Exo Ligament

A new means of ankle sprain prevention.
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MSc. Thesis
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SUMMARY

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This thesis presents the research that was conducted to develop an injury preventive means that provides effective external support to the ankle joint without reducing comfort and flexibility.

It was recognized that the currently available braces all rely on fixing something tightly around the ankle region. Although it has been proven that the use of ankle braces can reduce the accident rate [2,3,140,104], these are often rejected by athletes due to their inconvenience.

The similarity between the evolved principle of the foot's ligaments and the preferred basic function of an ankle support was guiding the analysis and concept development process. A solution was found that restricts the relative motion between two rigid parts (the foot and the lower leg) by an external ligament means. This comprises a construction that is positioned around the users ankle and subsequently connected to an attachment feature on the shoe.

An ankle sprain injury occurs when high impact forces make the foot rotate beyond its normal range of motion. This should be restricted by the external ankle support. The challenge to effectively transfer a force from the foot to the lower leg was solved by the development of a half open clip that allows to exert pressure onto the malleoli without the need for strapping something tightly around the ankle.

The final result of the development process was the achievement of a technical proof of principal accompanied by a patent application describing the innovative principle of motion restriction. A range of prototypes were successfully tested by athletes.

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PREFACE

Preface

In 2009 I was participating in a course called Anatomy and Surgical Techniques for Engineers. Especially the anatomy of the foot took my interest since I occasionally suffer from a sprained ankle myself. It was furthermore learned that the injury is a major problem, occurring in numerous sports.

Two years later the opportunities, to elaborate on an idea for a sprain preventive product during my graduation have been investigated, were explored by contacting the people that later turned out to be very important in fulfilling this assignment. I would like to thank my supervisory team, as well as all the other consulted professionals, for their efforts and enthusiasm.

The graduation project covered a total period of 22 weeks in which subsequent development stages were present as is illustrated in Figure 1. The entrepreneurial character of the process, without the involvement of a company, was positively experienced and I am satisfied with the result which is presented at the end of this thesis. The application process for a patent made the project especially interesting.

The report has been written to understandable by experts as well as previously uninformed people. I tried to clearly explain the different aspects of the project such that a coherent overview was generated.

Fleuren

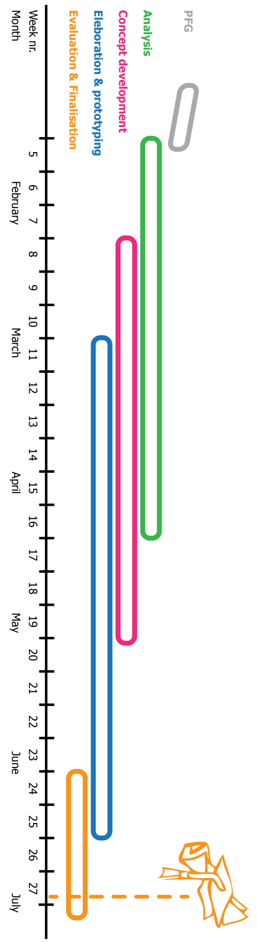


Figure 1. *Planning of the graduation project.*

ANALYSIS

Analysis

For the development of this new sprain preventive product numerous factors had to be investigated. First of all, a better understanding of the functional anatomy of the ankle, the ankle sprain injury and the foot in general were needed. Also the technological feasibility and market potential were important to address.

This chapter points out the efforts that have been taken during this broad investigation. At the end of each section, the consequences for the Exo Ligament concept will be explained. These served as design criteria for the further development, described in this thesis. The expertise and tools of the TU Delft, Erasmus Medical Centre and other professional institutes were of great use in fulfilling the necessary research.

The used terminology, especially in the first sections of this chapter, will be unfamiliar to most readers. An index has been included at the end of this thesis to enable quick requiring of background information on the subjects which are discussed in the following chapters.

Anatomy

In this section the functional anatomy of the foot and ankle will be explained. That includes a detailed picture of the bone positions, muscles with tendons, ligaments and other tissues of the foot. This information is necessary to develop a product that seamlessly connects to the user's own musculoskeletal system. To begin with, some general anatomical terms of location will be given which are necessary for understanding the report.

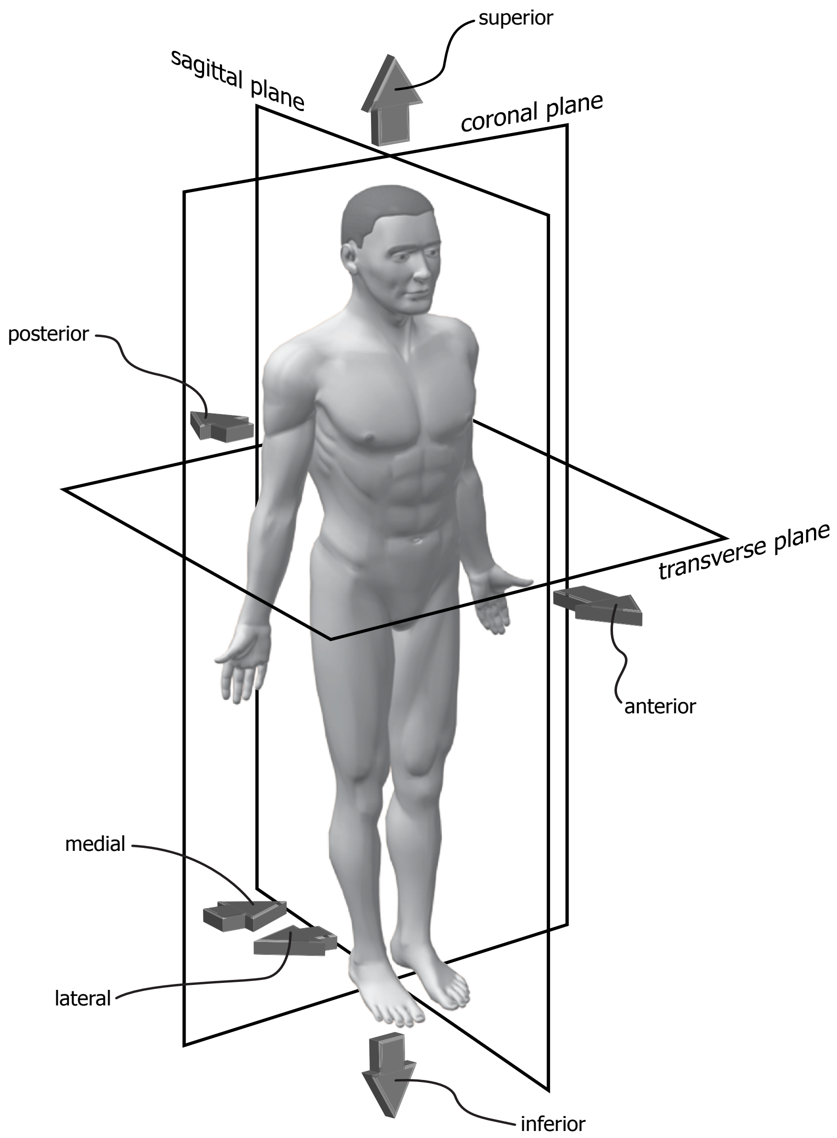


Figure 2. *Anatomic terms apply to the body when it is in the anatomical position. A person is standing erect with the feet facing forward, arms hanging to the sides, and the palms of the hands facing forward.*

Anatomical Terms of Location

When discussing the anatomy of the human body it is important to know what you are looking at specifically, in which plane an image is taken and from what direction. In medicine in general and anatomy in particular, an official nomenclature is defined to be sure people all over the world talk about the same thing. This applies to the human body in general, as well as to parts of the body such as the ankle and foot. As a reference, Figure 2 shows the standard anatomical position of the body.

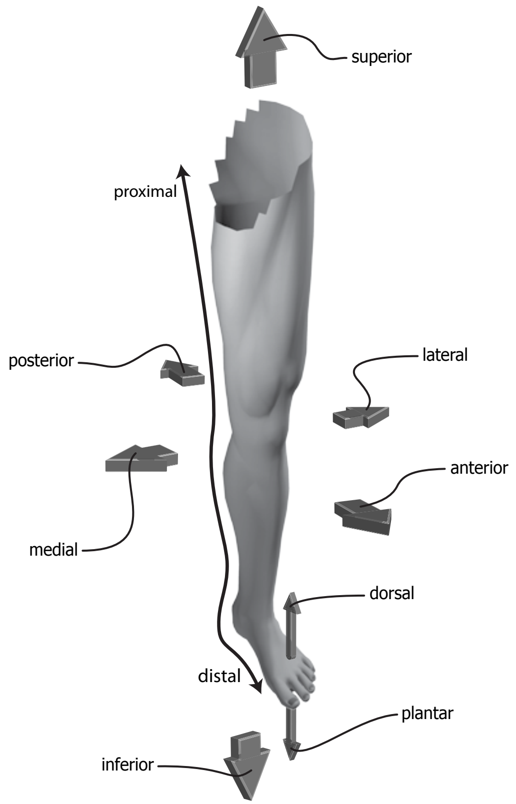


Figure 3. *The lower left extremity. The image displays all relevant terms of direction.*

Location of Body Parts

The location of a body part is often denoted relative to the location of other parts. In some cases the same term has a different meaning for different sections of the body. Since this might cause confusion when studying other literature, a complete overview is given below.

- Posterior parts are located towards the back of the body. They are positioned behind anterior parts which are located more towards the front of the body. In addition, the terms ventral (towards the belly) and dorsal (towards the back) apply to the trunk. Palmar (towards the palm of the hand) and dorsal (towards the back of the hand) apply to the hand and plantar (towards the sole of the foot) and dorsal (towards the back of the foot) apply to the foot.
- Superior parts are located towards the top of the body. They are positioned above inferior parts which are located towards the bottom of a body. In addition, the terms caudal (side of the tail) and cranial (side of the skull) apply to the trunk.
- Medial parts are located towards the midline of the body when viewed from the front. In contrast, lateral parts are located further away from the midline of the body.
- Proximal parts are located towards the centre of the body, or towards the beginning of a structure. Distal parts are located further away from that reference point. In case of the trunk, when for example the heart is seen as the centre, a proximal part is located towards the heart. In case of the limbs a proximal part is located towards the attachment point to the trunk of the body.

Cut Through Planes

An illustration can display a cut through of the human body. In that case one of the following 3 perpendicular planes is used.

- A sagittal plane is a vertical plane which passes from front to rear dividing the body into right and left sections. The plane through the centre of the body can be called the medial (sagittal) plane.
- A coronal plane is a vertical plane that divides the body into anterior and posterior sections. In some occasions it is called a frontal plane.
- A transverse plane is a horizontal plane that divides the body into superior and inferior sections.

Views from Different Directions

To avoid confusion, the direction from which an image is taken is also important to know. The same terms which are used to describe the location of body parts apply.

A body part can be at an anterior location when it is positioned towards the front of the body. Likewise, an image can display a anterior view when it is taken from the front. A few common views of the foot are given in Figure 4.

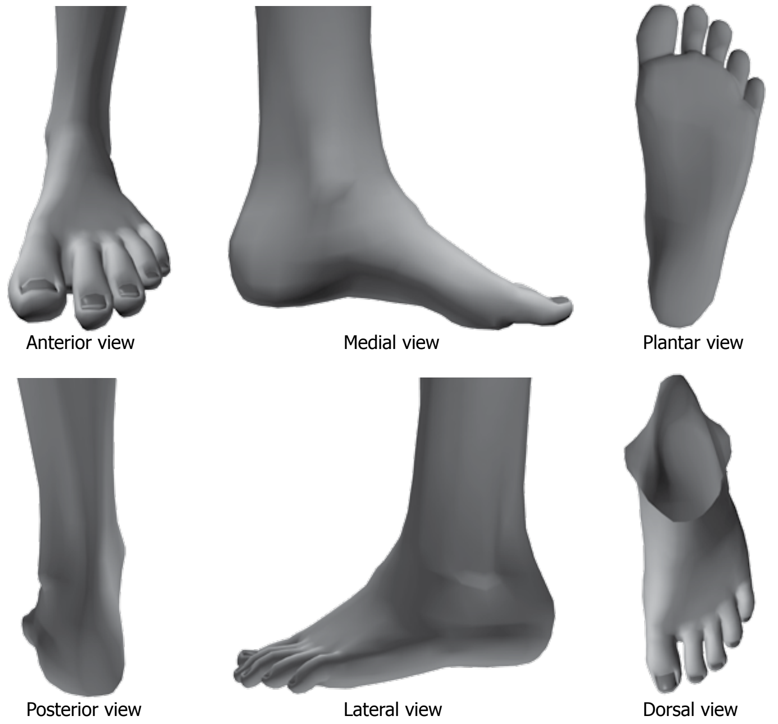


Figure 4. *Views of the left foot and ankle from different directions. The dorsal and plantar view only apply to the foot below the ankle. The terms proximal and distal apply to a transverse plane above that point.*

Anatomical Layers

With the general rules of anatomy in mind a description of the foot and ankle will be given below. Firstly , the skeleton will be discussed. Subsequently, other layers will be added one by one to clearly illustrate the coherence between parts.

Analysis, Anatomy

Skeleton

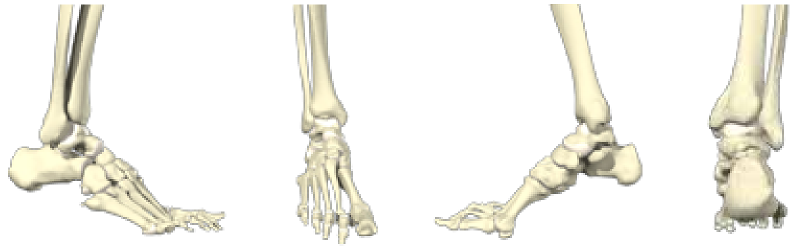


Figure 5. *Skeleton of the right foot. Viewed from the lateral, anterior, medial and posterior side respectively.*

The lower leg consists of only two bones, the fibula ant tibia. By contrast, the foot consists of many small bones whose interconnections enable its complex movements.

At the places where different bones articulate (connect) a joint is formed. At these locations, the bone surfaces are covered with a layer of articular hyaline cartilage. This offers a firm, smooth and relatively friction-free layer to facilitate joint movement. In addition, the joints are protected by surrounding articular capsule. The location and names of the different bones are illustrated Figure 6.

- The fibula is the lateral of the two bones of the lower leg. The tibia is larger and located at the medial side of the leg.
- The characteristic extruding pieces of bone around the ankle belong to the lower parts of the tibia and fibula. They are called malleoli.
- The bones at the proximal side of the foot are called the tarsal bones or tarsals. They include everything from the talus to the start of the metatarsals.
- The talus connects the foot to the lower leg (cruris). The distal articular surfaces of the tibia and fibula articulate with the superior part of the talus and together form the talocrural joint (or ankle joint).
- The talus articulates to a few bones of the foot. One of them is the navicular on the medial side of the foot. The talonavicular joint is formed at that location.
- The calcaneus is the largest and most plantar of the tarsal bones. It forms the heel of the foot and its superior surface is connected to the talus to form the talocalcaneal joint.
- The distal surface of the calcaneus connects to the cuboid at the lateral side of the foot to form the calcaneocuboid joint.
- The cuneiform bones connect the tarsals to the metatarsal bones 1, 2 and 3. They are called the medial, intermediate and lateral cuneiform respectively. The metatarsal bones 4 and 5 articulate with the cuboid. These all belong to the tarsometatarsal joints.
- The cuneiforms, as well as the metatarsals, also articulate with each other mutually.
- The phalanges (proximal, middle and distal) form the skeleton of the toes and the hallux is the phalange of the big toe. Movement of the toes happens in the metatarsophalangeal joints as well as the interphalangeal joints.

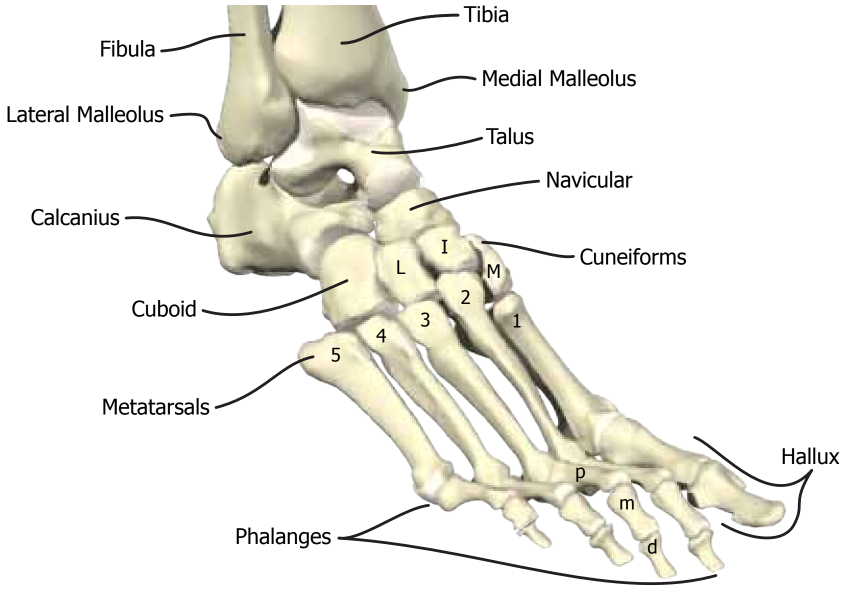


Figure 6. *Bones in the foot and ankle region. Medial-lateral view of the right foot.*

Ligaments

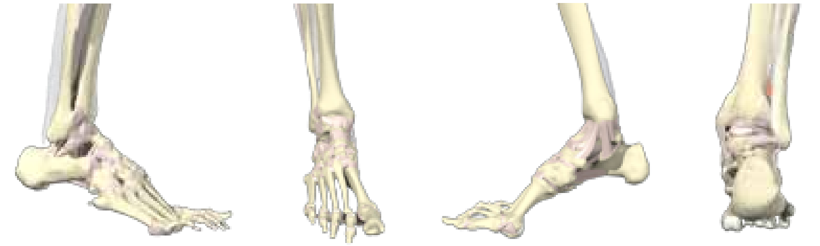


Figure 7. *Ligaments of the right foot. Viewed from the lateral, anterior, medial and posterior side respectively.*

Bones are connected to each other by ligaments which restrict the relative motion between the bones and ensure the integrity of the bony system. Ligaments are made of a visco-elastic, fibrous tissue. They show a form of creep under tensile forces, and the ligaments return to their original shape when the tension is removed.

The fibula and tibia are kept together by several ligaments among which the firm interosseous membrane that connects the two shafts. Their relative motion is very much restricted by this connection. In the foot, a total of 108 ligaments can be found. Numerous ligaments keep the tarsals, metatarsals and phalanges together. In the light of this research a more detailed description will be given of the ligaments that restrict the motion of the ankle joint. They are illustrated in Figure 8.

At the medial side of the foot the medial collateral ligament (deltoid ligament) can be found. It is a thick and very strong band. The deltoid ligament is proximally connected to the malleolus of the tibia. The ligament is made up of different layers that connect to different points at the distal side.

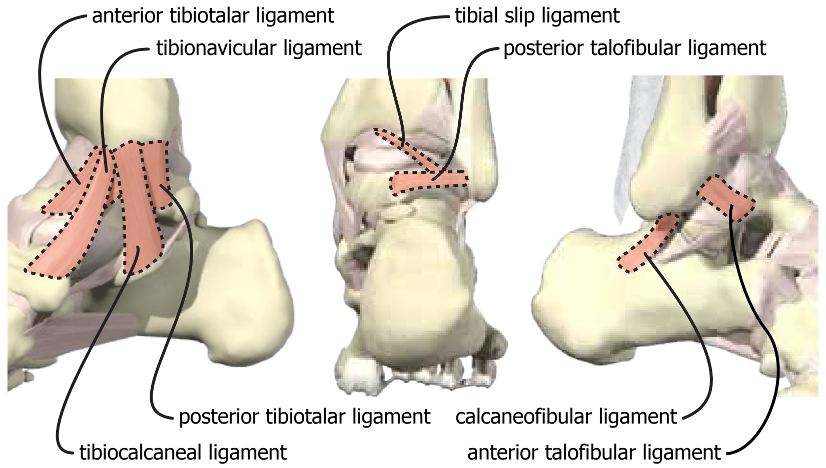


Figure 8. *Lateral collateral ligament and medial collateral ligament of the ankle joint. Viewed from the medial, posterior and lateral side respectively.*

- The tibionavicular ligament attaches distally to the navicular bone.
- The tibiocalcaneal ligament runs down vertically and attaches at its distal side to the medial aspect of the calcanius.
- The posterior tibiotalar ligament runs in a postero-lateral direction and attaches distally to the medial side of the talus.
- The anterior tibiotalar ligament attaches to the medial surface of the talus.

The lateral collateral ligament of the ankle joint is more important for the inversion lesion and is weaker and less extensive than the medial ligaments of the ankle. It is often regarded as being one functional unit, however, it is composed of three different parts. They are attached proximally to the malleolus of the fibula and connect distally to the bones of the foot.

- The anterior talofibular ligament passes antero-medially to attach to the lateral surface of the talus neck. It is the least strong component of the lateral collateral ligament.
- The calcaneofibular ligament is the largest of the lateral collateral ligament. It attaches distally to the lateral surface of the calcaneus.
- The posterior talofibular ligament is the strongest component of the lateral collateral ligament. It passes horizontally from the malleolus in a postero-medial direction to the posterior side of the talus.
- The tibial slip is an extension from the border of the posterior talofibular ligament and attaches proximally to the tibia.

Muscles and Tendons

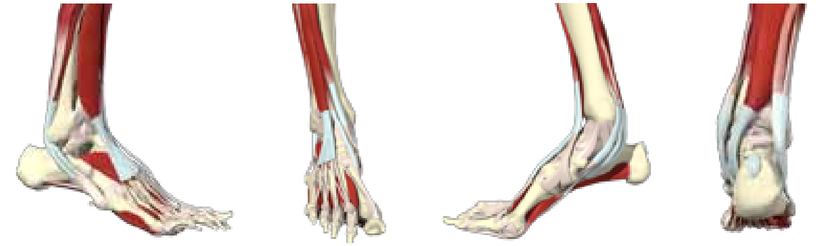


Figure 9. *Muscles and tendons of the right foot. Viewed from the lateral, anterior, medial and posterior side respectively.*

Movement is achieved by using the muscles of the foot. A muscle can be an extensor, flexor, abductor or adductor. In general, a flexor is a muscle that, when contracted, bends a joint or limb in the body. By contrast, an extensor is a muscle that extends or straightens a limb or body part. In case of the muscles in the lower leg and the foot, these terms relate to the toes being flexed and extended, not the ankle. An abductor draws a limb away from the median sagittal plane of the body and an adductor provokes a movement towards the midline of the body.

Muscles are connected to the bones by tendons. These are tough bands of fibrous tissue which distribute forces to move the bones and are capable of withstanding tension. It is illustrated in Figure 10 how the tendons that curl around the bones of the foot, are wrapped in tendinous sheets. It is their function to facilitate free movement and lubricate the moving surfaces to reduce friction between tendon and bone. Furthermore, it can be seen in Figure 11 how most of the tendons are held in place by band-like structures called retinacula.

The muscles that facilitate motion around the ankle joint will be described briefly on the following pages. Different layers of muscles are apparent, located superficially or deep below the surface. The movements that are mentioned to explain their function will be further explained in the 'Joints and Motion' section.

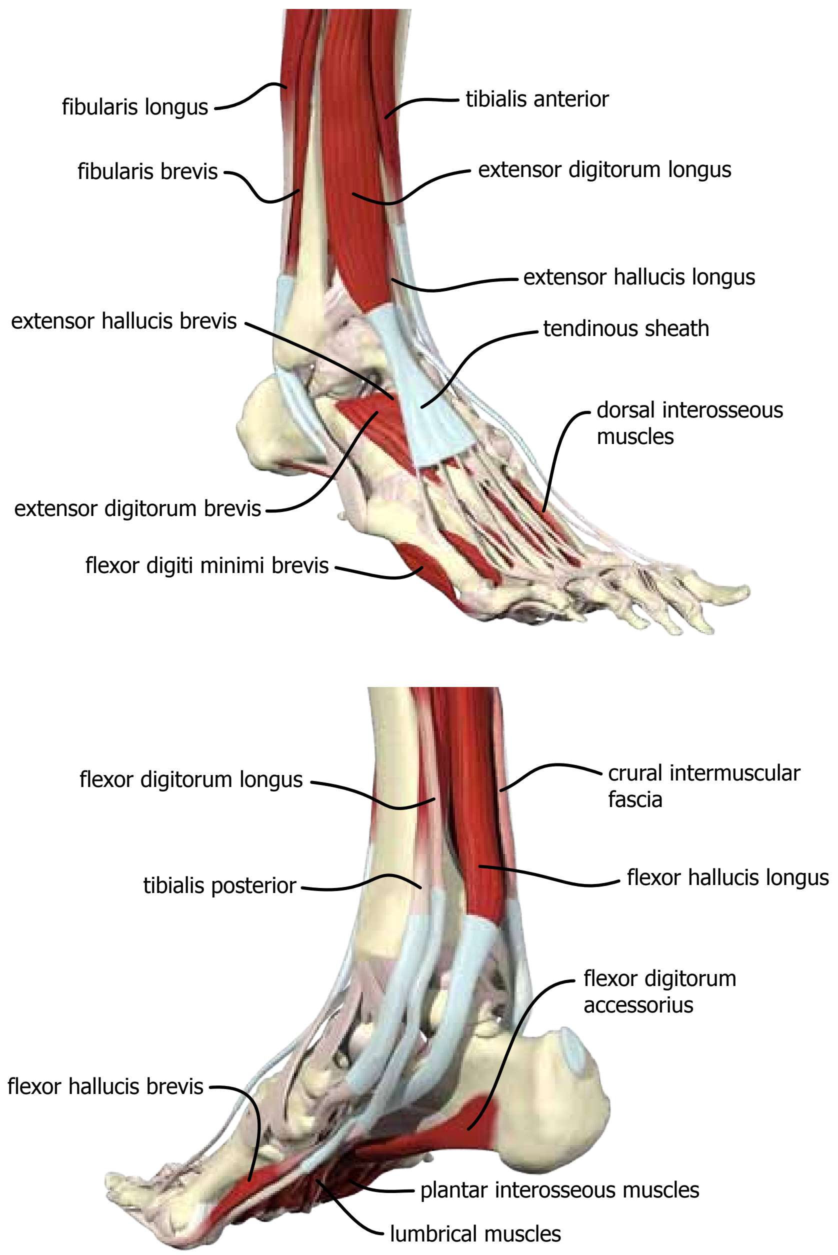


Figure 10. *Inferolateral view and posteromedial view of the foot showing most of the muscles and tendons.*

- The fibularis longus muscle can be found, together with the fibularis brevis muscle, in the lateral compartment of the leg where it arises from the lateral proximal side of the fibula. Its tendon runs vertically downwards behind the tendon of fibularis brevis, through a groove formed by the lateral malleolus. The tendon of fibularis longus then runs forward to the cuboid and passes diagonally across the sole of the foot. Finally it is attached medially to the first metatarsal and the medial cuneiform, thus forming an anatomical 'stirrup'. The fibularis longus muscle everts the foot and is also capable of plantarflexing the ankle joint.
- The fibularis brevis muscle is proximally attached to the lateral shaft of the tibia. Its tendon is, after passing the malleolus, attached to the base of the 5th metatarsal. The muscle is an evertor of the foot and a relatively weak platarflexor of the ankle joint.
- The tibialis anterior muscle lies just lateral of the tibia. Proximally, it arises from the anterior side of the tibia. The tendon of the tibialis anterior muscle passes over the anterior aspect of the ankle joint, just lateral to the medial malleolus. It inserts into the medial cuneiform and at the base of 1st metatarsal bone. Tibialis anterior is capable of dorsiflexing the ankle joint and is an invertor of the foot.
- The extensor digitorum longus muscle, has its origin proximally at the medial side of the fibula. Distally, the tendon passes over the anterior side of the ankle joint. It then splits into four slips that diverge on the dorsum of the foot and insert into middle and distal phalanges. The muscle extends the lateral four toes and assists in dorsiflexion of the ankle.

- The extensor hallucis longus muscle lies between the tendon of tibialis anterior and the tendon of extensor digitorum longus. Proximally, the muscle has its origin at the middle of the fibular shaft. Distally, its tendon crosses anterior to the ankle joint and then continues in a medial direction on the dorsum of the foot to insert eventually into the distal phalanx of the hallux. The extensor hallucis longus muscle acts to dorsiflex the hallux and assists in dorsiflexing the ankle joint.
- The flexor digitorum longus muscle can be found in the posterior compartment of the leg. It is proximally attached at the posterior side of the tibia and its tendon passes in a groove behind the medial malleolus together with the tibialis posterior. It runs into the foot sole and then divides into four tendon slips which ultimately insert into the distal phalanxes of the four lateral toes. It is a plantar flexor of the ankle joint, and is particularly active in maintaining the erect position during stance. In addition, it flexes the phalanges of the four lateral toes.
- The tibialis posterior muscle originates at the posterior side of the tibia and fibula. After passing the malleolus, its tendon inserts distally into the navicular, but also sends extensions to all of the tarsal bones (except the talus) and some metatarsal bones. The tibialis posterior muscle is an invertor of the foot. Additionally, it assists in plantar flexion of the ankle joint.
- The flexor hallucis longus muscle is yet another muscle in the posterior compartment of the leg. It arises proximally at the posterior side of the fibula and develops into a strong tendon, which runs into the sole of the foot. Eventually it inserts into the base of the distal phalanx of the hallux and two separate slips attach to the flexor digitorum longus tendons of the 2nd and 3rd toes. The muscle flexes the hallux and assists in plantar flexion of the foot at the ankle joint.

Figure 11. *Inferolateral view and posteromedial view of the foot showing most of the muscles and tendons.*

- Together with the two heads of gastrocnemius, the soleus muscle forms the triceps surae muscle. The triceps surae accounts for the bulk of the calf. The muscles arise proximally at the posterior side of the leg and give rise to tendons that fuse to form the tendo calcaneus. The tendo calcaneus inserts distally into the posterior surface of the calcaneus and allows the muscles to plantarflex the ankle joint.
- The plantaris muscle is proximally attached above the knee joint. This short muscle ends up into a long tendon which runs all the way down to insert into the surface of the calcaneus. The plantaris muscle is a weak flexor of the knee joint and a weak plantar flexor of the ankle.

Vessels and More

Figure 12. *These images illustrate all different tissues in the foot underneath the skin. viewed from the lateral, anterior, medial and posterior side respectively.*

Besides the skeleton, ligaments and muscles, also other structures can be found in the foot. In this paragraph a few of them, that can be found at a relative superficial location, will be described.

