MASTER THESIS

The effect of a novel orthosis on ankle kinematics in simulated sprain

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Abstract

The first line of treatment after an ankle sprain is orthosis wear. Normally the lateral ligaments stabilize the ankle in the frontal plane. When the supporting ligaments are injured post-injury, they are unable to do so, thus an external mechanical support is needed, to ensure ankle stability.

Most modern ankle orthoses are stiff, restricting the foot's movement, making them suboptimal for the joint's function or mobility. Herein a newly designed, active orthosis that utilizes the mechanical properties of shear thickening fluids is tested. The aim of this study was to investigate the novel active orthosis during unexpected ankle inversion (i.e. sport-like movements), and the effect of a passive placebo orthosis (elastic band orthosis).

Sixteen participants with ankle instability and a history of ankle-sprain, performed single-legged drop landings and sudden inversion tilt perturbations on a motorized supination test platform, designed and constructed for this double-blinded, placebo-controlled study and compared against three conditions (i.e. active orthosis, passive placebo orthosis, and no orthosis). During ten falls at two different speeds, three-dimensional kinematic data were collected, from which ankle frontal plane angles were calculated. Assessments were performed using Statistical Parametric Mapping (SPM).

Results showed that there was a significant smaller ankle inversion with the active orthosis compared to the unbraced (no orthosis) controls. In contrast, no significant difference in ankle inversion angle during sudden ankle inversion, was found between the passive placebo orthosis and unbraced (no orthosis) controls. Our findings imply that the novel, active, elastic orthosis does restrain the ankle in a sudden joint inversion, thus preventing a further sprain injury. Additionally, no apparent placebo effect was found with the passive orthosis. These results highlight the role of orthosis design on biomechanical function during sports-related and injury-prone movements.

Acknowledgements

I would like to express my deep gratitude to those who have supported me through this process either with their help, mentorship, or patience.

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A special thank you to my family: My parents, who supported me through my studies and thus allowing me to follow my dream and pursue my studies abroad. **Prof. Dr. Iordania Constantinou** for relentlessly pushing me to complete my thesis, despite how busy I believed I was. Also, I must thank my dog **Pixel**, for keeping me entertained and distracted, when I should have been focused on my writing. My promise to him, to complete my dissertation as soon as possible so we can take longer walks again, kept both of us very motivated. Last but not least, I want to thank **Andria Constantinou** for always believing in me, loving me, and helping me in every way I needed. Nothing would have been possible without her.

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List of Abbreviations

ANOVA	Analysis of Variance
CAI	Chronic Ankle Instability
HFL	Hind-Foot Lateral
HFM	Hind-Foot Medial
ICC	Intraclass Correlation Coefficient
JWI	Julius Wolff Institute
LMA	Lateral Malleolus
MET01	1st Metatarsal
MET05	5th Metatarsal
MIP	Motorized Inversion Plate
MMA	Medial Malleolus
SPM	Statistical Parametric Mapping
STF	Shear Thickening fluids
TUTI	Tuberosity of Tibia

1. Introduction

1.1. Rationale for the clinical investigation of external ankle orthosis.

The ankle is surrounded by various ligaments (fibrous connective tissue) that connect bones to other bones, adding stability and limiting the joint's range of movement. However, when the foot is moved past its normal range of motion, the excess stress, strains the ligament complex that supports the ankle. If the stress is great enough to push the ligament past its yield point, then the ligament becomes damaged or sprained (Wikstrom, Wikstrom, & Hubbard-Turner, 2012). This can be caused by: excessive external rotation, inversion or eversion of the foot caused by an external force, and/or high velocity (Chu et al., 2010).

Along with the knees, ankles are the main weight bearing joints of the body that we rely on for nearly all daily movements. Therefore, when these joints are compromised (e.g. after an injury), our daily activities and quality of life are often greatly affected. The ankle is also a major component in our balance system, so maintaining strong, stable ankles is important for preventing future injuries. Ankle sprain is one of the most common sport-related injuries, accounting for up to 30% of sport injuries (Watanabe et al., 2012). It is estimated that two million acute ankle sprains occur each year in the United States alone (Haraguchi, Toga, Shiba, & Kato, 2007).

What makes ankle sprains particularly challenging, is that despite how common they are, a full recovery is hardly ever achieved. On the contrary, a significant recurrence rate as high as 73% is reported (Yeung, Chan, So, & Yuan, 1994). When patients suffer recurrent episodes of ankle sprains, chronic ankle instability (CAI) might develop, reported in up to 40% of patients following an acute injury (Hintermann, Valderrabano, Boss, Trouillier, & Dick, 2004). The reasons are that the ligaments became stretched, decreasing the stability of the ankle, and the ankle muscles are weakened, due to the limited mobility.

The common clinical practice following an ankle sprain is a functional rehabilitation workout program (Webster & Gribble, 2010); however, a surgical intervention may be needed if the rehabilitation program fails. External support, such as elastic bandages, taping and orthosis, both during, and after treatment, increases the therapeutic effect, since they not only support the treatment but also reduce the risk of re-injury. Having said that, there is a challenge in finding a good external support for athletes, as they must be able to provide adequate stability by restricting the movement of the ankle, without affecting their physical fitness or performance (Gunay, Karaduman, & Ozturk, 2014).

1.2. Orthoses

An orthosis (*pl. orthoses*) is a device worn on the body for therapeutic purposes; alternative terms used are splint, brace, and support. Orthoses work by applying forces to the body that can either assist or resist motion. The therapeutic goals of applying these forces are typically to decrease pain, improve gait stability, facilitate mobility, and/or improve endurance. An orthosis can achieve these goals through various ways, like decreasing or redistributing forces across weight-bearing structures, enhancing joint stability, or improving alignment among body segments. More commonly, orthoses serve to accommodate, modify, or control permanent deformities or movement dysfunctions (Edelstein, 2012).

External support using orthoses is widely used to prevent ankle sprains among athletes, since it reduces the incidence of ankle sprains in previously sprained ankles (Gunay et al., 2014). They do so by: improving the proprioceptive function of a previously injured ankle, becoming a stability structure that protects the ankle, preventing inversion movement, and maintaining the ankle in proper anatomical position at impact (Choisne, McNally, Hoch, & Ringleb, 2019; Ghai, Driller, & Ghai, 2017; Mohammadi, 2007; Stasinopoulos, 2004). This support is often needed in patients with ankle instability, in order to compensate for the sensorimotor loss and the increased peroneal reaction time to resist a sudden inversion movement. Thus, the effectiveness of ankle orthoses has been widely studied in athletic populations.

