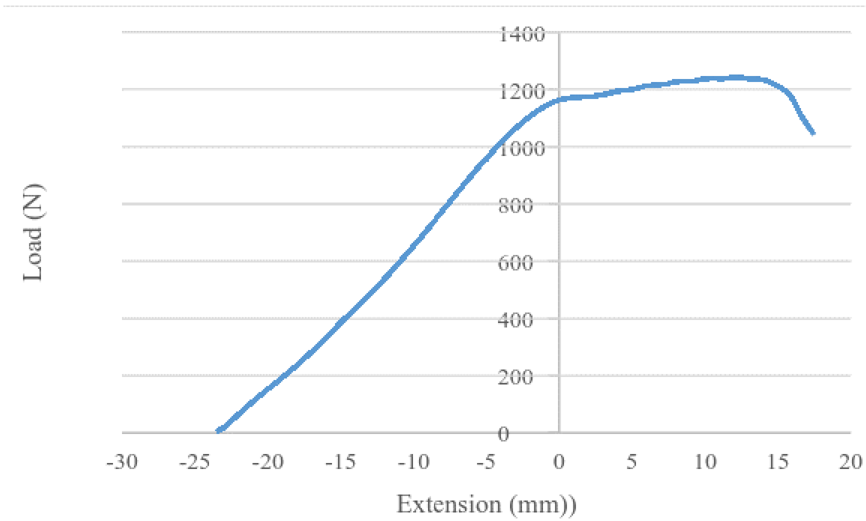

Figure 24: Load and Extension of a Fabric Reinforced Oil Resistant Buna N Rubber Strip .Load and Extension of a Fabric Reinforced Oil Resistant Buna N Rubber Strip pulled at a rate of 30 mm/min.

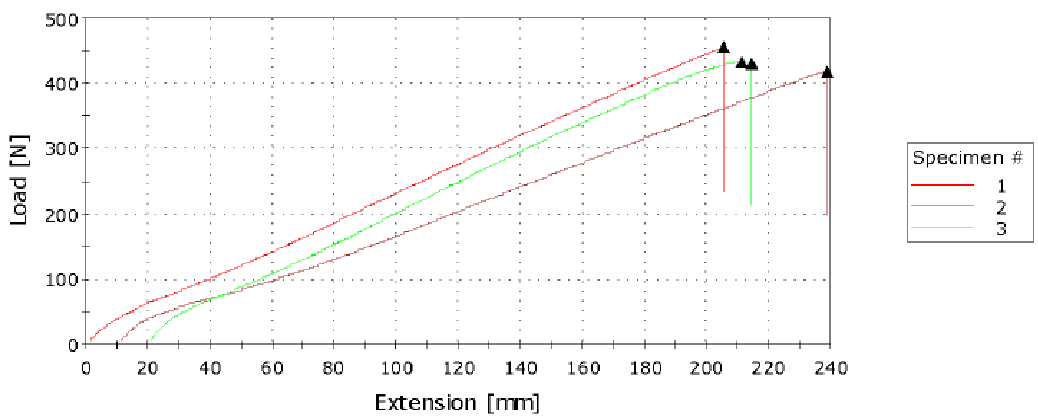

Figure 25: Load and Extension of a Neoprene Strip. Load and Extension of a Neoprene Rubber Strip pulled at a rate of 200 mm/min.

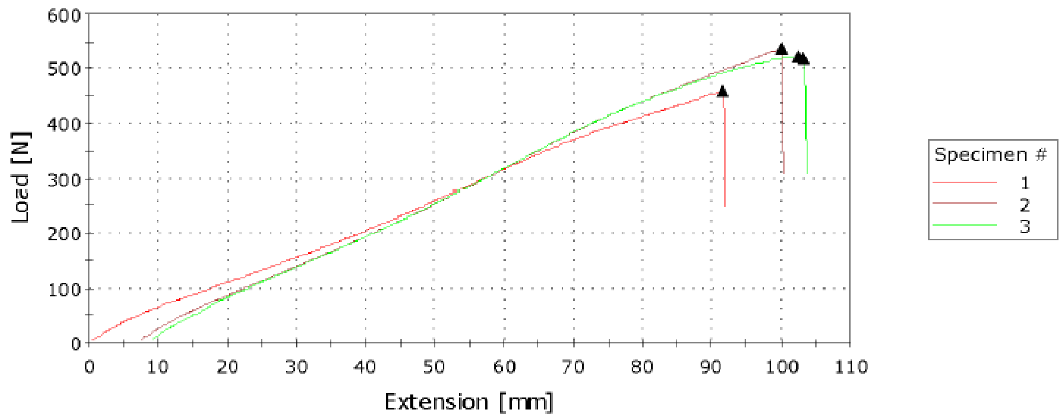

Figure 26: Load and Extension of a High Strength Multipurpose Neoprene Strip. Load and Extension of a High Strength Multipurpose Neoprene Rubber Strip pulled at a rate of 200 mm/min.

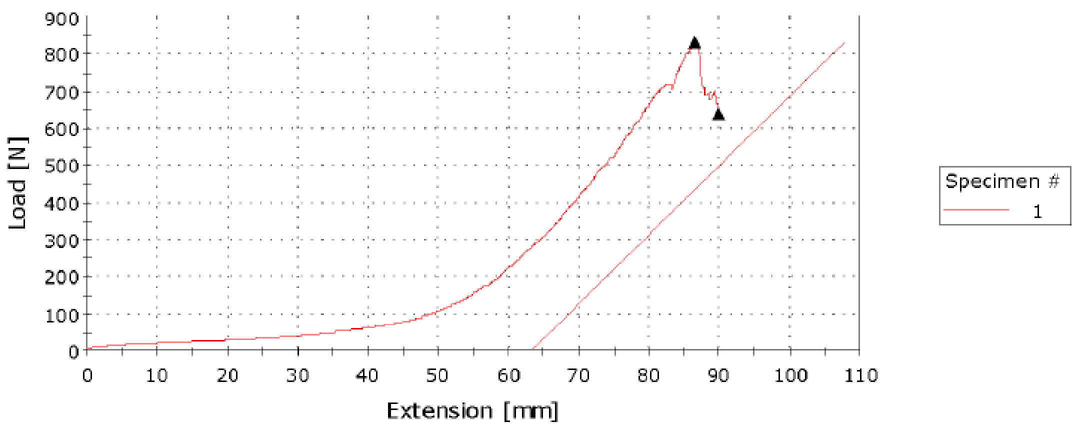

Figure 27: Load and Extension of an Elastic Strip. Load and Extension of an Elastic Strip pulled at a rate of 30 mm/min.

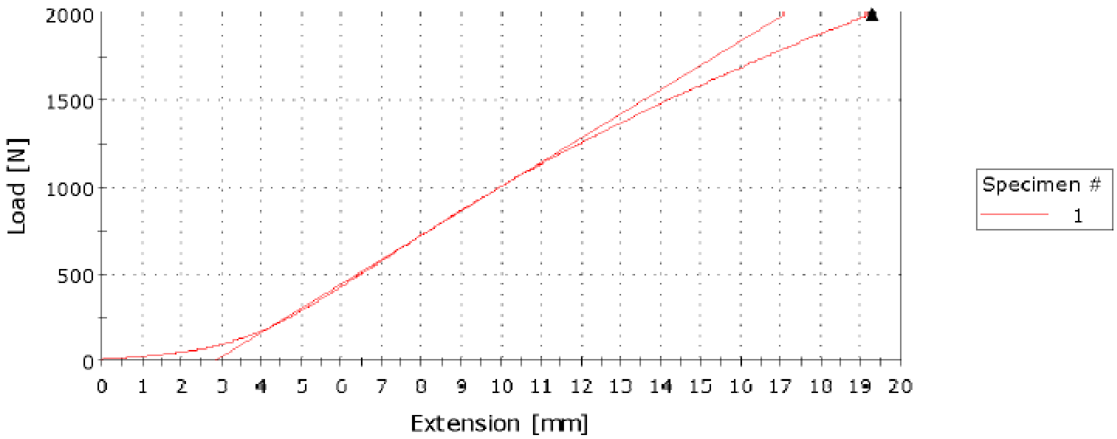

Figure 28: Load and Extension of a Cotton Strip. Load and Extension of a Cotton Strip pulled at a rate of 30 mm/min.

From these results, the group compared obtained experimental values with material values found in literature for the samples. Table 3 below shows these values.

Table 3: Comparison of experimental values of tension material testing. Comparison of experimental values for material tensile tests using the Instron machine.

Material	Trial	Experimental E (MPa)	Experimental UTS (MPa)
Fabric Reinforced Oil Resistant Buna N Rubber	1	116.86	25.71
	2	101.32	28.37
	3	9.00	3.06
Neoprene Rubber	1	3.30	9.04
	2	2.60	8.70
	3	3.30	9.02
High Strength Multipurpose Neoprene Rubber	1	6.36	9.67
	2	7.62	10.82
	3	7.30	10.66
Ultra Strength Neoprene Rubber	1	44.53	21.82
	2	Incomplete	Incomplete
	3	Incomplete	Incomplete
Elastic	1	17.24	20.86
	2	Incomplete	Incomplete
	3	Incomplete	Incomplete
Cotton	1	116.14	25.55
	2	Incomplete	Incomplete
	3	Incomplete	Incomplete

Rubber was eliminated as a design choice because of prototyping limitations. Elastic and cotton did not have these limitations and also displayed suitable mechanical behavior that matched the team's design criteria.

Nonlinear Material Testing

The final round of material testing was for specially-selected nonlinear elastics to be used for the lateral band of the brace. Five different materials were tested to see their nonlinear behavior as well as their strength. Of the five materials, the 2” Latex Elasbelt Webbing exhibited a load-extension curve best suited for the design, as shown in Figure 29.

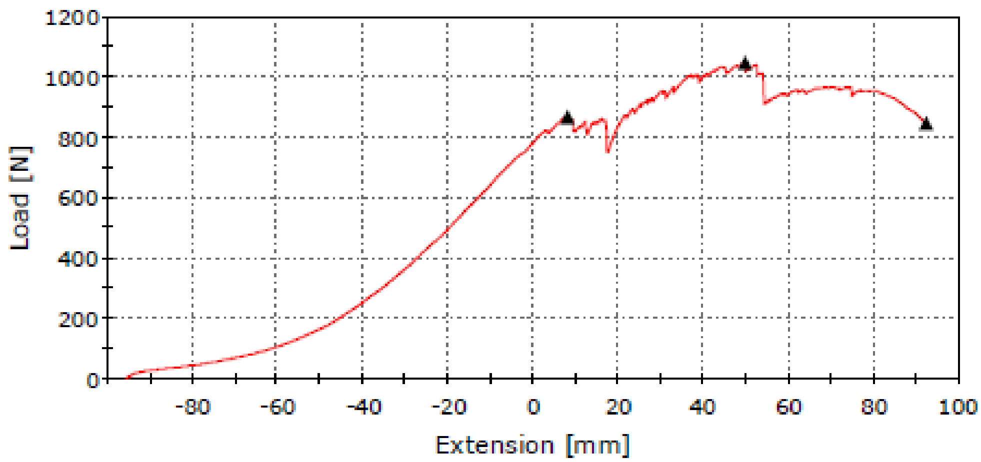

Figure 29: Load and Extension of 2” Latex Elasbelt Webbing. Load and Extension of 2” Latex Elasbelt Webbing pulled at a rate of 30 mm/min.

All of the tested elastics displayed nonlinear behavior under tension. Prototyping capability, thickness, and the modulus range were the deciding factors in the final material selection.

4.7 Active Drop Plate Design

4.7.1 Initial Concepts

While the static plate tested the effect of surface angles on ankle rotation, a testing method was needed to simulate how a rapid fall would affect ankle rotation while using various braces. After initial analysis with the static plate, the team created a dynamic drop plate with a hinged flap that would fall to a 30 degree angle. The fall simulated a rapid inversion similar to one that could cause ankle injury. After consulting with the advisor, the team created a SolidWorks model of the drop plate, as seen below in Figure 30. The drop plate consisted of four main structures. The right side platform was for the stable foot and was connected to a second platform using a hinge. Test subjects would place the foot being tested on the left platform with all of their weight. The left platform was dropped and ankle rotation was measured. The platform was dropped quickly so the test subject would not anticipate the sudden rotation, and muscle response would not construe the data. This drop plate design had two main safety features. The first was a block of material on the left platform. The block would stop the ankle from sliding off the platform and from over-inverting, which may lead to an ankle sprain. Additionally, a pad of soft material would be placed underneath the drop platform to increase impact time and minimize impulse that may occur when the platform hits the ground.

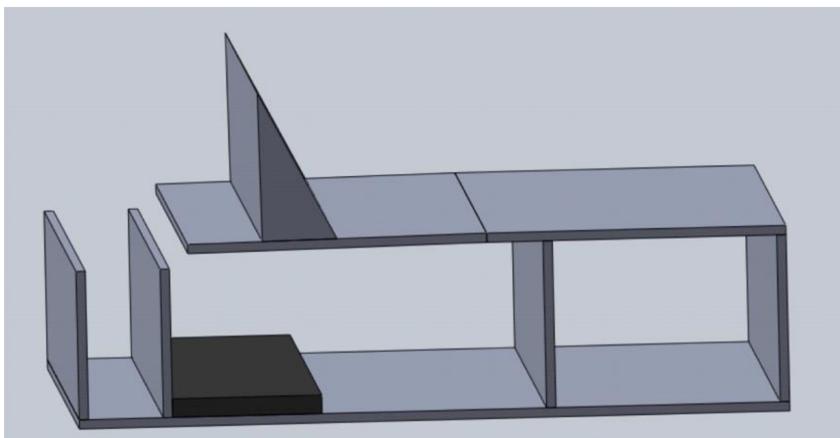

Figure 30: Drop plate SolidWorks model. SolidWorks model of dynamic drop plate that simulates how a rapid inversion would affect ankle rotation while wearing various braces.

The team met with a consultant at WPI's Machine Shop regarding the drop plate design. Originally aluminum was considered for the drop plate, however, the consultant believed that the cost of constructing the drop plate out of aluminum would not be feasible. The cost to manufacture the aluminum drop plate would be well over the team's budgeted cost of $200. Furthermore, the consultant did not believe using aluminum for this application would be safe for the test subject. The vertical members of the design would be unstable under testing and would require additional material and complicated manufacturing techniques to adjust. Manufacturing techniques needed to construct the drop plate would also negatively impact the durability and strength of the aluminum. Additionally, the ¼" of aluminum would not be rigid enough to hold the weight of a person, and the hinge connecting the two platforms would rip out under pressure. The consultant suggested using wood to manufacture the drop plate.

4.7.2 Construction

With these considerations in mind, a wooden drop plate testing device was constructed out of plywood and carpeting. Trigonometric functions were used to determine the dimensions of the device so that the resulting drop occurred at 30 degrees. The base was 19" by 15"; this was the largest piece of wood in the design for added stability during testing and to make transporting the device easier. The vertical supports were 5" high and 14" long. The platform that the test subject stood on was 15" across and 15" wide. All of these wooden pieces were from the same piece of plywood that had a 31/32" thickness. A nickel plated piano hinge was used for the piece of wood dropping down from horizontal. Velcro was used to attached carpeting squares for the dropping wooden piece to land on to absorb the shock of the drop. Another piece of wood was cut from the plywood and had a cut running horizontal to the piece. Another piano hinge was used. Eyelet hooks were added, and string was added on each side. This piece of wood is placed under the movable dropping piece of wood, and is removed by pulling hard away from the device.

4.8 Prototypes

Based on the OpenSim® simulation, the adjusted strap orientation was determined to be effective at restricting inversion. Two prototypes were then developed based on this adjusted strap orientation. Both prototypes were constructed using different means and materials.

The Cotton Strap with Adjoining Sleeve, shown in Figure 31, used a stiff material to restrict inversion. The first component of this design was a neoprene sleeve base. A cotton strap was wrapped around the ankle with extra reinforcement on the lateral part of the ankle. The design also focused on conforming to the anatomy of the user. Therefore, metal snaps were used to tightly attach the cotton strap to the user's foot. While the stiff material did slow the rate of inversion and the snaps made the brace conform to the foot, both the stiff material and the snaps limited adjustability of the device. The brace was only able to correctly fit one subject, and different materials and attachment options were needed.

Figure 31: Picture of Cotton Band device. The stiff cotton band on the lateral side of the ankle was designed to have high inversion resistance.

The Lateral Ligament Elastic Straps with Velcro Attachments, shown in Figure 32, consisted of a padded foam top piece that wrapped around the leg directly above the ankle and an elastic band bottom piece that wrapped around the instep of the foot. The padded foam was chosen to provide comfort and to anchor the straps. Two elastic straps on the lateral side of the ankle were attached to the top and bottom pieces in directions relating to the ATFL and CFL. The first elastic strap attaches with Velcro to the anterior aspect of the leg on the foam pad to the plantar aspect of the foot on the bottom piece. The next elastic strap starts between the posterior and lateral aspect of the leg on the foam pad and runs to the instep of the foot on the bottom piece.

Figure 32: Picture of Velcro device. The straps attempted to mirror the approximate positions of the ATLF and CFL while still conforming to the ankle anatomy.

4.9 Conceptual Final Design

4.9.1 Adjustability, Price, Comfort

A key requirement of the design was the adjustability and personalization available to each patient. The Elastic Straps with Velcro Attachments design was able to conform to different users because of the adjustable Velcro straps. The Cotton Strap with Adjoining Sleeve design did not adequately meet this requirement because the metal snaps did not allow for enough adjustment between users. Both the Cotton Strap with Adjoining Sleeve and the Elastic Straps with Velcro Attachment prototypes were made to be sold at a retail value of $40 or under. The Cotton Strap with Adjoining Sleeve was found to be comfortable to the user because of the neoprene sleeve base. The metal snaps on the sleeve, however, were determined to be uncomfortable. The Elastic Straps with Velcro Attachment prototype had a supportive foam pad that was comfortable for the user and the elastic straps conformed to the user anatomy, which added to the comfort level.

4.9.2 Function-Means Chart

The two prototypes were evaluated based on a function means chart, shown below in Table 4.

Table 4: Function Means Table Brainstorming the means to meet each desired device function helped evaluate the efficiency of the prototypes

	Means	
Function	Lateral Ligament Cotton Strap with Adjoining Sleeve	Lateral Ligament Elastic Straps with Velcro Attachments
Balance restriction of ankle inversion and mobility of ligaments	Cotton straps wrap around ankle to provide increased stability	Two elastic straps on the lateral side of the ankle provide increased resistance to ankle movement
Conforms to ankle anatomy	Straps attach to a sleeve	Padded foam top piece and elastic band bottom piece
Adjustable to user	Metal sew-on snaps attach straps	Velcro attaches straps

Therefore, the final design combined the best aspects of the two prototypes. For the highest adjustability the design will use Velcro. For ease of use the design used a neoprene sleeve and followed the band orientation of the Cotton Strap with Adjoining Sleeve. For added comfort the final design included the supportive foam pad.