- Fascia is separating, or binding together muscles, muscle groups and other soft tissues of the body. It wraps everything together underneath the skin and is in many cases a convenient point of attachment for other structures. Just below the skin the fascia contains a layer of fat tissue. A thick fat pad is located underneath the calcaneus.
- The arteries are blood vessels that carry blood away from the heart to the structures of the foot. The two principal arteries to the foot are the posterior and anterior tibial arteries. The anterior tibial artery is the smaller of the two and arises at the posterior side of the leg. At the ankle, it lies midway between the malleoli and then passes into the dorsum of the foot. The posterior artery also runs at the posterior side of the leg but ends between the medial malleolus and the calcaneus, in the so called 'tarsal tunnel'.
- The veins are blood vessels that carry blood to the heart and away from the foot. To efficiently carry away the blood, numerous veins are located around the superficial fascia of the foot.
- The nerves are made up of neurons. They serve to transfer signals to and from the central nervous system. Sensory information about the state of the structures in the foot is collected by the sensory nerves and the muscles are activated by motor nerves.
- Lymph is a fluid that surrounds all the cells in the body. Excessive fluid of a swollen ankle or infections will be transported by the lymph vessels to one of the lymph nodes in the body where it can be filtered.
- Finally, directly on top of the fascia, the skin can be found. This is a soft tissue covering of all the other body parts.

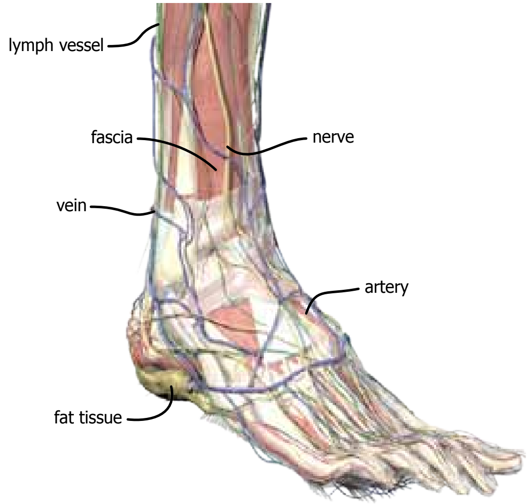


Figure 13. *Some of the tissues underneath the skin viewed from an inferolateral perspective.*

Exo Ligament Consequences

It is most easy to understand the function of the ligaments when the foot is represented as one single unit moving relative to the lower leg. Two rigid parts, the leg and the foot, move away from each other during activity. The ligaments are connected to both these parts and try to restrict this motion. An analogy can be seen with an external ankle support which also attempts to restrict the motion by connecting the foot to the leg. This will be further elaborated upon in the 'External Ankle Support' section.

In the 'Muscles and Tendons' paragraph it was illustrated which muscles are the most important plantar and dorsal flexors of the ankle, as well as invertors and evertors of the foot. In the 'Joints and Motion' section these terms will be further explained. The muscles of the foot are continuously used during sporting activity. When a support has to be attached tot the ankle region, it is important to developed a solution that does not squeeze the tendons. In addition, the arteries, veins, nerves and lymph vessels should not be strangulated for a long period.

The superficial fat and fascia layers facilitate the movement of the skin relative to the deeper structures of the body. This has to be taken into account when attaching a support to the skin and will be further discussed in the 'Motion Restriction' section.

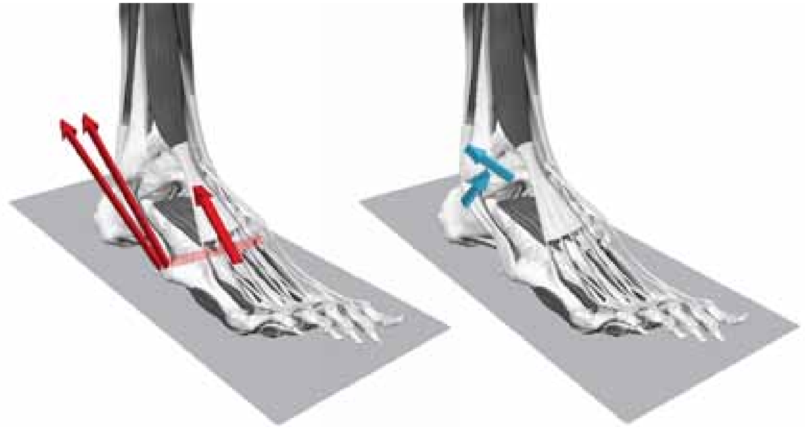


Figure 14. *The direction in which the evertor muscles (red) and lateral ligaments (blue) are pulling at the foot.*

The mechanism of an ankle sprain will be explained in the 'Inversion Trauma' section. The evertor muscles that are discussed in this section and the lateral collateral ligament are able restrict the ankle sprain motion. Therefore the direction in which they exert a force, and the places where they attach to the foot, are interesting to keep in mind when developing an ankle support. They are illustrated in Figure 14. One of the evertors (the fibulares brevis muscle) is passing underneath the sole to exert a force at the medial side of the foot.

Joints and Motion

This section is to illustrate how the foot moves and what movements cause a sprained ankle. The movement of the foot is complex. 57 joints, which can be found between the 26 foot bones, often allow combined movements in more than one direction.[25] Since most joint motions are coupled with each other as well, it is difficult to describe the overall movement by describing the exact motion in every single joint. For the sake of this project, the most important motions with respect to an ankle sprain are reviewed.

Motion Measurement

The degree of motion that a joint allows is studied by several authors. Generally however, the available data are restricted to the average of maximum rotation between subjects. The measurements are often dated and only performed manually. In addition, these publications all use slightly different methods for measuring rotation which undermines the possibility of a proper comparison.

The measurements of Russe are relatively extensive and convince to be reliable.[24] He proposed the SFTR method where motions starts at the neutral position and are executed in the sagittal, frontal, and transverse planes or as rotation. The SFTR data will be used as a reference for the given ranges of motion (ROMs) in this section. Most measured ROMs are the result of muscle activity, this is called active ROM; motion by an external force is called passive ROM.

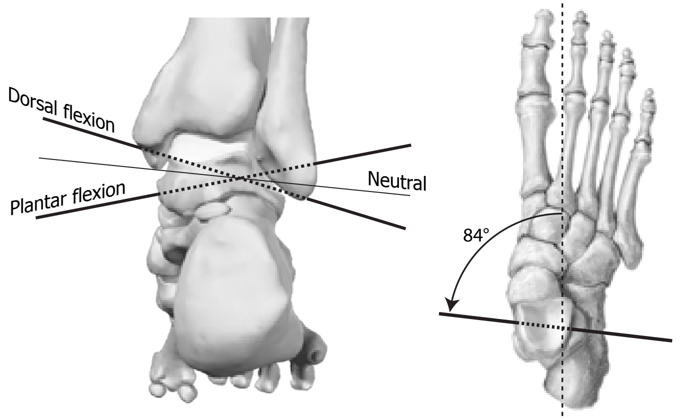


Figure 15. *The location and directions of the talocrural joint axis.*

The Talocrural Joint

The main movement of the talocrural joint can be recorded in the sagittal plane. This is illustrated in Figure 16. Plantar flexion means moving the toes down and dorsal flexion means moving them up. The range of motion varies considerably between people. The SFTR study shows an average of 45° plantar flexion and 20° dorsal flexion.

The talocrural joint, or ankle joint, allows the talus to rotate relative to the lower leg. The axis of this joint is described as passing through the centres of the left and right malleoli, however, this axis changes direction due to movement.[5] It deviates from its neutral position during plantar flexion and dorsal flexion as can be seen in Figure 15. This is due to the fact that the radii of the articular surface of the talus are different at the medial and lateral sides.[5] The difference in inclination was found by Lundbert et al. to be 37° on average.[19] As can be seen in Figure 15, the axis forms an 84° angle with the midline of the foot which runs from anterior to posterior.[20]

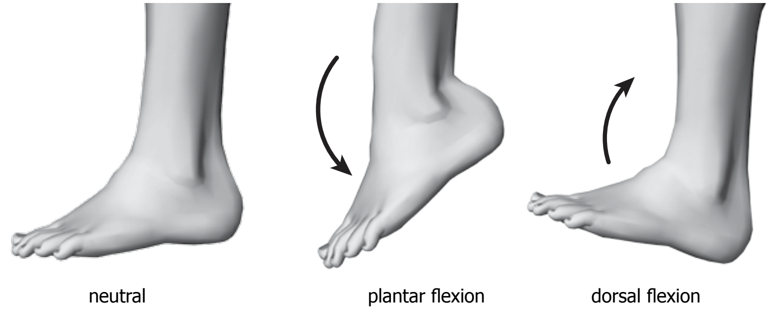


Figure 16. *Sagittal movement of the left foot facilitated by the talocrural joint.*

Besides dorsal and plantar flexion, the ankle joint also allows some adduction and abduction of the foot. The talus can rotate slightly relative to the leg around a vertical axis, which is caused by its loose suspension between the tibia and fibula. Although the movement is usually very small, adduction of a few degrees is possible in a plantar flexed position of the foot.

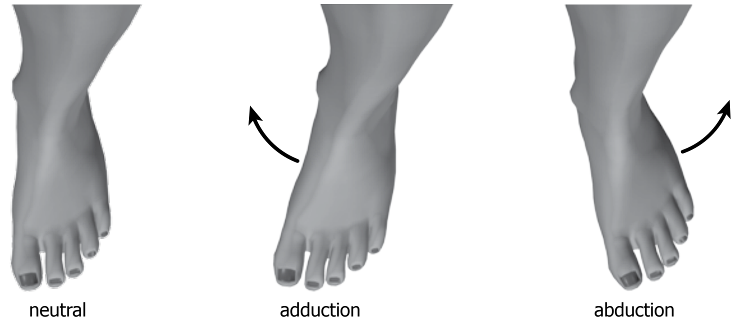


Figure 17. *Transverse movement the left foot facilitated by the talocrural joint.*

The Talotarsal Joints

The other main movement of the foot takes place in the talotarsal joints. This is illustrated in Figure 18 and further explained in the paragraphs below. Both the subtalar joint and midtarsal joint belong to the talotarsal joints.

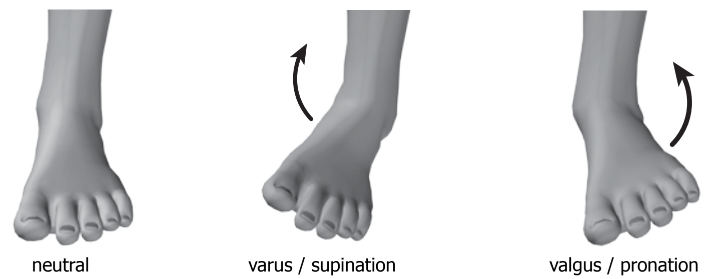


Figure 18. *Movement of the left foot facilitated by the talocalcaneal, talonavicular and calcaneocuboid joints.*

Subtalar Joint

The subtalar joint allows the calcaneus to twist relative to the lower leg and talus. This is called varus when the calcaneus is twisted to the inside and valgus when the calcaneus is twisted to the outside. An average of 5° varus as well as 5° valgus have been measured in the SFTR study.

The subtalar joint includes both the talocalcaneal articulation and the talocalcaneal part of the talocalcaneonavicular articulation. Snijders et al. describe the axis of the joint going forward and upwards starting from the heel.[24] In neutral position the axis forms a 42° angle with a horizontal line as can be seen in Figure 19. Furthermore, it forms an angle of 16° with the midline of the foot.

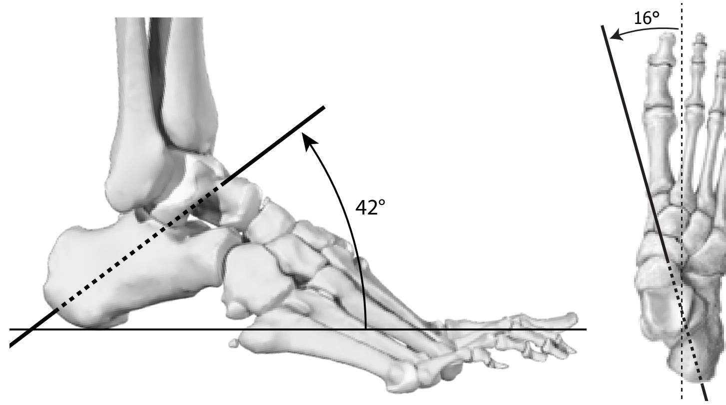


Figure 19. *The location and direction of the subtalar joint axis.*

Midtarsal Joints

The midtarsal joint allows the forefoot to twist relative to the talus and calcaneus. This is called supination when the forefoot is twisted to the inside and ronation when the forefoot is twisted to the outside. The SFTR study reports a ROM of 30° supination and 20° pronation.

Both the talonavicular and calcaneocuboid articulations belong to the midtarsal joints. Recent research indicates a single axis that is changing over time with the position of the foot.[28] However, the most commonly used model is a two axis one. The first axis being called longitudinal and the second one oblique.

The longitudinal axis forms a 15° angle with a horizontal line in the neutral position. It deviates slightly from the midline of the foot by 9° angle. The oblique axis forms a 57° angle with the horizontal line and is deviated by 52° from midline of the foot. The axes of the midtarsal joint are illustrated in Figure 20 and Figure 21 respectively.

Analysis, Joints and Motion

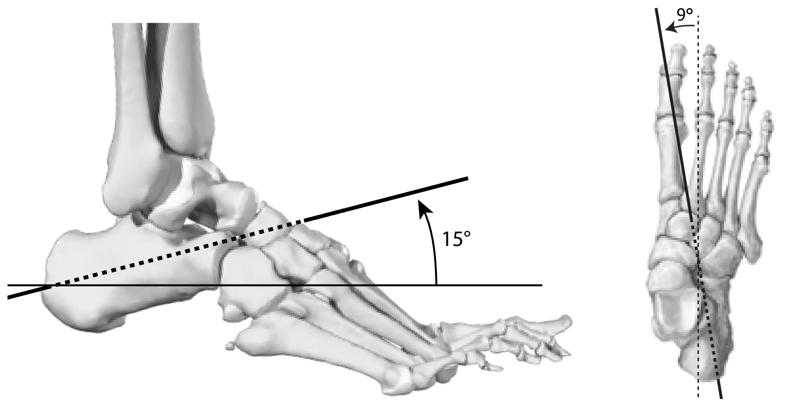


Figure 20. *The location and directions of the longitudinal midtarsal joint axis.*

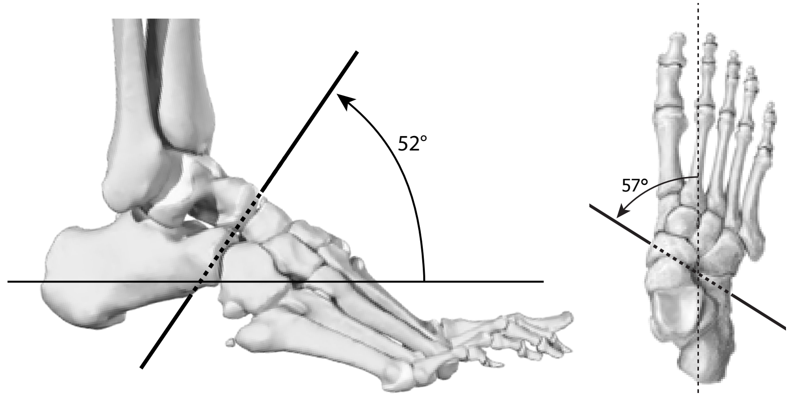


Figure 21. *The location and directions of the oblique midtarsal joint axis.*

The oblique axis allows a small degree of plantar flexion and dorsal flexion of the forefoot. However, as Tweed et al. stated, this motion is restricted when the foot is plantar flexed.[28] The single oblique axis is actually a substitute for two separate axes of rotation: one through the talonavicular and one through the calcaneocuboid articulation. When the foot is plantar flexed and supinated these axes cross and the motion is blocked. Literature about the ROM around the midtarsal axes is very scarce.

Varus and Valgus, Supination and Pronation

Since the bones in the foot are interconnected to a high degree, varus/valgus and supination/pronation cannot occur as separate movements. The foot moves for example to a varus position around an axis through the talocalcaneal joint. Consequently, the calcaneus will move and cause some pronation around the calcaneocuboid joint. The SFTR study reports a combined movement in the talotarsal joint of 30° varus/supination and 20° valgus/pronation.

Inversion and Eversion

Ankle sprains mostly occur when the foot moves into an inverted or everted position which happens when the movements described above are combined. The injuries are therefore called ‘inversion trauma’ and ‘eversion trauma’ respectively.

Inversion is the movement of the foot when plantar flexion, adduction, varus and supination are combined. Eversion is the movement of the foot when dorsal flexion, abduction, valgus and pronation are combined. These movements are illustrated in Figure 22. Adjacent joints influence each other’s ROM. Therefore inversion and eversion cannot be calculated by merely adding their sub movements.

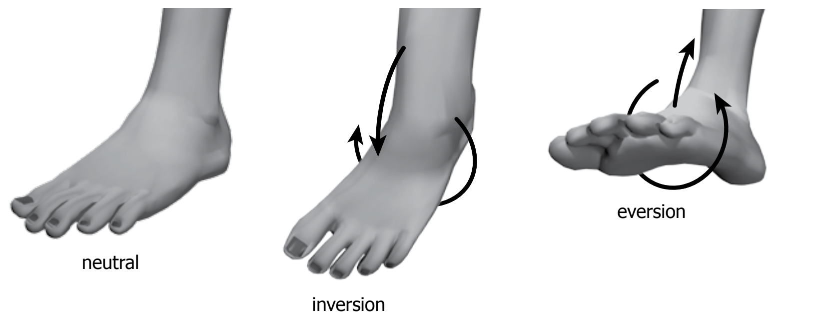


Figure 22. *The combined inversion and eversion movements of the left foot.*

Distal Intertarsal and Tarsometatarsal Joints

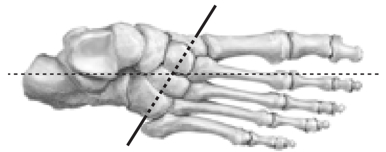


Figure 23. *The combined axis of the intertarsal and tarsometatarsal articulations. An approximation of the position and direction.*

There is only little motion possible between the articular surfaces of the navicular, cuboid, cuneiforms and metatarsal bones. Although they are strongly interlaced, Snijders stated that a combined movement up to 15 degrees plantar flexion is possible.[24] The axis of this movement is approximated and illustrated in Figure 23.

Differentiation in Range of Motion

The ROM of the ankle joint is different for every individual. It has been recorded that standard deviation of approximately 8° can be expected for plantar as well as dorsal flexion of the foot.[8] Normal data for individual difference in talotarsal motion and inversion/eversion is generally not available in the literature. It can be expected that these movements show a high degree of deviation as well.

The axes of rotation are measured from anatomical landmarks on the leg. For example, as stated above, the medial and lateral malleoli are reference points for locating the talocrural joint axis. Since anthropometric data shows huge differences in foot dimensions between people, the position of axes is also different in each foot. Additional information regarding anthropometry can be found in the 'Motion Restriction' section.

The effects of age and gender are investigated by Chung and Wang.[8] Different age and gender groups tend to have different capabilities in joint motion. The supporting tissues of the joints (eg. ligaments) tend to degenerate, and hence in general 'shrink' with increase of age, resulting in a reduction of joint ROM. Females tend to have greater ROMs in lower limb joints. This is due to slight anatomical, and perhaps physiological, differences. The amount of plantar flexion of the ankle joint appeared to reduce with 11% between younger (age 16-30) and older (age 46-64) age groups. Females had a slightly greater mean ROM than males with respect to plantar flexion (25.4° vs. 24.4°).

Besides age, gender and individual differences, other factors such as time of day, daily activities and ethnic difference may also have effect on joint ROMs. Boone and Zane state the amplitudes of motion of the left and right joints are consistently similar.[7]

Exo Ligament Consequences

The active ROMs which were measured in the SFTR study are indeed actively performed ROMs and hence are not the maximum rotations that can occur. When an external force is applied to the foot (passively performed ROMs), the joint will be able to rotate further, even before an injury happens. For the development of an ankle support it is important to know which of these motions should be allowed and which should be restricted. However, it is difficult to exactly determine an individual's maximum (passive) ROM, since applying an large force to the foot is unethical.

An external support will be able to restrict the inversion movement by restricting the rotation around the different axes. However, the ROM described in this section has to be translated to a change in distance from a point on the leg to a point on the foot, in between which the support is attached. This will be further elaborated upon in the 'Motion Restriction' section.

It was discussed that the differences in ROMs between people are large. Therefore, also the motion that should be restricted by an external ankle support will be different for most individuals. A solution should be developed that is highly and individually adjustable so that a large group of people can conveniently use the device.

Analysis, Inversion Trauma

Inversion Trauma

Together with knee injuries, the inversion trauma has been identified in many studies as the most common injury in sports such as netball, volleyball, football, hockey, basketball, and long distance running.[13,21]

Extended data are collected by the Dutch organisation 'Consument en Veiligheid' and will be discussed in this section.[12] This organisation performs a yearly poll concerning sports injuries among 11,000 Dutch people. Data concerning the population in different continents has been consulted for comparison as well.[13,15,32] The causes and risk factors associated with the inversion trauma will be discussed at the end of this section.

Ligament Sprains

In the 'Anatomy' section it was described that ligaments are connected to bones and serve to restrict the motion of a joint. However when too large a force is applied, the ligaments can get stretched and damaged. This is called a trauma or sprain.

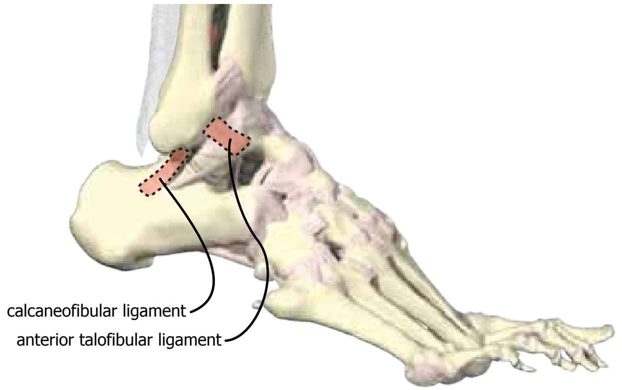


Figure 24. *The ligaments that get damaged first in case of an inversion trauma.*

The inversion trauma can happen when there is an abrupt supination/varus in combination with plantar flexion and adduction of the foot. In the 'Joints and Motion' section it was illustrated that this means the foot is twisted to the inside. The anterior talofibular ligament will in most cases be damaged first, followed by the calcaneofibular ligament.

Global Problem

A trend is identified that shows a global increase in sports activities. This mostly results in a healthier lifestyle but unfortunately also more sports injuries occur. An ankle injury happens 600,000 times a year in only the Netherlands, mainly during sporting activity.[12]

470,000 (78%) of the ankle injuries are classified as ankle sprains and only half of the victims applied for medical attention. This is likely to be due to the difference in severity of inversion traumas and people's previous experiences. The medical treatment costs of the ankle sprains are estimated to be 40 million euro yearly in the Netherlands. In addition, the costs of work absenteeism caused by ankle sprains are estimated to be 150 million euro every year. Research in the United States shows an estimate of over 2 million yearly sprains in that country at a cost of over 4 billion dollar.[6,9]

Inversion vs. Eversion

Ankle sprains occur in 75 to 80% of the cases at the lateral side of the foot.[13,33] This is consistent for recreational and competitive sports. The direction in which the foot is moved during a sprain firstly depends on external influences. When too much weight is applied to the foot and the sole points inward, an inversion trauma is likely to follow. When the sole points outward, an eversion trauma might happen.

There are some important anatomical differences that facilitate an inversion sprain as opposed to an eversion sprain. First of all, it was discussed in the 'Anatomy' section that the medial collateral ligament is relatively thick and strong. Therefore, it is able to resist larger forces.

Furthermore, the malleolus of the fibula is extending further down on the lateral side than the tibia malleolus does on the medial side. This creates a bony block to eversion since the talus is less likely to twist out of its suspension.[13]

In addition, the talocrural joint is less stable when the foot is plantar flexed compared to a dorsal flexed foot. This is explained to be a cause of the wedging shape of the talus.[5] Its width is diminishing from front to back. Figure 25 illustrates that, when plantar flexed, only the back of the talus is located between the distal sections of the tibia and fibula. Consequently the talus has more freedom of motion, this is referred to as a loose packed joint position as opposed to a close packed joint position.

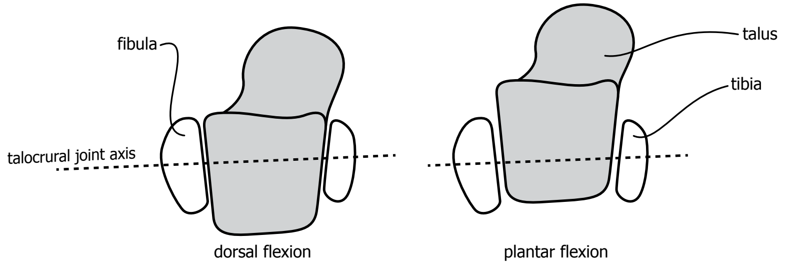


Figure 25. *A proximal view of a cross section at the height of the ankle . During plantar flexion the talocrural joint is less stable due to the wedging shape of the talus.*

Finally, it is important to not that the position of the foot during walking and running is in inversion, on the edge of the inversion trauma.

Injury Scenario

80% of the inversion traumas is the result of an unfortunate landing of the foot.[12] This can be the result of stepping on a uneven surface or landing after being disoriented. A injury scenario is illustrated in Figure 26. In most cases the victim is falling forward due to his or hers own velocity. It is as if one is rolling over his feet, which is why the injury is also referred to as a rolled ankle.

The injury mostly happens during sports involving running, cutting, jumping or physical contact. Fore example in soccer a lot of sprains are sustained during player contact.[33] It is reported that after impact by an opponent, a player is often landing with the foot in a vulnerable inverted position.

Figure 26. *Inversion trauma scenarios. The runner is landing on an uneven surface.*

Sprain Severity

When an ankle is sprained, the ligaments of the ankle are either stretched, partially torn or completely torn. Ankle sprains can therefore range from mild, to moderate, and severe.

A type 1 ankle sprain is a mild sprain. It occurs when the ligaments have been stretched or torn minimally. Symptoms might be a mild pain, little swelling, and joint stiffness. There is minimum loss of function and it is possible to return to activity within a few days after the injury (with a brace or taping).

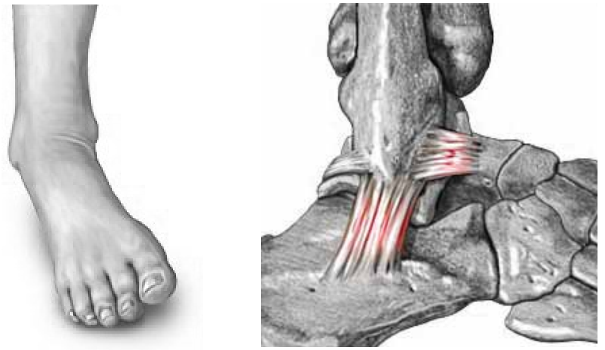


Figure 27. *Mild sprain. The ligaments are just slightly stretched or torn.*

A type 2 ankle sprain is a moderate level sprain. It occurs when the ligaments are partially torn. Symptoms are moderate to severe pain, swelling, and joint stiffness. There is moderate loss of function with difficulty of walking. It can take up to 3 months before regaining full strength and stability in the joint.

Analysis, Inversion Trauma

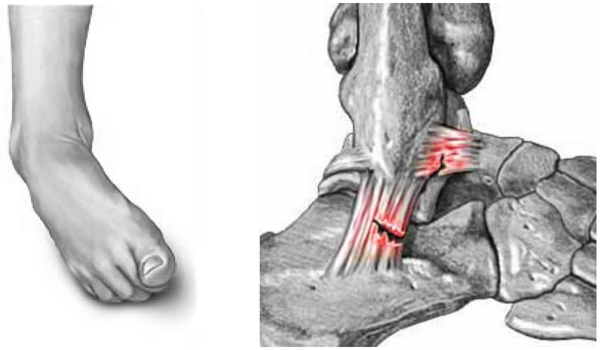


Figure 28. *Moderate level of sprain. The ligaments are partly teared.*

A type 3 ankle sprain is the most severe ankle sprain. It occurs when the entire ligament is torn and there is great instability of the ankle joint. Severe pain may be present initially, followed by little or no pain due to total disruption of the nerve fibres. Usually some form of immobilization is required for several weeks. It can be managed conservatively with rehabilitation exercises, but a small percentage may require surgery. Recovery can be as long as 4 months.

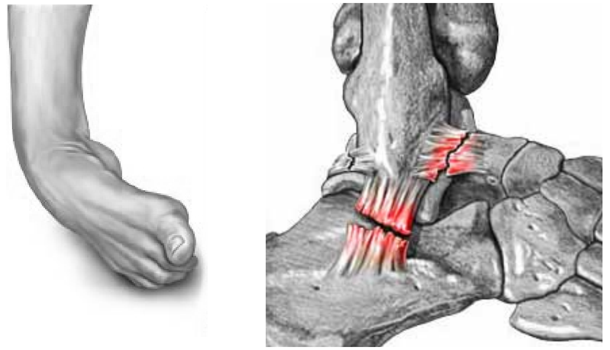


Figure 29. *Severe ankle sprain. The ligaments are fully teared.*

Recovery

Physiotherapists unanimously agree that the recovery of a sprained ankle will be most auspicious when dealt with the following guidelines carefully.

- Just after the accident the ankle should be cooled several times a day to reduce swelling and pain. The foot can be raised above heart level when simultaniously compressing the swelling. Blood flow stimulating measures like hot packs, alcohol and hot showers should be avoided. Physiotherapist H.J. Fokkers informed about a ultrasonic wave habilitation method. After a trauma it can be timely applied to reduce swelling and further stimulate the healing process. The ultrasound is able to penetrate deep under the skin.
- The ankle should be given enough rest so the ligaments maintain in a stable position and healing can occur. If pain persists it is advised against bearing a lot of weight on the ankle, however, early movement is important to inhibit tendon contractures.
- When the swelling stops and pain reduces, more activity is possible. Stretches and repetition of inversion/eversion exercises are of great importance to regain strength and stability. Exceeding ones pain limit should be avoided.
- When returning to normal activity level, special care should be taken the first year after the accident. High risk movements should be avoided and an external ankle support can be applied to reduce the risk of reinjury.