For example, it was shown that wearing ankle orthosis improved single-limb standing balance in athletes with functional ankle instability, and the use of various braces significantly increased the likelihood of preventing inversion during a jump landing (Ubell, Boylan, Ashton-Miller, & Wojtys, 2003). Similarly, in a randomized controlled trial study with 2562 U.S. basketball players followed for 2 years, a protective effect of taping and a 50% reduction of sprains during games were reported (Thacker et al., 1999). External support using either an ankle orthosis or ankle taping during sports, can reduce the risk of an ankle injury – but orthosis are generally considered to be superior.

A comparison between taping and laced ankle brace, showed laced ankle braces to be twice as effective in preventing ankle injuries. (Callaghan, 1997; Willem van Mechelen, de Vente MSc,

& van Mechelen, 2000). Another significant difference is the perceived comfort ratings of bracing over taping (Verbrugge, 1996). Another aspect to consider is the complexity of taping. Apparently not only is it more time-consuming than putting on an orthosis, but there is also greater room for application error and thus compromising their effectiveness (Mickel et al., 2006). Further comparisons between semi-rigid orthosis and adhesive tape, revealed maximal losses in mechanical restrictions in taping at 20 minutes into exercise, where orthosis only demonstrated minimal losses (Rarick, Bigley, Karst, & Malina, 1962). This implies that, once an athlete gets on the field, the ankle tape could loosen and not provide enough ankle support. Overall, bracing appears to offer a more reliable form of sports-related support for ankle injury prevention.

1.3. The pathophysiology / multifactorial nature of chronic ankle instability

1.3.1. *Ankle joint complex*

The ankle joint complex (Figure 1) consists of three articulations: the talocrural, subtalar and distal tibiofibular joints. The three joints work together to allow coordinated movement of the hindfoot in three cardinal planes: the sagittal plane (plantarflexion and dorsiflexion), the frontal plane (inversion and eversion) and the transverse plane (internal and external rotation). Hindfoot motion does not occur in isolation but rather in a coordinated, coupled motion, best described as pronation (dorsiflexion, eversion and external rotation) and supination (plantarflexion, inversion and internal rotation) (Rockar Jr, 1995).

The biomechanics of the ankle is complex, with joint stability provided by three groups of ligaments: the lateral collateral ligaments, the medial collateral ligaments and the tibiofibular syndesmosis (Brockett & Chapman, 2016) (Fig. 1). In a loaded ankle, the osseous anatomy is the most critical, as the talus compresses into the bony mortice, resulting in primary stability. Whereas in an unloaded ankle, a combination of static ligamentous restraints and musculotendinous units play more vital roles, with each ankle ligament contributing a different function, depending on the position of the foot and ankle in space (Tanaka & Mason, 2011). In an inversion sprain, the most commonly injured ligament is the anterior talofibular (Colville, Marder, Boyle, & Zarins, 1990). Anatomic classification of ankle sprains is based on the number of affected ligaments. In first degree sprain there is a partial or complete tear of the anterior talofibular ligament, in second-degree sprain both the anterior talofibular and calcaneofibular ligaments are either partially or completely torn and in third-degree sprain the anterior talofibular, calcaneofibular, and posterior talofibular ligaments are injured (Rosenberg, Beltran, & Bencardino, 2000).

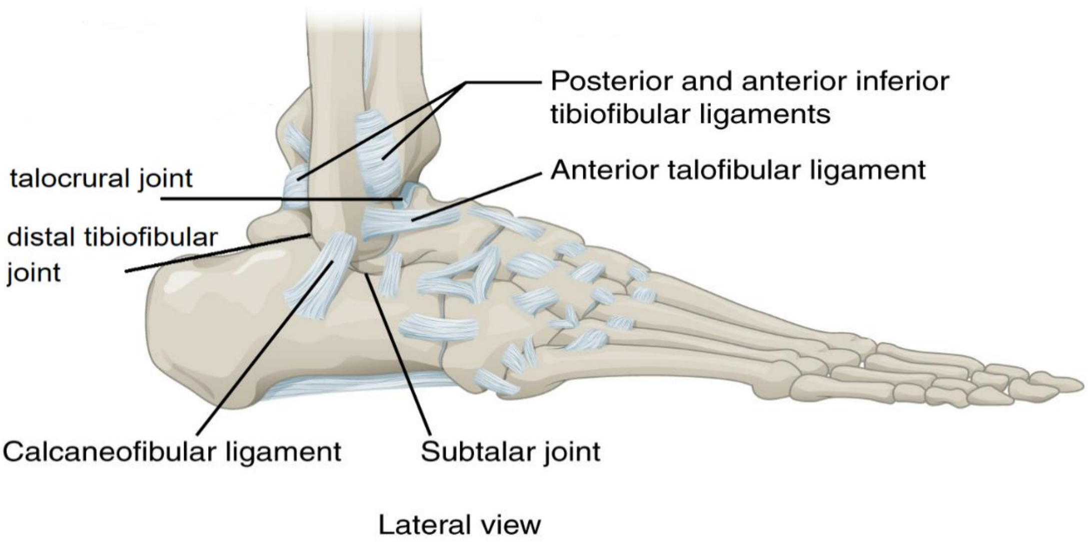

Figure 1: Ankle joint complex (Figure taken from https://singaporeosteopathy.com/tag/ligament/)

1.3.2. ***Ligament healing after injury***

When damaged, ligament function is restored by the formation of scar tissue, a biomechanically inferior connection. The remodeling phase of ligament repair lasts months to years and can have a great effect on joint biomechanics. During this time, the ligament can either adapt with functional improvement or degrade and fail, depending on the functional demands placed on the remodeled tissue (Hauser et al., 2013). During the recovery phase, viscoelastic properties recover to ~10-20% of normal, implying that scars tend to stress-relax to a greater extent, and therefore can maintain a load less efficiently than healthy ligaments (Frank, 2004). Ligament scars also have inferior creep properties (i.e. deformation), creeping twice as much as normal during cyclic and static loads; that is only a fraction of the initial load that caused the injury in the first place (Thornton, Leask, Shrive, & Frank, 2000). Meaning that a healing ligament does not fully recover. It is weaker, less stiff and able to absorbs less energy than normal ligament (Frank, 2004). In summary, ligaments tend to heal with much less strength and elasticity than the original tissue (being more lax). This could explain the high rate of reoccurrence.

1.3.3. *Muscle weakness*

Another contributing factor for the frequent recurrent episodes of ankle sprains is muscle weakness. As a result of the lower mechanical restraint in the ligaments, in addition to the sensorimotor loss, weakness of the peroneal muscles is related to chronic ankle instability. Loss of evertor strength reduces the ability of these muscles to resist inversion and return the foot to a neutral position preventing an inversion sprain. Li et al. (2018) observed that CAI participants exhibited reduced ankle evertor activation compared to healthy individuals, when performing a double-leg landing with the injured limb landing on the tilted surface. In simple words, this could potentially place CAI patients at a higher risk of “giving away”, resulting in further sprain injury. The same study showed that during the landing phase, an increased tibialis anterior activation in the CAI patients led to increased co-contraction of ankle muscles in the sagittal and frontal plane, thus suggesting that this frontal plane activation could reduce the energy dissipation at the ankle joint.