4.9.3 OpenSim® Prototyping: Band Properties

Although the design resisted inversion in the simulations, it actually proved over-restrictive. The next step was to investigate how altering the actuator band properties impact the inversion results. Altering the band properties changed the stiffness of the band. Tests were run to see how changing the force-length curve altered the behavior of the ankle during the drop. The first test used a linear elastic band, represented by a linear force-length curve (Figure 33). To find a band that provided allowance to 20 degrees, but was restrictive afterward, the curve was changed to be nonlinear (Figure 34). Using this band, the initial inversion would require very little force to strain the band. However, as the angle increased the stiffness of the band also increased, making the brace more restrictive at high angles.

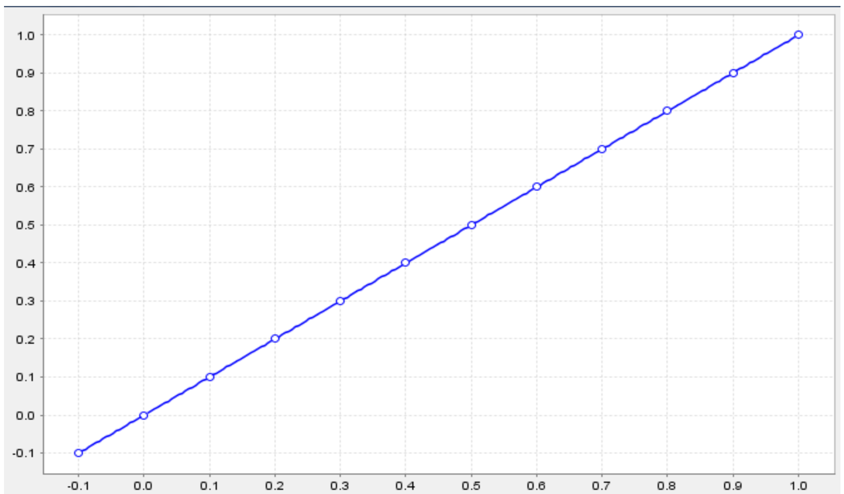

Figure 33: Linear Force-Length Curve. This figure represents the linear behavior of the actuator under a tensile load.

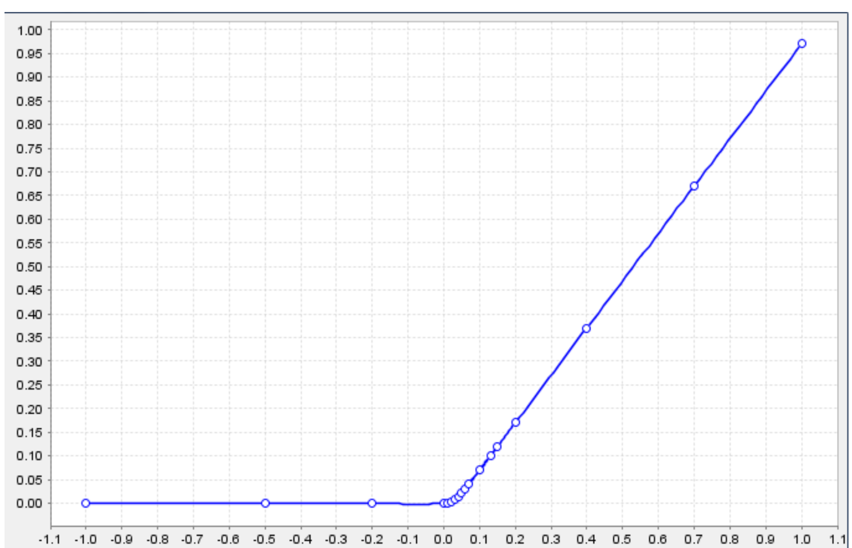

Figure 34: Nonlinear Force-Length Curve. This figure represents the nonlinear behavior of the actuator under a tensile load.

Next, the group observed the effect of the pcsa_force on the subtalar angle over time. One trial was completed for a pcsa_force of 0, 500, 1000, 1500, 2000, and 2500. The results are shown below in Figure 35.

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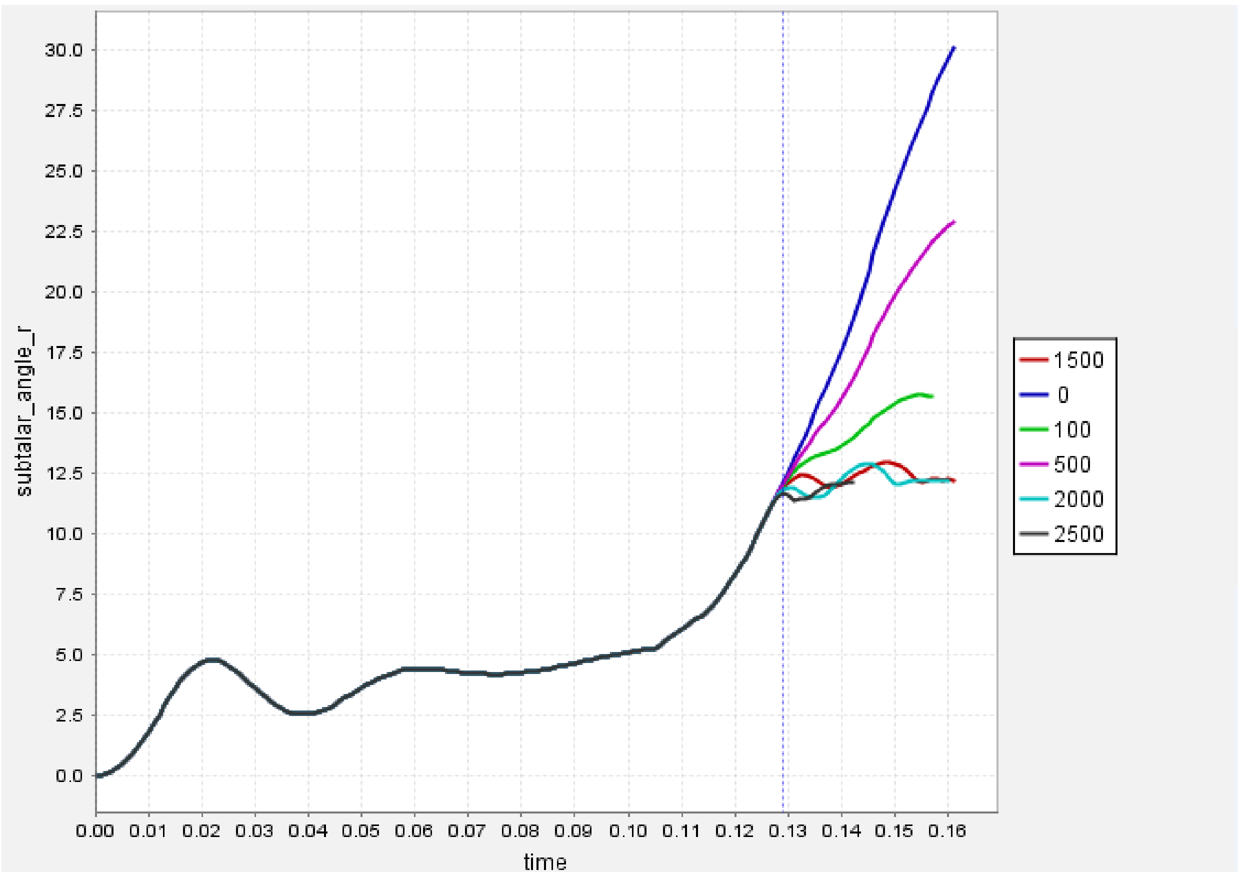

Figure 35: Changing pcsa_force in Ankle Inversion. Each line represents the ankle inversion angle during a simulated fall with different nonlinear band stiffness.

The vertical line represents the point that the foot made contact with the plate. A clear difference can be seen in the early trials compared to no force. A force of 500 reduced the maximum inversion from 30 degrees to 22.5 degrees. Increasing the force afterward showed diminishing returns on the results. In fact, the trials ran at 1500, 2000, and 2500 all showed the same behavior.

Next a test was run to see the effect of the initial length on the results. Here the pcsa_force was set to 1000, and the plate angle to 30. A resting length of 0, 0.44, 0.45, 0.46, 0.48, and 0.5 were tested. The results are shown below in Figure 36.

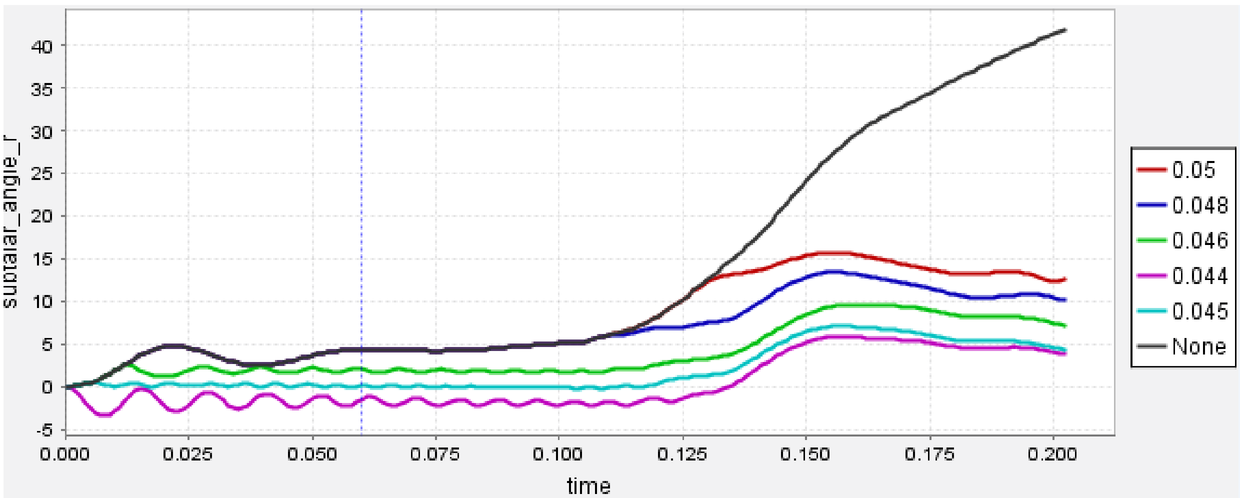

Figure 36: Changing Band Resting Length During Ankle Inversion Modeling. Each line represents the ankle inversion angle during a simulated fall with a different amount of pretension in the band.

This test demonstrates how initial tension in the band provides resistance to inversion. In this graph, the impact point was around 0.13 seconds, and after this point the band with the shorter resting length had the lowest maximum inversion.

Unfortunately, pre-tension and pcsa_force variables proved to be very difficult to translate into real-world values. Prototyping and measurement constraints limited any pre-tension in prototype designs, and the pcsa_force units were unknown. This meant that the group could not refine the design specifics using the OpenSim® program. Instead, the knowledge of the potential behavior of nonlinear bands drove the experimentation of different elastics that could potentially achieve the same results as the simulations.

4.10 Feasibility Study of Prototypes

From computer simulations, the group knew that the adjusted strap orientation was effective in restricting inversion. The Cotton Strap with Adjoining Sleeve used metal snaps to attach the cotton strap to the sleeve in a stirrup structure. The Elastic Strap with Velcro Attachments used Velcro to attach multiple straps to the sleeve in orientations that mimicked ligaments. Both braces fixed issues that the ring device had with anchoring points, and they were easier to manufacture than the previous brace. The cotton stirrup brace conformed to the user's anatomy better than the Velcro sleeve, and in preliminary testing, was shown to slow the rate of ankle inversion. It was determined that the snaps attachment method would not allow for as much adjustability as Velcro would.

5.0 Design Verification

This section contains the methods and results of testing.

5.1 Passive Muscle Results

5.1.1. Passive Muscle Testing

Goniometer measurements were taken according to the ankle injury management's guide for assessing ankle range of movement (Keene, 2010). A universal goniometer with a scale from 0 to 360 degrees was used to determine the movement of the joints relative to the angles of shafts of the bones rotary motion. This movement is also called range of motion (ROM). The team tested the active range of motion of the subjects from an anatomic starting position through unaided voluntary movements that did not cause the subjects pain.

Five subjects were used in this experiment. The testing parameters included subjects' left and right ankles under the test conditions of no brace, Futuro Infinity Adjustable Black Precision Fit Ankle Support, up & up Ankle Brace Elastic Medium, Futuro Sport Deluxe Adjustable Black Ankle Stabilizer, Stromgren Double Strap Ankle Support, and Aircast Air-Stirrup ankle brace. The subjects were tested for ankle dorsiflexion, plantar flexion, inversion, and eversion movements of both the right and left ankle. The ankle was placed in an elevated starting position, and positioned in neutral plantar grade that has the foot and ankle create a 90 degree angle with the leg. This position was considered to be 0 degrees.

For dorsiflexion and plantar flexion the arms of the goniometer were lined up with the subject's fibula and fifth metatarsal with the axis resting just below the lateral malleolus. For dorsiflexion the subjects moved their foot towards their head and for plantar flexion away from their head. For inversion and eversion the arms of the goniometer were lined up with the subjects tibial crest and second metatarsal with axis centered on the front of the ankle in the middle of the medial and lateral malleoli. The starting position of the ankle was relaxed for inversion and eversion. The subjects moved their foot inward to measure inversion and outward to measure eversion.

5.1.2. Passive Muscle Results

The no-brace average measurements were 28.7 ± 3.3 degrees inversion, 17 ± 10.7 degrees eversion, 12 ± 2.6 degrees dorsiflexion, and 61 ± 12.3 degrees plantar flexion. The Aircast and Futuro Sport Deluxe Adjustable Black Ankle Stabilizer had the greatest restriction on inversion with 23 ± 2.6 degrees and 23.1 ± 6.6 degrees, respectively. The up & up Ankle Brace Elastic Medium had the least restriction on inversion at 26 ± 3.7 degrees. Also noted was the Aircast had the highest restriction on eversion and dorsiflexion at 10.8 ± 3.4 degrees and 9.8 ± 1.9 degrees, respectively. The Futuro Sport Deluxe Adjustable Black Ankle Stabilizer had the highest restriction on plantar flexion at 50.8 ± 16.6 degrees. This averaged data with its standard deviation values is summarized in Figure 37 below, and the complete list of data is in Appendix B.

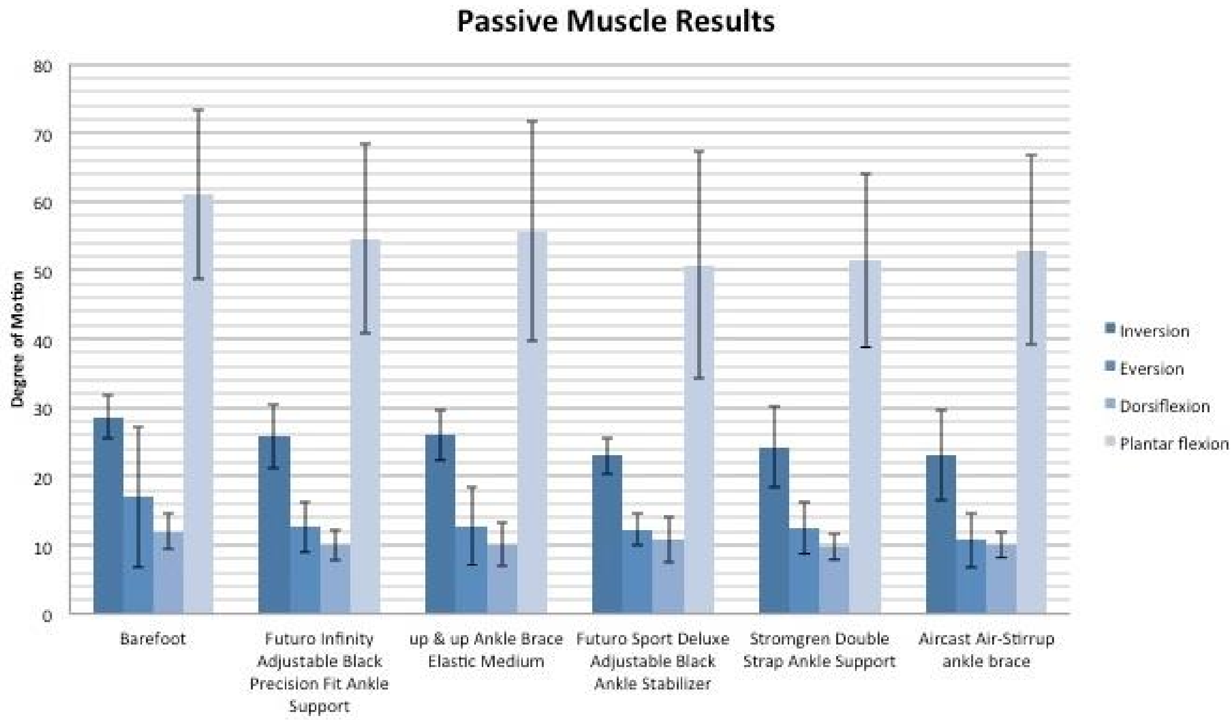

Figure 37: Passive Muscle Results .Passive Muscle Results obtained by measuring with a goniometer display range of motion in all planes for multiple braces.

Single-factor ANOVA analyses were done for inversion, eversion, dorsiflexion and plantar flexion for barefoot and each ankle brace. This was intended to determine if various braces had an impact on the degree of ankle movements. At a 95 percent confidence interval, the p-value was found to be greater than 0.05 for each ankle movement and thus insignificant. A potential source of this discrepancy could be the range in mobility of each individual test subject's feet. Therefore, two-factor ANOVA analyses were performed to determine the effect each test subject had on the results. For this analysis it was assumed that each individual foot of every test subject would impact the results. It was found that there is a statistically significant (p-value < 0.05) difference between each subject's right and left foot for all four ankle movements. Additionally, it was discovered that there were significant differences between the inversion and plantar flexion measurements of the braces and no brace condition, as shown in Appendix G.

Eversion and dorsiflexion were not significantly different amongst the braces and barefoot measurements.

Next the two conceptual prototypes and the final design were tested on two subjects' left and right feet. This was done due to limitations on the size of the prototypes and their inability to fit all of the original test subjects. Therefore, statistical analysis was unable to be performed on the data. Figure 38 below shows the averaged results of the two subjects' ankle inversion for barefoot, the three semi-rigid braces previously used, the soft neoprene brace, the Aircast rigid brace, Cotton Strap with Adjoining Sleeve, Elastic Strap with Velcro Attachments, and the final design. The final design prototype showed the highest restriction on inversion at 20.8 degrees, when compared to a barefoot control. The Cotton Straps with Adjoining Sleeve Prototype had the next highest restriction on inversion at 21.0 degrees.