Recurrent Ankle Sprain

Not everybody is equally sensitive to spraining the ankle. Some sportsman never or seldom experiences the injury, while others are unfortunate and sprain their ankle often. This distinction is most probably due to reflex skills and anatomical differences which determine the stability of the ankle. In the case of soccer players, research showed that 48% to 73% of the ankle sprains lead to a subsequent injury.[31]

When the ankle is sprained repeatedly, one suffers from a recurrent ankle sprain. This is a serious problem since it can result in permanent damage to bone surfaces, ligaments and other tissues which introduces chronic instability. People end up in a vicious circle where every injury increases the risk for a recurrent sprain.

In consultation with Neuroscientist G.J. Kleinrensink, it was learned that, besides mechanic instability, the inversion trauma damages proprioceptive receptors in the ankle joint and ligaments. Furthermore, due to the inversion trauma, the peripheral nerves around the ankle joint can be stretched beyond their limits, sesulting in decreased motor and sensory nerve conduction velocity. As a consequence it will take longer for a signal to get, via the central nervous system, to an muscle in the foot, hence slowing down reflex responses, which are illustrated in Figure 30. A loss of proprioception results in a greater challenge to adapt to an unexpected change of motion.

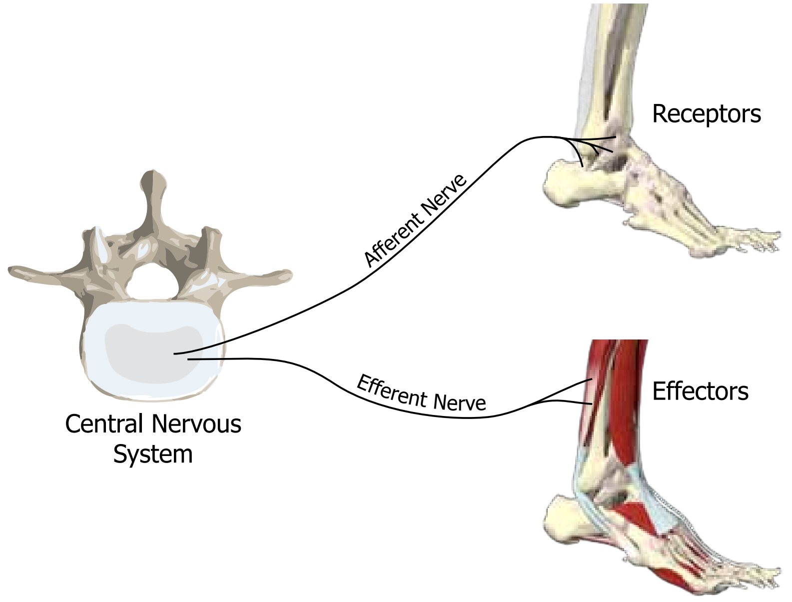


Figure 30. *Proprioception in the ankle region. Reflexes are transferred from receptors in the joints and ligaments (receptors), through the nerves and central nervous system, to the muscles (effectors) of the foot.*

Forces in Ligament

When an external force is applied to the foot it has to be transferred through the talus and the talocrural joint. The talus is loosely held into position by the ligaments around the ankle joint. Therefore, during an inversion trauma, it will be pulled out of place. Figure 31 illustrates how a force is exerted on the foot during an ankle roll as described in the 'Injury Scenario' paragraph. The talus rotates around a point at its supero-medial side and reaction forces with the tibia and fibula are generated. The motion is further restricted by the anterior talofibular ligament which, in case of a trauma, cannot transfer enough force and gets stretched or torn. The articular bone surface at the points where the talus comes in contact with the tibia and fibula can get damaged as well.

When somebody falls, an explosive inversion moment of about 50ms can be recorded. As described in the 'Anatomy' section, the fibularis brevis and fibularis longus muscles are the main evertors of the foot. However, in a reflex, the minimum time required for these muscles to react is more than 60ms which is not fast enough to accommodate the sudden explosive motion during a sprain injury.

Among the lateral ligaments the anterior talofibular ligament is the weakest. The ultimate load was measured in vitro to be 138,9N as opposed to 345,7N for the calcaneofibular ligament. The anterior talofibular ligament is approximately 20-25mm long, 7-10mm wide and 2mm thick.[13] No in vivo research is reported about the forces involved in ankle sprains. It is impossible and also unethical to conduct dynamic ankle sprain test in the laboratory.

A simple experiment with a scale showed that, by pressing the foot down in an inverted position, the pain limit was reached at a ground contact force of 300N. However, ground contact forces can be several times one's body weight after a jump. How these contact forces translate to a force in the ligament can unfortunately not be measured nor calculated easily.

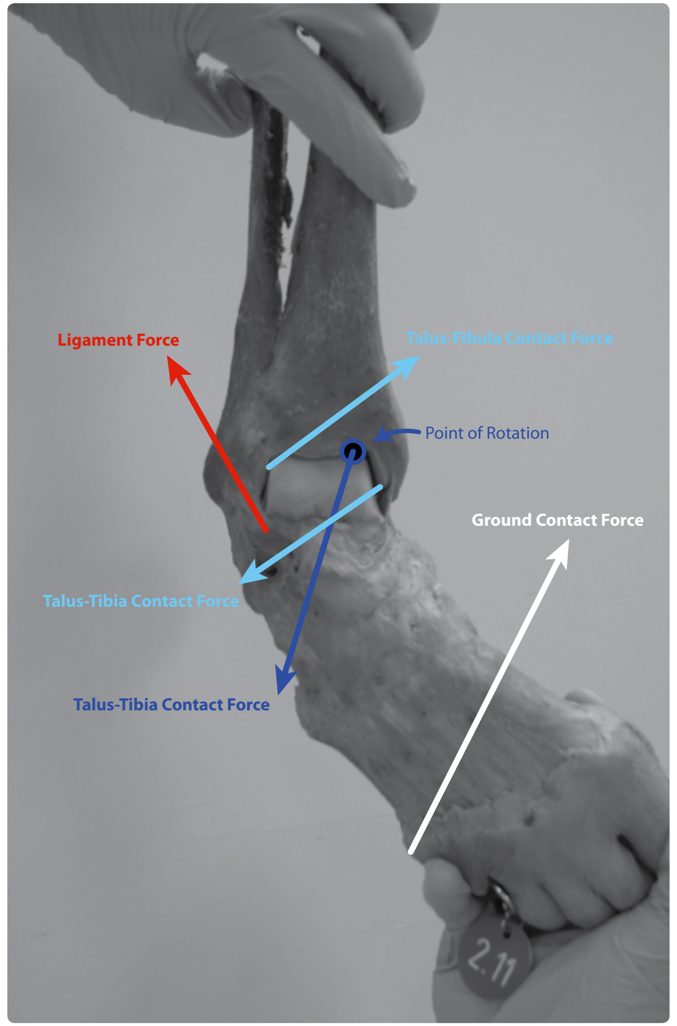


Figure 31. *An abstract representation of the forces which are exerted on the foot during an ankle sprain.*

Sports

Several studies have identified the lateral ankle sprain to be the most severe injury in multiple sports. Nevertheless, statistics are available that indicate which sportsmen suffer most.[12,30] Relevant data sets are included in Appendix A.

Table 1. ***Sports with the highest rate of ankle sprains in the Netherlands.***

	Yearly ankle sprains (NLD)	Percentage of total	Yearly victims
Soccer	186,000	31%	1 out of 5 soccer players
Running	66,000	11%	1 out of 8 runners
Volleyball	36,000	6%	1 out of 8 volleyball players

The total number of ankle sprains for a certain sport is related to the amount of people that practice this sport. Consequently, the sports that suffer most ankle sprains are not the same sports everywhere. In the Netherlands 31% of all ankle injuries happen during soccer, followed by running and volleyball with 11% and 6% respectively. In contrast, the sport with the highest rate of ankle sprains in the US is basketball.

Multiplying the above percentages with the total amount of ankle injuries every year (600.000) gives the of the amount of ankle injuries per sport. When this is divided by the amount of sportsmen practicing that sport, which data is also illustrated in the literature, an indication of the ankle injury likeliness can be calculated. It happens to 1 out of 5 soccer players, 1 out of 8 runners and 1 out of 8 volleyball players each year.

Other data is showing the total amount of sports injuries per 1000 played hours of sport, which is called the occurrence density (o.d.) Indoor soccer is on top of the list with a o.d. of 6,1. It is followed by the sports basketball, hockey, soccer, handball, karate, volleyball, running an squash with a o.d. ranging from 3,1 to 1,9 respectively. It is not completely validated to say that a fixed part of the o.d. is the result of ankle sprains, but it does indicate which sportsmen are relatively vulnerable for injuries.

Table 2. ***Sports with the highest injury o.d. in the Netherlands.***

	o.d. (injuries per 1000 hours of activity)	Amount of injuries
Indoor soccer	6.1	74,000
Basketball	3.1	51,000
Hockey	2.3	72,000
Soccer	2.1	420,000
Handball	2.1	26,000
Karate	2.1	18,000
volleyball	2.0	80,000
squash	1.7	27,000
running	1.9	110,000

More risk factors

In the literature it is illustrated that 50% of all ankle sprains is occur in people between the age of 15 and 30.[12] This is a consequence of most sportsmen being relatively young. Up to the age of 35 half of the Dutch population practices a sport and after the age of 55 this is reduced to only 3 out of 10 people.[30] The fact that most ankle sprains happen to young people is also a result of a changing emphasis in sporting activity. While young people focus on competitive sports, older people sport mainly to stay healthy.

Besides anatomical differences with respect to the ankle region there are certain body dimensions that have some influence as well. For example, people suffering from overweight are more likely go get an ankle sprain. Also foot characteristics, like a wider foot, have been mentioned to increase the risk of the injury.[22]

Exo Ligament Consequences

The development process will be focussed on preventing damage to the anterior talofibular ligament. Since this is the ligament that is stretched or torn in most cases, a solution should be developed that reduces the load on this particular ligament.

Half of the inversion trauma victims seeks medical attention while the other half deals with the problem without professional assistance. A sales plan should be developed to effectively get through to all these sportsmen that suffer from the injury. In addition, the people that are most likely to be interested in an effective ankle support are the ones that suffer from a recurrent ankle sprain. This is acknowledged by Vriend et al. in their cost-benefit analysis for ankle braces.[31]

The forces that are present in the case of a type 3 ankle sprain are very large and even braces that totally fixate ones ankle joint cannot prevent all injuries. Fortunately most of the ankle sprains are of a type 1-2 severity and can be prevented more adequately. The developed support's effectiveness has to be tested as soon as possible. In the 'Motion Restriction' section it will be discussed how the anterior talofibular ligament can most effectively be relieved of excessive forces.

Several sports with a high rate of ankle injuries are presented in this section. The development of a universal product that is applicable for all these sports would reach the biggest potential market. However, during the new product development process, it might be interesting to adapt to the needs of one or a few sports.

The highest percentage of ankle sprains happen to people between the age of 15 and 30. Furthermore, the 'Joints and Motion' section pointed out young people still have relatively flexible joins which makes them an interesting focus group during the early development process.

The discussed risk factors increase the likeliness of suffering from an ankle sprain. However it should be kept in mind that it is most important to keep the ankle healthy. Sufficient exercise will strengthen one's ligaments and movement skills to prevent an injury.

External Ankle Support

Research has indicated that external ankle supports and tape both reduce the risk of ankle injuries in sports.[2,3,14,10] The current prevention methods have been discussed with sports physiotherapists and other medical specialists. Their opinion is not analogous on all subject matter, but together with data from the literature, a coherent overview is generated. This section discusses the (desired) effects of external ankle supports and gives an overview of the current ankle supporting products on the market.

Mechanic Support

The most obvious effect of an ankle brace is its mechanic support to stabilize the ankle joint, however, this is also the most overestimated aspect. The forces that are exerted on the talocrural joint and the lateral ligaments, when full body weight lands on an inverted foot, are very high. No brace is available that can prevent all injuries. As discussed in the inversion trauma section, a brace that effectively gives mechanic support can only prevent injuries where the present forces are relatively small, or reduce the severity of injury in case of a type 1-2 sprain.

It is often suggested that the use of a brace reduces one's own ankle activity which might weaken muscles and ligaments and increase the risk of injury. Since this could be a serious argument against the use of ankle support, physiotherapists have been contacted for clarification. It is their prevailing belief that the above is very much exaggerated since sports usually require a high level of ankle activity, despite the use of a braces. Exercising will never reduce one's strength. In addition, recent studies have shown that muscles latency to inversion did not change after consistent ankle brace use.

Furthermore, Physiotherapists stated that the muscles only play a small role in preventing the injury so training them does not directly reduce the risk for an ankle sprain. This is due to the fact that the reaction time of the muscles is often too long which is discussed earlier in the 'Inversion Trauma' section.

Foot Position at Impact

An indirect consequence of a brace's mechanic support is the ability to control foot position when the foot is hanging in free air. This can be during the swing fase of running or during a jump. A sprain is less likely to occur when the foot lands in a neutral position as opposed to an inverted position.

The aim of most braces is to restrict inversion motion. This can have considerable effect in free air since no external forces are applied to the foot. It is suggested that ankle bracing or taping corrects ankle joint positioning at landing rather than provide mechanical support to the ankle joint.[13]

Increased Exteroception

As mentioned before when discussing the recurrent ankle sprain, proprioception is the ability to sense where ones body is in space. It is easier to adapt foot position with a good sense of the relative position of neighbouring parts in the ankle region. Besides proprioception there is other sensory input, like vision, that improves one's coordination skills. Although often confused with proprioception, the sensitivity to stimuli originating from outside the body is called exteroception.

When the foot moves into an inverted position, a support often puts pressure to the user's skin. When this is recorded in an early stage by the nerve endings in the skin around the ankle region, the muscles might act to correct foot position and prevent an injury. However, since this happens unconsciously it is difficult to justify this effect of an ankle support.

The pleasant supporting feeling of an ankle support is related to the discussed proprioception and exteroception. Although mechanically ineffective, a brace can still help a user to feel more secure and as a result move more naturally. And this, in turn, increases the user's own coordination skills.

The best known method for preventing ankle sprains is the use of a tape, and up to now, physiotherapists and their patients still consider this to be the most favourable option. The supporting effects of a tape are not inferior to the other supports discussed in the next paragraph.[10] Furthermore a taped ankle fits easily in one's shoe and it is relatively comfortable to sport with.

The supporting effects of tape have been widely investigated and will be further discussed later in this section. It is concluded that the use of tape can reduce the number of injuries. However, there are some disadvantages to taping as well.

To begin with, a tape should be applied carefully to have the desired effect, ideally by a professional. It is a time consuming job, and the costs of taping can be very high over time.

Additionally, the use of tape can cause irritation to the skin. Special (expensive) kind of tapes should be used to prevent this problem. Furthermore it has been recorded that the effect of a tape reduces during exercise. Movement and sweat will cause the tape to loose its adhesiveness.[10]

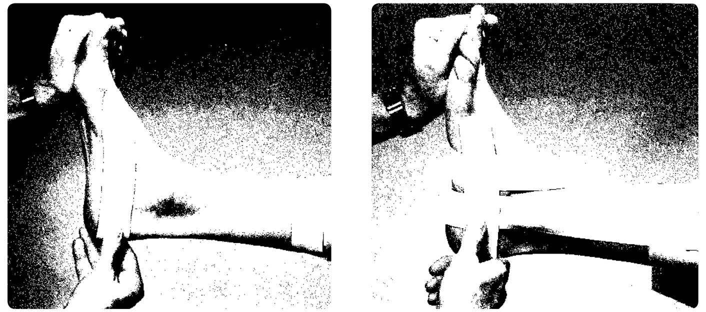


Figure 32. *Pull-on bandage type braces. Left: Rucanor 'Lightweight', right: Push 'Med '.*

Currently Available Ankle Supports

This paragraph illustrates the type of ankle supports that are widely available and which can be used during sports. Their construction ranges from semi-rigid to elastic and their fastening methods differ. The products that are displayed as a reference are the most popular ones in their class and are developed by European and American companies.

Figure 33. *Semirigid type braces. Top left: Push 'Aequi', top right: Mc David 'Ankle x', bottom left: Ankle Active 'T1' , bottom rigth: Bauerfeind 'Malleoloc'.*

The rigid type braces which can be seen in Figure 33 are constructed with one or more rigid parts which are fixed around the lower leg. Supination is restricted by a part of the brace that extends downward on the sides and underneath the sole of the foot. In some cases extra support is supplied by straps. The braces are blocking some of the foot's active ROM although plantar/dorsal flexion is claimed to be maintained. For this reason the T1 and 'Ankle x' feature a hinge. They are not comfortable to wear in a shoe and look, except from the 'Aequi', quite bulky. The rigid parts are tightly fixed against the leg which causes discomfort, especially at the edges. The Malleoloc partly overcomes this problem with a material on the inside of the brace that can be shaped to better fit the user.

Figure 34. *Pull-on bandage type braces. Left: Rucanor 'Lightweight', right: Push 'Med '.*

The pull-on bandage type braces are mimicking the principle of a tape job. They are illustrated in Figure 34. A strap is pulled around the ankle joint in a 8-figure which is applied on top of a (neoprene) sleeve. They are relative comfortable to wear, although over time, they can exert irritating pressure onto the skin. Their supporting effect varies between different materialization, for instance more elastic straps offer increased flexibility but less support.

Figure 35. *Lace-up type braces. Left: Active ankle 'Lightweight', right: Mc David 'power lacer'.*

The lace-up type braces illustrated in Figure 35 make use of a non-stretching carcass that is wrapped around the ankle and tightened with a lacing system. The braces offer relative effective support but unfortunately also reduce the active range of motion by fixating a part of the forefoot. Some versions offer reinforcement by a strap as seen by pull-on type braces.

Figure 36. *Elastic wrap type braces. Left: Bauerfeind 'Malleotrain', right: Thuasne 'Elastic wrap'.*

The elastic wrap type braces which can be seen in Figure 36 are made from a stretching material and can be worn as an additional sock. They offer the most flexibility but very little mechanic support. Their only function is to give some compression and thereby supplement the proprioception with exteroception.

Properties and Price

The products that can be seen in Table 3 have been tried for the sake of this research. Some are available in general sports shops, others can only be found in specialized stores. The price of a brace differs per type and brand, from dozens to a hundred euro.

The comments about support that are made in Table 3 apply to the mechanic support of the braces. This was tested by pushing an inverted foot on the ground.

Table 3. ***Tested ankle brace properties and prices.***

 Bauerfeind 'Malleoloc'	+ Good support. + Plastic forms to foot. - Restricted in motion. - Complicated to fit and bulky.	€95
 Push 'Aequi'	+ Moderate support. + Rigid part is not bulky. - Edges of rigid part hurt the skin.	€90
 Push 'Med'	+ Easy to fit in shoes. - Limited support. - Time consuming fixing procedure. - Edges of strap compress the skin.	€90
 Mc David 'Ankle x'	- Limited support because of inproper fitting. - Most difficult to get use with shoes.	€80
 Mc David 'lighweight'	+ Good support. + Easy to fit in shoes. - Reduction of active ROM. - Time consuming fixing procedure.	€35
 Rucanor 'Lightweight'	+ Little reduction of active ROM. - High compression of skin by neoprene sleeve. - Limited support	€15
 Thuasne 'Elastic wrap'	+ No reduction of active ROM. + Comfortable to wear. - Very limited support	€15

Comfort vs. Support

Figure 37 illustrates how the different braces can be distributed on a comfort versus support scale. It can be seen that effective support of the ankle comes in most cases with reduced comfort. This is due to the braces becoming more bulky and motion restrictive, thereby exerting irritating pressure onto the skin.

The use of these inconvenient products would not have to be taken for granted when there would be a solution that is comfortable to wear, yet gives effective support. Such product is currently not available and therefore subject of this new product development. It will have to be positioned in the orange area of Figure 37.

Figure 37. *Distribution of tested ankle braces on a comfort vs. support scale.*

A research was conducted to find out what people consider to be good braces in terms of comfort and support. They were not asked to test the braces, but instead give a similar distribution as illustrated by Figure 37, according to their expectations. Figure 38 shows an impression of the results, which are included in appendix B. In general can be said that rigid braces convey a feeling of security at the expense of comfort.

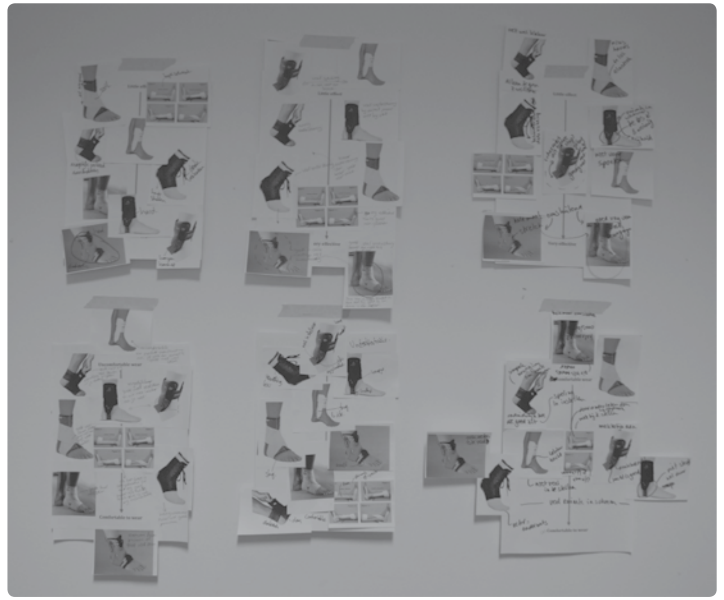


Figure 38. *Impression of comfort vs. support research.*

Practical Ankle Support Use

In consultation with different medical specialists and several brace users, a better understanding was created of the practical use of ankle supports. The amount of affinity people have with ankle supports is related to their injury vulnerability. To illustrate this, Figure 39 is showing a division of sportsmen on a vulnerability scale.

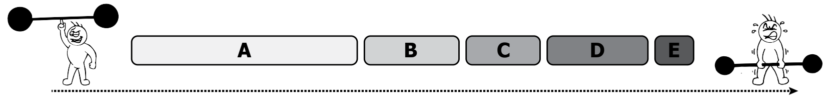


Figure 39. *Division of sportsmen on a vulnerability scale.*

First of all, as discussed in the 'Inversion trauma' section, there are a lot of people with relatively stable ankle joints (A). They never, or very rarely, sprained their ankles and do not really need to use an ankle support. There is also a group of sportsmen that occasionally sprains their ankle, but is reluctant to use the currently available ankle supports (B).

The people that actually use the conventional ankle supports can be further divided into two categories. There are those that only use a support for a certain time after suffering from an injury (C) and those that always use a preventive product (D). Sports physiotherapists argue that, amongst people with relatively instable ankle joints, more attention should be given to prevention. This implies an enlargement of group D in despite of group B and C.

The last group is formed by sportsmen who have chronic instable ankle joints (E). To practice their preferred sport they need a 'medical' brace, which needs to be individually modified to their needs by a specialist. These braces have to be produced very solid to restrict certain motions. This specific category is not subject of this investigation and therefore not included in the above description of conventional braces.

Cost-Benefit Analysis

Before introducing and promoting a new product on a large scale, an extensive analysis has to be performed to validate its effectiveness. Economic costs like purchase price, work absenteeism and medical costs have to be addressed.

A cost-benefit analysis (CBA) for the use of ankle braces in soccer has been performed by Vriend et al. in 2005. They focussed on people suffering from a recurrent with a number to treat (NNT) of 5. This means that, for every 5 soccer players using an ankle brace for an entire season, one ankle sprain can be prevented. Considering the average cost for an ankle brace and the costs for medical attention and work absenteeism, they concluded it is not economically effective to use ankle braces when playing soccer.

From an economical point of view an intervention only becomes effective when a cheap yet suitable brace is introduced and the population of users has a high risk of injury.

The outcome of a CBA will be different for every sport and population and Vriend et al. illustrate a number of factors that are highly variable which could influence their results. Moreover, consequences like reduction in quality of life and athletic absenteeism were not addressed in the above mentioned research. They may be more important to the user than economic value. As a result, if these factors could be expressed in money, it is likely that using ankle braces turns out to be effective in all cases.

Exo Ligament Consequences

Different brace effects have been discussed in this section. This includes mechanic support, foot position at impact and exteroception, which all rely on intervention of the external support. However it was also learned that this intervention introduces discomfort in case of the most effective braces. Figure 40 visualises one method of how it is thought that the discomfort can be reduced. Instead of fixating the ankle, the Exo ligament concept has to allow more flexibility (ROM), yet still provide effective support when the maximum ROM of a user is reached.

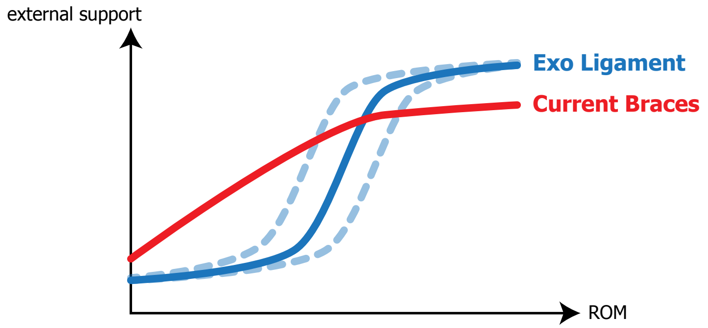


Figure 40. *Reducing discomfort by allowing more flexibility.*

The exact ROM/external support ratio which is suitable for an individual is hard to predict and will be slightly different for everyone. It could therefore be an opportunity to provide some adjustability, which is illustrated by the dotted blue lines in Figure 40.

It has to be taken into account that the price of currently available external ankle supports ranges from €15 to €100. For the future product to become successful on a large scale, this price should not be exceeded. In addition it should be considered to perform a cost - benefit analyses and scientific testing procedures before introducing a new external ankle support concept to the market.

Motion Restriction

The inversion trauma mechanism and the use of an external ankle support have been discussed in the previous sections. It was explained that an ankle support can supply mechanic support as well as influence foot position at impact. This section summarizes the efforts that have been taken to investigate how these effects can be optimized in a product that is comfortable to use and wear.

Ankle Support Connection

An external ankle support is activated, when during the inversion movement the foot moves away from the lower leg. This motion can be restricted by an ankle support when it transfers a force between the leg and the foot as illustrated in Figure 41.

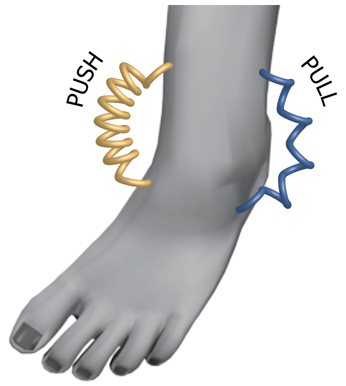


Figure 41. *An ankle support can help to restrict the inversion movement of the foot. It pulls at the lateral side and pushes at the medial side.*

The location and method of attachment to both the leg and foot have to be chosen carefully. First of all it has to be at a place where forces can be exerted without trouble. In addition, the effectiveness of an ankle support can be improved when the attachment points move further away from each other during the inversion movement. This is explained by a greater opportunity for motion restriction when a large displacement occurs between two points and a force can therefore be applied over a longer distance. This is illustrated in Figure 42.

Figure 42. *It is easier to restrict a motion to point B compared to point A.*

The connection will, in any case, show some elastic properties. This is due to the flexibility of the support itself and the connection to skin or clothing instead of rigid bones.

Computer Model

The possibility of using a computer model for further investigation has been explored. It was discovered that the biomechanical aspects of muscles, bones and ligaments have been incorporated into many models over the years. Some advanced models of the foot have been developed by XYZ Scientific Applications under the name Truegrid.[27] They offer a finite element model of the human foot which is illustrated in Figure 43. The model includes bones, ligaments, plantar soft tissue, and cartilage.

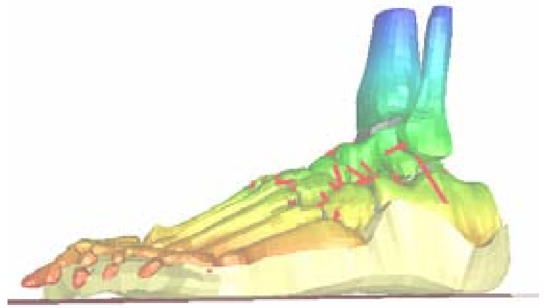


Figure 43. *Truegrid finite element model of foot .*

However, when developing a product that has to be attached to the skin, these models are not of great use. Factors like the deformation of soft tissue and sliding of a fixture relative to the skin are not taken into account. This was confirmed in consultation with F. van der Helm, who developed a biomechanical model at the University of Twente himself.[18] There is no comprehensive model available yet that could serve to effectively test a new sprain preventing product.

Experiments with the Truegrid software already produced a more detailed model of the forefoot which can be seen in Figure 44. It calculates deformations of soft tissue by external interventions. Further development of this concept hopefully enables computer models to effectively support product development in the future.

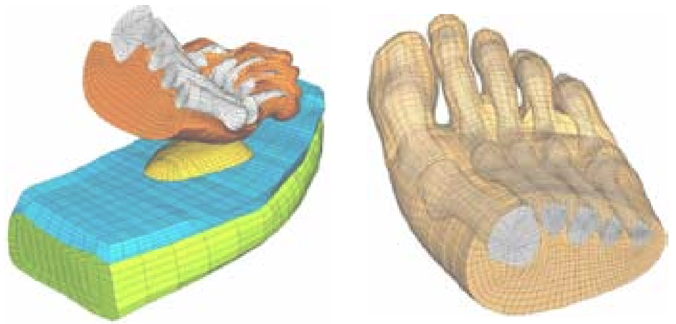


Figure 44. *Truegrid model of forefoot.*

Motion Measurement

The range of motion (ROM) of the foot has been discussed in the 'Joints and Motion' section. The position of the rotation axes and the separate movements they allow are described in detail. The following paragraphs demonstrate how the ROM of the joints is translated to displacements that can be recorded outside the body.

Figure 45 shows the foot when looking perpendicular to the axes (red dots) around which plantar flexion and supination take place. It is illustrated what happens with the distance between a fixed point just above the ankle region and another one on the foot during a 25° rotation. These points are chosen so that the direction of restrictive forces is similar to those described later in this section.

Some basic assumptions can be made concerning the motion that will be restricted by a connection between the fixation points. Supination is avoided to a greater extent than plantar flexion since the supination motion takes the spot on the shoe far away from the leg fixation (purple lines). Because the leg fixation is positioned close to the talocrural joint axes, there is little increase of distance during plantar flexion (green lines). However, in case this point of fixation is moved to the front, plantar flexion will be more effectively restricted when desired (blue lines).