1.3.4. *Peroneal reaction time*

Reaction time is a measure of the speed at which an organism responds to some sort of stimulus. When the foot is forced into a compromised position, the mechanoreceptors in the ankle ligaments and joint capsule sense the extreme or sudden movements and initiate a dynamic restraint. Various studies have shown the reaction time of the injured ankle to be prolonged (~70ms), compared to healthy, non-injured individuals (~60ms) (Denyer, Hewitt, & Mitchell, 2013; Lars Konradsen & Ravn, 1990; L Konradsen & Ravn, 1991; Linford et al., 2006). The measurement of the reflex time of the peroneus muscle group contraction in response to the inversion of the ankle, represents one way of obtaining information about functional instability.

1.3.5. *Proprioception*

Proprioception is the sense of the relative position of one's own parts of the body. Even if the person is blindfolded, he or she knows through proprioception where a limb is in space, e.g. an arm being above the head or on the side. In humans, proprioception is provided by proprioceptors and the fibrous capsules in the joints. Hence, when the limb is extended beyond its range of motion (in this case, after an ankle sprain) one’s sense of location of that limb is disturbed (Han, Anson, Waddington, Adams, & Liu, 2015). Possible experiences include a mismatch between the proprioception of the desired ankle position and its actual position, which can therefore interfere with the control of movements, e.g. possibly resulting in a fall while walking, especially when the attention of the person is focused upon something else, rather than the act of walking (Hertel, 2002).

Evidence suggests that application of joint stabilizers, enhances joint proprioception and stability, not only by altering the mechanical stability of the underlying musculoskeletal structures, but also by causing subtle changes in cerebral hemodynamics and musculoskeletal activation (Ghai et al., 2017). These findings support the clinical use of joint stabilizers as a prophylactic and rehabilitation measure in modern sports and rehabilitation settings (Armatas, Chondrou, Yiannakos, Galazoulas, & Velkopoulos, 2007).

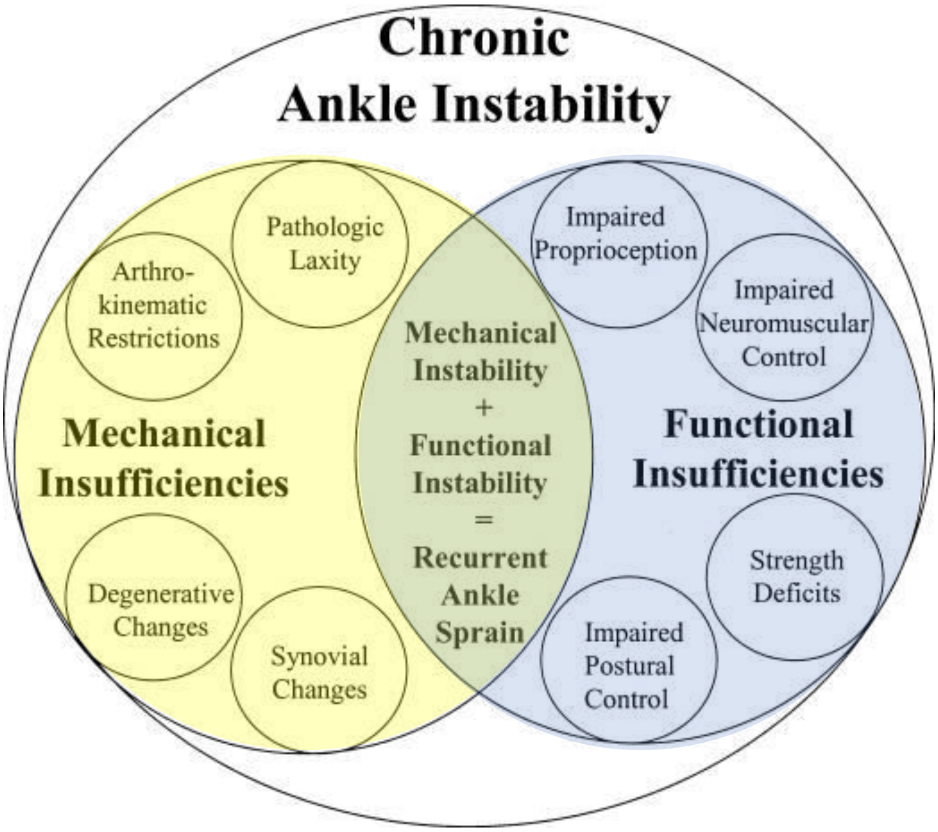

Figure 2: Mechanical and functional insufficiencies contributing to CAI. (Figure modified from (Hertel, 2002))

1.3.6. *Inversion angles and velocity*

Despite how common ankle inversion sprains are among athletes, it is difficult to replicate such injuries in clinical studies, in a safe or ethical manner. To study sprain mechanisms, simulators that imitate ankle inversion movements (i.e. landing positions prone to sprain injury), like tilt platforms or trapdoors, are designed. A wide range of safely implemented inversion angles have been reported in the literature, ranging from 20° to 50° (Eechaute, Vaes, Duquet, & Van Gheluwe, 2009; Osborne, Chou, Laskowski, Smith, & Kaufman, 2001). Even though, a 35° inversion has been reported to be sufficient to cause a real injury (Johnson & Johnson, 1993; Kristianslund, Bahr, & Krosshaug, 2011; Nawoczenski, Owen, Ecker, Altman, & Epler, 1985).

However, inversion angle is not the only parameter being considered; speed also contributes to the severity of an injury. Therefore, investigators have employed tilting platforms, with different kinematic controls that regulate the inversion velocity (i.e. the displacement of an object with respect to time), in order to create more realistic scenarios. The range of inversion velocities documented in the literature varied, from 50°/s to over 600°/s (Knight & Weimar, 2012; Lynch, Eklund, Gottlieb, Renstrom, & Beynnon, 1996). Notably, sprain accident cases were recorded during two separate laboratory trials, with a maximum inversion velocity recorded at 632°/s and 1752°/s, respectively (Fong et al., 2009; Mok et al., 2011). This suggests that a speed below 500°/s should be considered in similar trials.

In the quest of studying the real mechanism of ankle sprains under more realistic scenarios, Mok et al. (2011) analyzed two athletic injuries, using motion analysis on data collected from the injury surveillance system of the 2008 Beijing Olympics (using model-based image-matching). The analysis revealed that the ankle joint was 142° and 78° inverted, respectively, whereas the maximum inversion velocities were 1752 deg/s and 1397 deg/s, respectively. Similar studies that implement such new technologies and video documentation of live sports events, could mark a new era in research. By doing so, we might be able to fill the gaps of our current understanding, and subsequently help establish safer protocols for future trials (e.g. when testing new orthoses).