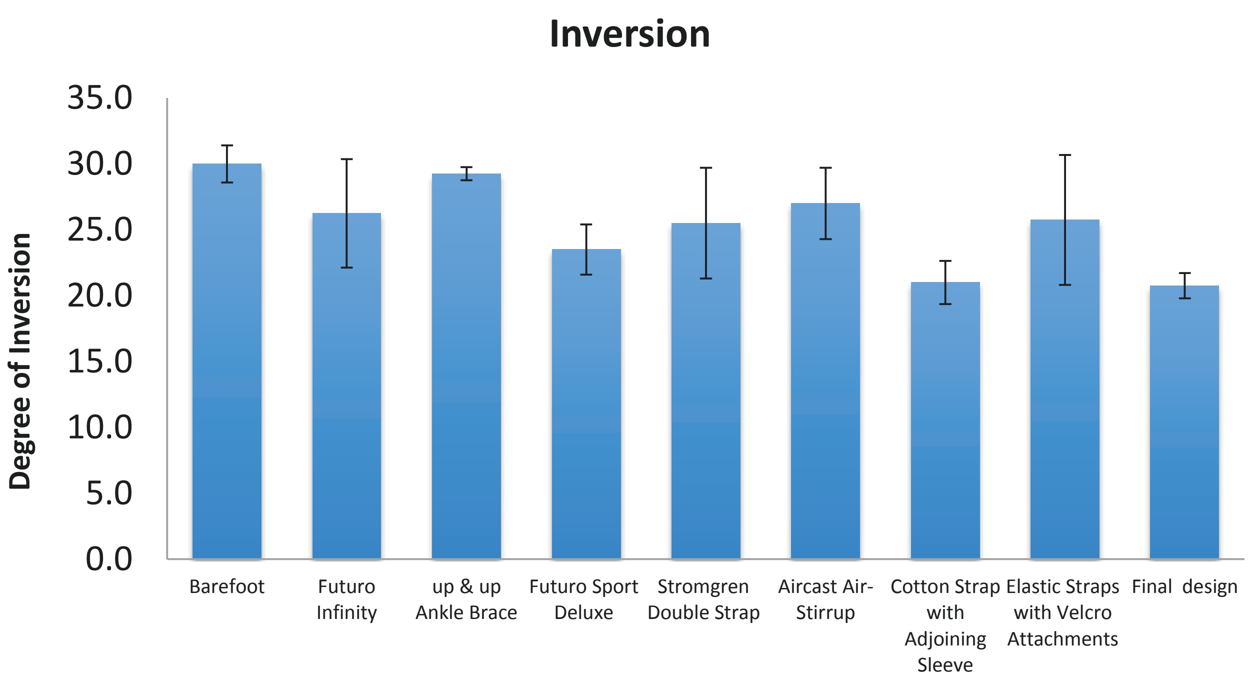

Figure 38: Passive Movement Ankle Inversion. The final design showed the most restriction in passive ankle inversion.

5.2 Dynamic Drop Plate Results

5.2.1 Dynamic Drop Plate Testing

One subject took part in dynamic drop plate testing using a custom fitted device. Drops were performed while barefoot, wearing each of the store bought devices, the group's prototypes (Cotton Strap with Adjoining Sleeve and Elastic Strap with Velcro Attachments), and the final brace design. Polhemus™ G4 Electromagnetic Tracking (EMT) software was used to measure the location of sensors during the test. Three sensors placed under, at, and above the rotational point of the ankle were used. In round one of testing, the sensors were placed on the medial part of the lower leg and on the ankle bone, as shown below in Figure 39. In round two, the sensors were placed on the fifth metatarsal, malleolus, and on the leg directly superior to the worn device. However, the sensors did not accurately measure the rate of inversion in round two and was therefore this data was not used. Data acquisition was performed at a rate of 120 Hz.

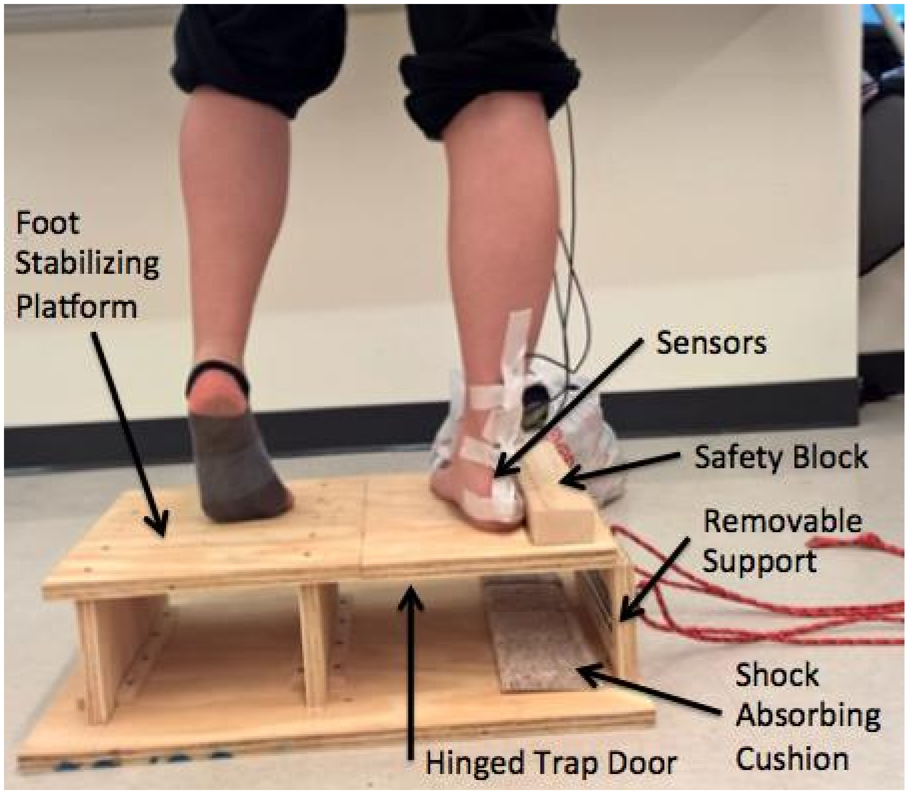

Figure 39: Drop plate Experimental Setup. Sensors along the rear of the ankle served to measure the inversion after the plate was dropped.

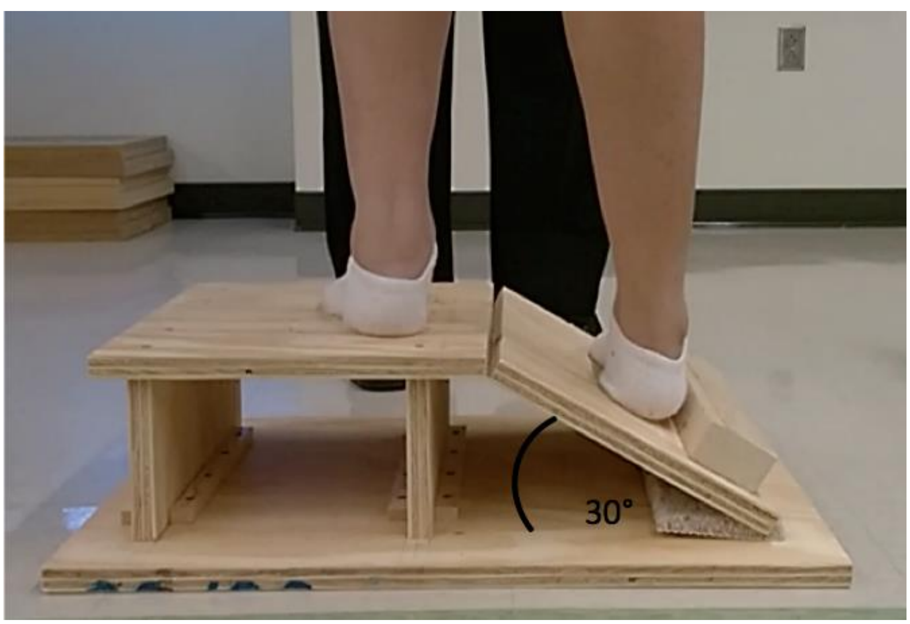

Figure 40: Drop plate. Drop plate after trap door release simulates ankle inversion to 30 degrees.

5.2.2 Dynamic Drop Plate Results

The EMT software exported the x, y, and z coordinates of each of the three sensors in a given time point. Vector analysis was then used to solve for the ankle inversion angle over time. The results of the data are shown below in Figure 41. The maximum allowed inversion angle was determined for each trial by looking at the maximum graph value, shown in Figure 42. Inversion rate was also determined by looking at the average rate from the drop point to the point of maximum inversion during the fall (Figure 43). A soft neoprene brace, rigid Aircast, the prototypes, and the final brace were all tested and compared to a barefoot control.

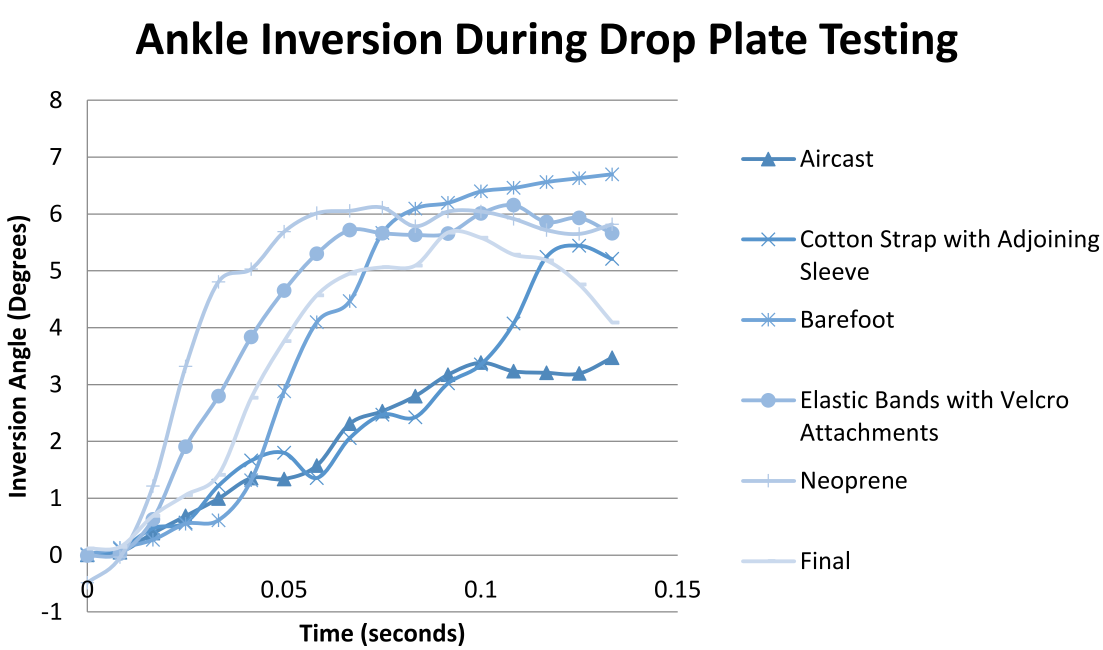

Figure 41: Ankle Inversion over Time from Dynamic Drop Plate Testing. This graph represents the measured ankle inversion angle over the course of the fall.

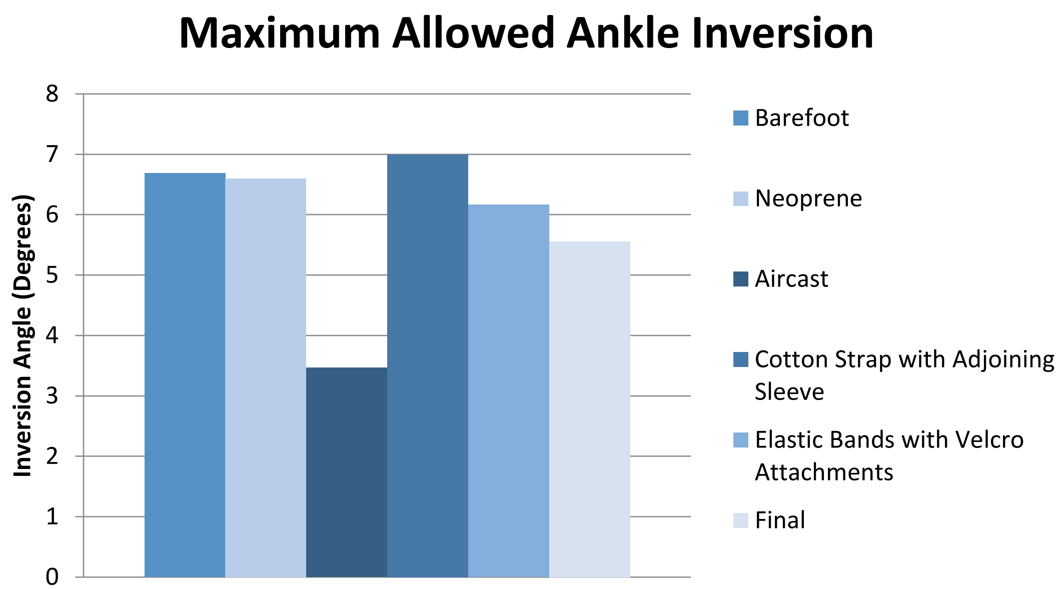

Figure 42: Maximum Allowed Ankle Inversion during Drop Plate Testing. The Aircast was the only brace to have a significant difference from the barefoot trial.

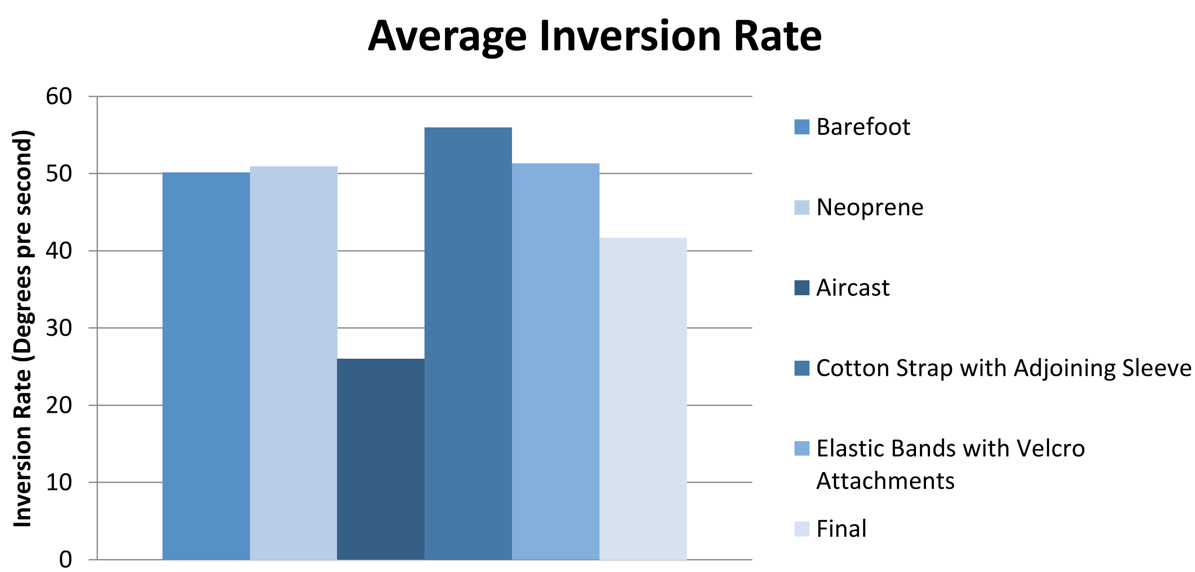

Figure 43: Average Ankle Inversion Rate during Drop Plate Testing. The Aircast slowed the rate by about 50%, while the final device slowed it by about 17%.

The Aircast showed the most resistance to inversion, both in the maximum value as well as the inversion rate. The rate was slowed by roughly 50 percent, while the final prototype slowed the rate by about 17 percent. Other braces did not show a statistically significant difference from the barefoot trial. The results are summarized in Table 5 below.

Table 5: Rate of inversion. The maximum allowed inversion level during the fall was averaged across the trials as well as the measured inversion rate.

	Barefoot	Aircast	Neoprene Sleeve	Cotton Strap with Adjoining Sleeve	Elastic Straps with Velcro Attachments	Final Brace
Maximum Inversion (degrees)	6.69	3.47	6.60	6.99	6.16	5.56
Inversion Rate (degrees/sec)	50.14	25.99	50.93	55.97	51.30	41.70

5.3 Gait Analysis Results

5.3.1 Gait Analysis Testing

The purpose of gait analysis for this project was to compare the differences in plantar flexion and dorsiflexion between being barefoot and wearing various ankle braces. It was hoped that the final brace design would allow for gait that depicted natural movement in the plantar flexion and dorsiflexion plane by comparing to barefoot data. Kinematic and kinetic data was collected and analyzed using AMTI Net Force and Polhemus™ G4 Electromagnetic Tracking (EMT) System software at a rate of 120 Hz. A walkway was designed with wooden blocks within two feet of the EMT source, as seen below in Figure 44.

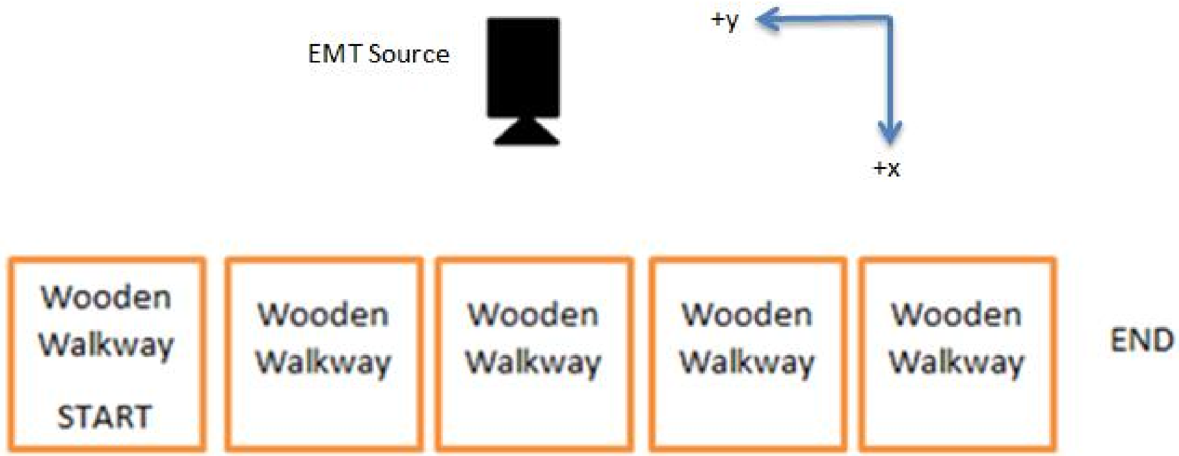

Figure 44: Gait Analysis Experimental Walkway Set-Up. A wooden walkway was constructed for the tests, and an EMT sensor measured the position of the ankle during each trial.