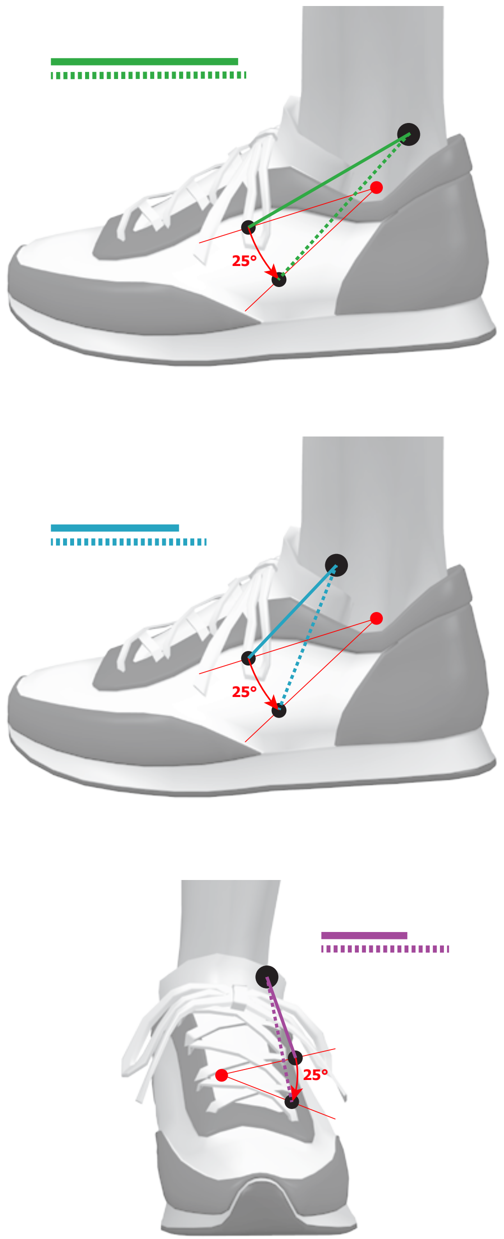


Figure 45. *The foot when looking perpendicular to the axes of rotation.*

3D Scanning

As discussed in the 'External Ankle Support' section, a support should preferably be applied such that the fatal inversion movement is restricted, some supination is allowed, and plantar flexion is for the most part unrestricted.

The illustrated rotations in Figure 45 are two dimensional. They give an indication of what happens when trying to restrict the supination and plantar flexion motion, but unfortunately cannot be directly translated to the three dimensional inversion movement.

A 3D scanner was used to record changes between the neutral and inverted position of the foot, an explanation of the process has been included in Appendix C. The distance change between several marker points was measured by drawing curved lines over the model surface as illustrated in Figure 46.

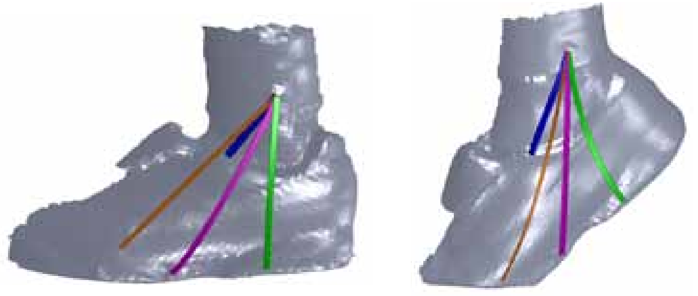


Figure 46. *Distance change measured with 3D-scan.*

The inaccuracy of the scanner turned out to be approximately half a centimetre which is too much for proper further investigation. Nonetheless it was recorded that the distance change from the ankle marker to a point on the shoe was biggest in an antero-inferior direction. This is illustrated by the blue and orange lines in Figure 46. Another distance change measuring method is proposed in the following paragraph.

Manual Measurements

Further research was conducted by manual measurements to more thoroughly investigate distance changes during supination, plantar flexion and inversion. First, a pilot was conducted with one subject to record the motion between multiple marker points on the leg and foot side (both bare feet and with two different shoes). The most interesting connections were subsequently measured with 5 additional subjects. The relevant findings will be discussed below. A detailed description of the process and the result are included in Appendix D.

Figure 47. *Measurements between markers at the leg and shoe/foot.*

- It is suggested before in the 'Joints and Motion' section that there is a high variation in ROM between people. Consequently there will be a high variation in the change of distance between fixation points on the leg and foot. To purely measure the influence of ROM, people with the same shoe size (42-43) were chosen as subjects for this investigation. They were wearing the same shoes to ensure the marker points to be at the same position during each measurement. Even between 5 subjects a high variation was measured. It can be assumed that the variation will be even higher when including different foot sizes.

- An ankle support can restrict the inversion motion by pushing at the medial side or pulling at he lateral side of the foot as was illustrated in Figure 41. Therefore, the measurements included the lengths of possible connections at the medial and lateral side. A brace will push at the medial side of the foot when the distance between a fixation point on both the leg and foot becomes smaller. Supination reduces this distance, though plantar flexion brings the points of attachment closer to each other as is illustrated in Figure 48. Consequently an ankle support at the medial side of the foot will restrict supination more than it restricts the inversion. Only a fixation point at the heel would move closer to the leg during plantar flexion, the movement caused by supination is very small at the heel area. It was therefore determined that the inversion can most effectively be restricted at the lateral side of the foot. In that case an ankle support restricts the movement by exerting a pulling force at the foot when the distance between the leg and foot becomes bigger. This happens during both supination and plantar flexion which was illustrated in Figure 45.

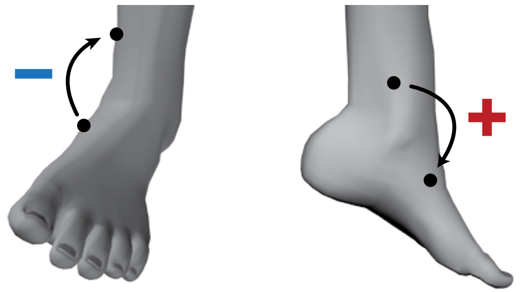


Figure 48. *fixation points moving towards each other during supination and away from each other during plantar flexion.*

- The most effective and convenient locations for fixating an ankle support are highlighted in Figure 49. It is a point at the postero-superior side of the lateral malleolus and a point around the postero-lateral side of the foot's dorsal arc. A force can effectively be transferred to the lower leg when directed from marker I to marker B. In that case the support will be able to make use of a form lock which will be further explained in the following paragraphs. The data about the distance change between marker I and marker B between neutral and supinated (s-n), pronated (p-n) and inverted (i-n) position of the foot is summarized in Table 4. It is considered to be a good direction for connecting the foot to the lower leg since the distance between marker I and marker B changes a lot. Furthermore, the fact that the marker on the foot moves further away from the marker on the leg during inversion than it does during plantar flexion (i-p) and supination (i-s), ensures the inversion movement is most restricted. The distance change between markers on a bear foot were measured to be smaller. A marker in the same direction but applied around the sole of the foot shows even bigger changes in distance to marker I but it is less convenient to attach an ankle support at that location.

Table 4. ***Difference in I-B distance between neutral and rotated positions***

	s - n	p - n	i - n	i - s	i - p
Average	12	9	20	8	11
Maximum	24	10	29	12	20
Minimum	8	5	14	4	4

Figure 49. *markers I and B on the lateral side of the leg and foot.*

Sequence of Prototypes

It was discussed in the 'External Ankle Support' section that the attachment of an ankle support to the lower ankle region is one of the biggest challenges to face. During the development of an improved attachment method several prototypes were made. An ankle support that effectively transfers forces, yet does not introduce discomfort, had to be physically tested.

The following paragraphs illustrate how the support evolved from a strap around the ankle to a simple form lock. The prototypes illustrated in Figure 50 were used during sporting and normal activity as well as tested with a dedicated testing apparatus which is explained in the following paragraph.

Figure 50. *Sequence of prototypes.*

Testing Apparatus

The ability of the prototypes to transfer a big force to the lower leg has been tested with the apparatus shown in Figure 52. More about the construction and an explanation of the testing procedure, as well as the testing results are included in Appendix E.

The testing subject's leg was fixed to the platform on which he was sitting and the foot was fixed in an inverted position. The ankle supports were attached to the lower leg and tensioned by a rope in the direction as described earlier in 'Manual Measurements' paragraph. This way the attachment to the leg could be tested with high forces (up to 500N) but without any risk for sprain injuries.

The applied force was measured with a force gauge and first gradually increased till 300N or till discomfort arised. Subsequently high impact forces were applied by pulling the rope instantaneously. Images from a high speed camera were used to analyse how much the ankle support moved relative to the leg during the impact.

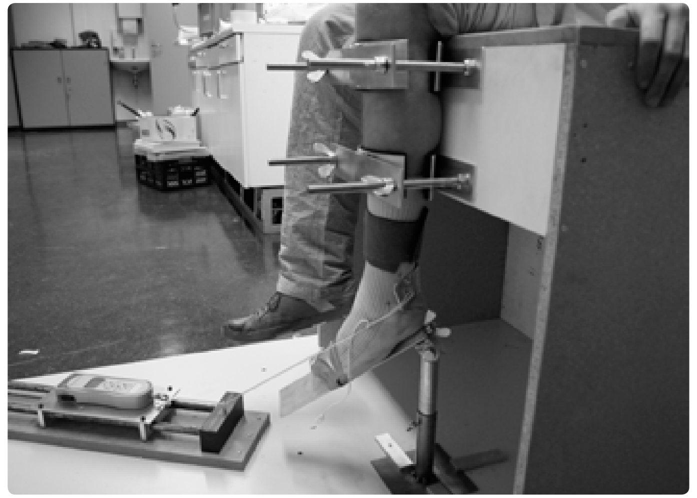


Figure 51. *Fixation of the leg and attachment of ankle support.*

Figure 52. *Testing apparatus.*

Prototype Phase 1

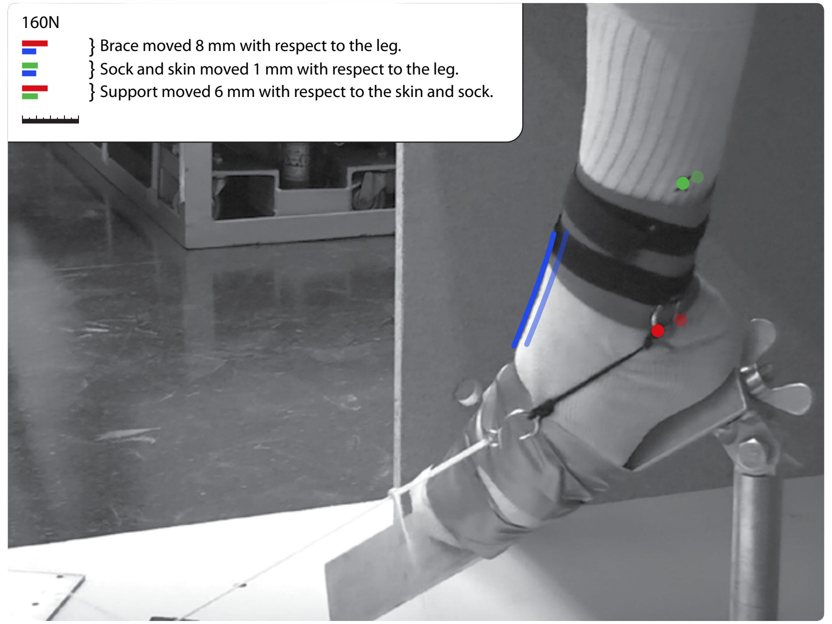


Figure 53. *Testing prototype 1.*

The first prototype was produced in an early stage of the development process. A band is strapped tightly around the ankle such that a metal ring is positioned on the lateral malleolus. When an external force is exerted, this ring is pulled against the malleolus to provide an opposing force. In addition, the friction between the band and the leg will further prevent the support from twisting around the ankle. An approximation of the involved forces is illustrated in Figure 54.

When pulling with a force above 100N, some discomfort was present. The metal ring is restricting the brace from moving but also introduced a painful pressure to the skin. It was understood that a force can effectively be exerted onto the lateral malleolus although the shape of the support should be designed ergonomically to increase the comfort.

Furthermore, it was discovered that tightly strapping something around the ankle reduces one's flexibility to move. This is because too much continuous pressure will be exerted onto the tendons which are discussed in the 'Anatomy' section. Especially the tendo calcaneus is not able to move freely anymore. A solution should be developed that positions the support around the malleoli, yet does not have to be strapped around the ankle tightly.

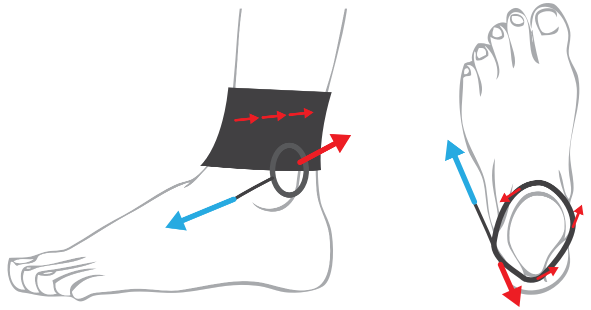


Figure 54. *Prototype 1 force transfer.*

Prototype Phase 2

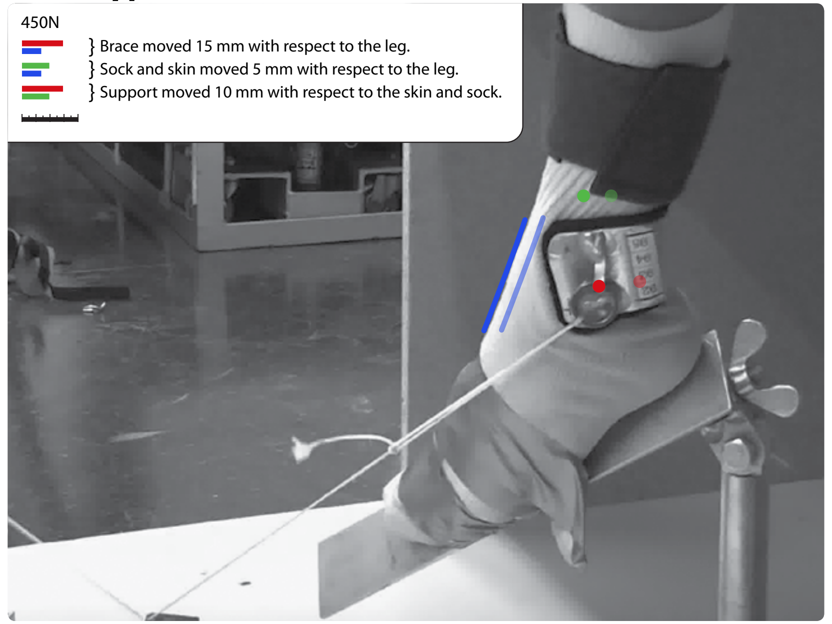


Figure 55. *Testing prototype 2.*

The second prototype is made by forging an aluminium sheet such that it fits the subject's ankle. An external force is applied around the lateral malleolus to a welded fixture at the outside of the support. A rigid material is used to ensure the support does not deform when it hits the malleolus.

The support is strapped around the ankle with a neoprene band. For this purpose an extrusion of the aluminium is positioned at the medial side of the leg, against the surface of the tibia. This ensures the support is not rotating around the pressure point at the lateral malleolus when an external force is applied. An approximation of the involved forces is illustrated in Figure 56

The aluminium is shaped in such a way that the tendo calcaneus is able to move freely. While being in contact with the malleoli, the support leaves some space at the posterior side of the leg.

When an external force of over 300N is applied, some discomfort arises. In comparison with Prototype 1, the force is exerted onto the malleolus more effectively. However, some local pressure points still exist. This is due to the fact that the forged aluminium still does not supply a perfect fit to the shape of the subject's ankle. A solution should be developed that better distributes the forces over a larger area of the malleolus.

The movements of the support that are recorded when applying momentary impact forces were slightly different each time. They ranged from 10-20 mm with an applied force around 400N. This is assumed to be due to the initial positioning of the support. Since it does not fit the ankle region perfectly, it can be positioned wrongly without being aware of doing that. A solution that better fits the user's ankle will less likely be positioned wrongly.

The freedom of motion for the tendo calcaneus was experienced as a big improvement. Since the band around the leg is not positioned high above the area where the tendons have to move a lot superficially, it did not introduce discomfort.

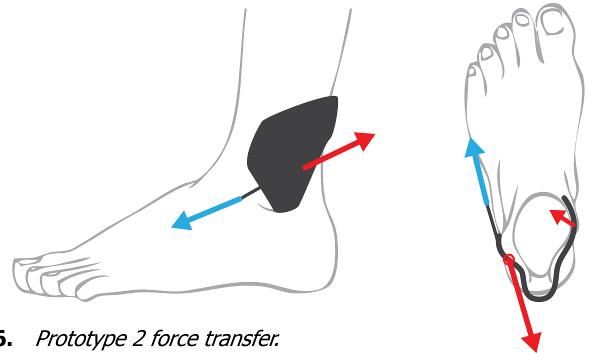


Figure 56. *Prototype 2 force transfer.*

Prototype Phase 3

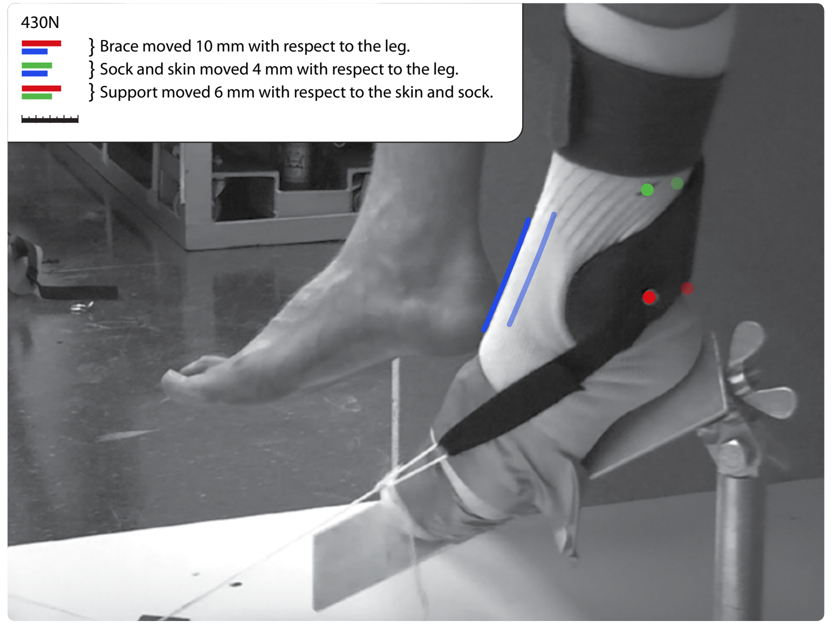


Figure 57. *Testing prototype 3.*

A similar support as prototype 2, yet one that perfectly fits the subject's ankle is made by forming it on top of a mold. Therefore a copy is made of the user's ankle region with a 3D scanner. The scan is edited with CAD software to get the desired support shape with a recess at the back for the tendo calcaneus.

Figure 57 shows a version of the phase 3 prototype made with carbon fibres. This material introduces an increased stiffness as compared with a plastic version without increasing weight..

An insert is fixed in between the carbon fibers to apply an external force. A thin neoprene padding is attached to the inside of the support and extends to form the band around the leg.

Due to the perfect form lock to the ankle, little discomfort arises at the malleoli regions when applying a force over 300N. However the sharp edges of the carbon support are introducing discomfort at the lower edges. In addition, the shoe came too much in contact with the brace while walking. A solution should be developed that does not have sharp edges pointed towards the body and is positioned slightly higher as is illustrated in Figure 58. The support does not have to be positioned lower than the most extruding parts of the malleoli.

As is illustrated in Figure 57, the brace moves around 10mm with respect to the leg when momentary impact forces are applied. A small part of this movement is due to the movement of the skin and sock. The remaining part of the displacement can be attributed to the movement of the support with respect to the skin and sock. It is assumed that the neoprene band around the leg is not able to prevent the support from twisting around the leg. A solution should be developed that makes use of the medial aspect of the support more effectively.

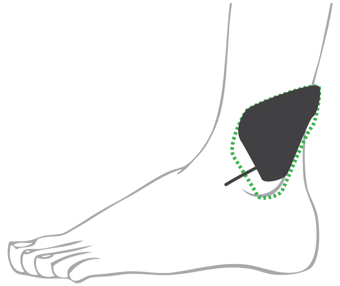


Figure 58. *The support does not have to be positioned below the most extruding part of the malleolus.*

Prototype Phase 4

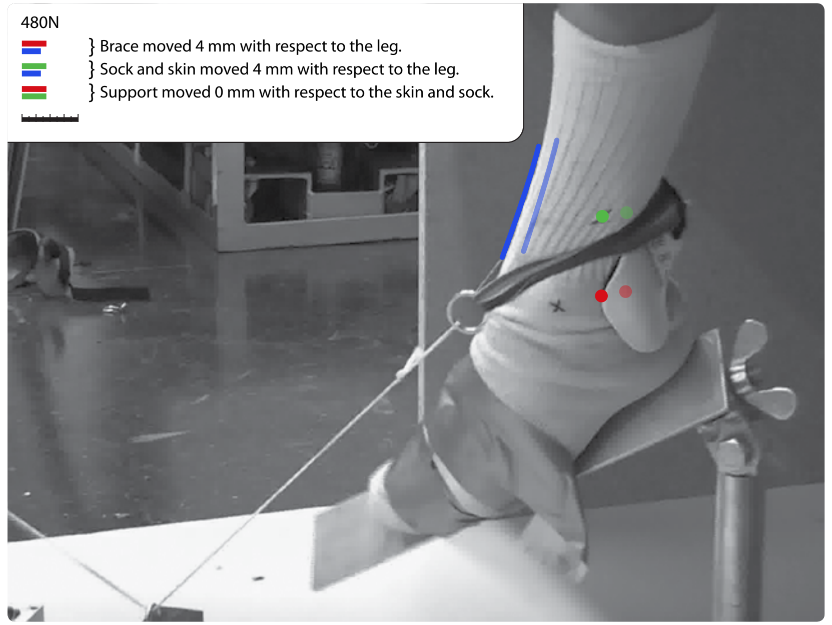


Figure 59. *Testing prototype 4.*

The fourth prototype is made using the same mold as was used for prototype 3 only this time a 4mm thick polystyrene plate was vacuum formed. This prototype allowed to test another method of attachment to the leg. A strap is fixed to the medial side of the support and connected with Velcro to the lateral side of the support after being guided through a fixture on the foot or shoe. This ensures the support will not twist relative to the leg since the forces are divided between the lateral and medial side of the support. An approximation of the involved forces is illustrated in Figure 60.

The connection with Velcro around the back of the support is positioned too high. When a force of over 300N is applied the support tends to tilt forward and the forces are not properly guided to the malleoli areas anymore. A Velcro connection is not strong enough to transfer the involved forces so another solution has to be developed.

The support is too flexible at the most posterior section. As can be seen in the proximal view of Figure 60, the involved forces will try to open up the support. When it is not stiff enough it will be pulled over the malleoli which reduces the effectiveness of the support and can cause discomfort at the heel.

When using the prototype during normal and sporting activity it was discovered that some areas of the support should be extended to prevent discomfort where the support presses on the skin. In Figure 62 can be seen how the next prototype is extended to the front at the medial side and more rounded at the lateral side as opposed to prototype 4. The connection of the straps is lowered as well to more effectively distribute the involved forces.

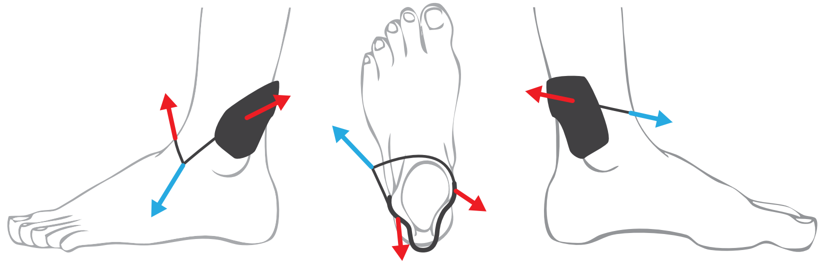


Figure 60. *Prototype 4 force transfer.*

Prototype Phase 5

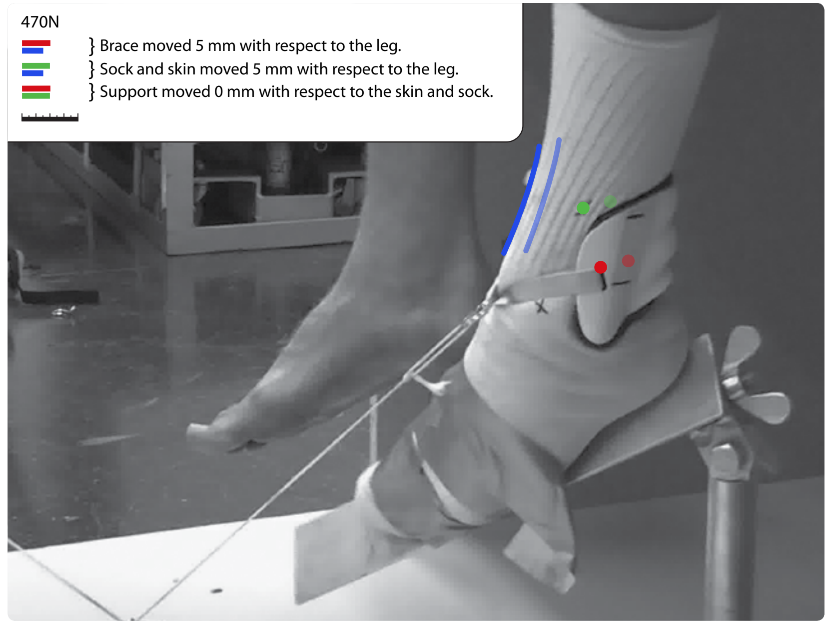


Figure 61. *Testing prototype 5.*

The fifth prototype is an improved version of the fourth prototype. It is also vacuum formed, although with a even thicker plate and an adjusted mould. The posterior side of the support is slightly higher and equipped with a wavy shape to make it stiffer. A strap is fixed to the lateral side of the support and connected to a buckle at the medial side.

The only discomfort that is experienced when a force of 300N is applied, is the edge of the strap that is connected underneath the plastic. Apart from that, the improved shape and stiffness of the prototype ensures the involved forces are distributed to the malleoli area effectively.

When momentary impact forces were applies to the support, it moved only half a centimetre relative to the leg. This was repeated several times without arising discomfort. It is assumed that this movement is mostly due to the elastic properties of the skin and sock.

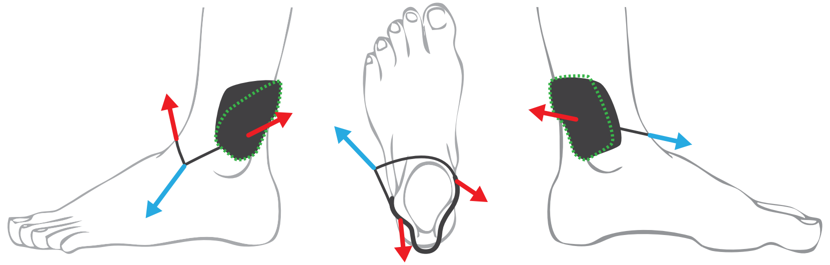


Figure 62. *Prototype 5 force transfer.*

Correct Force Transfer Validation

Since the strap is connected to an additional point on the support, one around the medial malleolus, the change in distance to a point around marker B as described in the 'Manual Measurements' paragraph, had to be verified. For the support to work effectively, this distance should increase when the foot is inverted.

The distance to a point on the lateral edge of the shoe was measured in a neutral, plantar flexed, supinated and inverted position of the foot with 20 subjects, the data is included in appendix F. It was discovered that the distance increases with a similar amount during supination and inversion. The distance from the lateral malleolus to the same point increases more during inversion than during supination and plantar flexion. This is in accordance with the earlier measurements, discussed in the manual measurements paragraph. In conclusion, the supination and inversion movement will both be supported. Inversion to slightly greater extend compared with supination. Figure 63 illustrates the involved forces at the location of a fixture on the shoe or foot as described in the previous paragraphs.

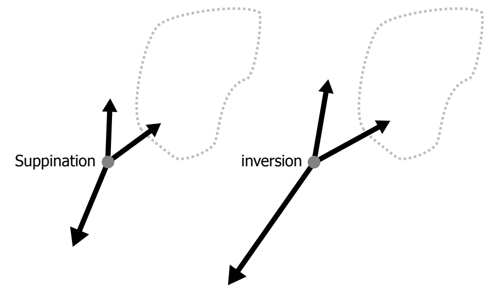


Figure 63. *Involved forces on a fixture point on the shoe or foot during supination and inversion.*

Anthropometry

The measurements A - D, indicated in Figure 64, have been recorded in researches amongst thousands of soldiers.[4,23] A group of Americans and French are taken as a reference and the averages of their measurements are illustrated in Table 5. The smallest P5 (U.S. females) and biggest P95 are also included. The original data are included in appendix G.

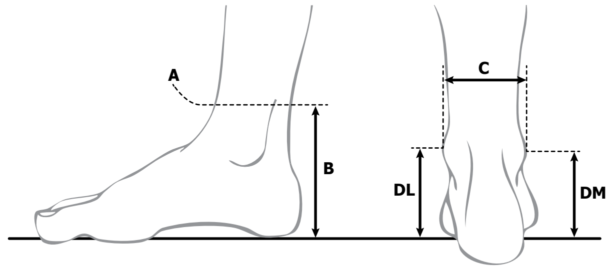


Figure 64. *Commonly recorded anthropometric measurements.*

The data indicates there is a lot of variation in body measurements between people. Furthermore, the different measurements are not all correlated with each other to a high degree. Having a high medial malleolus for example, does not necessarily mean the lateral malleolus will be high as well.