1.4. Novel orthosis and active module

The new orthosis (Fig. 3) examined in the present thesis was developed by Betterguards GmbH, to selectively restrict the inversion of the ankle. Its function could be described similar to that of a car seat belt; it utilizes the chemical properties of shear-thickening fluids, in order to allow movements below a certain force level, while restricting the ones that are high enough to cause an injury. A patented module (*V. Bichler, U.S. Patent No. US20150173926A1 (25 June, 2015)*) that contains the shear-thickening fluid is inserted on a cuff-like orthosis that surrounds the ankle and ties into the insole of the shoe (Fig. 3).

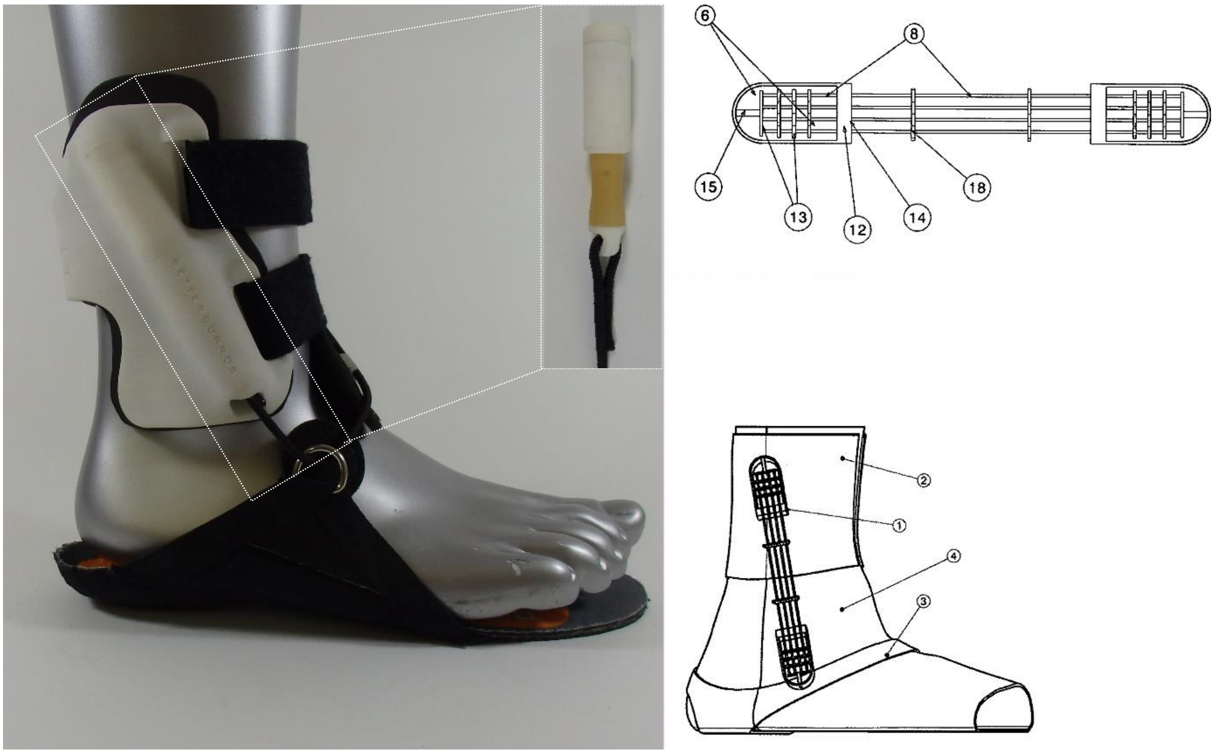

Figure 3: Active ankle orthosis and Shear-thickening fluid module. Courtesy by Betterguards® (2018). (1) Device, (2) & (3) Fixing structures, (4) Stocking, (6) Fluid, (8) Body, (12) Capsule, (13) Contours and characteristics, (14) Capsule with sealing system, (15) Retaining mechanism, (18) Guiding device

Shear thickening fluids (STFs) are characterized by an increase in effective viscosity when the shear rate increases above a certain critical value. This means that the higher the shear rate is, the more viscous the fluid becomes. Although STFs are much less common for industrial use compared to shear thinning materials, an increasing number of applications takes advantage of the shear thickening behavior of these fluids. Some examples include: STFs added to Kevlar® fabrics, in order to improve their ballistic protection capabilities (Galindo-Rosales, Rubio-

Hernández, & Sevilla, 2011), the addition of STFs in gloves to reduce vibration or protect the hands from jarring impact and STFs added in sport-shoe designs for energy dissipative construction (Ding et al., 2013). The main feature of STFs, that makes it particularly favorable, is their reversible process ability, meaning the fluid can return to its initial liquid state after removing the applied load (Gürgen, Kuşhan, & Li, 2017).

This technology was employed in designing this novel orthosis, since it allows for a free movement below a certain (angular) velocity threshold but disallows movement above it; this can be optimized for selective velocities (e.g. those in a sprain). This special feature is quite unique, considering an ideal joint stabilizer must provide optimized compression, be comfortable, fit the ankle correctly, and have maximum skin contact. These factors are especially crucial for optimal sports performance among professional athletes, while still maintaining an efficient injury prevention and rehabilitation process (Fu, Liu, and Fang, 2013).

1.5. Ankle inversion sprain simulators in biomechanical laboratories

Ankle inversion sprain is one of the most common sports injuries yet investigating such incidents in real life is rather complicated and replicating them on study participants is unethical. This has led to the design of simulators, such as tilt platforms and trapdoors, that can mimic ankle inversion movements in a laboratory setting, while ensuring the participants safety. In real life, ankle sprains occur in dynamic situations, e.g. running, jumping, or when stepping on uneven surfaces. The first reported study incorporating a tilt platform was in 1981 (Sprigings, Pelton, & Brandell, 1981). These first platforms only took into account the inversion angle, but as outlined above, an ankle sprain is rather multifactorial. Thus, in recent studies, more factors are taken into consideration when designing such simulators, including inversion, plantarflexion, and inversion velocity. Depending on the scope, investigators have employed these simulators to perform various motion tasks, e.g. standing, step down, jump landing or walking, to evaluate different effects, including muscle activation, sensorimotor influences, and external protectors (Ha, Fong, & Chan, 2015).

All simulators have their strengths and weaknesses, and design features should be considered based on the study aims. For the presented study, three main features were implemented: 1) Based on the fact that speed also contributes to the injury, our tilt platform had two kinematic controls, simulating a "fast" and "physiological" inversion movement. 2) A small force plate was built onto the non-tilting portion of the platform (i.e. non-injured foot) in order to ensure that patients placed 80% of their bodyweight on the injured leg and only 20% onto the force plate. 3) An external control triggered the fall unexpectedly, to reduce any anticipatory effect.