EMT sensors were placed at the fifth metatarsal, malleolus, and tibia above the brace for data collection to measure the position of these areas of the foot relative to each other. Vector analysis could then be utilized to calculate plantar flexion and dorsiflexion. To initiate gait, the subject first stood still, beginning on the START wooden block of the walkway. Once data collection began, the subject pushed off the wooden walkway with their left heel and began walking with their right foot forward. The subject continued on the walkway until the end, and data collection was completed. The subject was recorded for normal gait (barefoot), Neoprene Sleeve, Aircast, Futuro Wrap, Futuro Wrap with Metal Insert, Stromgen Double Strap Brace, Cotton Strap with Adjoining Sleeve, Elastic Straps with Velcro Attachments, and the final design. Three trials were performed for each situation. A still of the subject walking with the Futuro Wrap can be seen below in Figure 45. Stills for the rest of the trials can be seen in Appendix D.

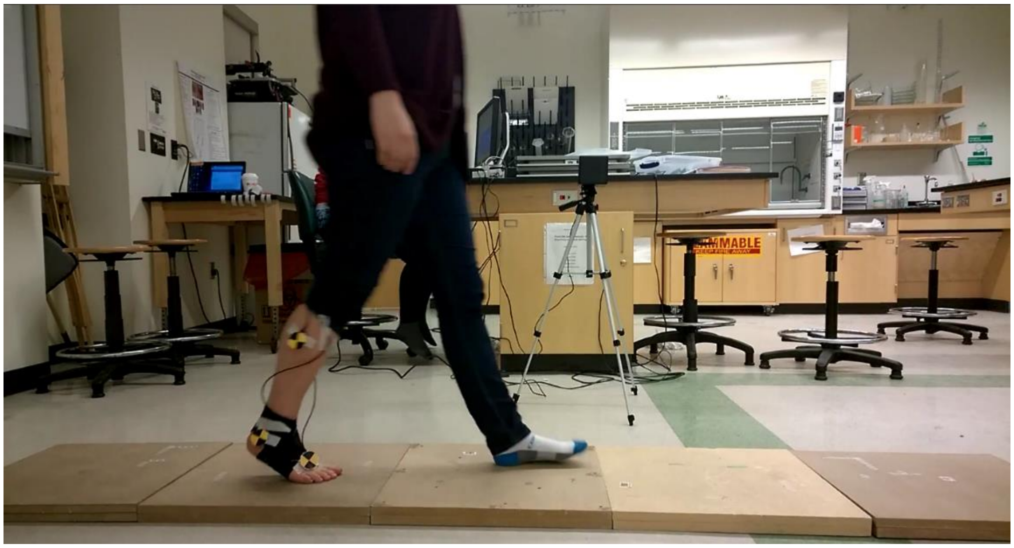

Figure 45: Gait Analysis Using EMT Sensors – Futuro Wrap. Sensor placement was selected so the flexion angles in the ankle could be measured as the subject walked across the wooden walkway.

5.3.2 Gait Analysis Results

The resulting maximum plantar flexion and dorsiflexion angles during gait for one test subject can be seen in the tables below. One test subject was analyzed due to variance between multiple subjects. This made it difficult to compare the different braces. Please see Discussion in Chapter 6 for further elaboration.

Table 6 Maximum Plantar Flexion for Different Braces. Resulting plantar flexion angles during gait were measured, recorded, and averaged using EMT software. Given in degrees.

Trial	**Barefoot**	**Stromgen**	**Aircast**	**Futuro Sports**	**Futuro Wrap**	**Neoprene**	**Cotton Strap with Adjoining Sleeve**	**Elastic Straps with Velcro Attachments**	**Final Brace**
1	100.38	110.83	102.32		110.44	111.31	118.66		80.08
2	103.97	109.09	110.79	113.90	113.52	115.23	116.66	129.64	83.15
3	99.37	113.15	113.64	107.30	117.13	125.99	110.53	122.76	92.16
Average	101.24	111.02	108.92	110.60	113.70	117.51	115.28	126.20	85.13
STD	2.42	2.04	5.89	4.67	3.35	7.60	4.23	4.86	6.28

The average maximum plantar flexion angles for barefoot was 101.24, serving as a standard to compare the braces to for barefoot. Most of the braces increased the maximum plantar flexion compared to barefoot: Stromgen (9.66%), Aircast (7.59%), Futuro Sports (9.25%), Futuro Wrap

(12.31%), Neoprene (16.07%), Cotton Strap with Adjoining Sleeve (13.87%), and Elastic Straps with Velcro Attachments (24.65%). The final design, however, decreased maximum plantar by 15.91%. Please note that outliers were excluded, as in Futuro Sports Trial 1 and Lateral Ligament Elastic Straps with Velcro Attachments Trial 1.

Table 7 Maximum Dorsiflexion for Different Braces Maximum dorsiflexion angles were measured and averaged over three trials. Given in degrees.

Trial	Barefoot	Stromgen	Aircast	Futuro Sports	Futuro Wrap	Neoprene	Cotton Strap with Adjoining Sleeve	Elastic Straps with Velcro Attachments	Final Brace
1	36.42	46.11	38.16		42.76	42.68	42.05		29.27
2	28.16	45.75	41.86	39.29	40.89	42.47	39.82	47.56	25.31
3	38.78	43.38	41.19	35.53	45.64	46.73	44.26	48.44	23.79
Average	34.45	45.08	40.40	37.41	43.10	43.96	42.04	48.00	26.12
STD	5.58	1.48	1.97	2.66	2.39	2.40	2.22	0.62	2.83

The average maximum dorsiflexion angles for barefoot was 34.45, serving as a standard to compare the braces to. Most of the braces increased the maximum dorsiflexion compared to barefoot: Stromgen (30.86%), Aircast (17.27%), Futuro Sports (8.59%%), Futuro Wrap (25.11%), Neoprene (27.61%), Cotton Strap with Adjoining Sleeve (22.03%), and Elastic Straps with Velcro Attachments (39.33%). The final design, however, decreased maximum dorsiflexion by 24.18%.Please note that outliers were excluded, as in Futuro Sports Trial 1 and Lateral Ligament Elastic Straps with Velcro Attachments Trial 1.

Table 8: Range of Motion for Different Braces. Statistical analysis on the results was utilized to find the mean and standard deviation values for each trial. Given in degrees.

Trial	Barefoot	Stromgen	Aircast	Futuro Sports	Futuro Wrap	Neoprene	Cotton Strap with Adjoining Sleeve	Elastic Straps with Velcro Attachments	Final Brace
1	63.96	64.72	64.17		67.67	68.63	76.60		50.81
2	75.81	63.34	68.93	74.61	72.63	72.77	76.83	82.08	57.84
3	60.59	69.77	72.46	71.77	71.49	79.27	66.27	74.32	68.37
Average	66.79	65.94	68.52	73.19	70.60	73.55	73.24	78.20	59.01
STD	7.99	3.39	4.16	2.01	2.60	5.36	6.03	5.48	8.84

The average range of motion for each brace for barefoot was 66.79, serving as a standard to compare the braces to. The following braces decreased range of motion compared to barefoot: Stromgen (1.27%) and Final Brace (11.65%). The following braces increased range of motion compared to barefoot: Aircast (2.59%), Futuro Sports (9.58%), Futuro Wrap (5.70%), Neoprene (10.12%), Cotton Strap with Adjoining Sleeve (9.66%), and Elastic Straps with Velcro Attachments (17.08%). Please note that outliers were excluded, as in Futuro Sports Trial 1 and Elastic Straps with Velcro Attachments Trial 1. The corresponding graphs can be seen in Figure 46, Figure 47, and Figure 48 below.

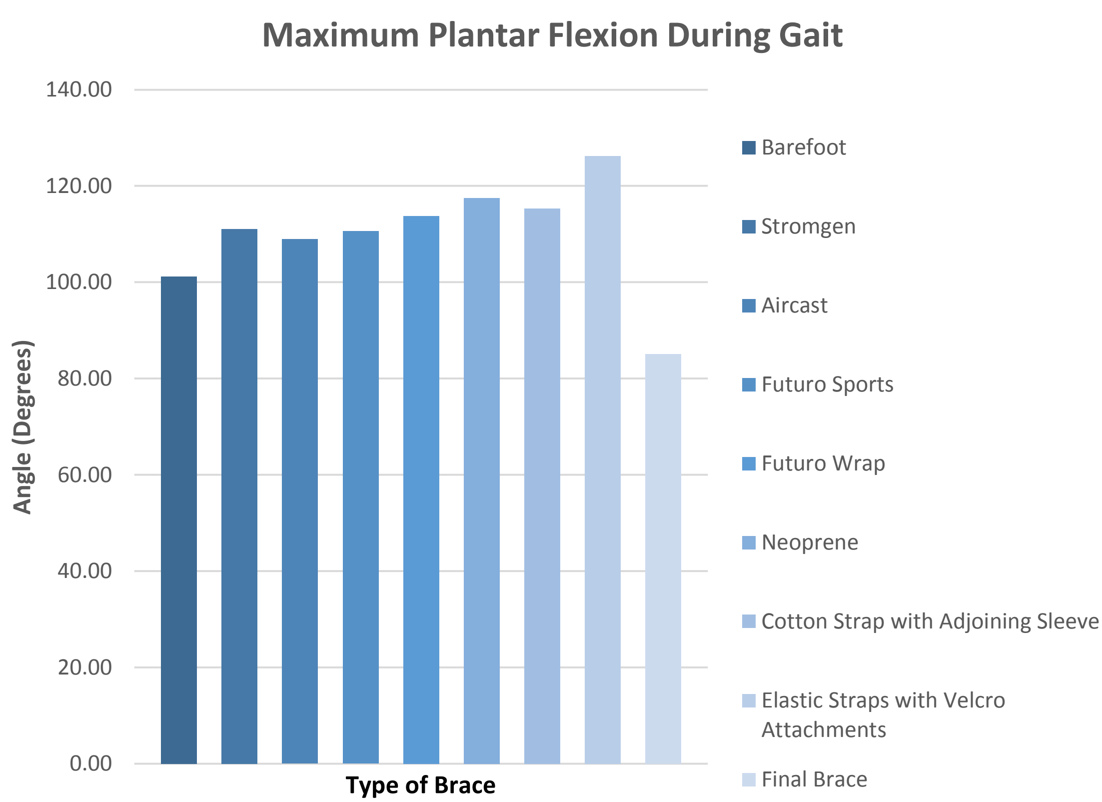

Figure 46: Maximum Plantar Flexion During Gait. Differences in the maximum angle while walking were measured and recorded.

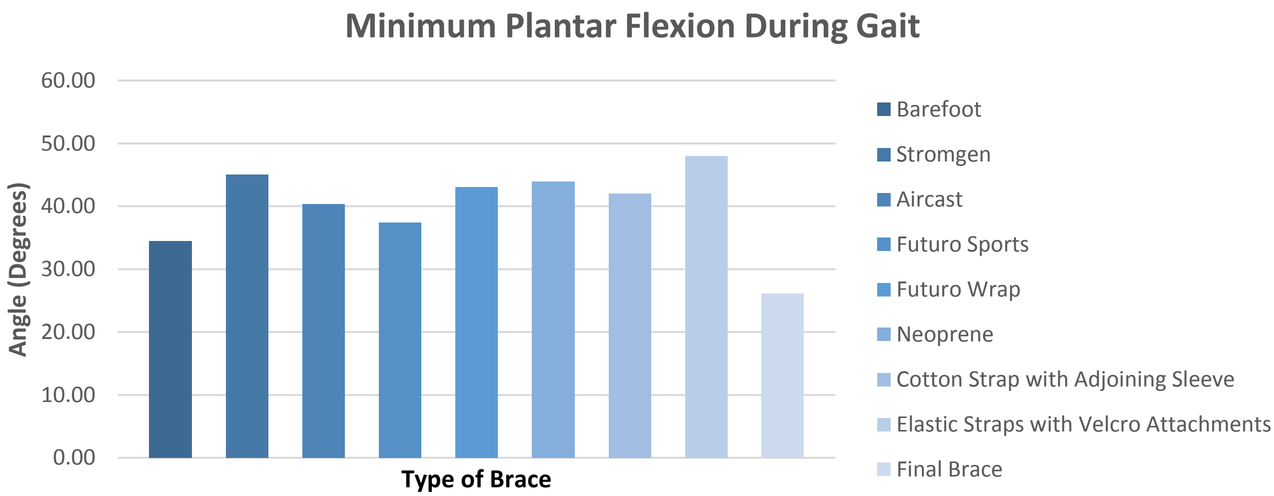

Figure 47: Minimum plantar flexion during gait. The range of motion was defined as the difference between the maximum and minimum flexion angles for each brace.

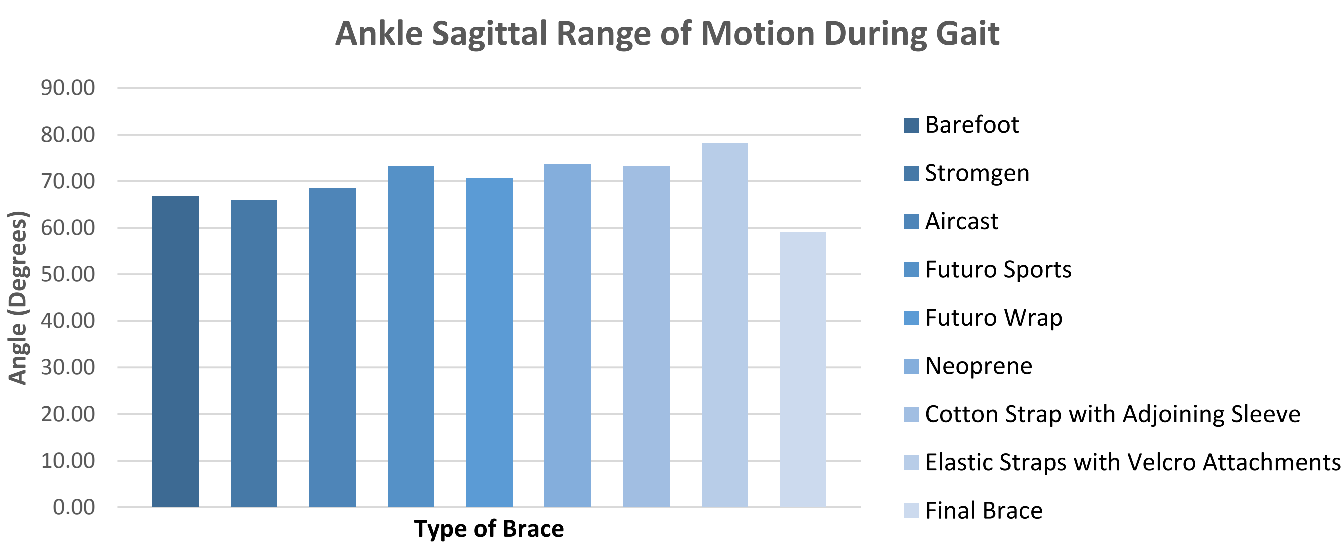

Figure 48: Range of motion. The minimum plantar flexion angle, also known as the maximum dorsiflexion angle, was measured for each brace during gait.

Two-factor ANOVA analyses were performed to determine the effect each test subject had on the results. For this analysis it was assumed that each individual foot of every test subject would impact the results.

Table 9: ANOVA for different test subjects. Results of ankle flexion testing ANOVA comparison.

Comparison of Ankle Flexion Angles for Different Text Subjects					
	Brianna	**Emily**	**Krupa**	**Kristina**	**Tom**
Average	42.87	53.29	33.16	71.25	35.55
St. Dev	5.30	17.10	3.56	4.093	9.04
P-value	1.07E-08				

It was found that there is a statistically significant (p-value < 0.05) difference between each subject's gait results for each brace. Single-factor ANOVA analyses were done for barefoot and the following braces: Stromgen, Aircast, Futuro Sports, Futuro Wrap, Neoprene, Cotton Strap with Adjoining Sleeve, Elastic Straps with Velcro Attachments, and the final device.

Table 10 Comparison of angles between bare feet and braces *ANOVA results of different brace conditions*

Comparison of Ankle Flexion Angles for Barefoot and Braces							
	Barefoot	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Average	47.30	46.38	46.15	53.12	37.50	48.69	47.03	51.62
St. Dev	14.14	17.92	15.82	14.45	21.29	18.012	20.231	18.22
P-value	0.26							
Braces: 1 - Stromgen, 2 - Aircast, 3 - Futuro Sports, 4 - Futuro Wrap, 5 - Neoprene, 6 - Cotton Strap with Adjoining Sleeve, 7 - Elastic Straps with Velcro Attachments, 8 - Final Brace								

This was intended to determine if the type of brace had an impact on the plantar flexion, dorsiflexion, and therefore the range of motion. The p-value was found to be greater than 0.05 for each brace and thus insignificant.

6.0 Discussion

This section discusses the results, and the implications of this project.

6.1 Passive Muscle Measurements

The up & up Ankle brace elastic medium had the least restriction on inversion and plantar flexion. This result was anticipated because it was the softest brace used in testing. An unexpected result was that the Futuro Sport Deluxe Adjustable Ankle Stabilizer restricted inversion slightly more than the rigid Aircast Air-Stirrup. This may be due to slippage of the ankle within the Aircast under non-weight bearing conditions.

Compared to the ankle injury management's guide for assessing range of movement for the ankle, barefoot inversion should range from 0 to 35 degrees, eversion from 0 to 30 degrees, dorsiflexion from 0 to 20 degrees and plantar flexion from 0 to 50 degrees (Keene, 2010). A similar study by Elis resulted in the following average measurements for a no brace test condition: 39 degrees inversion, 23 degrees eversion, 43 degrees plantar flexion, and 25 degrees dorsiflexion (2002). The majority of the results were comparable to this range, however some of the subjects exceeded this range of motion, particularly in plantar flexion. This could be an indication of lax ligaments or higher flexibility. A larger test group would be ideal to determine a more consistent average.

The results from the second round of testing for the final design are a promising indication that the final design can restrict inversion under non-weight bearing conditions. Specifically, that the orientation of the straps used for both the final design and the Cotton Straps with Adjoining Sleeve prototype aids in the restriction of inversion, as supported by the biomechanical simulations in OpenSim®.