Table 5. ***Anthropometric data amongst soldiers.***

	P5	mean	P95
A: Minimum ankle circumference	190	220	251
B: Minimum ankle circumference height	93	119	151
C: Malleolar breadth	59	71	81
DL: Lateral malleolus height	49	67	85
DM: Medial malleolus height	61	77	93

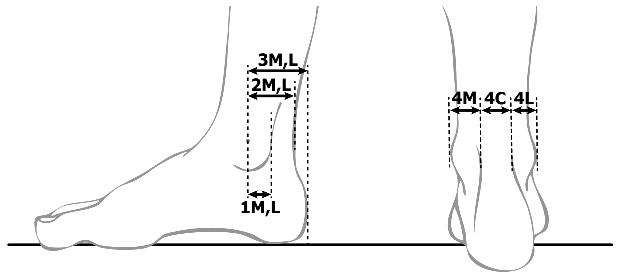


Figure 65. *Relevant additional measurements for positioning on ankle.*

To effectively create the form lock as described earlier in this section, additional anthropometric data is relevant. This includes the distance of the medial and lateral malleoli with respect to the heel and the distribution of the total malleolar breadth (C). The commonly recorded measurements as well as these additional measurements are conducted with 20 subjects for the sake of this research. In order to get an understanding of the variation the results are illustrated in Table 6.

It can be seen that difference in height between the medial and lateral malleolus (DM-DL) varies from 4 to 19 mm. The difference in distance from the medial malleolus centre to the calcaneus tendon and the lateral malleolus centre to the calcaneus tendon (2M-2L) varies from 3 to 12 millimetre.

Table 6. ***Additional anthropometric data.***

	minimum	mean	maximum
A: Minimum ankle circumference	196	221	240
B: Minimum ankle circumference height	97	127	149
C: Malleolar breadth	60	70	76
DL: Lateral malleolus height	65	72	84
DM: Medial malleolus height	73	85	92
1L: Centre to posterior aspect of lateral malleolus	16	21	26
2L: Centre of lateral malleolus to calcaneus tendon	34	43	51
3L: Centre of lateral malleolus to heel	40	52	63
1M: Centre to medial aspect of medial malleolus	20	27	34
2M: Centre of medial malleolus to calcaneus tendon	42	51	62
3M: Centre of medial malleolus to heel	54	61	77
4M: Medial malleolus to calcaneus tendon	10	17	25
4C: Calcaneus tendon width	26	40	34
4L: Lateral malleolus to calcaneus tendon	12	17	23
DM-DL	8	13	8
2M-2L	6	8	11

Risk of Other Injuries

Due to the use of a form lock, considerable forces will be exerted onto some parts of the body. The concern for damaging tendons, bones or other tissues has been discussed with orthotherapist M.P. Heijboer.

Fortunately, the tendons and other tissues behind the malleoli can resist a high impact force as long as it is momentary. Furthermore, they will be pushed onto the groove behind the malleoli, which is described in the 'Anatomy' section.

According to M.P. Heijboer, there is little reason for concern about bone fracture since the impact can be very high without causing damage. He also argued that a limited number of injuries to another part of the body could be justified when a multitude of ankle injuries are prevented. As an example the ski boot was illustrated which largely prevents ankle and foot fractures. Unfortunately, as a consequence of the high and rigid boots use, more lower leg fractures are introduced.

Exo Ligament Consequences

The investigations described in this section resulted in a recommendation for preferred connection point locations and band directions, as illustrated in Figure 66. The connection point on the foot side should be positioned around the lateroproximal part of the foot's dorsal arc. The involved forces will be transferred to the lower leg most effectively when the connection points on the support are chosen just above the malleoli. With these connection points determined it was concluded that the band extends straight forward from the medial support side. The extension from the lateral support side forms an 30° angle with the horizontal.

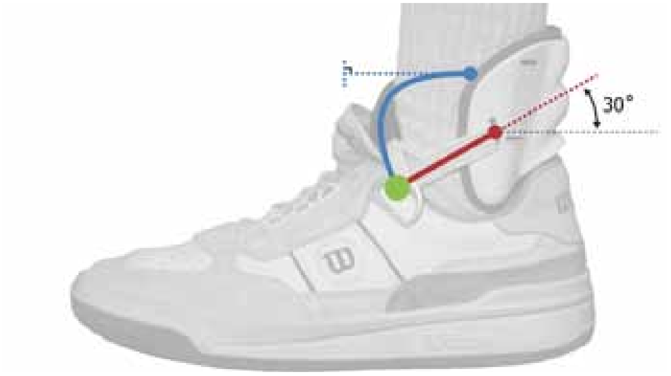


Figure 66. *Preferred connection point locations and band directions.*

Considering the variation in ankle and foot dimensions between people, some adjustability in the connection of the band might be necessary. In addition, more investigation of this variance would be necessary to develop a component that can be positioned around most ankles. It can therefore be more interesting to make additional custom components during further development.

It is difficult to figure out what kind of an inversion movement can be compared to the 500N force was exerted onto the prototypes during the tests described in this section. It also has to be noted that it was difficult to record repeatable measurements with the used testing apparatus, it is therefore not possible to use the results as scientific data. However, the recorded movement of the support relative to the leg gives an indication of the concept's effectiveness. In case of the fifth prototype this relative motion was approximately 5mm. Comparing this to the earlier recorded distance change between a neutral and inverted position of the foot (20mm), it can be concluded that attaching something between the foot and the leg will to some extend restrict excessive inversion motion.

Patents

A patent gives exclusive rights granted by national governments to the applicant. In exchange for public disclosure, the invention cannot be commercially exploited by others without permission of the inventor. A patent is, as opposed to copyrights or trademarks, only applicable to technical inventions. The valorisation centre of the TU Delft has shown interest in sponsoring a patent application for the Exo Ligament concept. Considerable efforts have been taken to get familiar with the process, researching the relevant literature and formulating claims.

Patent Application Process

The TU valorisation staff and patent attorneys have been consulted to guide the patent application process. Furthermore a seminar of Peter Watchorn, examiner at the European Patent office, has been attended.

Initially the aim is to get a Dutch patent registered. Eventually this could be extended to European or international registrations. There are some important differences concerning the patent application and prosecution in different regions, which will be indicated in this section.

When considering a patent application, the novelty of an invention should first be investigated. Research in databases like Espacenet and the Derwent Innovation Idex can be used to find conflicts with prior art. Furthermore, the information can help the inventor to further improve and specify his invention.

When existing patents show similarities, a new patent application can only be granted when a sufficient inventive step is shown. There must be a functional or structural change that will not be easily deduced by a person with average knowledge of the technical field. In the introduction of the patent it is common to refer to other publications. It should be stated what solutions are available already and why the present invention deals with the problem in a better way.

A patent application always contains data of the inventors and the title of the invention. It must include an abstract as well as the background and a description of the invention. In this description it should be clear what the problem is and why the present invention is a good solution to this problem. Some preferred embodiments of the invention should be given. Drawings are not mandatory but are often added to illustrate the invention.

The most important section of a patent is the claims paragraph. Owing to the claims of a patent, it is possible to defend ones exclusive rights. The first claim should be an independent claim and sets out the broadest protection by defining the most essential features of the invention. Subsequently, a number of dependent claims have to define more specific features.

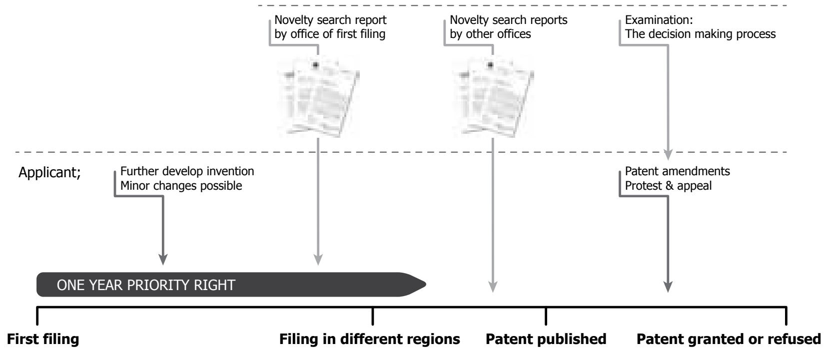


Figure 67. *The patent application process.*

When the invention details are sufficiently elaborated, they should be filed as soon as possible. In most countries the right to a patent for an invention simply lies with the first person to file. In the United States however, it the first to invent that has the right to a patent. Only after filing it is possible to disclose the invention, e.g. to investors.

Communication with other parties before filing should only happen with agreement of non disclosure. Any public disclosure before filing could undermine the right for the exclusive rights of a granted patent.

In most countries the applicant receives priority right after filing a patent application. This means it is possible to develop the invention during a one year period without affecting the filing date. During this period of priority right the applicant also has the first right to apply for a patent in other countries.

The priority right is denied when the proposed change in claims is too big. Another filing date will then have to be registered. Unfortunately, any public disclosure of the invention before this new filing date will undermine granting of the amended patent application. It is therefore advisable to, before filing and exposing the invention, make sure the invention works optimal for the intended purpose. All main characteristics should be evident.

The novelty and obviousness of the invention will be checked by the patent office. The applicant is allowed to make amendments or protest with legal arguments in the light of their search reports. Usually an amendment is made by integrating one of the dependent claims into the first claim. This can then secure the novelty over prior art. When the application complies with all legal requirements, the patent is granted.

When a patent is granted, the applicant has the right to prevent others from making, using, selling, or distributing the patented invention. However it is also possible to licence another party and in that way enable them to use the invention. In most countries these exclusive rights are valid for 20 years.

TU valorisation policy

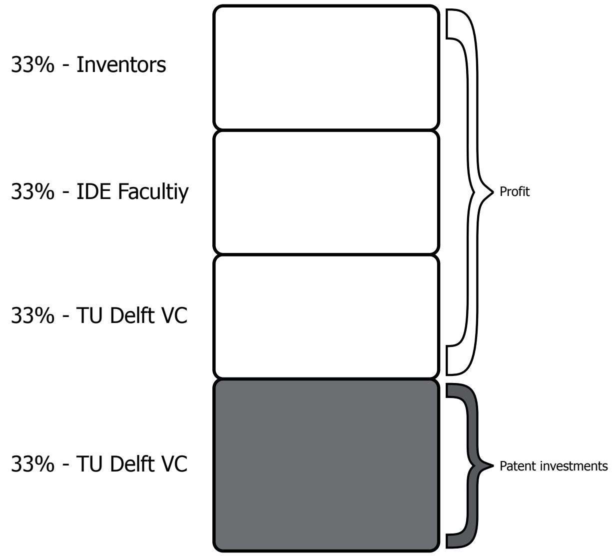


Figure 68. *The TU valorisation centre policy for profit sharing.*

One of the goals of the TU Delft valorisation centre is to protect the intellectual property of its employees and students. This is done so by giving assistance and support in applying for a patent. Especially those inventions that are commercially applicable are of interest. The TU Delft wants to make them easily accessible to market parties.

The valorisation centre will invest in the invention in return for a share of the profits when it is commercially exploited. Generally all profits after return of investment are divided by three. The first share is for the valorisation centre to support new applications. The second belongs to the faculty where the invention is coming from, in this case the IDE faculty. The last share is for the inventors.

Literature research

In consultation with information specialist J. Esser, a first literature research has been performed at the TU Delft library. It was learned how to efficiently create and combine search criteria to get the most relevant sets of publications as a result. The search profile that was used is included in appendix H.

Patents are provided with classification symbols which are convenient to use for more extensive investigation. Those of the most interesting publications served as a reference tool to find other relevant literature. For example the European classification symbol A61F5 stands for human necessities (A), medical or veterinary science (61), protheses and bandages (F) and orthopaedic methods or devices for nonsurgical treatment of bones or joints (5).

Current Solutions

There are thousands of patents concerning the ankle sprain injury. Some very unrealistic like the one illustrated in Figure 69, others showing feasible solutions that have already been introduced in the market.

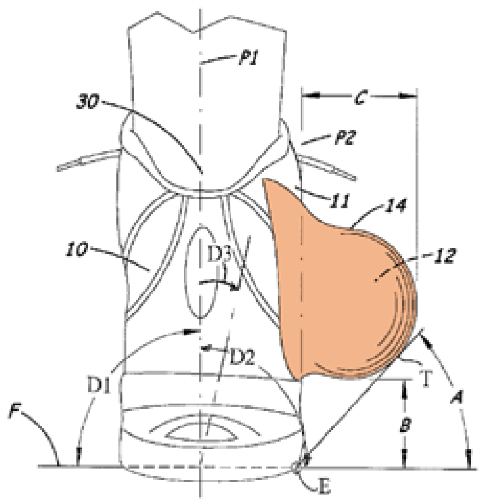


Figure 69. *A filed and approved patent application for a solution comprising a big ball at the lateral side of the foot.*

In the remaining of this paragraph, several patents that show some similarity with 'Exo Ligament basics' will be briefly presented and subsequently discussed. The original documents are included in appendix I.

Analylis, Patents

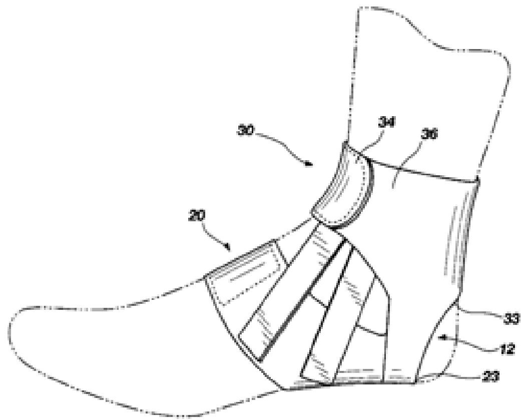


Figure 70. *Illustration of US patent 2011/0034846 A1.*

US patent 2011/0034846 A1, illustrated in Figure 70, describes a support that provides the joint with a normal range of motion while preventing abnormal motion that might damage the joint or connective bands. The patent claims the use of engagement elements that engage body parts and the use of straps between these engagement elements at locations associated with the joint.

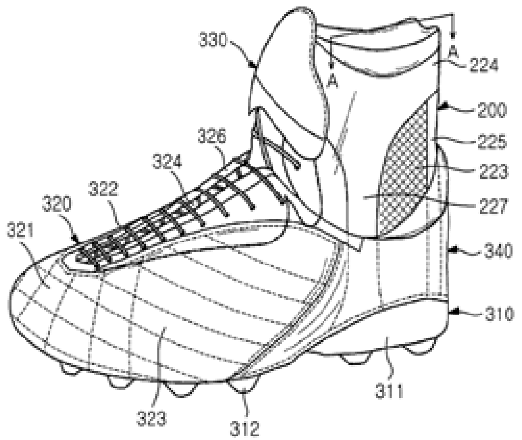


Figure 71. *Illustration of US patent 2006/0137226 A1.*

US Patent 2006/0137226 A1, illustrated in Figure 71, describes a method of ankle sprain prevention integrated in the shoe. One part of a support is fixed around the lower leg, another part on the inside of the shoe's heel section. Conservation of flexibility is claimed while the ankle is efficiently supported.

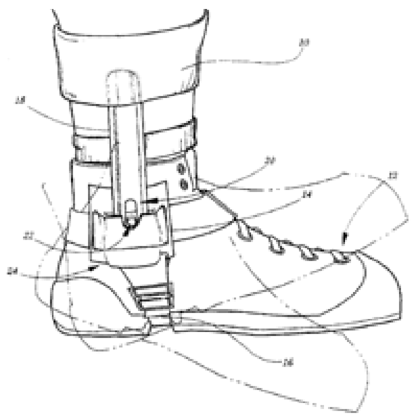


Figure 72. *Illustration of US patent 5,792,087.*

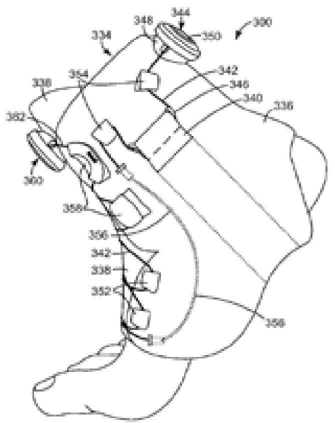


Figure 73. *Illustration of WO patent 2010/117723 A2.*

US Patent 5792087, illustrated in Figure 72, describes a method of preventing the inversion trauma while securing flexibility. A upper cuff is attached to the lower leg and connected by rigid bars to connection points on the shoe. This ensures that excessive inversion and eversion movements are prevented.

WO Patent 2010/117723 A2, illustrated in Figure 72, describes a adjustable stirrup mechanism in combination with a semi-rigid or rigid brace. By using the mechanism it is possible to apply tension to a supportive strap. This allows precise control over the freedom of motion and consequently the extend of protection.

Exo Ligament Consequences

The search for currently available solutions has revealed numerous claims that show similarity with the 'Exo Ligament' basics. It was learned that it will be difficult to get a broad protection granted. Some of the claims that can be extracted from the patents discussed in this section are stated below.

- Effective support of the ankle joint without reduction of flexibility.
- Application of supportive elements in the direction of the ligaments.
- Integration of an ankle support in the shoe.
- Application of supportive elements connected to the shoe.
- Application of a mechanism to adjust the extend of protection.

The publications covering the current state of art not only show what protection is not available, but can also be of great use to further elaborate on one's own invention. By doing additional research as described in the previous sections, the current state of art can be further specified and improved. Moreover, literature about the connection of the support to the lower leg and direction of supportive elements is scarce. This reveals opportunities for a new patent application.

As stated before, when applying for a new patent, it is important to keep in mind that a sufficient inventive step should be taken compared to the current state of art. Patent protection can be acquired by further specifying the relation between components and their physical properties. How the Exo Ligament patent application is eventually formulated taking that into account, is explained in the 'Exo Ligament Invention' section later in this report.

The intention to apply for a patent makes the development process of a new product especially interesting. It has been described how the ins and outs of the application process were learned and how the current state of art publications can help to improve one's own invention.

Unfortunately there are some restrictive measures that had to be taken as well. It is advised against talking about the development of product in public to protect the newness of an invention unless a non disclosure agreement (NDA) is signed by the recipients. That is why special care had to be taken when involving other people. During the graduation project, the advise of external parties was absolutely necessary to progress. The NDA that was used for correspondence with medical specialists and company representatives is included in appendix J.

CONCEPT

Concept Development

The Exo Ligament consequences that were discussed in the previous section served as input for further development. The aim of the made efforts that are described in this section, was to achieve a feasible product concept which could be prototyped and tested in order to achieve a technical proof of principle. In the light of the graduating student's design vision, it will first be illustrated what decisions were made with respect to the overall concept direction. Subsequently, a detailed description will be given of the required technical elaboration after the application of a patent.

Design Vision

The ankle sprain injury occurs far too often, most of the time during sports.
It is my goal to reduce the number of sprains in the Netherlands and all over world.

Victims

There are a lot of factors that have influence on the chance of getting an ankle sprain. Amongst other things it depends on ones level of activity and tendon strength which can be trained. However, due to anatomical differences, some people will be always be more vulnerable than others. Despite having relatively instable ankle joints, most of them still want to participate in their preferred sport. They will have to accept the chance of getting a sprained ankle every once in a while. It is them whom I want to help with a new device.

Solution

There are supports available that help to prevent and ankle injury. The group of people that is using these supports is too small. Without considering their effectiveness, it can be said that the current state of art does not appeal to the consumer.

It is my aim to develop a product that functions as well as, or better than the current state of art. Equally important, it should be easier to fit and more comfortable to wear. More people should wear a sprain preventing product during sports, which they will only do when the product is more attractive to use as opposed to the current state of art.

Concept Development, Design Vision

Development

A product should be developed that does not merely advertise itself as a medical brace. It will eventually have to be adopted by high numbers of sportsmen. Therefore considerable efforts are needed to make the solution viable on a large scale.

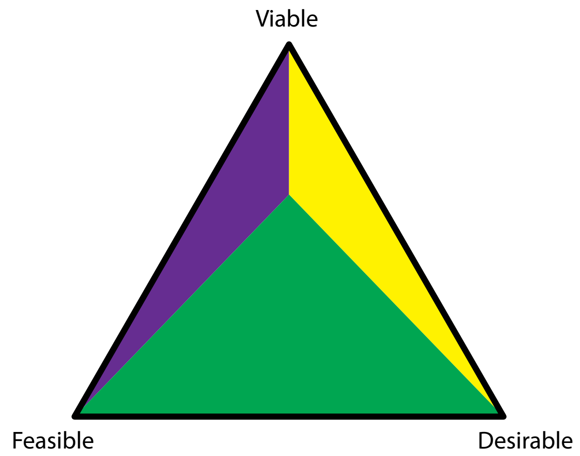


Figure 74. *Viable, feasible and desirable design thinking.*

The feasibility and desirability of the product are most important, which is visualised by the large green area. The focus in this early stage off the development process should be on the introduction of a concept that works well and people want to use. This will at a later stage be followed by a market introduction strategy.

Concept Direction

The preferred means of transferring a force to the lower leg has been investigated and is illustrated in the ‘Motion Restriction’ section. Simultaneously, a more conceptual approach was taken to explore the opportunities for an integrated solution to the problem.

Four possible concept directions will be explained in this section, this involves the conventional brace type and three different means to connect the ankle support to the shoe. Their pros and cons will be discussed in light of the design vision as described on the previous pages.

Conventional

A conventional type brace is used without interaction with the shoe. It is attached to the foot and the ankle separately. The ankle support will have to be firmly attached to the foot and not allow space for motion relative to the foot itself. The most common way to overcome this problem is the use of several straps, yet a firm attachment to the foot remains a challenge. Additionally, the foot attachment and band to the ankle support have to fit common shoes.

The support will have to be more comfortable to wear compared to current rigid braces. Attaching a brace to the foot is inconvenient, the efforts to do this have to be minimized. The foot attachment should be designed in a way that it causes minimal discomfort when fitting and wearing a shoe. The image of the user being injured, which is conveyed by a conventional type brace, has to change.

People that purely look for a functional product will be likely to think of a conventional brace first. When an ankle support will be introduced to the market that is very effective, yet easier and more comfortable to wear, this could be a good option. The threshold for buying this type of support is lower compared to buying a support that has to be combined with a shoe. However, it will be a true challenge to be distinctive between the supports of professional companies.

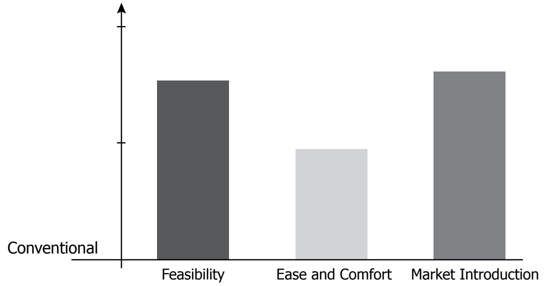


Figure 75. *Rating of conventional type brace.*

Figure 76. *Illustration of conventional type ankle support.*

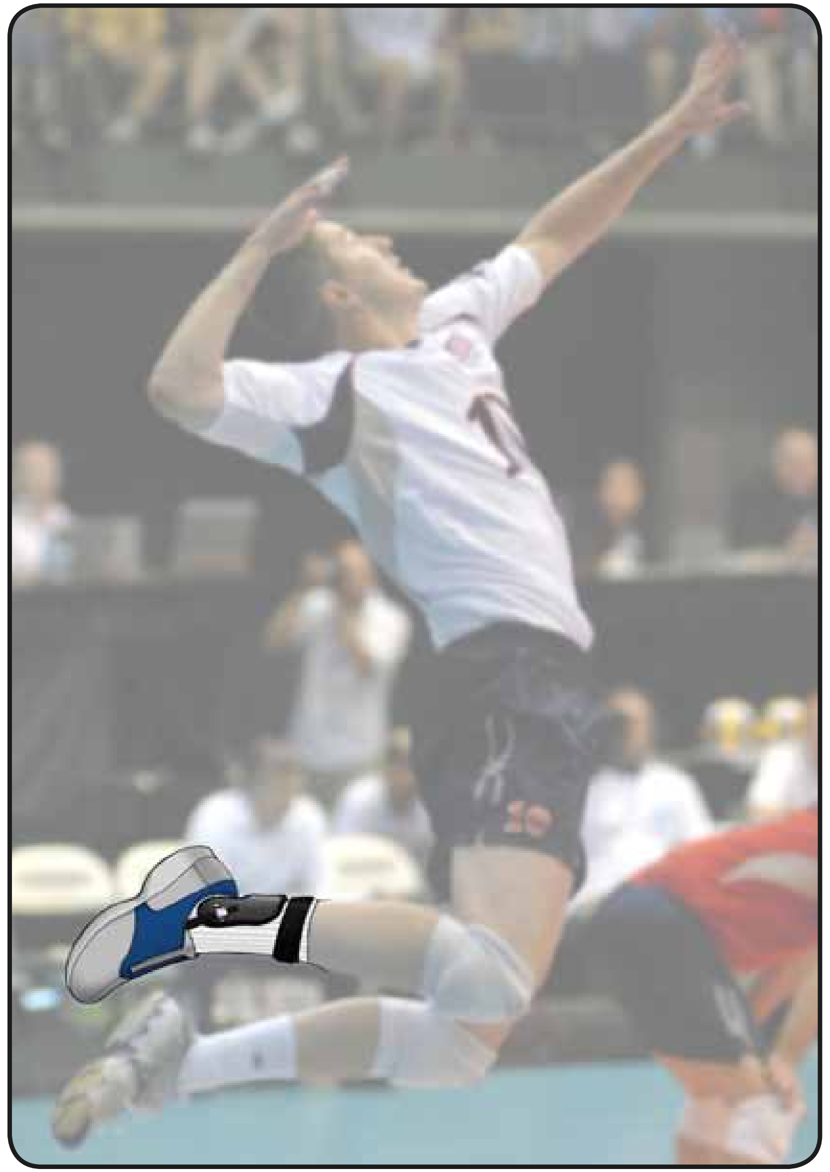


Figure 77. *Volleyball player with conventional type ankle support.*

Add-On

An add-on system makes it possible to attach the ankle support to any shoe. A component that can be fixed to the shoe is supplied with the brace. The method of attachment has to fit different shoes, which is why it is needed to develop a universal attachment system. Unfortunately not all shoes will be equally suitable. The attachment might be on the outside or interior of the shoe, underneath the inner sole, between the laces or fixed to the rubber of the sole. Considerable efforts should be taken to ensure the method of attachment is clear and secure.

When the support is properly fixed to the shoe and the shoe firmly fits the foot it is not necessary to attach a separate component to the foot itself. It could be an easy, convenient solution compared to existing braces. However, it is important to make sure the attachment method does not cause any discomfort or damage the shoe. The appearance of the connection and the shoe itself will most certainly not totally match which might look strange to the user.

The product could be an equally expensive product as the conventional type brace. The ankle support can be attached to the user's current shoes so they do not have to buy anything else. When a consumer buys the support it is important to make sure the shoe attachment is fixed properly and it is necessary to convince the user of the secure match with his current shoes. When the shoes are being replaced, the support has to be properly connected again.

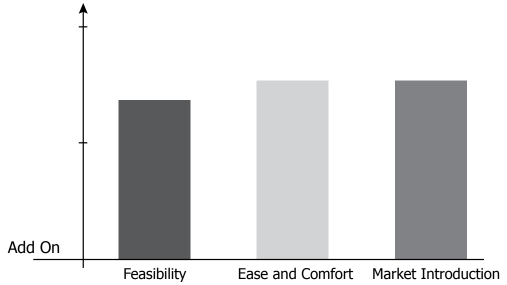


Figure 78. *Rating of add-on type ankle support.*

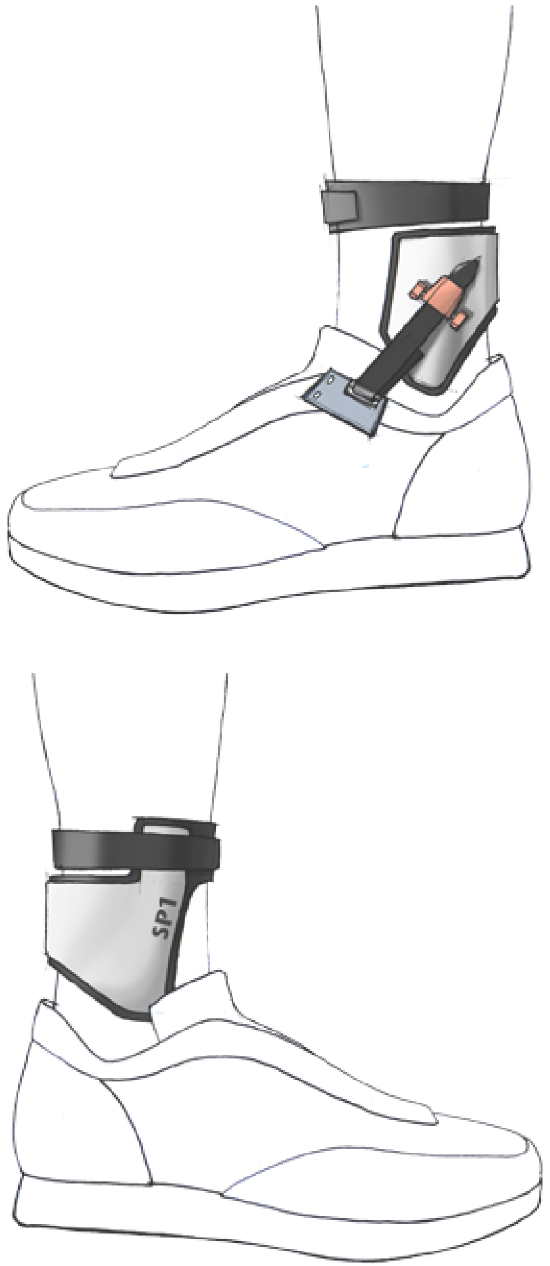


Figure 79. *Illustration of add-on type ankle support.*

Figure 80. *Tennis player with ad-on type ankle support.*

Modular

A modular system could be developed in cooperation with multiple shoe suppliers or by developing a new dedicated shoe. A support can then be attached to a special feature which is integrated in the shoes. When developing a modular system it is possible to make sure the two components (brace & shoe) work together perfectly. The shoe can be constructed in a way that is is firmly connected to the foot and supplies sufficient support.

People might like to choose a new shoe with their brace. It is only necessary to buy an ankle support every few years. The shoes last for a shorter period and can then be replaced with another pair that matches the brace. Nothing has to be attached to the foot other than the shoe which makes the system convenient to use. Since the shoes are produced with a feature that connects to the support, this gives the user a trusted feeling of an integral system.

It will be a challenge to work together with shoe manufacturers or to develop a new shoe. People will have to buy a new shoe when choosing to use this brace which might hold them back from purchasing. However, when it is possible to convince the consumer and shoe manufacturers a profitable business plan can be drawn. The brace could be sold separately and makes you buy the shoes from licenced companies. It could be an eye catcher in the shops.