1.6. Aim and Project plan

As outlined above, stimulating an ankle sprain, and studying the efficacy of protective external support can be very challenging. The presented work focuses on two main aspects: a) the possible protective effect of the novel orthosis and b) the possible effect of an orthosis application. More specifically, the aim of this study was to investigate the effect of wearing a novel active ankle orthosis, on the frontal plane ankle joint angle during an unexpected ankle inversion, taking into account the possible placebo effect of orthosis application.

Each orthosis (i.e. active or placebo) was compared to a control situation where no orthosis was worn. The passive placebo orthosis contained only an elastic band that functioned as a placebo to account for the effect of wearing an orthosis, regardless whether it provides support or not. The study used a double-blinded, randomized control design.

2. Methods

The study was conducted at Julius Wolff Institute (JWI) for Biomechanics and Musculoskeletal Regeneration Charité-Universitätsmedizin Berlin in Berlin, Germany.

The JWI has access to a gait lab equipped with cutting-edge equipment and is able to perform various motion analyses. It is equipped with 10 VICON Nexus cameras surrounding a large volume.

2.1. Motion capture

Motion capture is the recording of movement by an array of video cameras in order to reproduce these movements in a digital environment. This three-dimensional reproduction has many uses:

• Medical assessment of movement disorders

• Understanding of athletic techniques

• Generating lifelike character animation for movies, video games, broadcast, and webcast.

2.1.1. *How Vicon Works*

A typical motion capture space comprises an area – the capture volume – surrounded by several high-resolution cameras. Each camera has a ring of LED strobe lights fixed around the lens. The subject, whose motion is to be captured, has a number of reflective markers attached to their body, in pre-defined positions. As the subject moves through the capture volume, light from the strobe is reflected into the camera lens and strikes a light sensitive plate creating a video signal (Tebbutt, Wood, & King, 2002).

The Vicon Data station controls the cameras and strobes and collects these signals, along with any other recorded data (sound or analogue signals from force plates for gait analysis). Workstation (Vicon Nexus v.1.8.6) is the central application of the Vicon software suite used to collect and process the raw video data. It takes the two-dimensional data from each camera, combining it with calibration data to reconstruct the equivalent digital motion in three dimensions.

This can be viewed in Vicon Nexus as a virtual three-dimensional motion. After this reconstruction, the data may be passed to other Vicon applications for analysis and manipulation. Lastly, raw 3D data of the kinematics were exported and used in MATLAB for analysis.

2.1.2. *Markers*

Movements of the body were tracked using markers coated with a retroreflective material, which reflect light generated near the camera's lens. The camera's threshold can be adjusted so only the bright reflective markers will be sampled, ignoring other objects in the field of vision, for example poles that may reflect a bit of light etc.

The centroid of the marker is estimated as a position within the two-dimensional image that is captured. The grayscale value of each pixel can be used to provide sub-pixel accuracy.

Most of the markers were attached directly to the skin, but as all subjects needed to wear shoes on top of the orthosis for it to function, some markers were placed on the shoes. A 15.9 mm marker diameter was selected because it offered an adequate reflective surface for identification without obscuring neighboring markers.

2.2. Motorized Inversion Platform

A motorized inversion test platform (MIP), which could safely and suddenly invert the ankle, was built, and provided for the study by Betterguards GmbH. One side of the platform was motorized and could fall with the desired rotational velocity and on the non-falling side, an external force plate was fitted. Two different rotational velocities were used, 400°/s for active module activation and 150°/s to demonstrate that active module does not restrict movement below threshold. Each subject repeated five trials of each velocity, in a random order.

The platform was connected to a PC operated by a member of the product manufacture team (i.e. Betterguards, MIP operator). The MIP operator adjusted the speed (400°/s or 150°/s), based on a randomly, preselected order for each subject. The platform constituted a tilting and a non-tilting portion, where the injured and non-injured foot was placed, respectively. The external force plate, where the non-injured leg rested, was built onto the MIP, and connected as an external port in the VICON system. Patients were asked to place 80% of their bodyweight onto the tilting platform, so that most of their bodyweight was on the injured leg. The platform was activated only after ensuring that the weight was contributed between the two legs at 80% and 20% for 2 seconds. More photographs of the platform can be found in APPENDIX A.

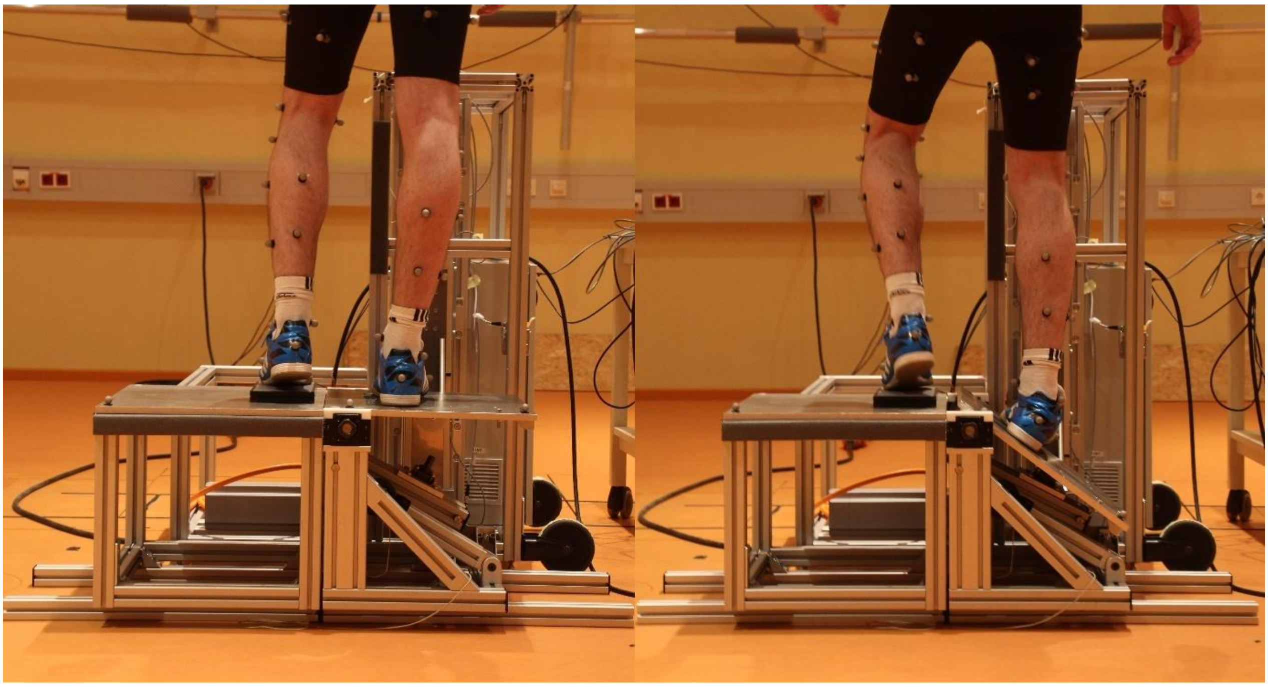

Figure 4: Patient standing on the MIP before and after the platform dropped. Right leg on the tilting platform, holding 80% of the subject's body weight. Left leg on the force plate of the non-titling side. (Image from (Agres, Chrysanthou, & Raffalt, 2019))

2.3. Patients

All protocols were developed according to the Declaration of Helsinki. The local ethics committee (EA1/335/16) approved the study. All subjects provided their written informed consent before their participation.