The limited test subjects used for this test influenced the accuracy of the results. To further validate the inversion results for the final design, the study population size would need to be larger. Additionally, the final design would need to have a range of sizes in order to test various subjects. However, these results show promise that the final design can restrict passive inversion when the brace fits the subject's anatomy.

6.2 Dynamic Drop Plate

A large assumption during these tests was that the three sensors accurately measured the inversion of the ankle during the fall. The maximum measured angle during the trials was only 7 degrees, despite the fact that the drop plate fell to an angle of 30 degrees. This is due to the sensors measuring changes on the surface of the skin, not on the actual joint itself. The group tested a variety of methods to measure the inversion angle, including sensors that ran up the medial side of the foot, measuring the bottom of the foot relative to the plate, and using motion capture to estimate the angle. The sensor placement alongside the back of the foot was selected because it showed the largest differences between the brace and barefoot data, so although the magnitude of the angles were smaller the relative differences could still be seen.

Another assumption was that the ankle inverted fully on the plate. The subjects were instructed to place all of their weight on the inverting ankle, and the plate was dropped without their knowledge. Any anticipation of the drop, having unequal weight on the inverting foot between trials, or the foot slipping out of the guard block could have influenced the outcome of the data. To remedy this, any trial with clear slipping, where the foot ended up on top of the safety block rather than beside it, was discarded for the analysis.

A final aspect that influenced data was the number of testing subjects that were used for the final device. Due to prototyping limitations on the Velcro, the brace was temporarily altered so it could fit comfortably on one user and conform to her specific anatomy. Therefore, the final brace only had one subject for testing, which statistically influenced the conclusions that the group made. While concrete conclusions were unable to be formed, the group was able to determine general trends about the performance of each brace from the data.

The drop plate results showed slight differences between trials. The Aircast was the only brace to prevent the maximum level of inversion compared to barefoot. It also slowed the inversion rate more effectively than any other brace. The only other brace to show a difference in inversion rate was the final prototype. This brace did not prevent maximum inversion angle, but it did provide resistance to inversion by slowing the inversion rate. The group found that the final prototype slowed inversion rate by 17 percent compared to barefoot trial. Although it was not able to fully prevent high ranges of motion, it was successful in slowing inverting rate to give the subject's peroneus longus and peroneus brevis muscles time to naturally counteract the fall.

A similar study looked at the rate of single-leg inversion **in** an unanticipated fall. This study also dropped the leg to 30 degrees, and measured the rate using motion capture sensors as well as EMG data. They found that a barefoot fall showed an inversion rate of 44.073 degrees per second (Dicus et al, 2012). The data showed an inversion rate of 50.12 degrees per second, which validates the sensor placement. To the group's knowledge, there have not been studies comparing the inversion rate with different braces for comparison.

6.3 Gait Analysis

From the two-way ANOVA, it was determined that the effect of braces on gait analysis cannot be compared between subjects due to variance between natural range of motion. Therefore, a single-factor ANOVA was conducted on the gait of one test subject. Single-factor ANOVA showed that there was not a statistical significance in ranges of motion between different braces. Consequently, the final design did not restrict or allow plantar flexion and dorsiflexion any more than the other conditions, including barefoot, that were tested.

When interpreting the results, many assumptions were made. It was assumed that natural foot strike was consistent and the three trials taken were representative of the subject's overall gait cycle. Calculations were made and determined using a wooden walkway, assuming that this walkway presented a long enough time period to provide a comparison between each splint. This may affect interpretation because the splint may act differently after a long period of time as opposed to the short experimentation time.

When applying the EMT sensors, it was assumed that placement was consistent for each trial. It was also assumed that the EMT sensors mirrored the ligaments, allowing for accurate plantar flexion and dorsiflexion calculations, even though the skin is elastic.

In literature, it is stated that the range of motion for plantar flexion is 0 to 20 degrees and dorsiflexion is 0 to 10 degrees for the ankle during natural gait (Clarkson, 2000; Cameron et al, 2014). By looking at the results inTable 6, Table 7, and Table 8, it is seen that the values for plantar flexion, dorsiflexion, and range of motion are not close to their respective literature values. This error is believed to be caused by the EMT sensors being inaccurate. There were many complications with the Polhemus system. Therefore, the gait data is not similar to literature values; however, the results can be compared relative to each other. These results show that the final design does not allow as high levels of plantar flexion, dorsiflexion, or range of motion as compared to barefoot or the other braces. The ANOVA showed that this was not statistically significant, indicating that the final brace design does not restrict or allow flexion relative to barefoot and other devices on the market.

Compared to the literature values, the experimental values had a higher range of motion. The group saw ranges three times higher than the literature values of 18.3 ± 7.5 degrees, likely due to sensor placement (Kitaoka et al.,2006). By not showing noticeable differences compared to barefoot, the device could avoid limiting gait efficiency and the adverse effects that accompany it. This prevents unstable gait, eventual complications in the knee joint, and can reduce the risk of reinjury by allowing full sagittal motion.

6.4 Meeting Objectives and Constraints

The final design was able to meet the objectives of this project. First the design was determined to restrict the rate of inversion. Simultaneously, the design permitted motion in the dorsiflexion and plantar flexion directions. The design was adjustable to different users because of the Velcro attachment points, which makes it comfortable for users. It also conformed to the ankle anatomy because of the elastic nonlinear material. Furthermore, it was machine washable which improved hygiene and durability of the device to the user. The final design was made within the market price constraint of under $40 by use of materials well under budget.

The final design was manufactured using materials bought at commercial stores that sell to the general public. Due to the team’s cost restrictions, materials were bought in small quantities. The final prototype cost $24.63 to make, as shown in Table 11, below.

Table 11: Cost of mass production. The prototype cost the team around $25 to produce.

Material	Dimensions	Our Price
Velcro® Brand	18 in	$3.50
Elastic Strap	25 in	$4.50
Elasbelt Webbing	12 in	$0.82
Neoprene Ankle Sleeve	100 in^2	$7.99
Upholstery Thread	900 in	$0.37
Cotton Belting	19 in	$1.94
Heavy Duty Foam Slab	66 in^2	$3.00
Stretch Sateen Fabric	132 in^2	$0.83
Knit Elastic	30 in	$1.60
	TOTAL	$24.63

A cost analysis was created to determine the price of the prototype if materials were bought in bulk from wholesale retailers. As shown in Table 12 below, if the brace were to be created in a factory and materials were obtained at wholesale prices, the final material cost of the brace would total $5.74.

Table 12: Cost to produce one prototype Bought in bulk, raw materials for the design would cost less than $6

Material	Dimensions	Bulk Price
Velcro® Brand	18 in	$0.54
Elastic Strap	25 in	$1.68
Elasbelt Webbing	12 in	$0.82
Neoprene Ankle Sleeve	100 in^2	$0.75
Upholstery Thread	900 in	$0.22
Cotton Belting	19 in	$0.34
Heavy Duty Foam Slab	66 in^2	$0.91
Stretch Sateen Fabric	132 in^2	$0.40
Knit Elastic	30 in	$0.08
	TOTAL	$5.74

The team aimed to sell the device at a final price of $40 or less. The cost of the brace from factory to retail store was analyzed and projected using cost analyses from the footwear industry. After factoring in wages, shipping, overhead costs and a profit margin for both the manufacturer and the retailer, as shown in Table 13, the final cost to the consumer was projected at $36.11, below the team's objective of $40.

Table 13: Cost to Consumer. The final projected cost of the final design met the cost objectives.

Line Item	Costs
Materials	$5.74
Wages	$4.08
Shipping	$0.50
Overhead (35%)	$3.44
Total Factory	$13.76
Cost to Retailer (50% profit for Manufact.)	$20.64
Cost to Consumer (75% profit for Retail.)	$36.11

6.5 Summary

Both initial prototypes had a variety of positive and negative attributes, and therefore the final design was a combination of aspects of both devices. The design was incorporated elastic straps, and they were attached to the sleeve with Velcro. The padded foam top from the Elastic Straps with Velcro Attachments prototype was sewn to the sleeve in order to provide additional comfort and prevent the elastic straps from excessive pulling on the sleeve. For additional ease of use, the attachment location of the strap on the sleeve could be indicated with differing colors.

6.6 Impacts of the Device

6.6.1 Economics

This device could be a good addition in the orthopedic brace industry. It will promote economic growth by creating jobs needed to manufacture and produce the device. It will also have a specific market, so while part of the orthopedic industry, it is not flooding the market with another device too similar to currently existing ones. Since the intended market price is comparable to devices available at the neighborhood pharmacy, all economic classes can afford this product.

6.6.2 Environmental

A main concept for this device is that the straps and sleeve are intended to be reusable. The sleeve is machine washable, so the material will not be wasted and disposed of. By choosing a rigid, intact material for the straps, the device will be durable and the quality of the device will be long lasting. Patients will then only need to buy a new brace every couple of years, depending on how often the brace is used. This will save the amount of material used, and ultimately the financial expenses that the patient is spending on the splints.

6.6.3 Societal Influence

It is intended that this product be available to all economic classes, so that all individuals can benefit from its healing properties. Additionally, the device is designed to be comfortable, have minimal odor, and be aesthetically appealing. With these properties, the patient wearing the device will not feel “different” from their peers with a bulky, cumbersome device as his/her injury heals.

6.6.4 Political Ramifications

One of the main factors stressed to the group by the UMass surgeons was affordability of the device, and not needing insurance coverage to purchase the device. A controversial political issue is that of universal health coverage, so that all patients can receive care. While this device will not require health insurance, it is important to note that the cost and manufacturability of the device were limited by resources within a specific price range, so that all of society could benefit from this healing device. That is, this device is designed to avoid the complicated nature of the health insurance industry, and not limit the pool of patients able to afford the device.

6.6.5 Health and Safety Issues

Due to the nature of the device, health and safety of the individual users was a major concern in the design process. The device is meant to have a positive effect on ligamentous injuries, thus a comfortable and safe design was chosen. The anatomically-inspired design resulted in a light device that would not hinder the patient, minimizing the risk of the brace excessively inhibiting normal movement and causing other injury. Materials were chosen based on calculations from average body weight and an OpenSim® model. Materials were customized to the model in order to restrict against inversion while minimally affecting other movements. Materials were chosen based on their properties, including use in in other medical devices.

6.6.6 Manufacturability

All of the materials used in the device are readily available. There are several pieces involved in the healing device kit, so production will take some time. Each of the graduated straps needs to be produced and tested. The sleeve itself is modeled after currently existing devices because neoprene sleeves conform to the ankle joint physiology well and create a foundation for the straps and Velcro to be attached to. Although production of one particular prototype will be more expensive, purchasing the materials in bulk will reduce the overall cost of each product.

6.6.7 Sustainability

The final design functional band is made from a durable woven cotton material and an elastic material. Additionally, the brace is made of cloth, foam, and has Velcro attachments. Gentle use of these braces will not cause failure. Wear over time and high levels of use can occur. To increase the longevity of the brace an industrial strength sewing machine could be used to manufacture the brace. These prototype designs will not cause the depletion of any natural resources.

7.0 Final Design Overview

This section serves as an overview of the final design of this project.

7.1 Final Design

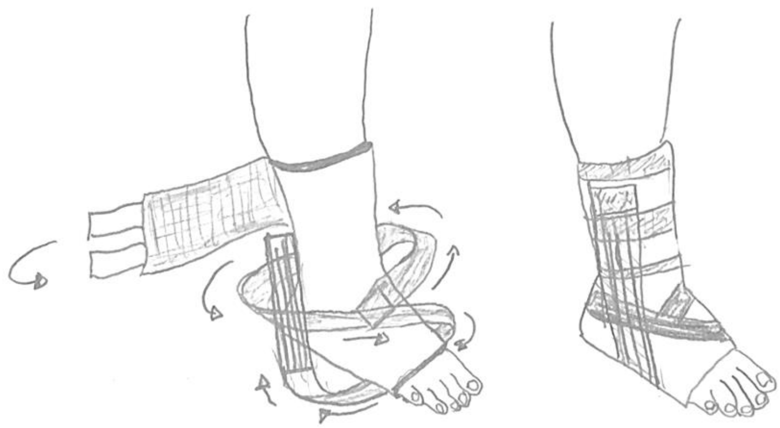

Figure 49: Final Design Schematic. The band wraps around the medial side of the ankle, under the arch of the foot, and vertically up the lateral side.

The final design was based on a concept that mimicked lateral ankle ligaments. The final design was comprised of a neoprene sleeve base. Attached to the sleeve was a supporting padded foam top piece that wrapped around the top of the sleeve and was secured to the ankle with two elastic bands that connect with Velcro. The supportive pad was necessary in order to prevent the functional band from excessive pulling on the sleeve. The functional band of the brace was a custom-made material comprised of linear woven cotton and nonlinear elastic material. Nonlinear elastic material was used because of its ability to stretch and conform to different users and its performance in the OpenSim® model. The band was oriented at the top of the foot and wrapped around the medical side of the ankle then returned to the top of the foot and wrapped around the arch of the foot and ran vertically up the lateral side of the ankle to attach to the top of the foam pad with Velcro. The Velcro attachment points and elastic component allowed for adjustability to user anatomy.

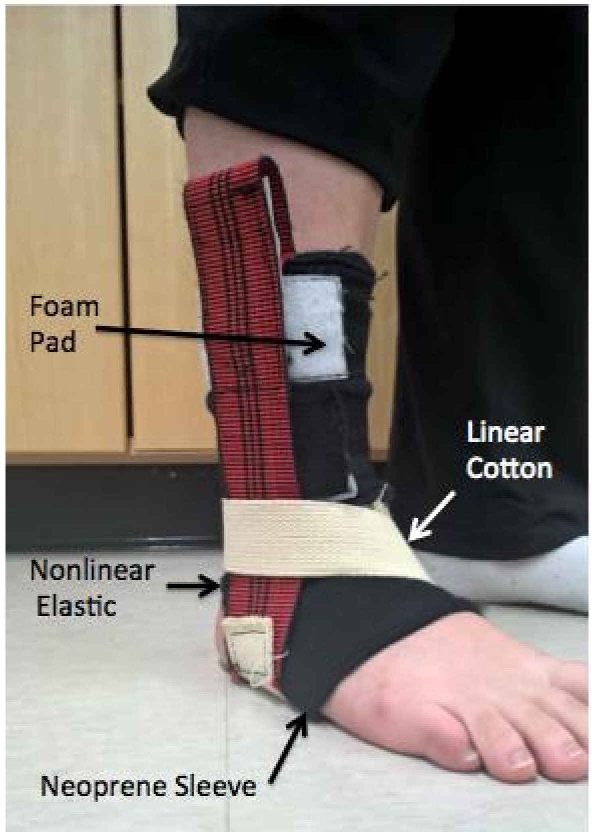

Figure 50: Final design Prototype. The design is made of a tan, linear cotton band and a red, nonlinear elastic strap wrapped around a neoprene sleeve.

7.2 Work-Task Sequence

To begin the project, the team researched current ankle sprain devices on the market and patents. This provided a starting point to identify gaps in the market and determine the objectives and constraints for the final device. A weighted design matrix was constructed to assist in this process. Once preliminary research was completed, alternative designs were drafted and compared to select the most feasible design. Calculations were performed to determine the material properties needed for the device material. Simultaneously, an OpenSim® model of the ligaments in the ankle was utilized for computational applications to assist in determining ideal material properties for the device. Materials were purchased, and an Instron machine was used to perform tension testing to select the material with the desired properties. This material was used to construct numerous prototypes.

Non-weight bearing passive movement testing was performed using a goniometer to test the restriction and mobility of each brace on the user. Ankle dorsiflexion, plantar flexion, inversion, and eversion movements were measured. Tests were also performed with a dynamic drop plate to evaluate rate of inversion under rapid conditions. Gait testing was performed to evaluate mobility of the brace in the sagittal plane. The data collected from each test was analyzed to compare the final device to other braces on the market to increase its competitiveness.

7.3 Materials

The group used different materials to produce the final device, all of which are available commercially and could be purchased in bulk. An up & up neoprene ankle sleeve was used as the base for the device. Eighteen inches of Velcro, 1/16 spool of black upholstery thread, and 19” of cotton belting were used from purchases made at Joann Fabrics. Sew classic bottom weight stretch sateen fabric was cut into two 5.5” by 12” to sew around 66 cubic inches of Airtex heavy duty foam. The device also used 30” of Dritz knit elastic, 12” of latex Elasbelt webbing, and one 25” StrapEZ strap. The group purchased these materials with the intent of creating one, developed prototype, and performed a cost analysis of what the materials could be purchased for in bulk, seen in Chapter 6.

7.4 Feasibility Study

To determine the feasibility of the design, manufacturability of the product was assessed. The device was created using readily available, easy-to-obtain materials. While a neoprene sleeve was bought for the prototype, ideally the sleeve would be custom-made out of neoprene. All equipment necessary to manufacture the sleeve and the brace are standard in footwear factories. Testing was conducted on the device to determine functionality of the brace in comparison to currently available braces. Finally, a cost-analysis was conducted to determine if the device would be competitive with other competing devices.

8.0 Conclusions & Recommendations

This section provides the conclusions and recommendations from the group for this project and future work.

8.1 Global Conclusions

8.1.1 Overview

The final prototype was able to restrict inversion, while still allowing for mobility of the ankle. In addition, the brace was comfortable to wear and easily applied by the user.

8.1.2 Results Summary

The final prototype was designed using a combination of simulations and tests on existing designs. Although it met the design objectives in OpenSim®, the team ran real-world tests to see how well the prototype actually functioned. The prototype was designed to allow inversion to about 20 degrees, but prevent any dangerous rotations that are too fast or severe. Limitations with the electromagnetic tracking sensors prevented the brace allowance to be accurately measured during drop plate testing. Instead, the team examined the brace in non-weight bearing conditions. The passive muscle goniometer results found that the final brace prototype displayed an allowance of 20.8 degrees, meeting the objective. Further testing is needed to see how the nonlinear material behaves at instantaneous time intervals during the fall, rather than how it performs as a whole, to see the initial allowance of the band. Next, the active drop plate was used to test that the brace would protect the ankle from injury. It did not prevent the ankle from inverting to a lower maximum amount, but it was successful in slowing the inversion by 17 percent. This helps reduce injury by giving the everting muscles in the leg time to counteract any dangerous motion, which takes 49-90ms to occur (Dicus et al, 2012). In the sagittal plane, the brace did not have a statistical difference in the dorsiflexion and plantar flexion range of motion when compared to natural walking. In summary, it slowed inversion rate and showed initial signs of allowance to 20 degrees, while not having a noticeable impact on gait.