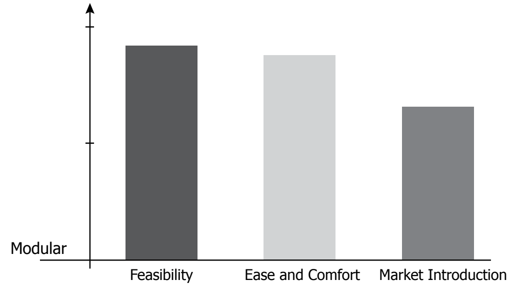


Figure 81. *Rating of modular type ankle support.*

Figure 82. *Illustration of modular type ankle support.*

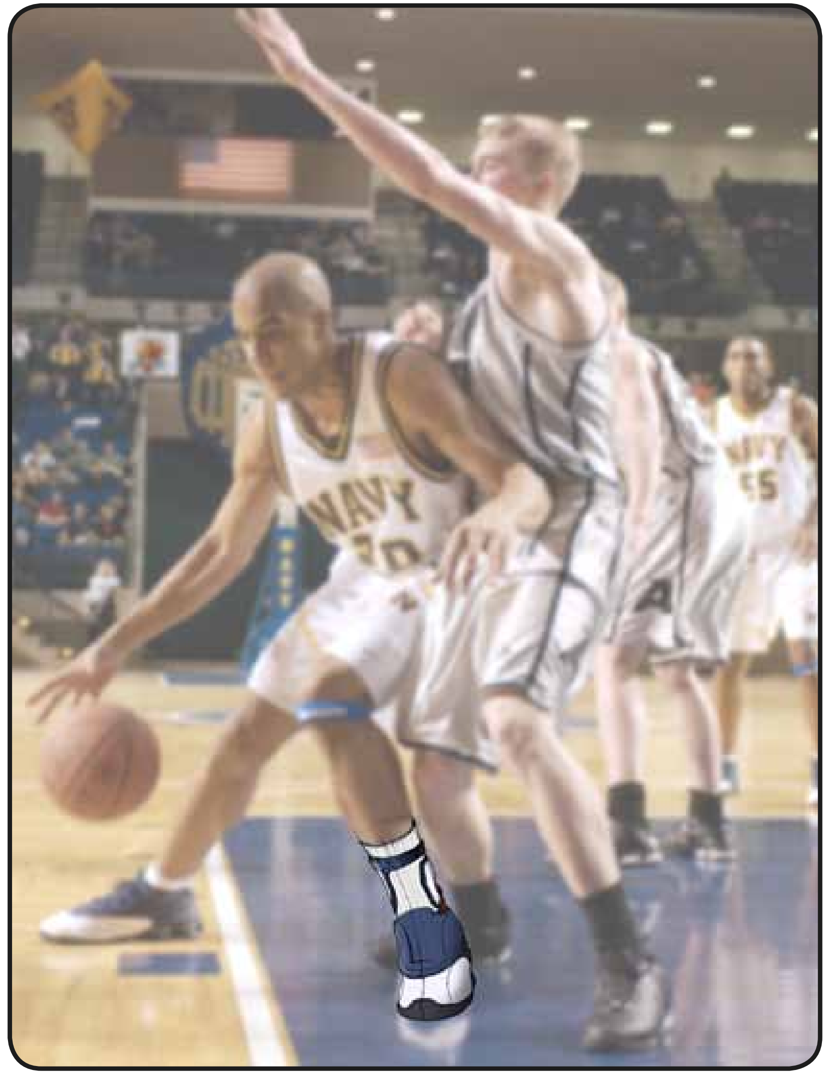
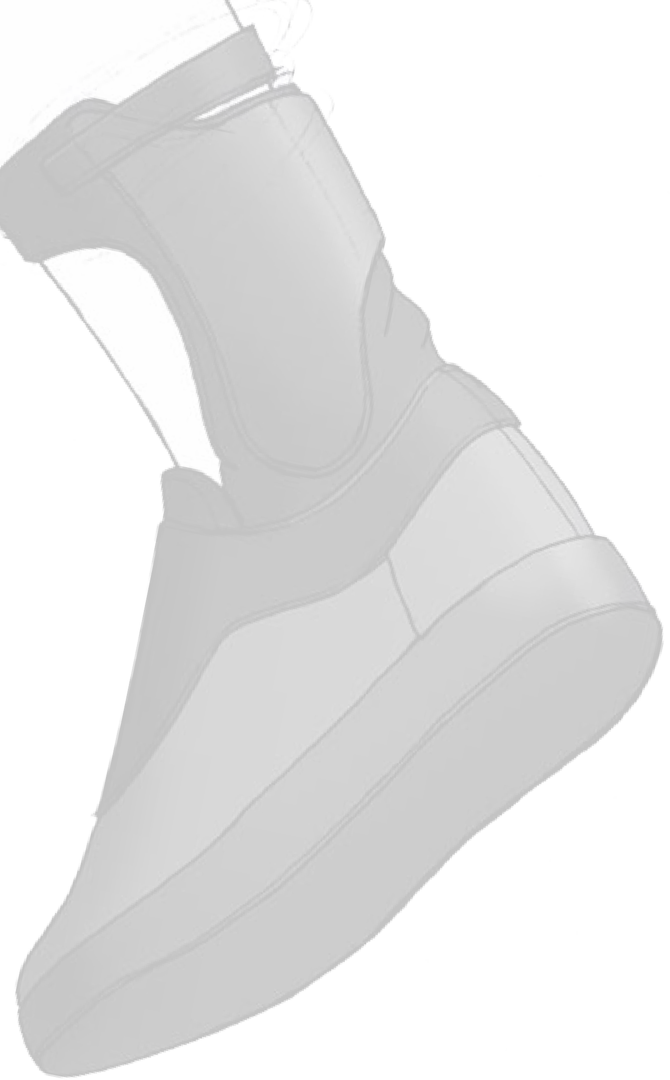


Figure 83. *Basketball player with modular type ankle support.*



Integrated

The ankle support can be integrated in shoes. That way it will not look like a brace but as a part of the shoe. When the ankle support would be totally integrated into a shoe it is most certain the system works since no mistakes can be made by attaching different components. When wearing the shoes, a user is definitely protected since the support is always attached.

An integrated solution could be nice looking. It could even become a kind of fashion item. Since it could be designed in a way it fits perfectly altogether, there would be little problems with comfort while wearing the product. When the user wants the support for only one ankle a problem might arise since the shoes are permanently connected to the support.

Introducing a new shoe concept to the market is a challenging task. There are huge brands that take up all space in shops. With this concept the shoe will have to sell the brace and the whole set has to be replaced when the shoes are worn out, which makes it a very expensive pair of shoes.

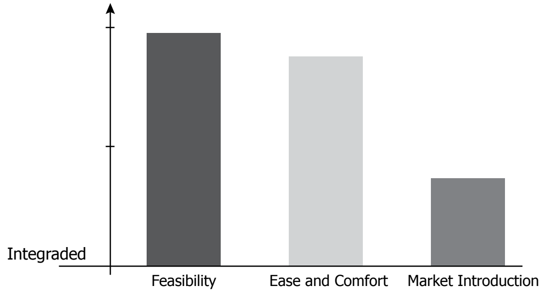


Figure 84. *Rating of integrated type ankle support.*

Concept Development, Concept Direction

Figure 85. *Illustration of integrated type ankle support.*

Figure 86. *Skateboarder with integrated type ankle support.*

Preferred Concept Direction

The advantages and disadvantages of the previously illustrated concept directions have been discussed with members of the TU valorisation centre as well as with experienced shoe and protection equipment developer Drs. W. van Bakel. In addition, the acceptance of the various concept directions and overall opinion of target users have been explored during brainstorm sessions as illustrated in Figure 87. A summary of the results is included in appendix K.

Figure 87. *Brainstorm session.*

The comparison between different concept directions is further illustrated by Table 7. The mentioned criteria will be described briefly below and are provided with a weighting factor to point out the most relevant product aspects in the light of the design vision.

- The feasibility grade indicates the expected certainty of an effective sprain preventive system after development. As discussed before, an integrated system scores high on this aspect.
- The ease of use grade comprises the ease of fitting the product as well as having the possibility to exchange parts to use the product over a longer time. The conventional type brace scores low on the fitting aspect. The integrated type looses some points on its versatility.
- The comfort grade indicates the expected level of comfort while using the ankle support system. Those concepts that do not require an additional fixture around the foot score high on this aspect.
- The intrusiveness grade indicates which concept directions are most expected to facilitate getting rid of the brace's current image and therefore make it a desired product instead of a medical instrument.
- The development grade gives an indication of the expected ease and possibility of bringing the concept direction to the market. Since the development of a shoe will require considerable efforts the modular and integrated types loose points there.
- The profits grade indicates the likeliness of the product to be accepted by the user and of gaining profits when the concept direction would successfully be introduced to the market.

The modular concept direction was found to be most promising. Having the opportunity to affect design directions for a supportive shoe with an integrated fastening feature was seen as a great benefit. This ensures the shoe and ankle support combination works effectively and allows the development of an innovative product that people will more likely want to use.

The development and market introduction of a dedicated shoe is challenging and needs a long term business plan, which is out of this project's scope. However some suggestions for the long development will be made in the 'Introduction Roadmap' section.

Table 7. ***Weighted comparison of concept directions.***

Criteria **Weighting Factor**	Feasibility 25%	Easy of Use 20%	Comfort 25%	Intrusiveness 5%	Development 15%	Profits 10%	**Total** **100%**
 Conventional	7	6	5	6	8	6	**6.3**
 Add-on	7	8	7	6	8	7	**7,3**
 Modular	8	9	8	8	7	9	**8,2**
 Integrated	9	7	8	9	5	5	**7,4**

Exo Ligament Invention

In the previous section it was illustrated how the findings of the 'Analysis' chapter have been implemented in a preferred concept direction. In this section it will be clarified how a preferred embodiment of the 'Exo Ligament' invention has been recorded in the patent application, which was presented to the Dutch patent office on the 10th of June 2011. The patent does not reveal a ready to use, technical elaborated, product. This will be further attended to in the next section.

Invention Description

The text of the patent application was written by attorneys of the Nederlandsch Octrooibureau in The Hague and is included in appendix L. The characteristics of the invention were communicated to these attorney during several meetings and by email correspondence. The final text was examined by the inventor before filing the application. In this paragraph the most important aspects of the invention will be briefly described. The represented patent drawings are provided with part numbers which are explained on the right.

In Figure 88 can be seen how a half open clip (3) is positioned around the lower leg (8). When the foot is inverted, the lateral shoe side (15) will move away from the clip. This motion can be restricted by a band (21) which is connecting a fastening ring (20) on the lateral shoe side to the clip. The construction (2) transfers the involved forces to the lateral and medial malleoli (17,18). For that purpose the clip features a lateral and medial support part (24,25), which are formed around the malleoli region.

Concept Development, Exo Ligament Invention

1. Shoe
2. Construction
3. Clip
5. Sole
6. Shoe exterior
7. Shoe heel
8. Lower leg
9. Ankle
10. First extremity
11. Second extremity
12. Connecting part
13. Fastening part
14. Medial shoe side
15. Lateral shoe side
16. Second fastening part
17. Lateral malleolus
18. Medial malleolus
19. Shoe instep

19'. Foot instep

20. Fastening ring
21. Band

21a. Lateral band part

21b. Medial band part

21'. Reinforcement

21'a. Distal reinforcement part

21'b. Heel reinforcement part

23. Tendon Calcaneus recess
24. Supporting part lateral malleolus
25. Supporting part medial malleolus
26. Lateral foot side
30. Invention assembly

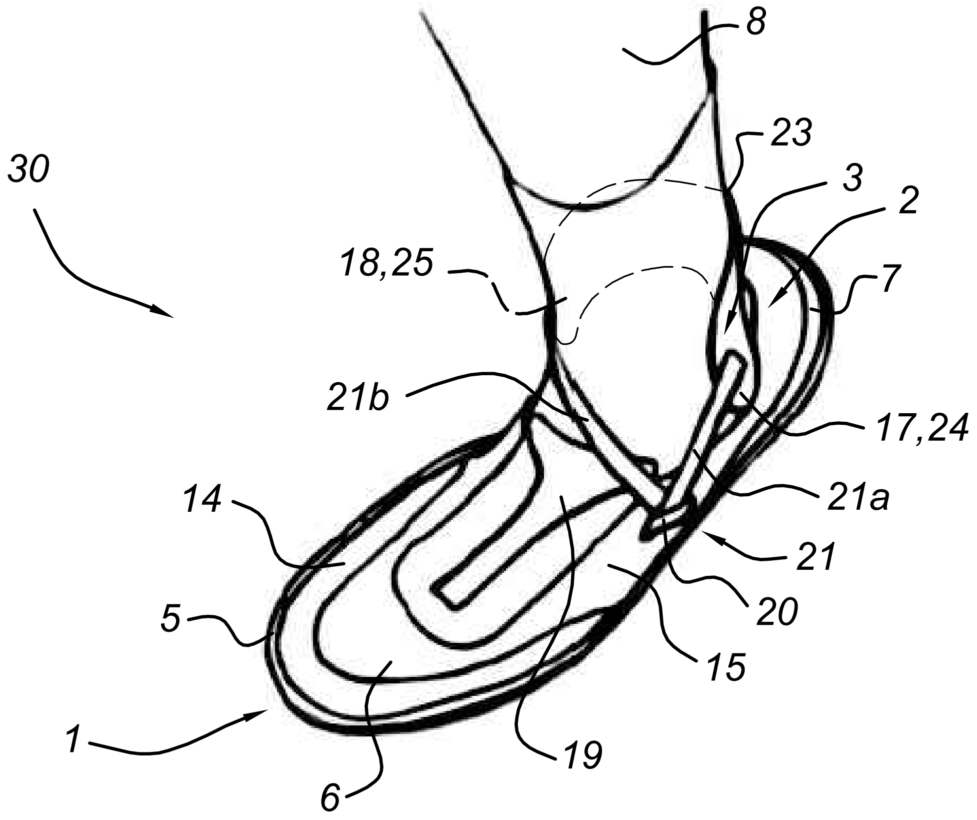


Figure 88. *Illustration of 'Exo Ligament' invention applied to an inverted foot.*

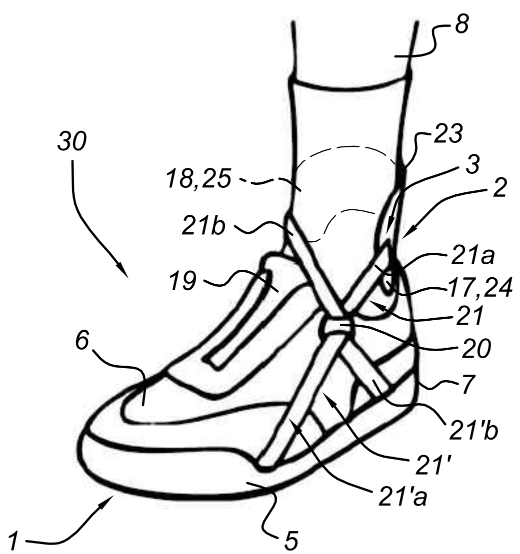


Figure 89. *Anterolateral view of 'Exo Ligament' invention.*

Figure 89 illustrates the foot with an embodiment of the invention in a neutral position. The same features as mentioned when discussing Figure 88 can be seen. An additional reinforcement (21′) might be necessary to ensure that the involved forces are transferred from the fastening ring to the sole (5) without damaging the lateral shoe side.

It can be seen in Figure 89 that the direction in which the band parts are tensioned is similar to the direction of the ligaments. The lateral band part (21a) in particular will support the antero talofibular ligament which is described to be the most vulnerable ligament in the 'Inversion Trauma' section.

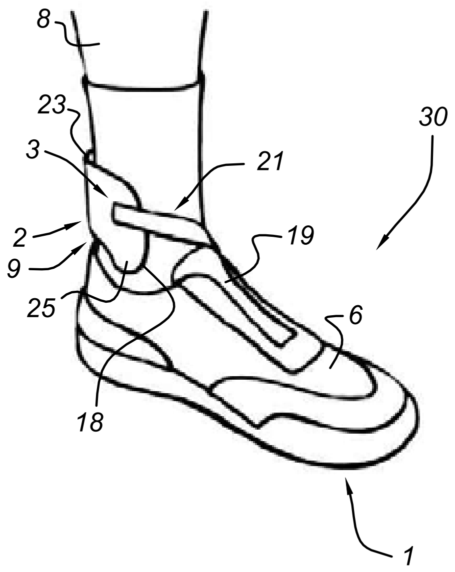


Figure 90. *Anteromedial view of 'Exo Ligament' invention.*

Figure 90 illustrates the foot with an embodiment of the invention, seen from the inside. The medial part of the clip is visible as well its connection to the band. The allowed range of inversion motion can be adjusted by tensioning the band with a fastening feature on the clip or shoe.

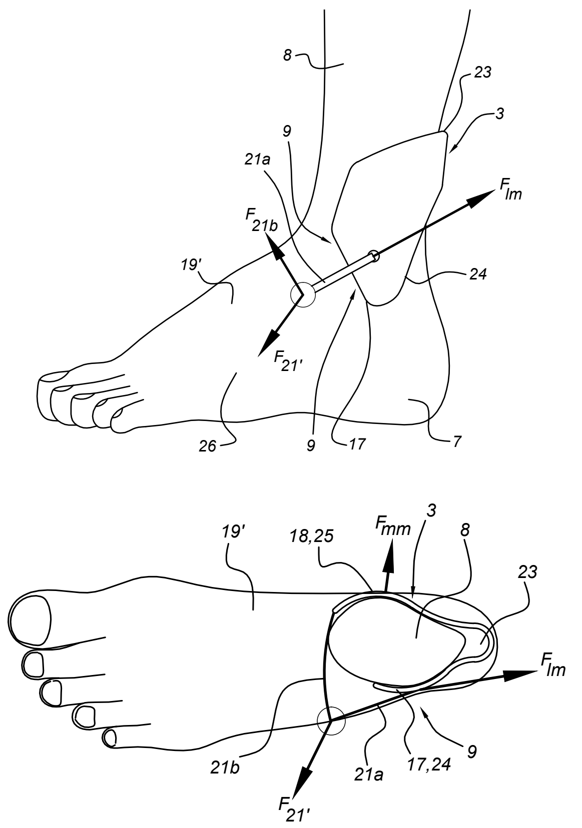


Figure 91. *Force distribution within an embodiment of the 'Exo Ligament' invention.*

Figure 91 illustrates how the forces are acting on the construction and lower leg when the foot is inverted. Force $F_{21'}$ will try to move the fastening ring away from the clip, however, this motion is restricted by the band which transfers this force to the clip. The forces exerted on the medial malleolus (F_{mm}) and lateral malleolus (F_{lm}) hold the clip into place.

In the proximal of Figure 91 can be seen that a recess (23) is provided for the tendon calcaneus to move freely and without irritation. The embodiment of the clip has to be stiff enough to ensure the clip is not pulled over the malleoli by force $F_{21''}$.

The inside of the clip will have a padding material that forms to the shape of the malleoli region and is able to reduce the local pressure onto the skin of the clip's edges in particular.

Technical Elaboration

Following the analysis and choice of concept direction, technical elaboration is needed to develop a feasible product. As will be described in the 'Preliminary Strategy' paragraph, this will at this stage of the development process initially involve a custom fitted ankle support which is connected to currently available shoes.

Preliminary Strategy

The preliminary strategy described in this paragraph has been of importance as a starting point for the technical elaboration discussed in the following section.

Figure 92. *An add-on system will be developed before trying to introduce a modular system design.*

In the previous paragraphs it was illustrated that the modular concept direction is most favourable to eventually achieve the design vision. However, in the earliest stages of development, a different approach needs to be taken since dedicated shoes are not available yet. A proof of concept and initial market introduction will more easily be achieved by further developing the add-on concept direction which is illustrated by Figure 92.

Concept Development, Technical Elaboration

During the investigations described in the 'Motion Restriction' section, basic experience was gathered about using different techniques to produce the various prototypes. The prototypes that produced the best results were exactly fitted to the user's ankle shape. Unfortunately, producing a custom component will, in any case, increase the cost of a product like the Exo Ligament concept. This should preferably be avoided but will be the most convenient solution when trying to achieve a proof of concept in a relatively short time.

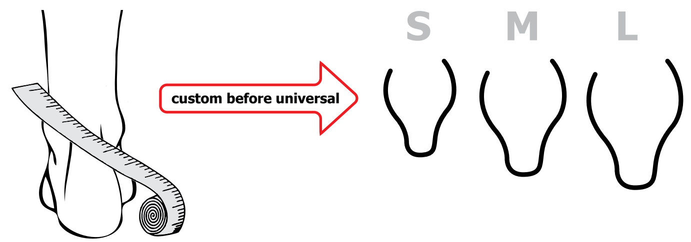


Figure 93. *A custom fitted ankle support will be developed before trying to introduce a more universal system.*

Anthropometric data showed a huge variance in ankle shape between people which complicates the development of a universal set of ankle supports. This development is inevitable for the product to become successful on a large scale which is why much more knowledge of the variation should be gathered at a later stage. The additional efforts that should be taken during further development of the product are denoted in the 'Introduction Roadmap' section.

Product Characteristics

The Exo Ligament consequences discussed in the 'Analysis' section can be further specified to physical attributes. Figure 94 illustrates the system that has to be developed and the separate components which need attention. An overview of their desired properties is given on the next page. In the following paragraphs, attention will be given to the shoe attachment, clip, clip-band fastening, padding and band respectively.

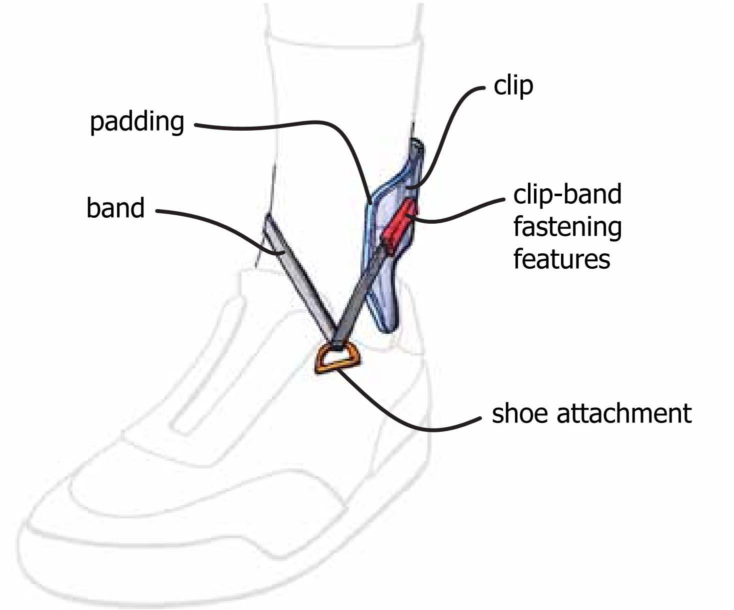


Figure 94. *Components that need technical elaboration.*

Shoe attachment.
- Must transfer a force of >500N from lateral shoe side to band.
- Must be possible to attach to currently available shoes.
- Must prevent damage to lateral shoe side.

Clip.
- Must transfer a force of >500N from clip-band fastening features to malleoli region.
- Must be shaped around the malleoli region of the user.
- Must not collide with the shoe during plantar flexion of the foot.
- Must have a recess at the back to allow freedom of movement for the tendon calcaneus.
- Must be stiff enough in order not to be pulled over the malleoli.
- Must allow the integration of clip-band fastening features.
- Must allow space for padding material.

Clip-band fastening features.
- Must transfer a force of >300N from band to clip.
- Must supply fixed connection at medial clip side.
- Must supply adjustable connection at lateral clip side.
- Can not feature sharp extruding parts.

Band.
- Must resist a force of >300N.
- Must transfer a force of >500N from shoe attachment to clip-band fastening features.
- Must be fixed to medial clip-band fastening feature.
- Must be detachable from lateral clip-band fastening feature.

Padding.
- Must be formed according to the clip's inside.
- Must be dens enough to distribute forces around local pressure points.

Shoe Attachment

Several methods of attachment to the shoe have been tested, during the investigations described in the 'Motion Restriction' section. The concepts involving the attachment of an extra band to the shoe itself are illustrated in Figure 95. The original drawings and images of the prototypes that were produced to test the shoe attachment concepts are included in appendix M.

Figure 95. *Representations of shoe attachment methods with an extra band connected to the shoe itself. Left: band attached to shoe exterior. Middle: band attached to outer sole. Right: band attached underneath inner sole.*

It was learned that a band attached to the shoe itself is not a convenient solution, since when the ankle support is disconnected, there is an additional loose item. Furthermore, a loose band at the outside of the shoe attached to the outer sole, can result in hooking onto something. A band at the inside of the shoe turned out to be less comfortable to wear.

The shoe attachment concepts that followed involved the attachment of a ring directly to the exterior of the shoe. The location of this ring was chosen according to the recommendations in the 'Motion Restriction' section. A D-ring as illustrated in Figure 96 is particularly interesting since it can be properly fixed at the straight side and allows the ankle support band to find its optimal position after tensioning. This method of attachment was found to be the most convenient solution in terms of short time realisation and resemblance to a more integrated solution in the future.

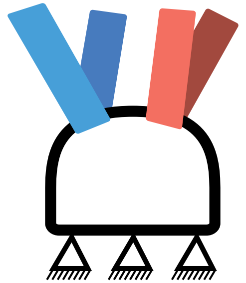


Figure 96. *Illustration of how a D-ring can be properly fixed and allow the band to find its optimal position.*

It was discovered that directly sewing the ring to the exterior of the shoe as illustrated in Figure 97, introduced high stresses onto the shoe's exterior. Some currently available shoes with flexible exterior material will not be able to handle the involved forces and damage might occur over time.

Figure 97. *D-ring which is directly sewed to the shoe's exterior.*

Figure 98. *D-ring which is sewed to the shoe's exterior by making use of a single strap.*

In Figure 98 it is shown how a strap is attached to the ring and sewed to the shoe's exterior. This method of attachment is able to better distribute the involved forces since the strap can be extended to the shoes sole. However, using a single strap, it is still difficult to predict whether the involved forces are being guided correctly. When a situation like illustrated in Figure 99 occurs, high stresses might be exerted onto one side of the strap which can damage the shoe's exterior.

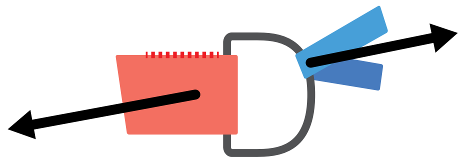


Figure 99. *Forces that are guided through the strap incorrectly*

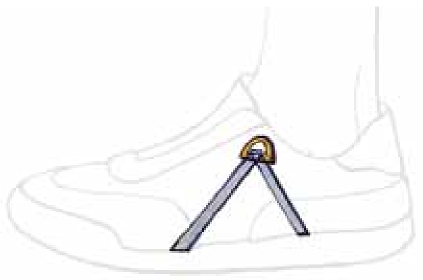


Figure 100. *D-ring which is sewed to the shoe's exterior by making use of a double strap.*

The use of a double strap, as illustrated in Figure 100, was found to be the most optimal solution for implementation at this stage of the development process. This configuration allows more flexibility in the alignment of the band and strap which is illustrated in Figure 101. Therefore, it ensures optimal support during both supination and inversion. These movements were discussed in the 'Motion Restriction' section.

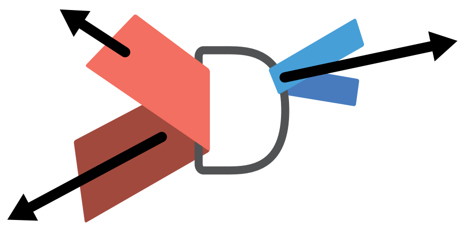


Figure 101. *The force guiding is improved by making use of a double strap.*

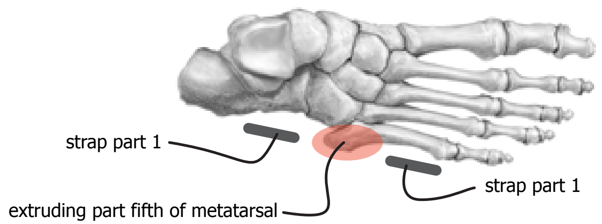


Figure 102. *Prevent discomfort at location of fifth metatarsal.*

In consultation with experienced shoe manufacturer Drs. W. van Bakel it was furthermore learned that an additional benefit of using two straps is the remained flexibility between the straps. The extruding part of the fifth metatarsal bone often causes discomfort in case of poorly designed shoes. When the two strap parts are positioned around this location as illustrated in Figure 102, this problem will be minimised.

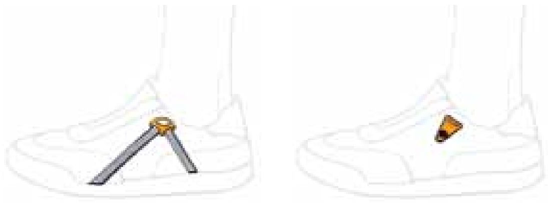


Figure 103. *Representations of possible shoe attachment methods after further development.*

When the development process continues after the graduation project, it is possible to develop a dedicated shoe attachment. This gives the opportunities for added functionality and a nicely integrated solution. In addition, when a reinforcement will be integrated in the shoes exterior, it is possible to extend this underneath the insole, mimicking the fibulares longus. In the 'Anatomy' section was described how the tendon of this evertor muscle passes underneath the foot to increase its effectiveness.

Clip

One of the challenges considering the production of the clip is the need for it to be a stiff component. As discussed in the 'Motion Restriction' and 'Exo Ligament Patent' sections, this is necessary to make sure the clip is not pulled over the malleoli. Variation in material and shape was implemented to the prototypes used during the 'Motion Restriction' tests. This are the two factors that mostly influence the stiffness of a component as illustrated in Figure 104.

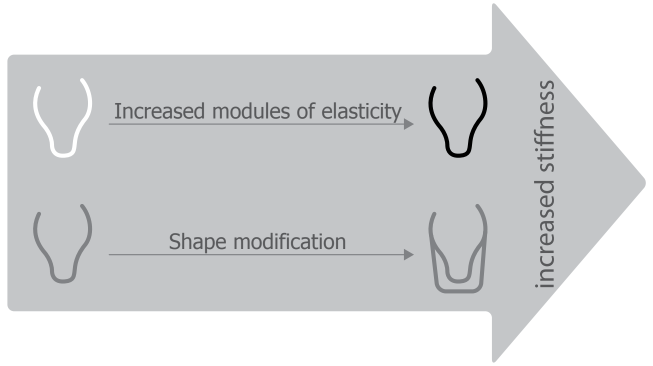


Figure 104. *Representations of possible shoe attachment methods after further development.*

The modulus of elasticity is defined as stress divided by strain. This means that a higher modulus of elasticity allows less strain and deformation. In addition, the tensile strength of a material gives an indication of the maximum load that can be applied before damage occurs. This figure should preferably be as high as possible.