A total of sixteen volunteer patients were recruited. Inclusions criteria were a history of unilateral lateral ankle sprain, at least in the year prior and participation in recreational sports for at least 3 hours per week. Exclusion criteria for this study were: any other injury or surgery on the lower extremity rather than an ankle injury within the last 4 weeks, a balance disorder, a foot deformity or any other problem in the lower part that could potentially affect the performance of this study.

2.4. Measurement preparation

2.4.1. *Preparation and calibration of the cameras*

Approximately thirty minutes before each trial, a lab preparation took place. Before the calibration, the cameras were masked to remove any reflections created by the room that may intervene with the real markers. To perform the calibration, a standardized wand with five reflective markers was used. The markers attached on the wand were at known positions and were used to calibrate the cameras, obtain their positions, and measure lens distortion. For more accuracy, each camera was set to record 9000 registrations of the wand at a 400Hz frequency. Additionally, during the calibration, the volume of the room was described to the cameras, ensuring an accurate 3D volume capture. Finally, the wand was placed flat down in a known position in the middle of the focusing point of the cameras and the volume origin was set.

Figure 5: Gait laboratory used in this study

2.4.2. *Patient preparation*

Upon arrival at the laboratory, the patient was introduced to the experimental setup and protocol. The patient's own training shoes was used for the trial, but they were previously mounted with the special orthosis insole on both, left and right shoes.

Body measurements were then recorded. Three circumferences of the patient's thigh and shank were measured (proximal/middle/distal), in addition to the leg length (from Anterior Pelvis marker to lateral malleolus marker), and foot length for both left and right leg. Moreover, body mass and height were documented.

2.4.3. ***Marker placement***

The marker set used was placed on 59 predefined anatomical points of the body, as shown in Fig. 6.

Based on the Oxford Foot Model to specifically assess hindfoot inversion (Stebbins, Harrington, Thompson, Zavatsky, & Theologis, 2006), in addition to the standard marker placement (Fig. 6), four more markers were added to each foot, in order to maximize the foot visibility. Specifically, two markers were placed on the lateral and medial of the hind foot, a marker on the fifth toe and a marker on the big toe. (Fig. 7)

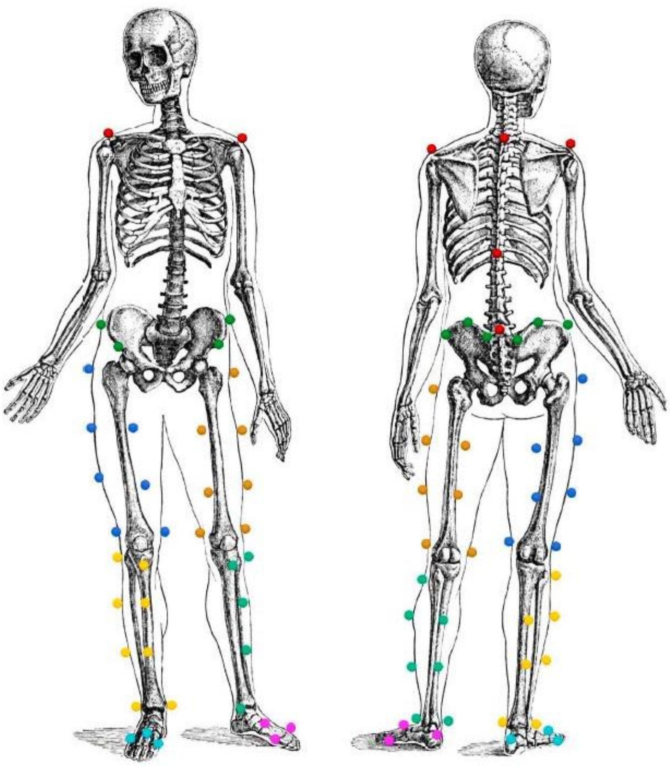

Figure 6: JWI markers set of lower extremity and trunk

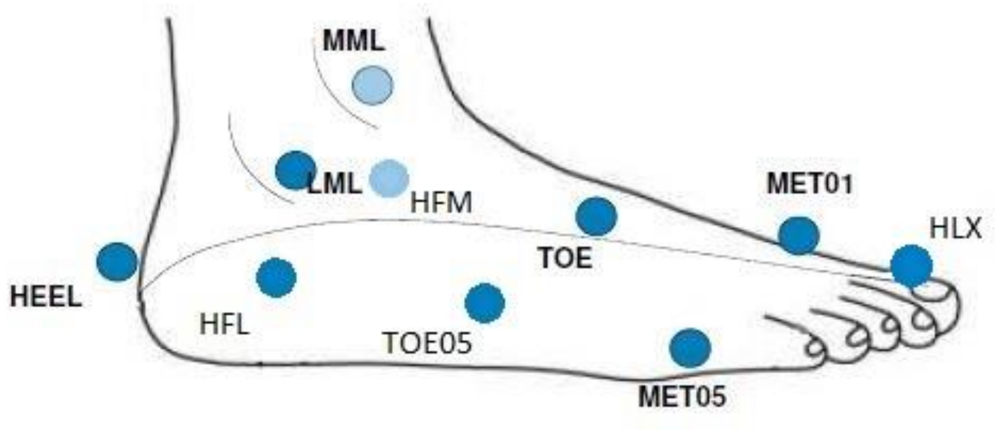

Figure 7: Complete foot marker set

2.5. Start of measurement

2.5.1. *Session 1: movement*

Calibration activity

First, static trials and calibration movements were recorded for both legs. Calibration movements included a star arc, knee flexion extension, foot flexion extension, foot circle and foot inversion eversion. These movements are used for the calculation of the knee angles and hip and are out of the scope of this thesis. The reason why the inversion and eversion movements were performed were to obtain the physiological range of motion as a baseline of comparison. Additionally, to minimize an injury possibility, the patients warmed up by doing the movement trials, before proceeding to the MIP trials described below.