8.1.3 Accomplishments

The team has accomplished much since the beginning of this project. Research has been completed to gain a better understanding of the overall problem. Using previous experiments, studies, and brainstorming, the team designed several alternatives. After discussion, a final design was chosen to pursue. Tension testing and biomechanical simulations were completed to determine the best material to use for the prototype, and whether the final prototype was better than other splints on the market. The dynamic drop plate served as a simulation for an involuntary ankle inversion that is rapid enough so the everting muscles cannot naturally counteract the ankle rotation. EMT sensors were used to measure the rate of inversion of the ankle so that each brace could be compared. Gait analysis was performed using an EMT system to measure plantar flexion and dorsiflexion, and compare differences in range of motion when wearing different devices.

Ultimately, the team has designed an ankle splint that is protective, adjustable, comfortable, and competitively priced. The brace slows the rate of ankle inversion to allow time for the everting muscles to react and prevent injury. It also allows for mobility by not altering flexion angle of the ankle during gait. The device consists of straps and Velcro that make it adjustable so that it will conform to ankle anatomy and can be universal for any user. It is also comfortable so that the user could wear it for long periods of time and it will not interfere with their daily activities. Costing under a retail value of $40, the splint is competitively priced and is predicted to perform well within the saturated market.

8.2 Recommendations

8.2.1 Unexplored Design Ideas

The team listed adjustable as a design objective for the dynamic brace. While the final brace was adjustable, the team explored other means of creating an adjustable device. In order to make the brace adjustable to the healing process, interchangeable bands of varying stiffness could be used. Stiffer bands would be used early in the healing process to restrict harmful motion when ligaments are highly injured, while less stiff bands would be used later in the healing process to allow for motion. Bands can then be switched as the patient heals.

In order to make the brace adaptable to any patient, a color-coded band system could be implemented to help consumers tension the strap. The degree of pre-tension needed in the stirrup strap is dependent on the size of the foot. Consumers with smaller feet would need to pre-tension the strap more than consumers with larger feet. Therefore, a color-coded band system should be developed to help users determine the amount of tension their brace needs upon application. Bands would use multiple, different-colored under-layers, which would individually show at certain tensions. For example, depending on the amount of tension in the strap, the band could appear blue at high tension or red at low tension.

8.2.2 Future Work

The team was unable to test all of the brace parameters, largely due to time limitations for the project. Long-term effects of the brace, including comfort, durability, and impact on gait, should be tested to see if the brace can be worn for long periods of time. In addition, different levels of physical activity in the brace should be investigated to see how well the brace performs. A long-term study could be utilized to determine if injured ligaments show improved healing when wearing the final prototype compared to market braces. Finally, improved testing methods could potentially measure the initial inversion of the brace with a higher degree of certainty to see the full impacts of a nonlinear material.

One of the main obstacles the group faced was the manufacturability of the device. Although there were several design alternatives, not all were feasible with the group's manufacturing ability. Future projects should look at ways to streamline the manufacturing process and utilize an assembly line set-up to reduce the amount of time needed to produce each portion of the device. Additionally, making the overall system more comprehensive could be further explored. This project focused on a specific portion of the healing process, but different materials with different elastic properties could be explored for use in other parts of the healing process. The other straps would be designed to mimic the group's device, so that the splint design could be used all the way through the healing process, but with different strap elasticity values as the ligaments begin to heal.

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Appendices

Appendix A: Weighted Design Matrix

		Design									
		Degree controlled boot		Minimalist design		Reinforced sleeve		Orthopedic Shoe		Double Ring Brace	
Criteria	**Weight**	Rating	Score	Rating	Score	Rating	Score	Rating	Score	Rating	Score
Restrict inversion	15	9	135	4	60	6	90	8	120	7	105
Allow movement	15	2	30	9	135	8	120	4	60	9	135
Adjustable	13	8	104	3	39	2	26	4	52	8	104
Conform to anatomy	12	6	72	9	108	9	108	6	72	9	108
Bear weight	11	8	88	4	44	5	55	8	88	7	77
Ease of use	9	3	27	5	45	8	72	7	63	6	54
comfort	8	4	32	7	56	7	56	5	40	7	56
price	7	2	14	9	63	8	56	4	28	6	42
fit in a shoe	5	1	5	9	45	7	35	9	45	6	30
not odorous	5	3	15	9	45	7	35	4	20	6	30
TOTAL	100		522		640		653		588		741

Appendix B: Goniometer Ankle Measurements

		Bri		Emily		Kristina		Krupa		Tom		Average		STD		Average	STD
		LF	RF	LF	RF	LF	RF	LF	RF	LF	RF	LF	RF	LF	RF	Total	Total
Inversion	Barefoot	29	30	30	23	32	29	32	28	23	31	29.2	28.2	3.310589071	2.785677655	28.7	3.27
	Futuro Infinity Adjustable Black Precision Fit Ankle Support	29	30	20	19	25	21	30	30	23	31	25.4	26.2	3.662239752	5.114684741	25.8	4.73
	up & up Ankle Brace Elastic Medium	29	30	27	19	29	29	27	25	23	22	27	25	2.19089023	4.147288271	26	3.65
	Futuro Sport Deluxe Adjustable Black Ankle Stabilizer	23	21	18	23	25	25	27	25	22	21	23	23	3.391164992	1.788854382	23	2.62
	Stromgren Double Strap Ankle Support	24	26	23	12	21	31	32	20	28	26	25.6	23	4.304880951	6.511528238	24.3	5.83
	Aircast Air-Stirrup Ankle Brace	23	29	12	12	28	28	23	30	20	26	21.2	25	5.807581252	6.633249581	23.1	6.62
Eversion	Barefoot	14	8	13	12	14	10	42	27	12	18	19	15	12.58967831	6.870225615	17	10.22
	Futuro Infinity Adjustable Black Precision Fit Ankle Support	17	9	12	8	17	11	13	17	14	8	14.6	10.6	1.889973545	3.382306905	12.6	3.63
	up & up Ankle Brace Elastic Medium	10	9	4	4	15	15	18	16	18	19	13	12.6	5.770615219	5.388877434	12.8	5.67
	Futuro Sport Deluxe Adjustable Black Ankle Stabilizer	15	10	13	15	10	12	10	9	15	14	12.6	12	2.138223562	2.28035085	12.3	2.41
	Stromgren Double Strap Ankle Support	9	7	11	11	10	13	16	18	18	12	12.8	12.2	3.371646482	3.544009029	12.5	3.75
	Aircast Air-Stirrup Ankle Brace	6	9	15	11	7	8	18	13	9	12	11	10.6	4.472135955	1.854723699	10.8	3.77
Dorsiflexion	Barefoot	11	18	15	12	12	12	10	10	10	10	11.6	12.4	2.047437423	2.939387691	12	2.62
	Futuro Infinity Adjustable Black Precision Fit Ankle Support	10	10	12	8	10	9	10	9	15	7	11.4	8.6	2.052315765	1.019803903	10	2.21
	up & up Ankle Brace Elastic Medium	10	10	17	9	8	8	5	11	11	12	10.2	10	4.437116181	1.414213562	10.1	3.14
	Futuro Sport Deluxe Adjustable Black Ankle Stabilizer	11	7	19	10	8	8	10	11	12	12	12	9.6	4.147288271	1.854723699	10.8	3.36
	Stromgren Double Strap Ankle Support	8	8	12	11	10	7	10	8	12	12	10.4	9.2	1.035374328	1.939071943	9.8	1.93
	Aircast Air-Stirrup Ankle Brace	8	9	13	11	10	7	10	10	10	13	10.2	10	1.32211951	2	10.1	1.91
Plantar Flexion	Barefoot	61	55	52	58	48	47	65	78	64	62	62	60	14.39444337	10.25670512	61	12.32
	Futuro Infinity Adjustable Black Precision Fit Ankle Support	68	52	49	36	47	57	75	75	47	40	57.2	52	11.92509958	13.81303732	54.6	13.87
	up & up Ankle Brace Elastic Medium	70	52	48	31	58	58	82	74	41	43	59.8	51.6	15.55596349	14.43052321	55.7	15.99
	Futuro Sport Deluxe Adjustable Black Ankle Stabilizer	58	49	29	30	52	50	75	79	45	41	51.8	49.8	16.55801921	16.26530049	50.8	16.59
	Stromgren Double Strap Ankle Support	60	48	47	31	54	52	60	77	40	45	52.2	50.6	7.546389865	14.97464524	51.4	12.60
	Aircast Air-Stirrup Ankle Brace	50	53	44	31	52	50	78	74	46	51	54	51.8	13.60882067	13.64404632	52.9	13.76

LF: left foot

RF: right foot

STD: standard deviation

Appendix C: Inversion Calculations

Assumptions:

- Looking at the ankle as a single joint (Subtalar) with 2 dimensional movement
- Only looking at a single ligament (ATFL)

Justification:

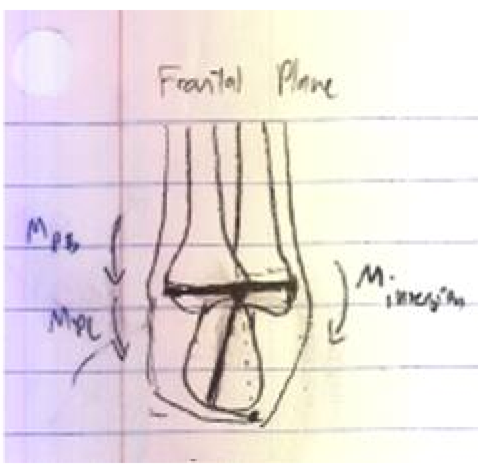
- The subtalar joint and AFTL are involved in the majority of ankle sprains[1]
- The ATFL possesses the lowest ultimate load among the lateral ligaments[1]

Additional Elements:

- Muscle everting moments of peroneus longus (17 Nm) and peroneus brevis (13 Nm)[2]
- Mean failure torque for an ankle is 45.3 Nm. Mean failure rotation was 41.4 degrees.[3]
- 20 degrees of foot rotation can be tolerated before the initiation of pain[3].
- In this case we are not looking at the effects of the loading rate and how it affects failure properties. This is because a study showed that rotation frequency does not have a noticeable effect on the failure angle or torque.[4]

Calculations

Moments around the ankle joint



$M_{PB} = 13Nm$
$M_{PL} = 17Nm$
$M_{Failure} = 45Nm$
$M_{excess} = 13Nm + 17Nm - 45Nm = 15Nm$

We need to prevent this 15Nm torque that is injuring the ankle with our brace

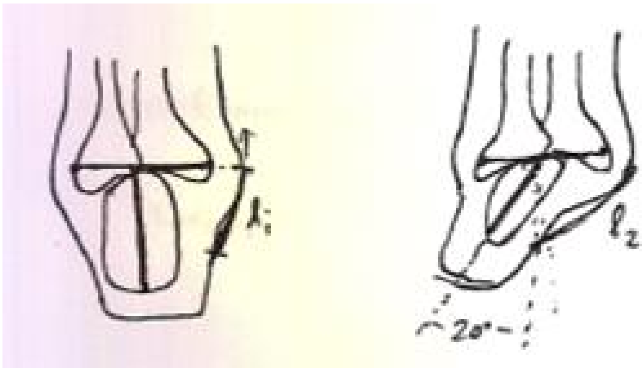
$M_{Excess} = 15Nm = F_{splint} * d_{splint}$ where F= everting force of splint and d=moment arm of splint

$d_{splint} \sim 0.0432m$ (Found from estimating distance based on anatomical pictures)

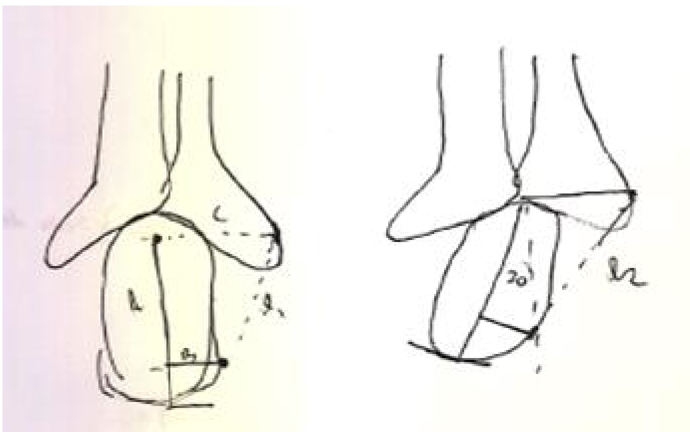
$$F_{splint} = \frac{15Nm}{0.0432m} \sim 350N$$

The next step is to treat the splint like a spring, where F=k*(l_2-l_1) and k=EA/l

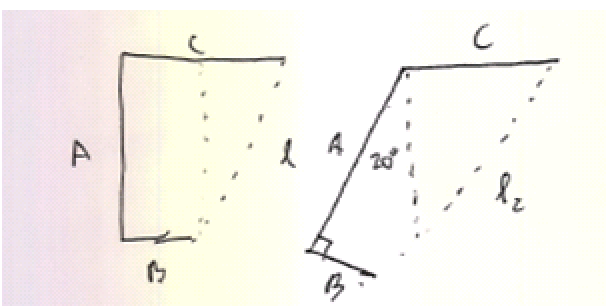
For angle = 20°



These distances were found by estimating based off anatomical pictures. The l_2 distance was found where the ankle angle reached 20 degrees, where pain initiation begins.



$l_1 = 32.6mm$
$l_2 = 34.3mm$
$l_2 - l_1 = 6.7mm = 0.0067m$



Estimating material stiffness
$350N = k(0.0067)$
k=52000N/m

$52000\ {}^{N}/_{m} = \frac{E*a}{l}$ where E=Young's Modulus, a = cross-sectional area, and l = length (around 0.0326m)

<u>Finding Young's Modulus (general)</u>
Estimated cross sectional area: a = 0.000125m^2
Estimated material length: l = 0.0326 m

$$52000\ {}^{N}/_{m} = \frac{E * 0.000125m^2}{0.0326m}$$

$E = 13.56\ MPa$

Finding Yield Strength and Young's Modulus at Failure

F = 350 N

A = 0.000125 m^2

σ = $\frac{F}{A} = \frac{350\ N}{0.000125\ m^2} = 2800000\ Pa$ = Yield strength

ε = $\frac{\Delta l}{l}$ = $\frac{0.0067\ m}{0.0326\ m} = 0.206$

E = $\frac{\sigma}{\varepsilon}$ = $\frac{2800000\ N/m^2}{0.206} = 13600000\ Pa$ = Young's modulus when failure begins

For angle = 30 degrees

$l_1 = 32.6mm$

$l_2 = 42.4mm$

$l_2 - l_1 = 6.7mm = 0.0098m$

Estimating material stiffness

$350N = k(0.0098)$

k=36000N/m

$36000\ {}^{N}/_{m} = \frac{E*a}{l}$ where E=Young's Modulus, a = cross-sectional area, and l = length (around 0.0326m)

Finding Young's Modulus (general)

Estimated cross sectional area: a = 0.000125m^2

Estimated material length: l = 0.0326 m

$$36000\ {}^{N}/_{m} = \frac{E * 0.000125m^2}{0.0326m}$$

$E = 9.39\ MPa$

Finding Yield Strength and Young's Modulus at Failure

F = 350 N

A = 0.000125 m^2

σ = $\frac{F}{A} = \frac{350\ N}{0.000125\ m^2} = 2800000\ Pa$ = Yield strength

ε = $\frac{\Delta l}{l}$ = $\frac{0.0098\ m}{0.0326\ m} = 0.301$

E = $\frac{\sigma}{\varepsilon}$ = $\frac{2800000\ N/m^2}{0.301} = 9.302\ MPa$ = Young's modulus when failure begins

Other Considerations:

- Plantarflexion increases moment arm of inversion so the ankle is more susceptible to sprain. It also can delay the response time of the everting muscles.[5]
- True ankle inversions involve a combination of adduction, inversion, and plantarflexion movements.

Sources

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Appendix D: Double Ring Design Dimensions and Measurements

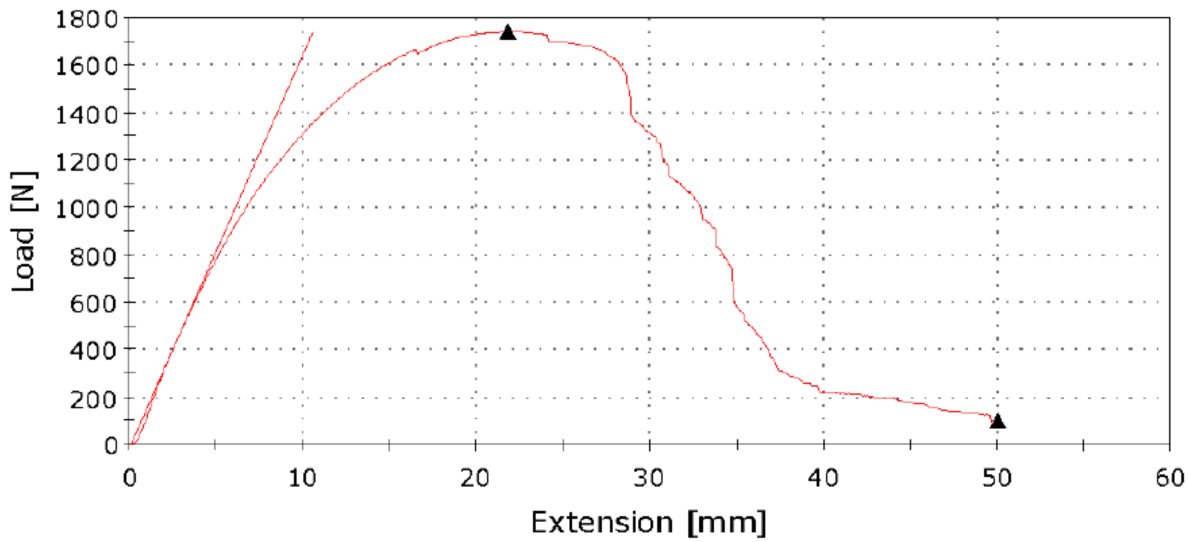
Calipers were used to conduct measurements for each strap. The length, width, and thickness of each strap was measured. The measurements for every strap can be seen in the table below. The label number corresponds with the labels in the figure above.