The stiffness of the component also changes when the shape is modified. In Figure 104 can be seen that an increased thickness at particularly the back of the clip will make sure that the lateral and medial sides are less likely to move away from each other.

Two methods of producing the clip, customized to the users ankle, will be discussed in the remaining of this paragraph. Both require the shape of the user's ankle region to be scanned, after which a 3D computer model can be generated.

After acquiring the scan it is possible to develop a mould that can be used to vacuum form a thermoplastic or laminate composite material. Both production methods have been attempted of which some images are included in appendix N. The obtained shell has to be provided with inserts for the connection of the band as is illustrated in Figure 105. These inserts can be added afterwards or can be directly laminated into the composite material. An overview of the process described above is illustrated in Figure 106. As becomes clear from the this illustration, a positive draft is needed to allow removing the finished shell from the mould. This unfortunately introduces a reduced design flexibility.

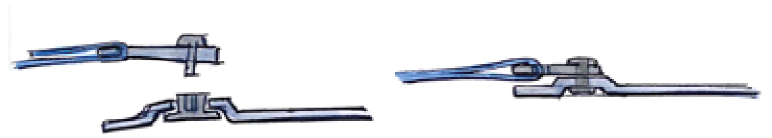


Figure 105. *An example of an insert to attach the band.*

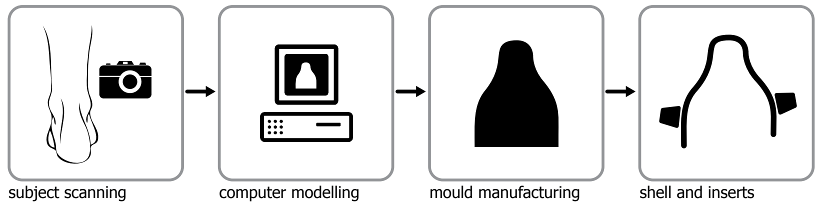


Figure 106. *Overview of the shell making process.*

Achieving the required stiffness with a plastic was found to be challenging, even with a modified complex shape. A composite material delivers superior stiffness without the necessity of a thick and heavy material. The opportunities with this production method have been discussed with Dhr. Cooijmans, managing director of Rifitech composites.

Figure 107. *Two mould configurations. Left: positive mould, Right: negative mould.*

It was learned that a positive, as well as a negative mould can be used as illustrated in Figure 107. The negative mould is able to produce a superior surface finish compared to the positive mould, since in that case the outside shape of the part is pre-defined. In order to achieve an accurate fit between the inserts and the shell, it was advised to provide the mould with flat, extruding surfaces as is illustrated in Figure 108.

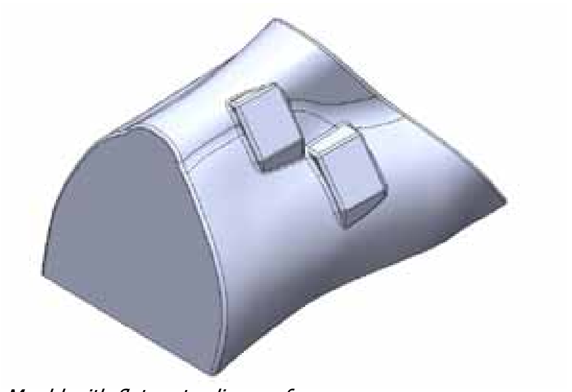


Figure 108. *Mould with flat, extruding surfaces.*

The production costs of a customized carbon fibre shell will be in the order of €100-€200 euro since the production and finishing of the parts is time consuming. These costs can only be reduced when a high number of a single universal part can be produced.

Another method of producing the clip is to use a 3D printing technique. After aquiring the scan, it is possible to fully design a component with computer software and subsequently send it to a rapid manufacturing company for production. 3D printing offers a high degree of design flexibility and allows the integration of additional functionality like the clip-band fastening features. An overview of the process is illustrated in Figure 109.

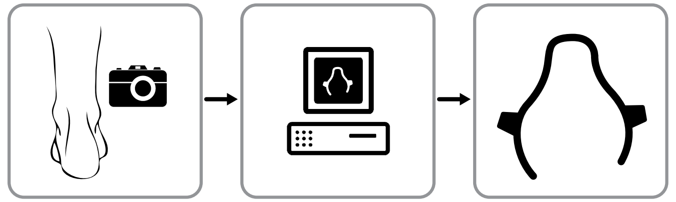


Figure 109. *Overview of the 3D-print making process.*

There are numerous 3D printing techniques and they are still developing. However, only a few of the techniques will be able to produce a reliable component at a relatively economic price. Initial trials have been made with fused deposition modelling (FDM). Images of these trials are included in appendix O. With FDM, components can be produced of materials like ABS and other commonly available plastics.

The most suitable production method will probably be selective laser sintering (SLS). A Nylon material (PA2200) can be used to produce a part that can resist relatively high stresses. The stiffness of the clip will be dependant on the designed shape. A clip as illustrated in Figure 110 can be produced by SLS for €60.

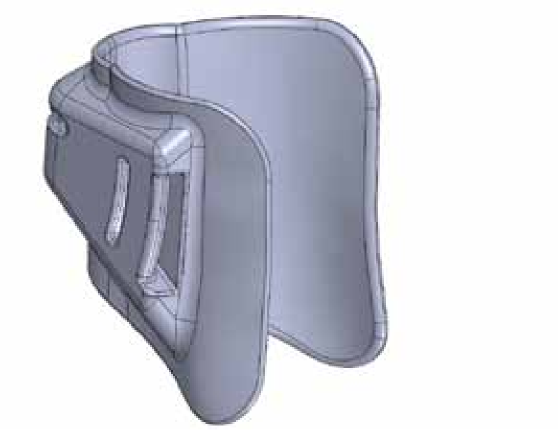


Figure 110. *3D printed clip.*

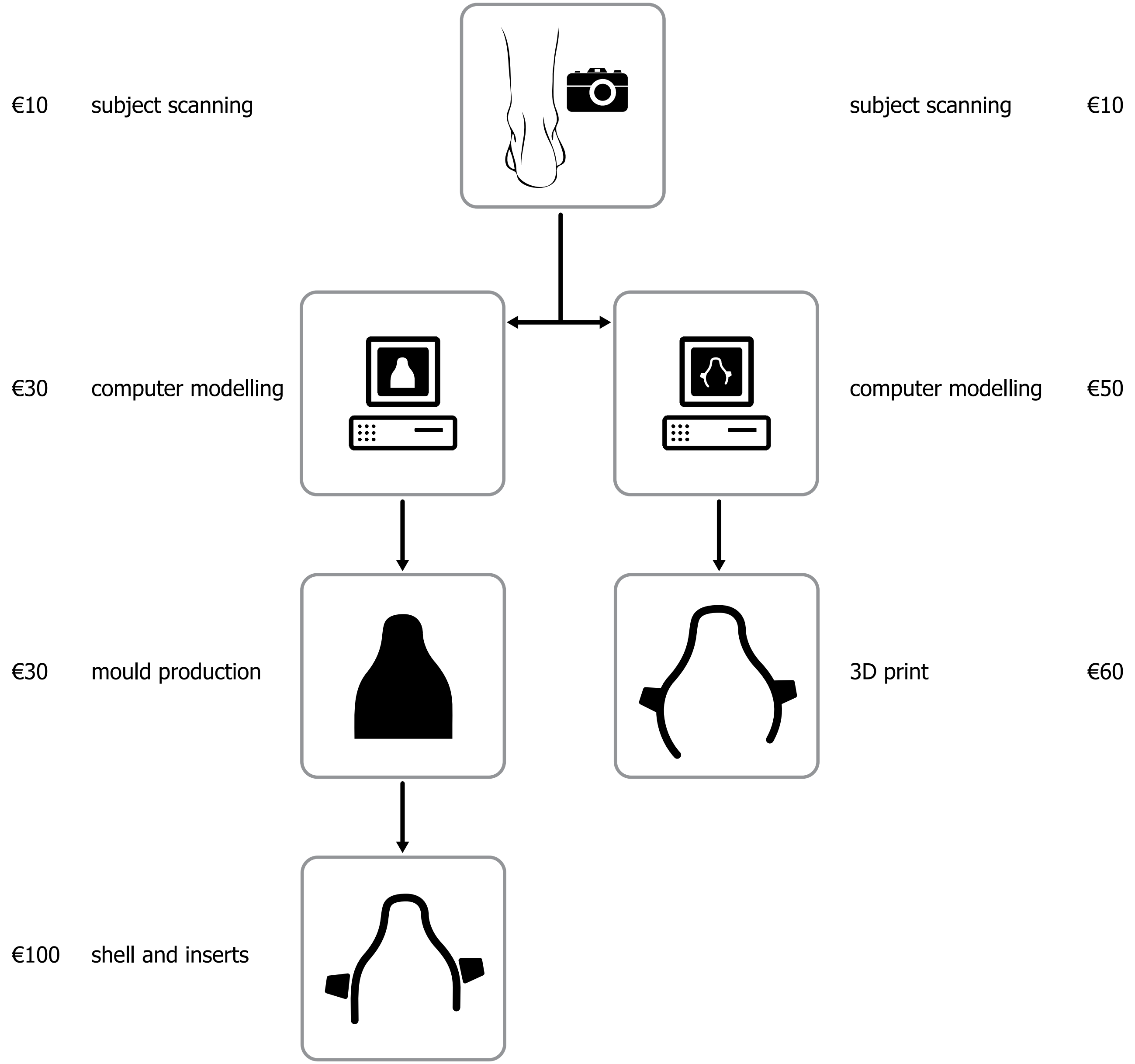


Figure 111. *Comparison between composite and 3D print production of clip.*

Figure 106 illustrates a comparison between the composite and 3D printing methods as described on the previous pages. The costs of production after basic optimization of the process are estimated and denoted in the figure. To begin with, €10 euro is calculated for making a scan. This involves the use of a 3D scanner and the necessary time of an operator (5 minutes).

The conversion of the 3D scan to a usable computer model will be executed by a professional who charges a hourly rate of at least €50 an hour. The costs of modelling a mould will be lower compared to modelling a slightly more complicated 3D print model. However, in case of the composite method, the costs of manufacturing the mold prior to the actual production of the clip has to be calculated as well. The estimated €30 euro includes the mould material (foam) and machining time.

The costs for laminating a composite clip and the production of a 3D printed clip have been discussed before , these are estimated to be €100 and €60 euro respectively. The total cost for the composite method production of the clip amounts to €170, those of the 3D print method amounts to €120. Considering these costs and the amount of design flexibility, the 3D print method is the best solution.

Due to the long delivery time for 3D printed SLS parts, the decision was made to use another printing technique. An Objet printer, available at the faculty of Industrial Design Engineering, was used to produce the first prototypes. VeroClear Blue, a material which unfortunately has inferior mechanical properties compared to SLS nylon, was directly available. The shortcomings of the material were not expected to have great influence on the first user tests. A explanation of the Objet printing technique and data sheets of the VeroClear Blue material, as well as from the other 3D print techniques and material, are included in appendix O.

Clip-Band Fastening Features

The band has to be permanently fixed to a fastening feature on one side of the clip. It has to be detachable from the other side in order to connect the ankle support to the shoe attachment.

Since some pressure was experienced on the skin during the 'Motion Restriction' tests, the idea rose to add some padding underneath the medial section of the band. Therefore the decision was made to permanently fix the band to the medial side of the clip. Even with the addition of a relatively broad padding this still allows the strap to be guided through the shoe attachment ring as is illustrated in Figure 112.

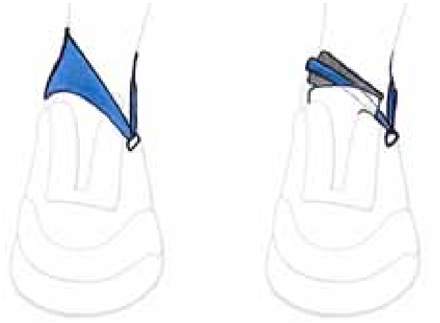


Figure 112. *Padding underneath the band's medial section.*

Numerous methods of attaching a band have been investigated. Both for the permanently fixed connection and the connection that needs to allow adjustability of the band's tension. The considerations that have lead to the choice for a set of fastening features will be discussed and illustrated in the remaining of this paragraph. Additional drawings are included in appendix P.

Figure 113. *Guiding of the band through a hole in the clip*

Figure 114. *Guiding of the band over the edge of the clip.*

The fixed connection of the band to the clip was, in case of the vacuum formed prototypes 4 and 5, executed by guiding the band through a hole in the shell as illustrated in Figure 113. It was discovered that the part of the band going underneath the clip caused pressure onto the skin when being tensioned. A more suitable solution is the construction illustrated in figure Figure 114, whereby the band is guided over the edge of the clip. The first prototypes will be produced by sewing the end of the band after being guided through the fastening feature on the clip.

Concept Development, Technical Elaboration

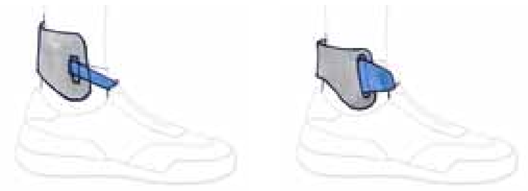


Figure 115. *A small and wide band respectively.*

A small and wide band are illustrated in Figure 115. The effect of connecting a wide part of the band to the clip has been investigated. At first sight it was thought that a band is able to effectively distribute the involved forces. However, when the band is not properly aligned, the forces will be distributed unevenly. This is illustrated in Figure 116. It is therefore advised to connect a smaller band at a predefined location to ensure that the clip will not be pulled in the wrong direction. While testing the prototypes discussed in the 'Motion Restriction', it was determined that this location should preferably be chosen just above the medial malleolus position.

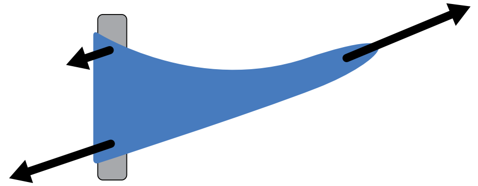


Figure 116. *Unevenly distributed forces.*

Figure 117. *Solutions that allow the band to rotate.*

In the 'Motion Restriction' section it was illustrated how the band is tensioned straight to the front at the medial side, however it will not be exactly similar for all persons. Figure 117 illustrates two solutions that overcome this problem by allowing the band to rotate a few degrees. As a result, the involved forces will in all cases be properly transferred from the band to the clip as is illustrated in Figure 118. A curved connection bar is the most suitable solution to integrate in the 3D printed component.

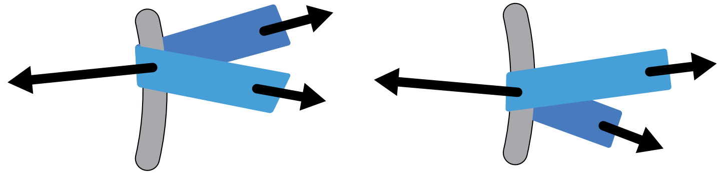


Figure 118. *Evenly distributed forces due to curve of connection bar.*

The connection of the band at the lateral side of the clip is chosen to be detachable in order to connect and disconnect the support to the shoe. The most interesting solutions will be described below.

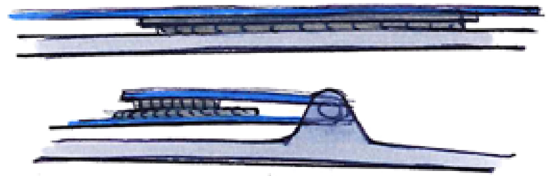


Figure 119. *Velcro connections.*

A widely applied method of attachment is the use of Velcro, some solutions are illustrated in Figure 119. Velcro is often the preferred material in strapping something around the human body. However, by applying large forces, the risk for peeling arises when the Velcro band is not properly aligned. In Figure 120 it is illustrated where the peeling starts and how this effects the connection. Since this also happened during the tests described in the 'Motion Restriction' section, it was decided not to implement a Velcro connection at this stage of the development process.

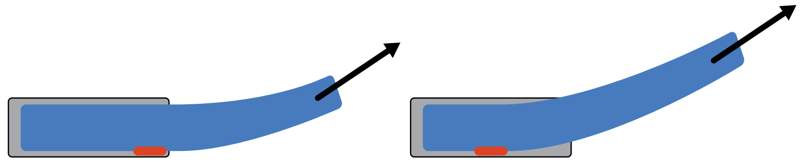


Figure 120. *Peeling of Velcro connection.*

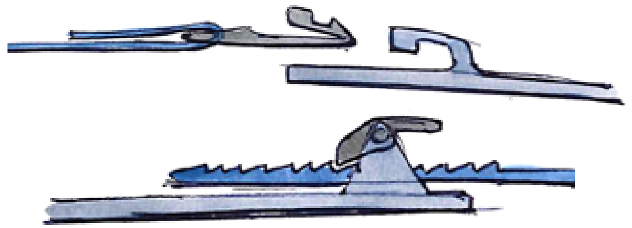


Figure 121. *Clipping mechanisms.*

Figure 121 illustrates two interesting clipping mechanisms that could be integrated in the 3D print. However, at this stage of the development process, it was decided to look for a strong, commonly available fastening feature to fix to the clip. Two self tightening solutions that were tested to be most suitable are illustrated in Figure 122. Images of the used prototypes are included in P.

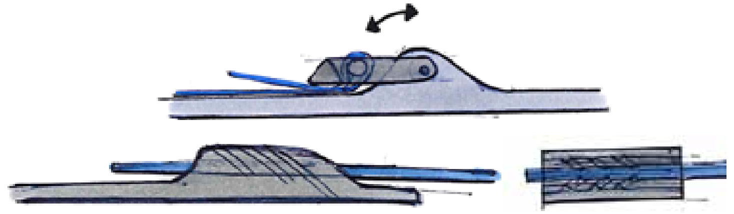


Figure 122. *Self tightening solutions.*

A clamcleat, commonly used in the sailing industry, proved to be very reliable. After tensioning the band, it is properly fixed in between the clamcleat's teeth and will not loosen during sporting activity.

In the 'Motion Restriction' section it was recommended to allow some band direction flexibility. An additional advantage of using a clamcleat is the possibility to pull in different directions as is illustrated in Figure 123.

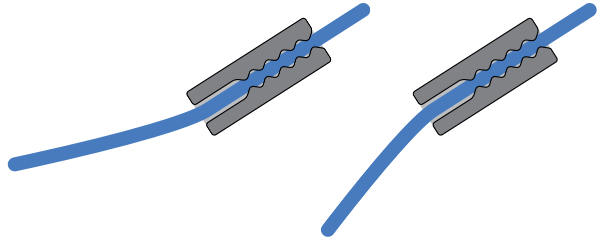


Figure 123. *Band direction flexibility.*

The properties of several clamcleats have been examined. Their specifications are included in appendix P. When the product is further developed, a clamcleat system could be integrated in the clip material or a clamcleat insert can be used. However, at this stage of the development process it was decided to fix a standard clamcleat to the clip. A small clamcleat is necessary to prevent the clip from becoming too big. The smallest size that could be delivered in a relatively short time is suitable for a 4-6mm thick rope. It was decided to use the CL 204 clamcleat and modify its shape when necessary.

Band and Padding

Suitable band materials are difficult to find in the regular retailing market like outdoor sports shops, sailing shops or sewing stores. Unfortunately, the shops were not able to give specifications of their materials which is why a lot of different bands were tested to gain the necessary experience. Images of these materials are included in appendix Q.

In order to attach the band to a clamcleat as described in the previous paragraph, a transition is necessary between a strap type material and a (sailing) rope. This is illustrated in Figure 124. Polyester was chosen to be a suitable material conform the recommendations for low stretchability made in the 'External Ankle Support' section. When the product is further developed, an integral solution can be developed. Though at this stage of the development process, it was inevitable to sew separate components together. A 20mm wide strap and a rope with a diameter of 4mm were chosen to use for the first prototypes. More information about these components is included in appendix Q.

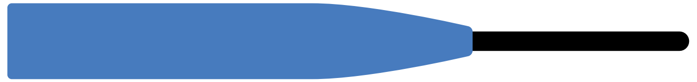


Figure 124. *Band to rope transition.*

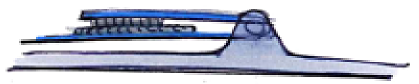
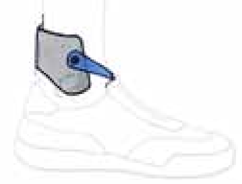
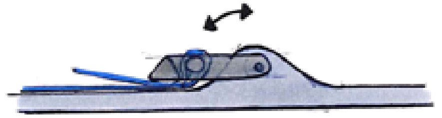
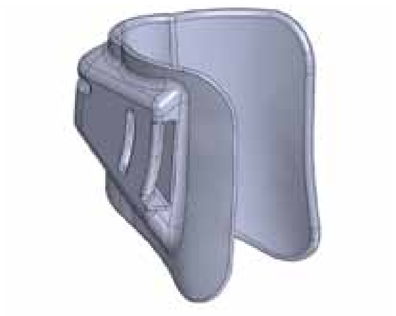
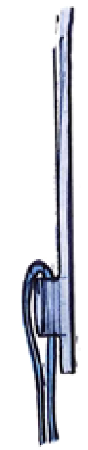
For example the Bauerfind Malleoloc brace, described in the 'External Ankle Support' section, is provided with a dedicated padding material. This material allows local pressure to be distributed over a larger area. However, a material like that is was not available for the Exo Ligament prototypes at this stage of the development process.

Cell rubber is the only padding material that was commonly available in sheets. In addition, some alternatives were found at the factory of an orthopaedic shoe manufacturer. Images of these materials are included in appendix Q.

Morphological Map

The design decisions made in the previous paragraphs have been summarised and are illustrated in the morphological map which can be seen in Table 9 below.

Table 9. ***Morphological map***

Shoe attachment	Clip	Fixed fastening feature		Detachable fastening
				
				
				

Prototype Trials

All the aspects which are discussed in the previous paragraphs had to be united in a working prototype. This paragraph discusses the trials that were performed before producing the customized supports for the user tests which are described in the 'User Tests' section.

A scan of the graduaduating student's ankle was used to produce the model for 3D printing which is illustrated in Figure 125. The clamcleat was glued inside a recess on the lateral side of the clip and the prototype was finished with a band and padding material. The result is illustrated in Figure 126. An appointment was made with a shoemaker to explore the possibilities of sewing the strap to the shoe. The produced trials are illustrated in Figure 127.

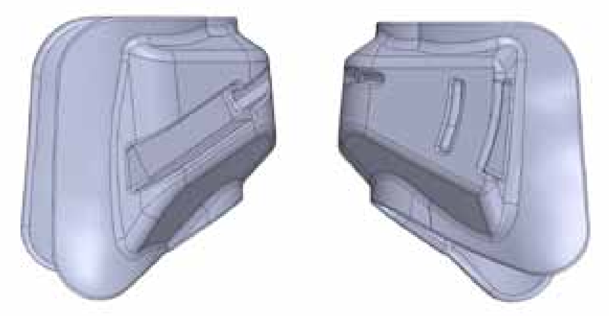


Figure 125. *First computer model.*

Figure 126. *First 3D printed trial.*

Figure 127. *Shoe attachment trials.*

The first prototype trial was tested extensively during sporting activity and the mechanic support of the brace was appreciated. However, the 3D print was relatively heavy and slightly too rigid due the high material thickness of the model. The mechanic properties of a 3D printed model are hard to predict and must therefore mainly be acquired by experience. It was decided to reduce the wall thickness of the model and hollow the section at the back. Holes on the inside of the clip were provided to remove the filler material which is added in the 3D printing process. The result was unfortunately too weak and damage occurred when trying to exert forces onto the clip. An illustration of the broken 3D print is illustrated in Figure 128.

Figure 128. *Second 3D printed trial.*

In order to be secure, it was decided to only slightly reduce the material thickness of trial 1 when developing the prototypes for the user tests. Other overall height and width of the model were found to be satisfying.

It was decided that the original size of the clamcleat could be further reduced to more easily fit the clip's dimensions. This was done by using a milling machine. The dimensions of the clamcleat recess were optimized to blend in with the modified clamcleat. It was furthermore decided to produce prototypes with and prototypes without a small beam as illustrated in Figure 129 to test its effect on positioning the band.

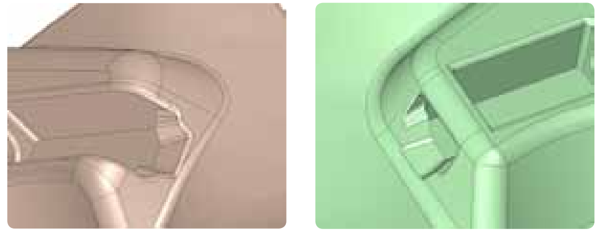


Figure 129. *Recess for clamcleat placement.*

To test which method of tucking away the overflowing piece of rope was most convenient it was decided to provide the prototypes with different slots for this purpose. These are illustrated in Figure 130.

Figure 130. *Slots for tucking away overflowing piece of rope.*

The padding material that was used for the first trial prototype was 3mm thick cell rubber. It was discovered that this material has very little influence on the distribution of local pressures. Therefore, it was decided to test different padding materials with the subsequent prototypes. In that case, caution should be taken since the padding's thickness influences the required space between the leg and clip that needs to be designed in the computer model.

In Figure 127 it can be seen that the shoe attachments were provided with a plastic or a metal D-ring. It was investigated which kind of fastener appealed to sportsmen most and the plastic ring was generally preferred. Therefore, the decision was made to use such a D-ring for the subsequent prototypes.

Figure 131. *Exo Ligament logo.*

To end with, a Exo Ligament logo was developed and it was decided to extrude this logo onto a surface of the 3D print which is illustrated in Figure 131. In addition, a mark for indicating where to place the support can be provided on the lateral clip side.

Figure 132 illustrates a computer model including the recommended changes discussed in this paragraph. The sides of the clip are extending downwards to the most extruding part of the malleoli. In the cross section, illustrated by Figure 133, it can furthermore be seen that the model is hollow and the curved connection bar is engineered thick enough to transfer the involved forces at the medial ankle side.

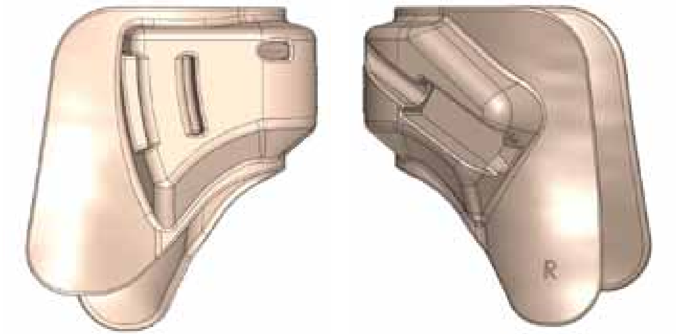


Figure 132. *Updated computer model.*

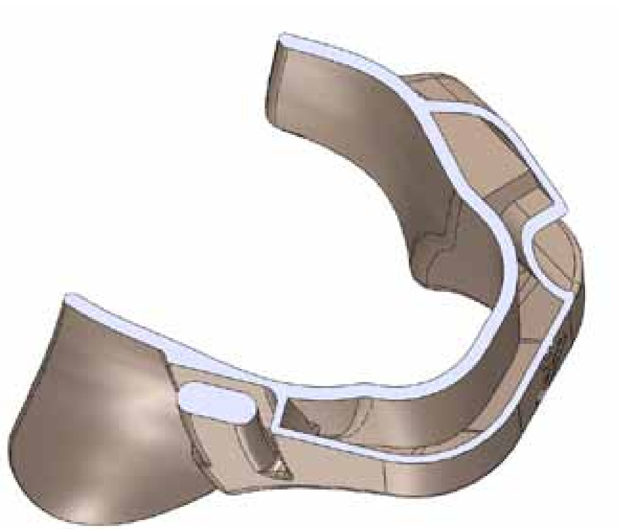


Figure 133. *Cross section of computer model.*

EVALUATION

Evaluation

This is the final chapter of this thesis. It will be illustrated how the concept that evolved from the analysis and concept development phase is evaluated. It was intended to validate the Exo Ligament concept as much as possible by executing a series of field tests and lab tests. These are followed by some final recommendations for further development and an overview of possible market introduction strategies.

Figure 134.

The photos that are introducing this section are taken by professional photographers W. Kooken and R. Britstra and the graduating student himself.

Figure 134: Studio photo (W. Kooken)
Figure 135: Runner photo (R.Britstra)
Figure 136: Basketball (R.Britstra)
Figure 137: Basketball (R.Britsra)
Figure 138: Soccer (R.Britstra)
Figure 139: Volleyball (M.Fleuren)

Figure 135.

Figure 136.

Figure 137.

Figure 138.

Figure 139.

User Tests

The conceptualizing process is completed with user tests, a very important step in the development of this product. Although a patent application was acquired on the technical aspects described in the 'Exo Ligament Patent' section, the functionality of the product was only tested by the graduating student himself. The acceptance of the new ankle support by target group users and the support's effectiveness will be discussed in this section.

Subjects

In the 'Inversion Trauma' and 'External Ankle Support' sections it was denoted which factors make somebody vulnerable for an ankle sprain injury. Three sports, illustrated in Figure 140, with a high injury rate were chosen for the first tests. The subject all practice their sport at a semi-professional level.

Figure 140. *The sports which are represented by the subjects*

In the Netherlands, the biggest part of all ankle sprains happens during soccer (34%). A lot of money is spend on taping since a suitable brace for playing soccer is not available.

Running accounts for 11% of all ankle injuries in the Netherlands. Runners are unlikely to use the current braces since they introduce irritation to the skin during long practice.

Basketball has a very high rate of injuries (3.1) per 1000 hours of activity. Braces are commonly accepted, yet often rejected due to loss of flexibility and discomfort.

Test Plan

Considerable efforts were spent by the graduation student and the external parties mentioned below to arrange the testing plan which is described in this paragraph. The foundation Sports and Technology offered financial help to facilitate prototyping. In addition, the employees of a highly regarded medical sports centre in Eindhoven, called SportMax, offered their help to find suitable test subjects.

The schedule presented in Figure 141 was planned to be fully executed in two weeks, starting from the scanning process. Appointments for making the scan, as well as for the lab tests and usability tests were made with the individual subjects. The first week of the test plan was reserved for producing the prototypes, followed by a week for the actual tests.