2.5.2. *Session 2: MIP*

Baseline without an orthosis

For maximum visibility, the MIP was placed in the center of focus of the cameras. The sample frequency of the VICON motion capture system was set at 400Hz. All patients were asked to follow a particular stance on the platform, having the injured leg on the dropping plate and the other on the built-in force plate. When 20% of the body weight was on the force plate, the recording started, and the MIP platform dropped. To ensure a natural reaction of an unexpected fall, the MIP operator used a random period of 1s ~ 3s before dropping the MIP.

2.5.3. *Repeat with orthosis*

The trials were then performed again, but this time wearing one of the two orthoses (novel active or placebo). The pick was random and only the MIP operator knew which one was being used.

2.5.4. *Day 02*

The patient returned to the laboratory within approximately 3 days. The trial was repeated under the same conditions, using the orthosis that was not used on Day 01.

The data collected during trials were transferred to the main server for further processing.

A visualization (Chevron list) depicting the study design can be seen at Figure 8.

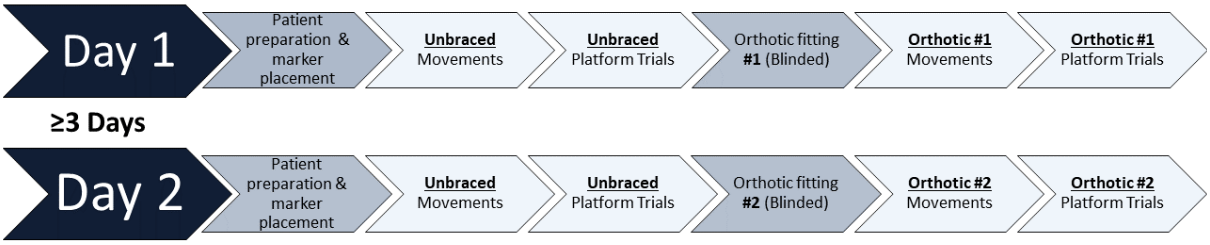

Figure 8: Visualization of the study design

2.6. VICON Processing

Firstly, using VICON Nexus, the markers were reconstructed with a core processing pipeline. For the core processing to run, a minimum of three cameras were required to start a marker construction and two cameras to keep track of it. In short, a marker must be seen by at least three cameras and stay visible to at least two.

To ensure the robustness throughout the study, a template containing the segments, joints and names of markers was created. To do so, the reconstructed markers were used. At least three markers created a plane/segment. Once all segments were defined, a relevant joint correlation with the neighbor segment was given. The joint could be defined as any types of joint, e.g. hinge joint, free joint. Lastly, each marker identified, had to be renamed to the corresponding marker name.

Later, in order to create the skeleton, each marker had to be identified and labeled manually. When all trials had been labeled, the three-dimensional trajectories and header of all labeled markers were exported to an ASCII file (.csv file) containing the locations of markers within the given volume. This allowed for data import in MATLAB for further processing.

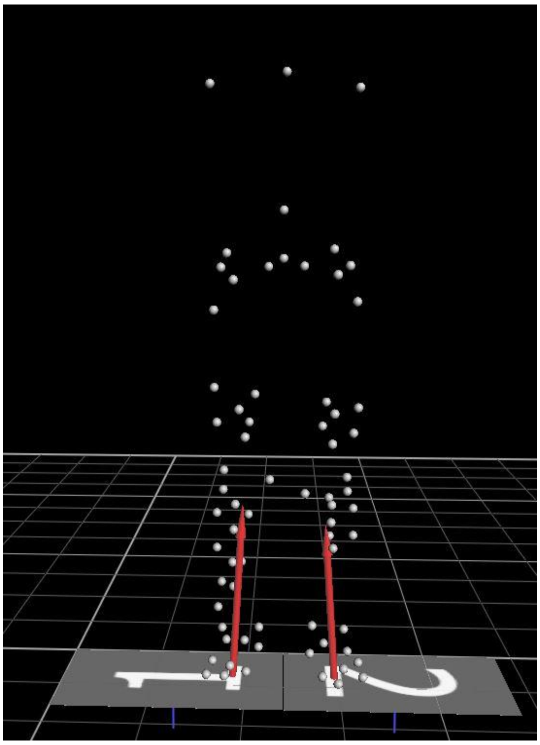

Figure 9: VICON Nexus trial unlabeled

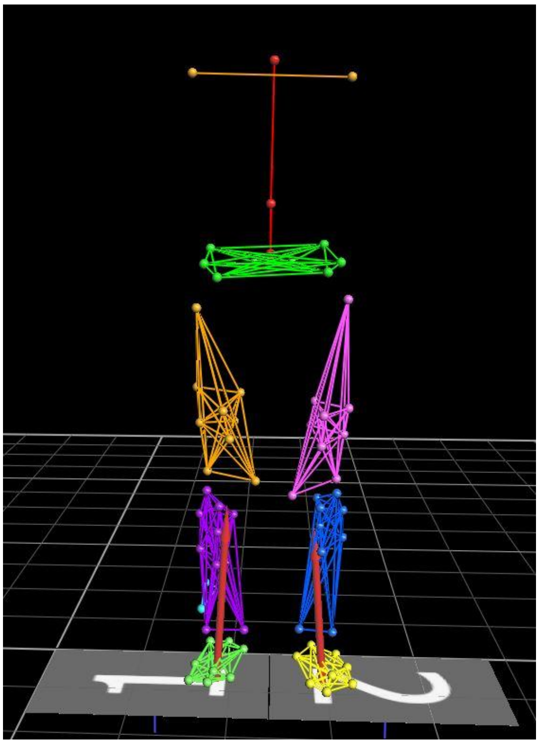

Figure 10: VICON Nexus trial labeled

2.7. Calculation of angles

For the calculation of the ankle angle, a MATLAB code was written. To obtain this angle different calculation ways were considered.

Such an analysis is very complex, due to the presence of two distinct joints, the tibiotalar and the subtalar, and their three-dimensional and multiaxial motion (Sancisi, Parenti-Castelli, Corazza, & Leardini, 2009). Various methods have been proposed in biomechanics for the description of its motion, such as Euler/Cardan angles, screw axis or helical axis and many attempts on standardization of joint motion have been previously made.

2.7.1. *Helical angles*

A helical axis represents joint motion as a rotation around a single fixed axis (Woltring, Huiskes, de Lange, & Veldpaus, 1985).

The helical axis method was first considered for the inversion angle, as it permits a description of body orientation, without referring to an arbitrary chosen axis of rotation. This means that the segment is free to move without restriction, on which rotation comes first (as it is with Euler angles). This was preferable due to the complexity of the ankle and because a helical angle can better decompose the smaller angle movements.