Strap Label	Color	Material	Length (mm)	Width (mm)	Thickness (mm)
1	Light purple	Cotton	130	24	1.4
2	Red	Polypropylene	82	24.5	1
3	Dark purple	Polypropylene	79	24.5	1.2
4	Blue	Polypropylene	27	24.6	1.8
5	Blue	Polypropylene	46.5	26	1.8
6	Dark purple	Polypropylene	65	24.3	1.2
7	Red	Polypropylene	84.57	24.5	1

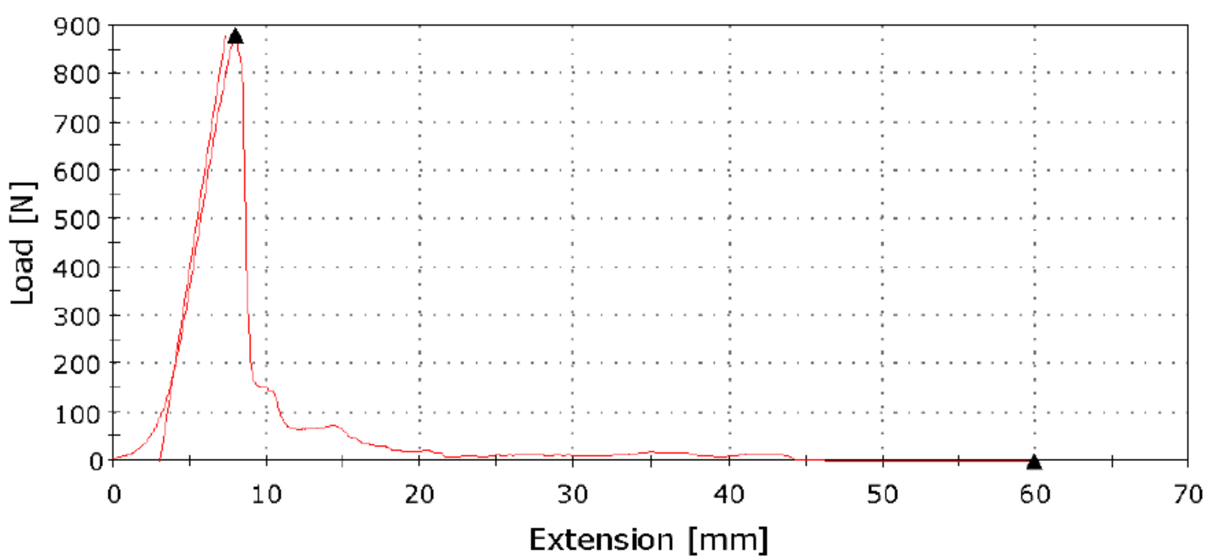
8	Light purple	Cotton	92	24	1.5
9	Light purple	Cotton	140.5	23	1.4

The opening at the top of the sleeve has a width of 106 mm. The opening at the bottom of the sleeve has a width of 85 mm. The thickness of the sleeve is 3 mm. The length of the left side of the brace is 144 mm from the top opening to the opening of the heel. The length from the bottom of the heel opening to the bottom opening of the sleeve is 62 mm. The length of the right side of the brace is 217 mm from the top opening to the bottom opening of the brace. The circular piece over the malleolus has a diameter of 50 mm.

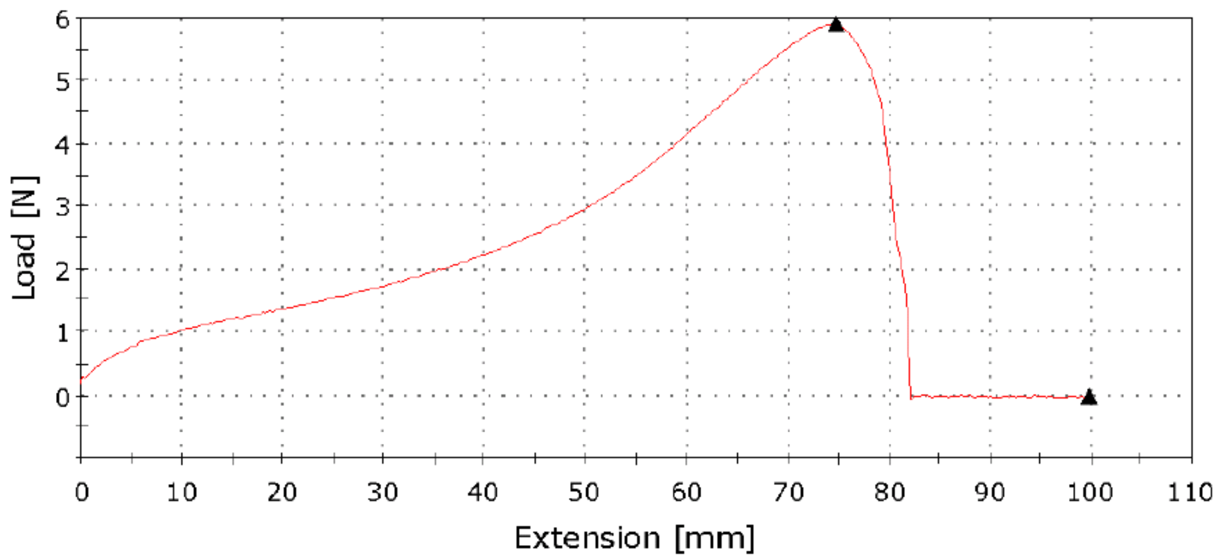
Appendix E: Uniaxial Tensile Testing



Load and Extension of a Polypropylene Strip



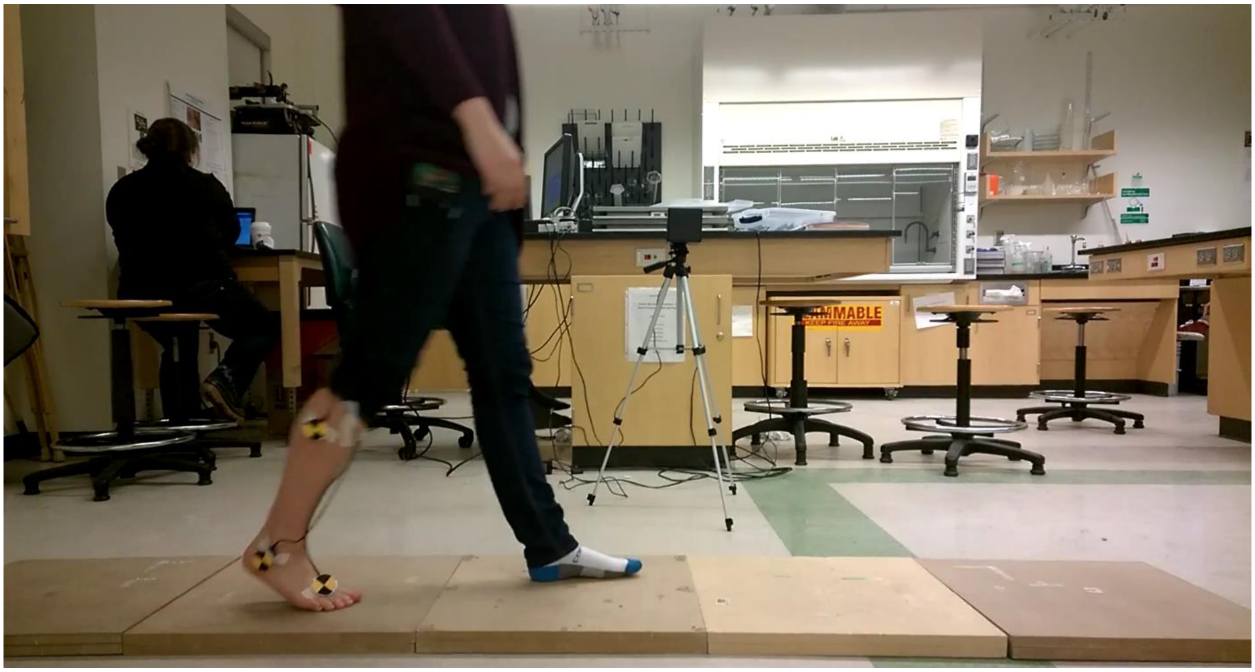
Load and Extension of a Cotton Strip



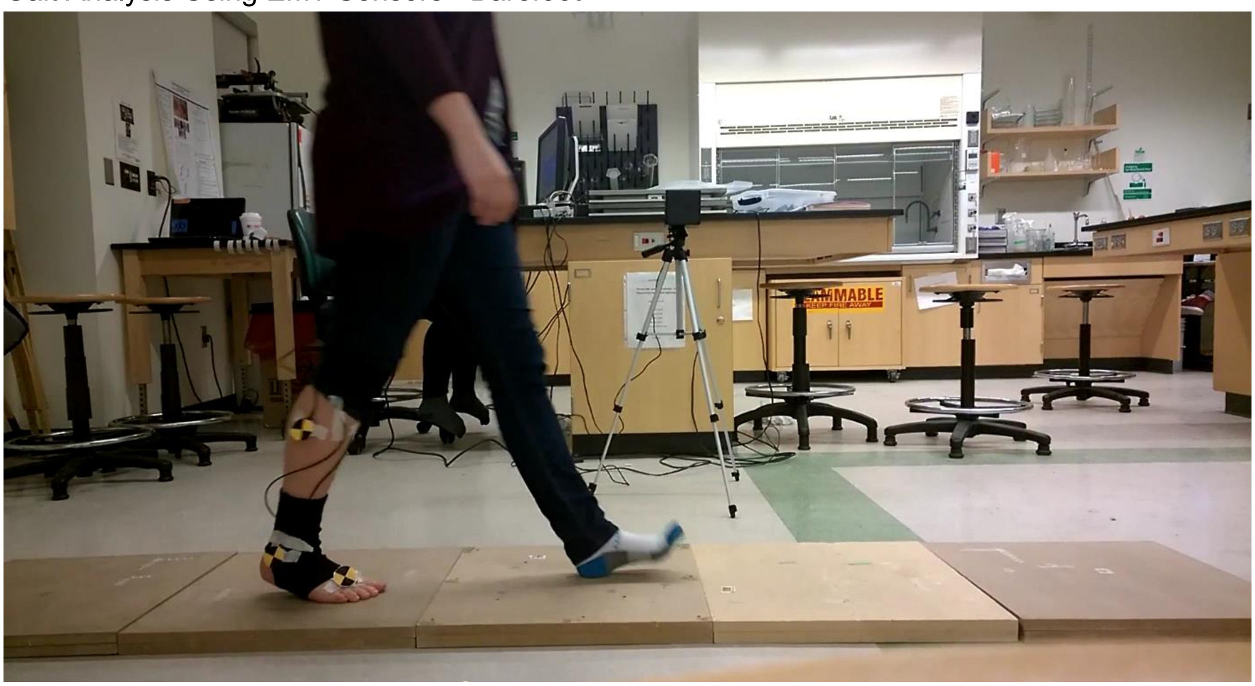
Load and Extension of a Silicone Skin Adhesive

The polypropylene was able to withstand a greater force and extension than the cotton. They both showed similar moduli values in the 400 to 450 MPa range, but the silicone had a much higher ultimate tensile strength. Both materials showed a sufficient value for the simplified two dimensional ankle model equations, but further testing would be required to see how the materials behave with a more advanced and realistic model. The silicone extended much farther than the other materials, but its modulus was much lower than the other materials and would not serve as a functional way to limit ankle inversion.

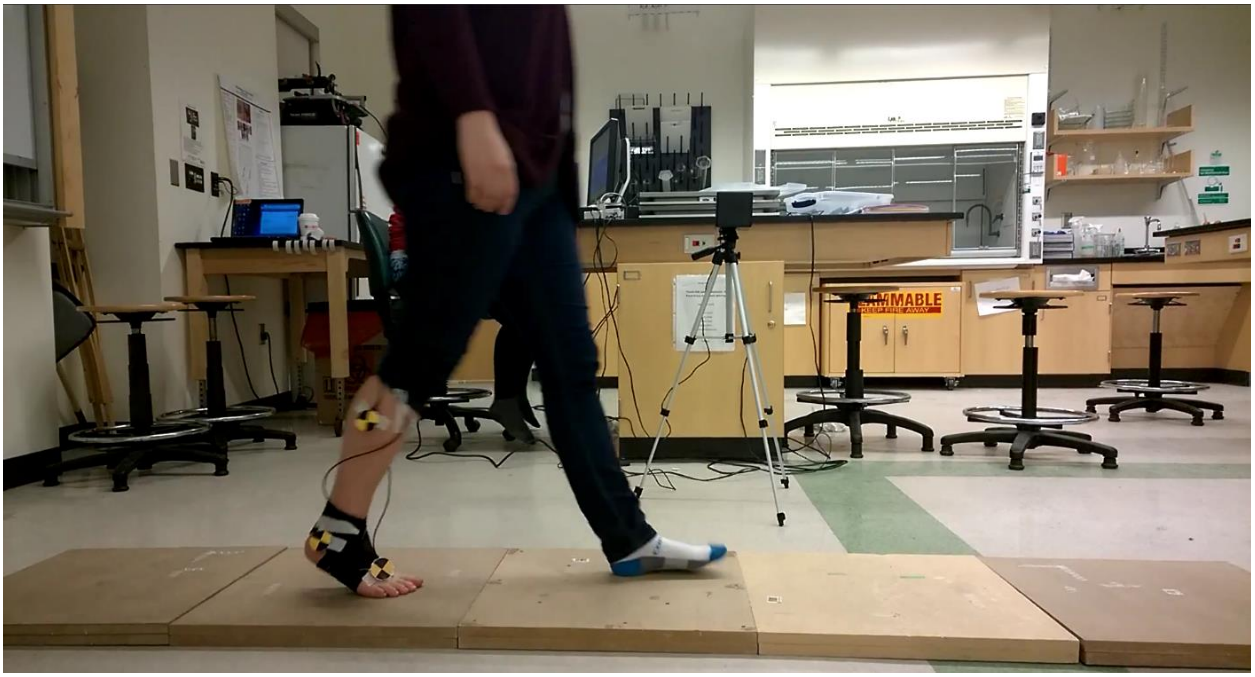
Appendix F: Gait Analysis using EMT Images



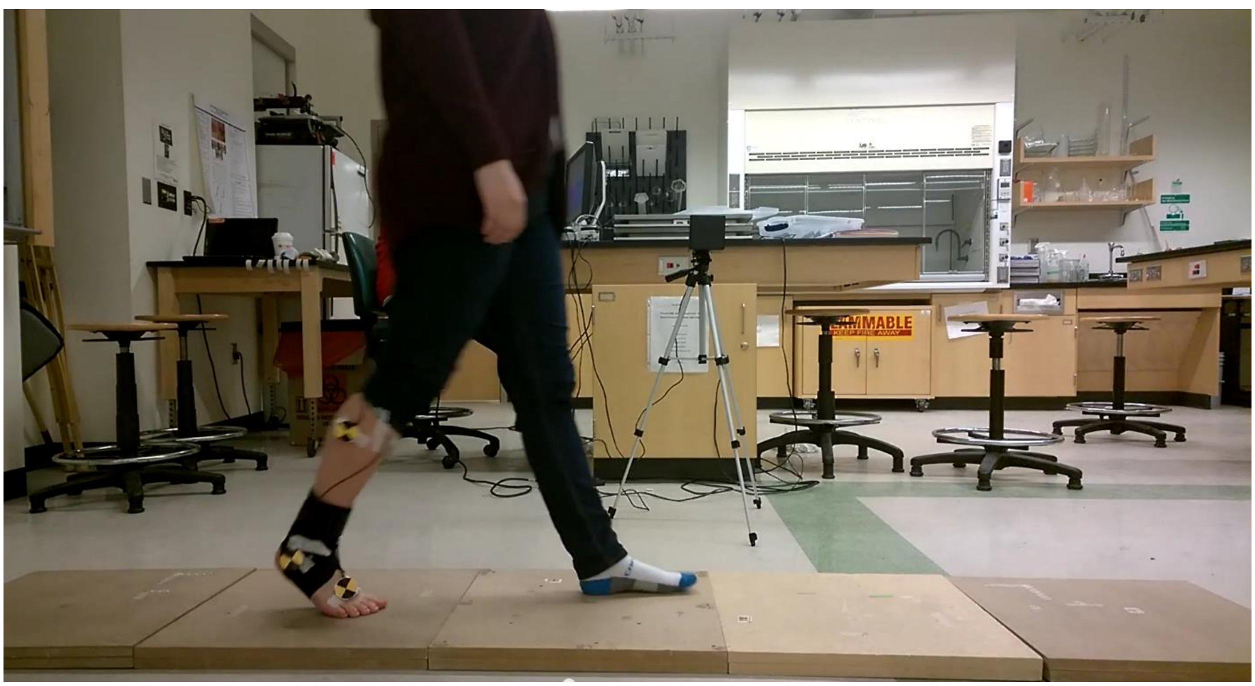
Gait Analysis Using EMT Sensors - Barefoot



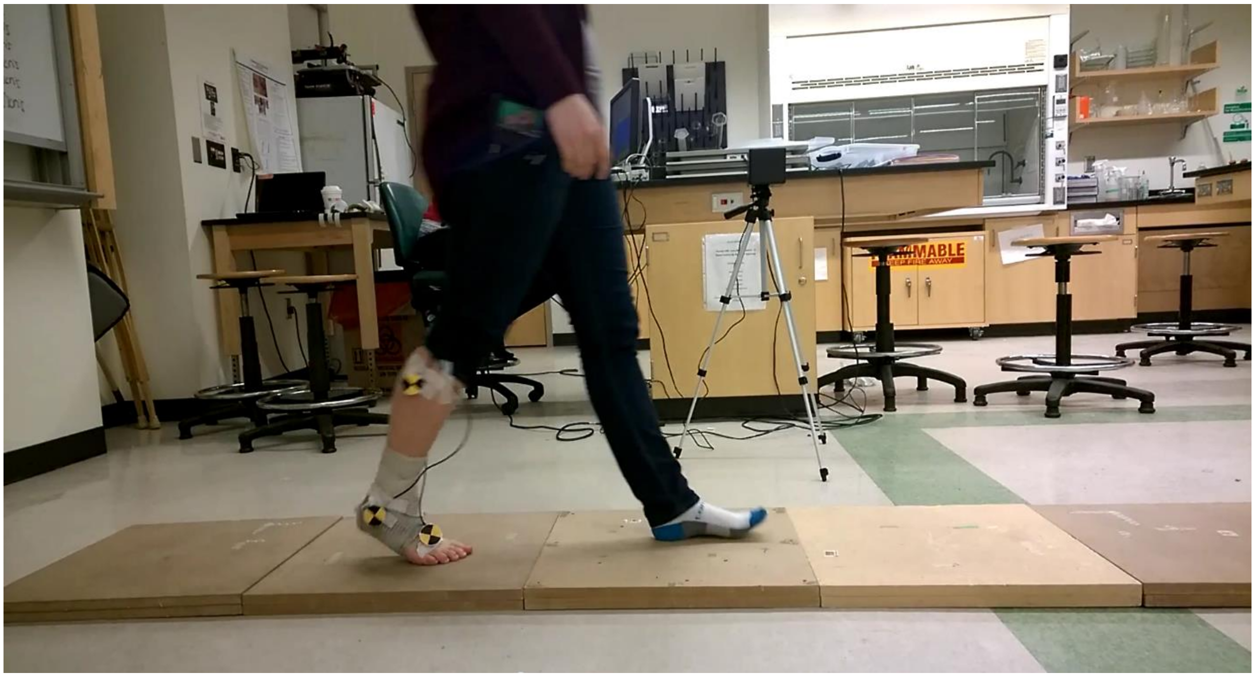
Gait Analysis Using EMT Sensors – Neoprene Sleeve