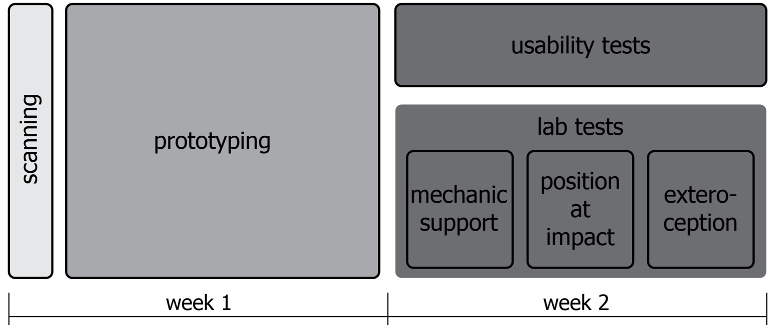


Figure 141. *Test plan.*

The 3D scanner of the Industrial Design Engineering faculty was used to make a copy of test subjects their ankle regions. The scanner was taken to Eindhoven and the test subjects were asked to all visit the SportMax location at the same day. Approximately 1 hour was reserved for each subject. The manufacturing of the prototypes took mainly place at the faculty's workshop.

The actual tests are divided into field tests and lab test. In order to test the usability of the product, the subjects were observed during one of their training sessions. The Foundation Sports and Technology facilitated the cooperation of a photographer, who came to the training session for taking promotional pictures.

The executed lab test were attending the three different effects of an ankle support which are discussed in the 'External Ankle Support' section. Appointments were made with the test subject to test the mechanic support of the prototypes and their influence on the foot position at impact. In addition, it was attempted to demonstrate the third effect of an ankle support, the potential improvement of exteroception. The results of the different tests are further discussed in the 'Lab Tests' paragraph.

Prototyping

In this paragraph a brief overview of the prototype's production process is illustrated by Figure 142 to Figure 148. The result, four different prototypes, is illustrated on the next pages.

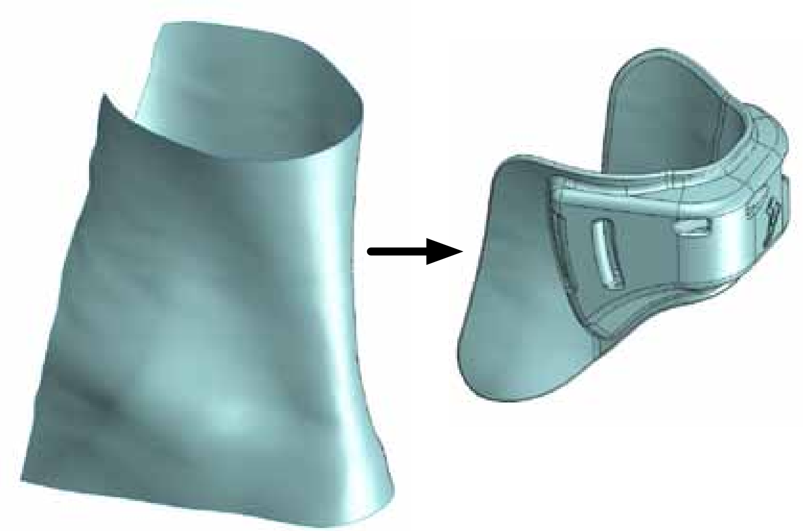


Figure 142. *A scan of the user's ankle is converted to a 3D surface with computer software and subsequently developed into a producable model.*

Figure 143. *The computer model is materialised with a 3D printer.*

Figure 144. *After cutting a clamcleat up to the right dimensions, it is glued into a recess on the 3D print.*

Figure 145. *The model is painted into the colour of preference.*

Figure 146. *The painted clips are provided with a padding material and the band is fixed to a fastening feature on the medial clip side.*

Figure 147. *The shoes are provided with a shoe attachment on the lateral exterior, including a reinforcement strap and D-ring.*

Figure 148. *When presenting the Exo Ligament prototype to the test subjects, the band is finished and cut to length.*

Figure 149. *Runner prototype.*

Figure 150. *Soccer prototype.*

Evaluation, User Tests

Figure 151. *Basketball prototype 1.*

Figure 152. *Basketball prototype 2.*

Field Tests

The field tests were the most exciting part of the evaluation process, since these would determine whether or not using the Exo Ligament prototypes was appreciated by the test subjects. The findings of this research are discussed on the following pages.

The subjects were primarily asked to comment on the ease of fitting the brace and the comfort of wearing it. Besides that, the general acceptance of the product by the subjects themselves and their fellow athletes was observed. The recommendations for further development that were extracted from the test results are discussed in the 'Recommendations' paragraph.

The subjects were asked to wear the product during one of their training sessions. A soccer tournament, basketball training and running workout were attended by the graduating student in subsequential order.

Figure 153. *Basketball players.*

"This is the most comfortable brace I have ever used."

"I would love to have one when they are ready"

The participating basketball players were used to wearing braces, they both sprained their ankles several times before. One of them stopped using braces for a over year at the moment of testing, he rejected them due to the discomfort and reduced flexibility. The other subject has very instable ankles and is therefore forced to use braces at all times.

The braces were used during one of their trainings sessions of 1,5 hours. Both subjects were enthusiastic about the Exo Ligament's comfort. They commented not be aware of wearing it at all. Although it did not seem to have influence on their ankles flexibility of movement, the supportive effect was noticed when making an inversion movement.

Interesting to witness was the start of the training session where the subjects' fellow athletes were met, some of them wearing braces as well. Reactions of surprise and approval about the looks were recorded and the concept had to be explained. Especially the ease of fitting the Exo Ligament support was appreciated.

“I think the ankle support does not affect my running performance”

The running athlete who was participating in the tests was training to join several contest shortly after the testing period. He sprained his ankle before during running, yet did not think the benefits of using a brace were proportional to the loss of flexibility.

The runner was asked to run for 5-10 kilometres and afterwards comment on his experiences. He was pleased with the freedom of movement when wearing the Exo Ligament support. However, after running a few kilometres, some discomfort was experienced around one of the clip’s edges. It can be concluded that the tests confirmed the increased risk amongst runners for irritation to the skin.

Figure 154. *Runner.*

Evaluation, User Tests

Figure 155. *Soccer player.*

“I can move freely, without any restrictions, yet feel the supportive effect“

The participating soccer player sprained his ankle several times before and was often forced to use taping. However he does not use tape every time due to its inconvenience.

The Exo Ligament support was used during two matches of a tournament and the product was experienced as valid tape replacement. It was stated that other braces are useless, since they do not fit in the soccer shoe and as a result reduce comfort and flexibility. The Exo Ligament support can easily be used in combination with the soccer shoe and shinguard.

The reaction of fellow soccer players and supporters was detected when walking around the tournament area. It was learned that the general opinion was divided. Several people were saying the product was too thick and something on the top of the sock in general doesn’t appeal to soccer players. However, others stated that this is just a matter of mind set and the Exo Ligament support could be a welcome innovation.

Lab Tests

In addition to the field tests which are described in the previous paragraph, a series of lab tests was executed. The objectives were to get experience with the testing procedures and acquiring a preliminary assessment of the Exo Ligament effectiveness. In this paragraph, the actions that were carried out to test the mechanic support, foot position at impact and exteroception will be discussed in subsequential order.

Appointments were made with the test subjects on two different locations and at two different days. The SportMax centre offered to use one of their offices and a specialised sports equipment centre in Mol (Belgium) offered the possibility to use a dedicated testing apparatus. An EMG scanning session was planned at the Erasmus Medical Centre in Rotterdam where the graduating student himself was the test subject.

Figure 156. *Construction to attempt measuring torque and rotation.*

The mechanical support of the Exo Ligament support should preferably be tested with a dedicated testing apparatus. Only one of these machines is available in the Netherlands and it was unfortunately not possible to arrange some of its operating time during the graduation project.

It was attempted by the graduating student himself to develop a construction that measures the angle of rotation and the needed torque when inverting the foot. This construction is illustrated in Figure 156. However, it was discovered that the involved forces, when an ankle support tries to restrict the inversion motion, are of a magnitude that made accurate measurements difficult. Such a apparatus needs to be very solid in order to prevent deformation and movement of the construction.

Figure 157. *Scale measurements.*

As an alternative, the mechanic support has been tested by executing simple test. The subjects were asked to press with an inverted foot onto a scale until they felt an uncomfortable pain in their ligaments. An image of this procedure can be seen in Figure 157. The maximum force which they were able to exert was recorded, both with (EL) and without (NB) the Exo Ligament support. The procedure was continued several times, the averages are included in Table 10.

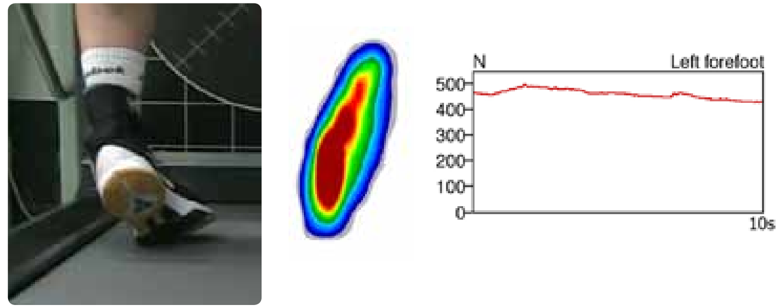


Figure 158. *Force plate measurements.*

The testing method was repeated a few days later by using a force plate. With this force plate, it was possible to record the exerted pressure by the foot for 10 seconds and plot the total force into a graph, this is illustrated in Figure 158. The maximum force during this interval was taken as a reference and is included in Table 11. The procedure was executed without a brace (NB) and with the Exo Ligament Support (EL). As a reference the Push Aequi Brace (PA) was also tested.

Table 10. ***Results of mechanic support tests (scale).***

	NB (N)	EL (N)	EL-NB (N)
Subject 1	310	550	240
Subject 2	350	550	200
Subject 3	230	360	130
Subject 4	160	360	200

Table 11. ***Results of mechanic support tests (force plate).***

	NB (N)	PA (N)	EL (N)	PA-NB (N)	EL-NB (N)
Subject 1	400	500	580	100	180
Subject 2	280	430	600	150	320
Subject 3	390	500	490	110	100

The original test results of both the scale tests and force plate tests are included in appendix R. It is difficult to exactly reproduce the measurements that are discussed in this section and the result can therefore not be regarded as scientific data. Nevertheless, an indication of the Exo Ligament's effect is given by the additional force (EL-NB) that can be exerted onto an inverted foot before the pain limit of the subject was reached.

Especially interesting is the comparison with the Push Aequi brace. In the 'External Ankle Support' section it was denoted that this is one of the most expensive and supportive braces available. Table 11 shows that the added support of the Exo Ligament (EL-NB) is as much or more compared to the added support of the Push Aequi (PA-NB). It can be concluded that the supportive effect of the Exo Ligament support promises to be satisfying after further optimization of the product.

The mechanic support tests described on the previous pages were supplemented with experiments to investigate the effect on foot position during landing. It was discussed in the 'External Ankle Support' section how a brace is able to adjust the rotational of the foot relative to the lower leg when the foot is lifted from the ground.

Figure 159. *Setup to record foot position at landing.*

In order to record the foot position just before a landing, the subjects were asked to run on a dedicated testing treadmill for 15 seconds. Figure 159 shows the test setup. Screenshots were taken from an recorded video and analysed with the treadmill computer software. This resulted in the images that are illustrated in Figure 160. Four different landings were recorded during the 15 seconds interval of which the average angles are included in Table 12. The procedure was executed without a brace (NB) and with the Exo Ligament support (EL). The Push Aequi brace (PA) was tested as well to serve as a reference. The original test results are included in Appendix R.

Table 12. ***Results of foot position measurements.***

	NB	PA	EL	NB-PA	NB-EL
Subject 1	7,7°	5,0°	4,1°	2,7°	3,6°
Subject 2	6,7°	3,1°	4,1°	3,6°	2,7°
Subject 3	2,6°	4,8°	-5,7°	-2,2°	8,3°

Figure 160. *Images to analyse foot position.*

In Table 12 can be seen that both the Exo Ligament and the Push Aequi influenced foot position to a similar amount in the case of subject 1 and 2. It has to noted that the results of subject 3 show unexpected values. It is unclear why wearing the PA resulted in a more pronated landing (-2,2°). The overdone correction (8,3°) when using the Exo Ligament can be explained by the fact that subject 3 was asked to exaggerate the tightening of the ankle support.

In discussion with movement scientist Dhr. D. Hoeyberghs, it was learned that a slightly supinated foot position is natural at first ground contact. This is confirmed by the positive angles that were measured during the run without a brace. It was furthermore discussed that the extend to which a correction of the foot position influences the risk for spraining the ankle will be different for every individual. The perfect landing position cannot be quantified and is something that can best be judged by the users themselves. The Exo Ligament's high degree of adjustability is therefore seen as an innovation that could introduce a more suitable solution for a lot of people.

In the 'Inversion Trauma' section, the proprioception system is explained. Furthermore, it was noted in the 'External Ankle Support' section how an ankle support might supplement the proprioception with exteroception. This can improve one's coordination capacity by using the sensory input from the skin when it is pressed by the ankle support.

To test this effect, the possibility to record the response speed of the invertor muscles is explored. With the cooperation of neuroscientist Drs. M.P.J.M. van Riel it was possible to reserve a day in the test week for Electromyography (EMG). This technique allows to detect the electrical potential, generated by muscle cells when they are activated.

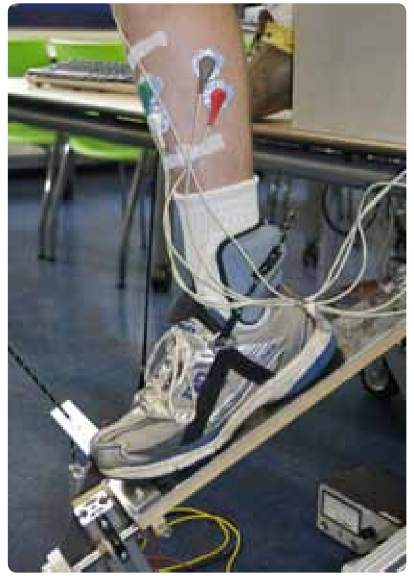


Figure 161. *EMG setup.*

It was decided to develop a test construction, involving a retractable foot rest and start button as can be seen in Figure 161. By activating a release, a signal was send from the start button to a computer, and the foot rest was simultaneously retracted. A more detailed description of the construction is included in appendix S.

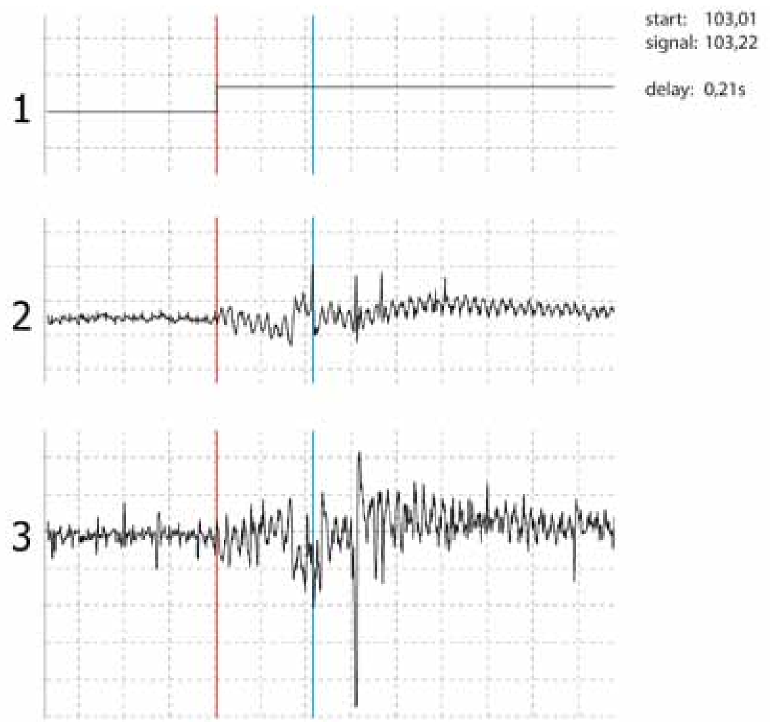


Figure 162. *Plot of EMG.*

The EMG sensors were positioned to receive signals from the evertor muscles. The signals that are plotted in Figure 162 are respectively the start button signal (1), the signal coming from the extensor digitorum longus (2) and the fibularis longus signal (3).

The test results are included in appendix R. Three EMG's were recorded with the Exo Ligament Support and three without. Although a slight increase in response speed was indicated by these recordings, the amount of scans should be increased to draw any valid conclusion. It is therefore decided that the current EMG test did not produce usuable data, however, the experience with the process will be usefull during further development.

Conclusions & Recommendations

Following the design iterations which are described in the 'Analysis' and 'Concept Development' section, some final conclusions and recommendations for further development of the product will be denoted in this paragraph.

The overall use of the product was considered as a success by the test subjects. The ease of fitting, comfort of wearing and effective support were highly appreciated. Some additional remarks are made on this page to illustrate the aspects that should make the new Exo Ligament support a wanted consumer product.

- The looks of an ankle support are important, the concept should be appreciated because of the innovative design. In that case it will not be a purely medical intervention.

- There are no restrictions to use the product around the ankle during basketball, soccer or other contact sports when the size of the ankle support is kept to a minimum. Neither did the attachment on the shoe introduce problems with the soccer player's ball handling.

- The ease of fitting the brace makes fellow athletes jealous. This advantage should be communicated to the consumer.

- The principle of attaching an ankle support to the shoe could be an economic alternative to taping for sports where the use of braces is too inconvenient (e.g. soccer).

- When it is possible to introduce the system to famous athletes, the amateur and semi-professional sportsmen will be more likely to start using the system.

- The brace could be an interesting innovation for sportsmen that reject the use of braces due to the introduced inflexibility. The Exo Ligament has proven to be more comfortable during practice.

- The comfort of wearing the brace should be the main focus point when developing for sports like running, where freedom of movement without irritation is a must.

- Efforts should be invested to develop suitable distribution channels. It should be easy for the consumer to get the Exo Ligament ankle support.

- It would be an added benefit which can be advertised when the padding material can be removed to wash it every now and then. In that way the lifetime of the clip can also be increased.

The technical details of the design are discussed extensively in the 'Concept Development' section, and it is recommended to build on the same principles during further development. In the remaining of this paragraph, some approved aspects of, and minor adjustments to, the different components will be briefly discussed.

To begin with, the band shows some wear and tear at the place where it is guided through the shoe attachment. It should be investigated what type of band is more suitable for this application. Dedicated materials like for example Dynema are available to be used in consumer goods. In addition, the friction between the band and the shoe attachment ring should be minimized.

Secondly it was learned that the 3mm thick padding materials gave inferior support compared to the 5 mm thick padding materials. When producing additional prototypes, it is recommended to use the thicker type foam sheets. Additionally, the opportunities for using a more dedicated material to distribute the involved forces onto the skin, should be investigated.

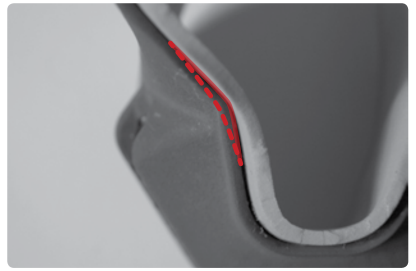


Figure 163. *Removing sharp edges from the clip.*

The runner experienced some discomfort after prolonged activity. This was due to the relatively sharp edge on the inside of the clip where the surface that is customized to the user's ankle meets the tendo calcaneus recess. This is a very important issue and should be solved by rounding off the edge at the bottom of the clip. This is illustrated in Figure 163.

Unfortunately, not all 3D prints survived the excessive forces that were applied to the foot during the lab tests. When the band is tensioned, it is pressed onto the medial edge of the clip and causes the formation of a crack at the same location for two different prototypes. This is illustrated in Figure 164. It was discussed in the 'Concept Development' section that the used prototyping material is very brittle and it is expected that a nylon SLS printed clip is able to resist the involved forces. However, the indication of this weak point in the design should be taken into account during further development.

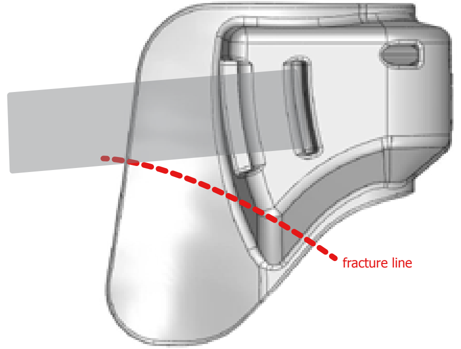


Figure 164. *Location where a crack occurred.*

The method of connecting the band to the lateral side of the clip was experienced as a convenient solution. The band did not loosen during sporting activity nor did it irritate the skin. The dimensions of the clip-band fasteners that proved to be satisfying during tests, are illustrated in the figures on this page.

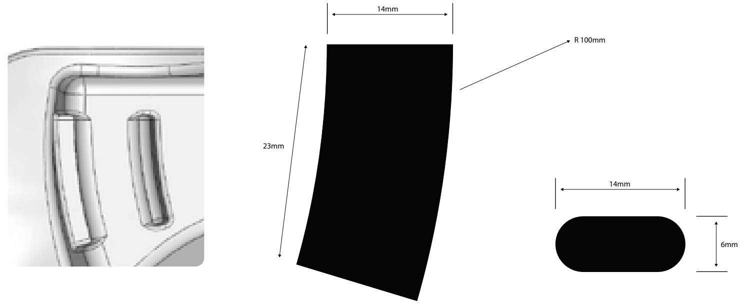


Figure 165. *Dimensions of the curved connection bar.*

The width and thickness of the prototype's connection bar are illustrated in Figure 165, it proved to be strong enough to resist the involved forces. It is recommended to further investigate if the dimensions, especially the thickness, can be reduced. When using a 20mm band, it was learned that a 23mm wide connection bar allowed enough flexibility for different foot sizes. This can be seen in Figure 149 to Figure 152.

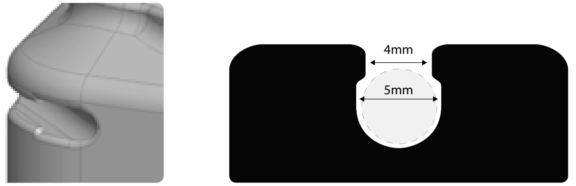


Figure 166. *Dimensions of the slot to tuck away the rope.*

The most convenient slot solution to tuck away the 4mm rope was found to be a 5mm recess with an entry of 4mm wide as is illustrated in Figure 166.

For the production of the prototypes, a clamcleat was modified to fit a recess on the 3D printed part. This is a time consuming process and a more standardised solution, integrated in the print, should be developed. When the needed strength of the clamcleat teeth can not be achieved with 3D printed materials, it is advised to experiment with clamcleat inserts as illustrated in Figure 167.

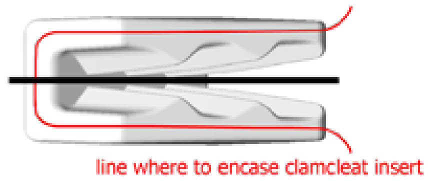


Figure 167. *Clamcleat insert*

Figure 168. *SLS model with integrated features.*

Figure 168 illustrates a computer model that would be suitable for the SLS production process. It can be seen can be seen that a clamcleat feature is integrated in the 3D print. The holes at the inside of the clip serve to remove excessive support material, which is used during the 3D printing process.

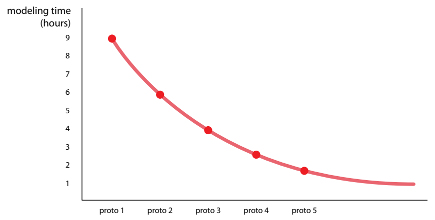


Figure 169. *SLS model with integrated features.*

Figure 169 illustrates the hours that were needed to make a computer model of the different prototypes. A learning curve can be seen and the earlier estimation in this report of a maximum 1 hour modelling time can be achieved.

However, it is recommended to investigate the opportunities of a more universal system, as soon as possible, during further development of the product. An adaptable system as is illustrated in Figure 170, making use of a deformable thermoplastic, might be an interesting solution. In discussion with material specialists of the company Promoulding b.v., it was learned that suitable materials for this purpose are available.

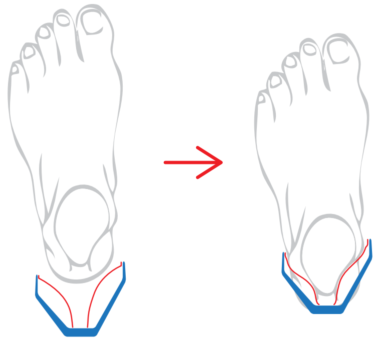


Figure 170. *SLS model with integrated features.*

Introduction Roadmap

To finalise the 'Evaluation' section, some initial thoughts for further development will be shared. Although it has been the focus of this research to achieve a technical proof of principal, the opportunities for realisation in the future have often been the subject of discussions. It was discovered that, even amongst professional business developers, there are different ideas for the best market approach. On the basis of Figure 171, a few possible scenarios will be discussed. The green bars in this figure represent the extend to which the design vision, reducing the number of sprains in the Netherlands and all over world, can be accomplished. It has to be noted that it does not have to be one or the other, several strategies can be introduced in parallel.

Customized Ankle Support Sales

The current state of art comprises a fully customized ankle support and separate shoe attachment. It has been demonstrated in this thesis how such a solution can be materialized. With relatively little development efforts it is possible optimise the concept and make a custom support that can be sold through specialized sales channels like physiotherapist practices.

The market potential of this strategy is bound to the fact that producing a customized component requires time and money. This will only be spent when people are convinced of the Exo Ligament's benefits. Those people that have instable ankle joints and reject the use of conventional braces, could be especially interested in this innovation. In addition, the concept could be interesting for sports clubs that spend vast amounts of money on taping their athletes.

Direct Market Introduction

Provided that investors are interested in the concept, it could be a good strategy to approach the consumer as fast as possible with the product. This can be tried in cooperation with an existing sports equipment company or by introducing a new and dedicated sprain prevention brand. Lots of development efforts and money will be necessary to make a universal system that can be used by all people. The large variance in ankle dimension should be mapped as soon as possible to make this work.

When an affordable product is developed, the challenge of convincing the consumer to buy this new ankle support and accompanying shoes still remains. When this is eventually achieved by a strong marketing campaign, the market potential can be relatively high.

Scientific Research

The user tests described in this thesis have given an indication of the new ankle support's effectiveness. However, to officially claim that this intervention will reduce the ankle sprain accident rate, more research is needed. The most ethical development choice would be to await the results of clinical trials before approaching the consumer with a new product.

A phased introduction strategy could therefore be started by executing clinical trials with a customised solution as elaborated upon in this thesis. During these test it is possible to explore the opportunities for a more universal system. When the first (custom) products are being sold it should be clear if a more universal system can be developed. In that case the market can be expanded with an affordable product that lots of athletes can use and the proof of its effectiveness will increase the market potential.

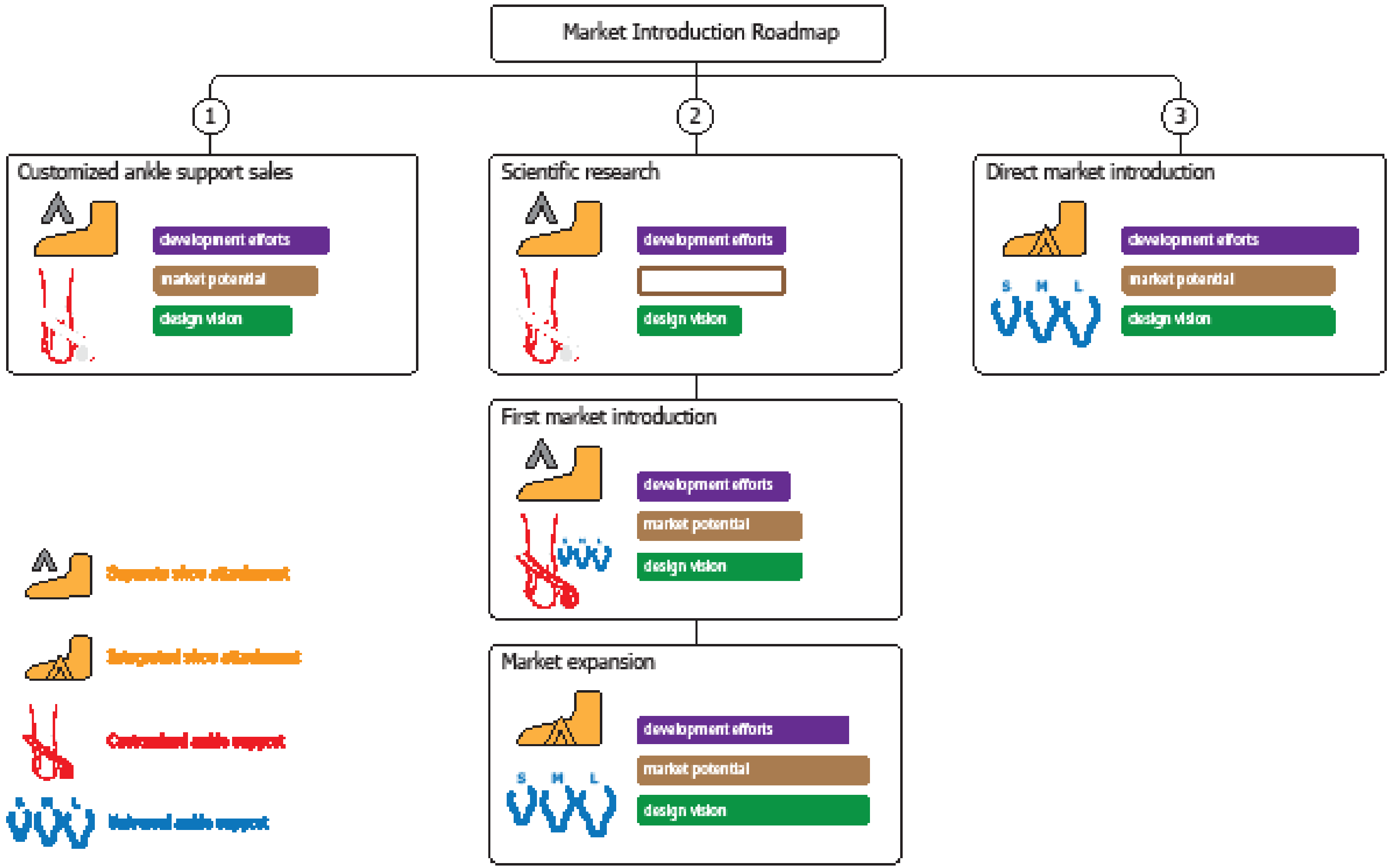


Figure 171. *Market introduction roadmap.*

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