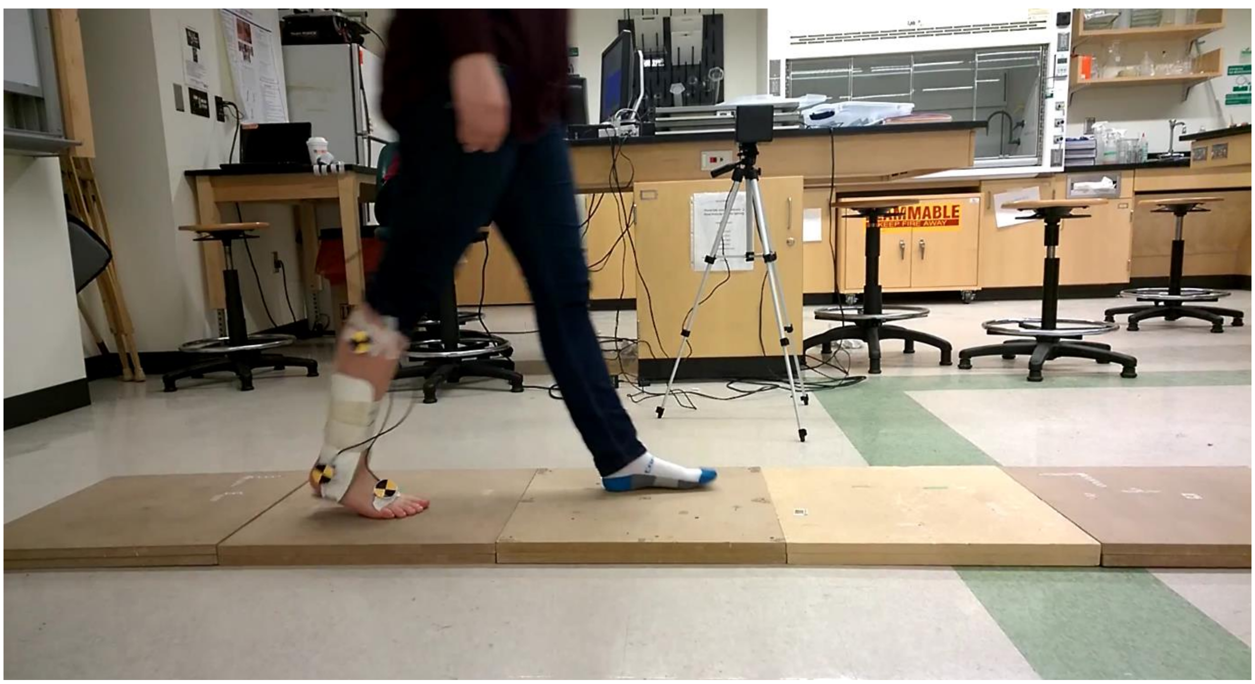
Gait Analysis Using EMT Sensors – Futuro Wrap



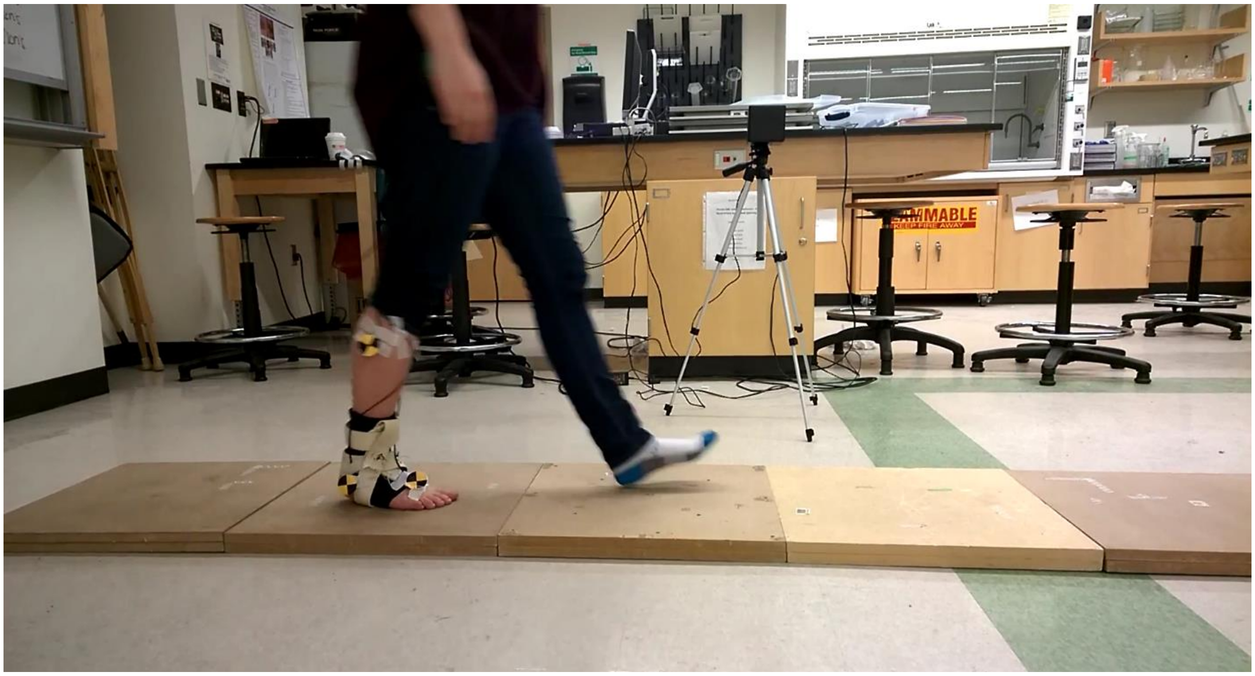
Gait Analysis Using EMT Sensors – Futuro Wrap with Metal Insert



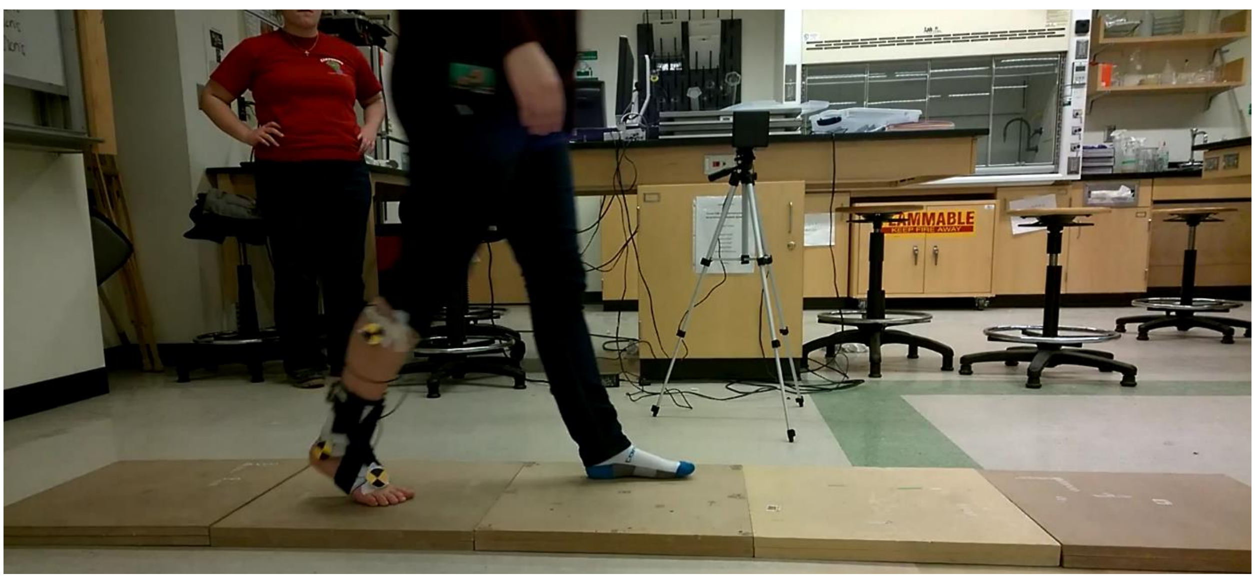
Gait Analysis Using EMT Sensors – Stromgren Double Strap Brace



Gait Analysis Using EMT Sensors – Aircast



Gait Analysis Using EMT Sensors – Lateral Ligament Cotton Strap with Adjoining Sleeve



Gait Analysis Using EMT Sensors – Lateral Ligament Elastic Straps with Velcro Attachments

Appendix G: ANOVA Analysis for Passive Muscle Testing

Comparison of Inversion Angles for barefoot and braces						
	Barefoot	**1**	**2**	**3**	**4**	**5**
Average	28.7	25.8	26	23	24.3	23.1
St. Dev	3.27	4.73	3.65	2.62	5.83	6.62
P-value	0.0105611					
Braces: 1-Futuro Infinity Adjustable Black Precision Fit Ankle Support, 2 -up & up Ankle Brace Elastic Medium, 3- Futuro Sport Deluxe Adjustable Black Ankle Stabilizer, 4- Stromgren Double Strap Ankle Support, 5- Aircast Air-Stirrup Ankle Brace						

Comparison of Plantar Flexion Angles for barefoot and braces						
	Barefoot	**1**	**2**	**3**	**4**	**5**
Average	61	54.6	55.7	50.8	51.4	52.9
St. Dev	12.32	13.87	15.99	16.59	12.6	13.76
P-value	0.0105657					
Braces: 1-Futuro Infinity Adjustable Black Precision Fit Ankle Support, 2 -up & up Ankle Brace Elastic Medium, 3- Futuro Sport Deluxe Adjustable Black Ankle Stabilizer, 4- Stromgren Double Strap Ankle Support, 5- Aircast Air-Stirrup Ankle Brace						

Appendix H: Patent Research

Cooper Active Brace

A patent was awarded to Ronald L. Cooper in 1991 for his ankle brace design. The brace was designed for active people, especially those that partake in athletic activity. The brace aims to support the medial and lateral portions of the foot to prohibit further injury. The foundation of the design consists of a stretchable underline extending from base of the foot to the base of the calf. Inelastic medial and lateral straps originate at the sole of the foot and pull upwards to secure to the underliner. The straps create tension on both sides of the foot to support the medial and lateral ligaments and limit inversion, yet also allow the foot to maintain a natural position. A protective strap wraps around the underliner adjacent to the ankle to hold these medial and lateral straps in place. All straps are secured to the underliner preferably by hook and loop fabric, such as Velcro, in order to be adjustable for a multiple foot sizes. The brace has a thin design for use under a shoe, and may be used for acute or chronic ankle injuries (US Patent 5050620 A, 1991).

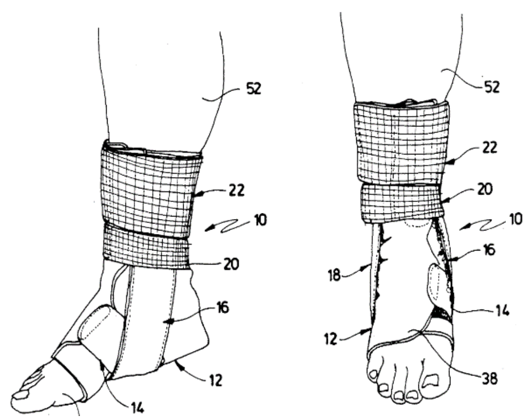


Figure: Cooper Active brace was designed for active people, especially those that partake in athletic activity

Grimm Double Bladder Brace

In 1992, a patent was awarded to Tracy E. Grim for an ankle brace that comprises of two bladders: one which is made of an orthopedic gel and the other designed to be an inflatable bladder to press the gel against the ankle, shown in Figure below.

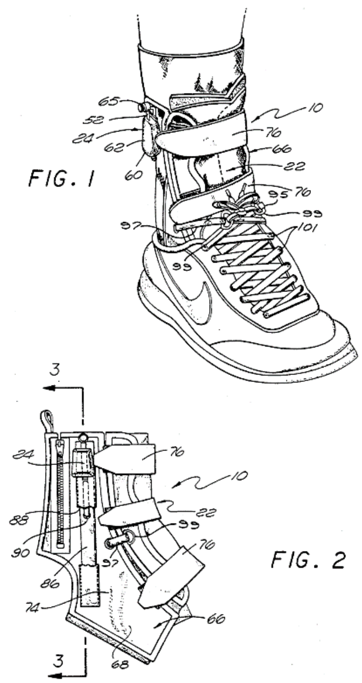


Figure: Grimm double bladder brace. Grimm Double Bladder Brace comprises of two bladders: one an orthopedic gel and the other an inflatable bladder that presses the gel against the ankle

The gel bladder is intended to conform to ankle anatomy and is also removable so it can be heated or cooled. The two bladders are secured to a canvas sleeve-like brace that securely fits the ankle. Additionally, elastic bands that stretch from the back of the brace and over the top of the foot are used to anchor the brace. The ends of the straps are tightened with D-rings located on the lateral side of the brace. The two bladders are designed to restrict ankle inversion and eversion for Grade I and II ankle sprains. The brace is narrow enough to be worn under a shoe.

Smith & Nephew Custom-Fitted Brace

In 1998 a patent was awarded to Smith & Nephew for a custom-fitted ankle splint, shown in the Figure below. This device focuses on healing injuries to the ATFL by protecting against excessive eversion and inversion and allows for plantar flexion and dorsiflexion. The brace is custom fit to the patient's anatomy using a cast mold and resin. Atmospheric moisture hardens the splint. The device consists of two segments: The first and second attachments are held together by hook-and-loop materials that are sewn on. There is a woven fabric layer and a foam material made of EVA or polyurethane. The outer layer is made of synthetic, hydrophobic material. The padding, substrate, and outer layer are held between overlying layers which are sewn together to make one complete device. The first and second splint portions are the same shape and have a symmetrical centerline. The device is preferable because it is light-weight, can be custom-fit to each patient, and can be used on either the left or right foot (US Patent,5980474, 1998).

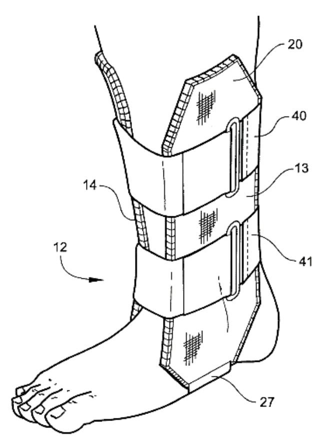


Figure: Smith & Nephew Custom-Fitted Brace Smith & Nephew Custom-Fitted Brace focuses on healing injuries to the ATFL by protecting against excessive eversion and inversion and allows for plantar flexion and dorsiflexion

Draper Protective Brace for Joints & Associated Methods

A patent was awarded to Shane D. Draper in 2011 for protective ankle braces for joints and associated methods, shown in Figure 12. The brace focuses on stabilizing joints in the body to prevent injury while allowing for close to full range of motion of the joint. The design, specifically for ankle injuries, is comprised of an engagement element that secures the brace to the ankle. At least one supporting strap, which extends from one part of the engagement element to another, mimics the function of a fibrous connective tissue in the ankle, such as a ligament, tendon, or fascia. The connective strap is approximately in the location of the connective band in the body, and the tensile strength of the strap may match or be higher than the tensile strength of the corresponding connective band. At least one strap of the brace withstands a tensile load of 3000lb/s^2. One supporting strap is made of poly-paraphenylene terephthalamide or ballistic nylon. The device was designed to improve upon other soft braces, which don't provide enough support, and rigid braces, which are bulky (US 20110034846 A1, 2011).

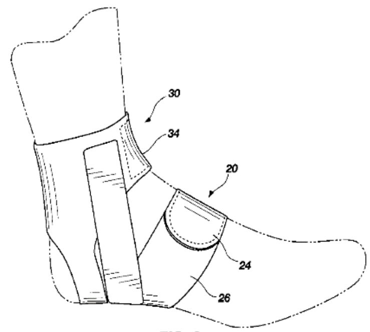


FIG. 3

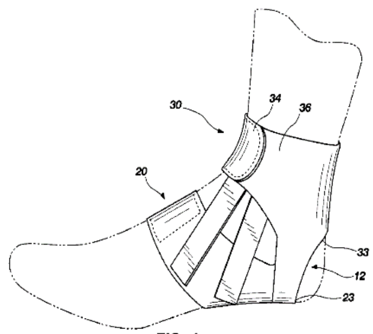


FIG. 4

Figure: Draper Protective Brace for Joints & Associated Methods Draper Protective Brace for Joints & Associated Methods focuses on stabilizing joints in the body to prevent injury while allowing for close to full range of motion of the joint

Janis Removably Mounted Brace

A 2003 patent was granted to Leonard Janis for a removably mounted ankle brace that is comprised of a main body and support straps, shown in Figure 13. The main body is made of a flexible, non-elastic material. It contains separate side sections, a rear section, and a bottom section. Two pairs of support straps serve to provide support for the ankle and the internal ligaments. One pair of stabilizing straps is attached to the main body of the brace and wraps around the rear portion of the ankle to provide horizontal support. A second pair of straps is attached to the side of the main body and wraps over the top of the foot, under the sole, and is pulled vertically upward to the side of the brace. This is to provide vertical support by restricting the displacement of tibia and fibula relative to the talus. The two pairs of straps hold the ankle in a correct anatomical position to stabilize the joint. Restricting movement in both the horizontal and vertical directions provides positive support for the ATFL and CFL by restricting any forces that strain the ligaments. The design also allows the brace to be constructed at a low cost compared to current braces on the market (US6663583 B1, 2003).

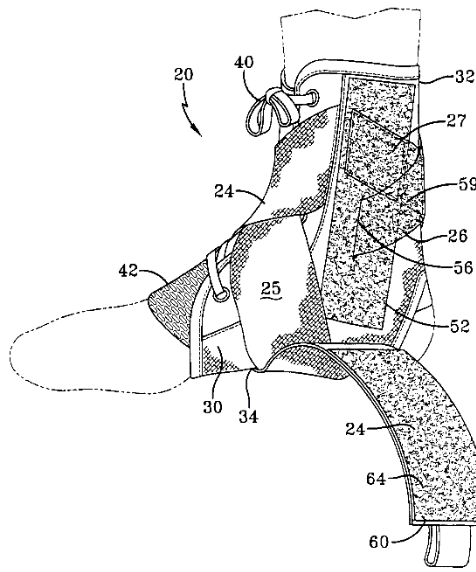


Figure: Janis Removably Mounted Brace. Janis Removably Mounted Brace is comprised of a main body and support straps that Restrict movement in both the horizontal and vertical directions