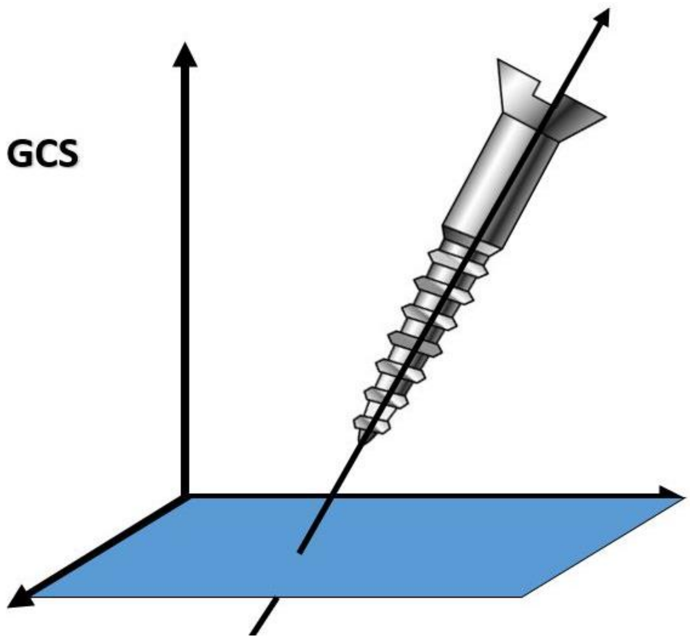

Figure 11: Helical/Screw principle

2.7.2. ***Euler angles***

In the Euler angles method, Cartesian coordinate systems are defined in the fixed and moving segments of a joint. At any joint position, Euler angles describe the orientation of a rigid body with respect to a fixed coordinate system by three ordered rotation angles around the coordinate axes on the moving segment or on the fixed segment. The magnitudes of the three rotation angles depend on the sequence of rotation. Because only the rotation of the joint can be described by Euler/Cardan angles, to describe the general spatial joint motion completely, an additional three-dimensional vector representing the position of the moving segment coordinate system with respect to the fixed segment coordinate system is required. Since the rotation angles are referred to the moving segment coordinate system, the translation has to be described with different coordinate system separately, which does not facilitate the interpretation (Ying & Kim, 2002).

2.8. Code development

For the development of a suitable code, data from a pilot test subject were used. A number of tests were performed for feasibility in the patient's cohort: to ensure best visibility of markers and proper use of the MIP platform.

The maximum inversion – eversion movement data were used; obtained from the calibration movements (section 7.2). Analysis of this movement could identify if the code developed gave accurate and correct data.

Firstly, Euler angles were used as it is the most widespread method of analyzing joint movement. However, the obtained angle was not good enough, possibly due to the subject "rocking" on the frontal plane. The calculation of the inversion angle was imprecise.

Helical angles were tested afterwards. The way the helical/screw calculation was set, was taking into account both the plantarflexion and the inversion movement. The extracted angle was found to be more realistic.

However, this was not the case for the MIP trials.

At the beginning of the analysis it was decided to continue with the Helical/Screw angles. But when processing the MIP data, some of the angles were quite off (with some angles being over 35 degrees, exceeding the maximum value the platform can reach). The explaining was that the foot would sometime slip, and so abduction movement was influencing the angle. What this meant is that what was calculated, was expressing the whole movement range (inversion and plantarflexion). On the contrary, Euler angles express the movement of only one plane. Since our scope was to investigate the effect of the orthosis on its ability to protect the ankle in the frontal plane, the Helical/Screw method was dropped, and Euler angles were further developed and implemented.

The same MIP trials of a random subject were calculated using the two techniques and then plotted. In the following Figure (Fig. 12) a comparison of the helical and Euler angles calculated is shown. Note that the helical angles exceed the maximum 35 degrees that the platform reached.

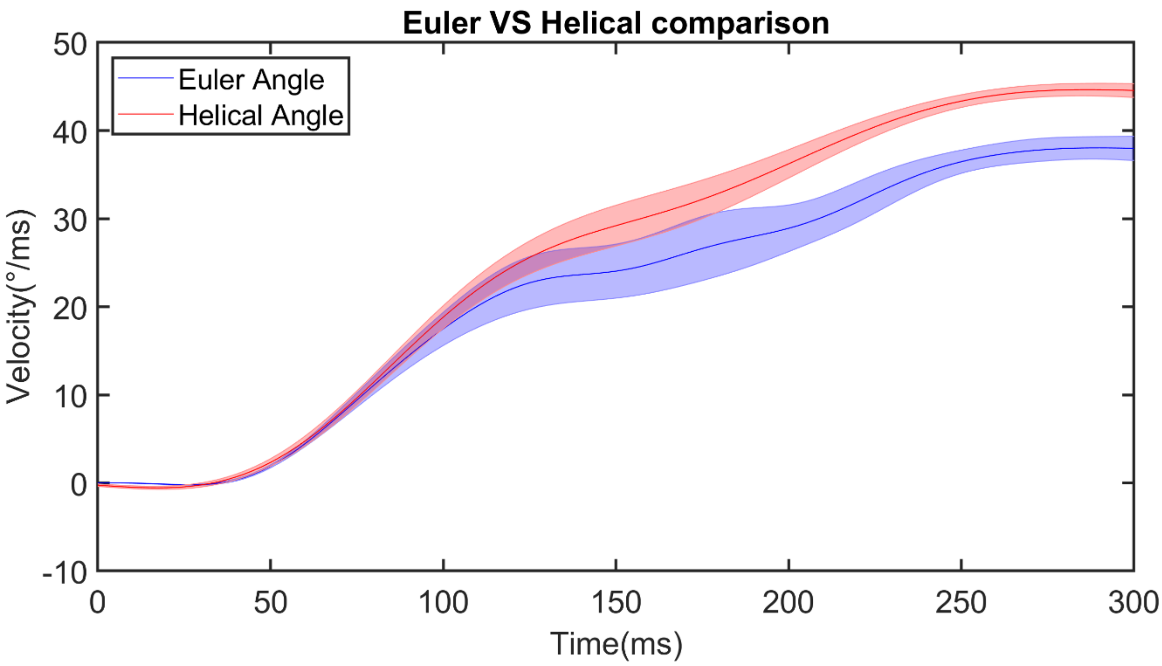

Figure 12:Comparison of output - Euler and Helical Angles

2.8.1. ***Code structure***

All the csv's files were loaded in the MATLAB workspace and separated by the patient's code. A sub function read the data from the csv and separated them by markers. The previously defined markers were loaded in the workspace. The markers data were passed from a Butterworth filter design (MATLAB's butter function), to remove the noise produced by bad marker visibility, markers shaking, etc. The filter was designed as a 4th order lowpass filter, with a normalized cut off frequency of 20Hz.

An example of the filtering can be seen in Figure 13 were a 400°/s angle trial is visualized.

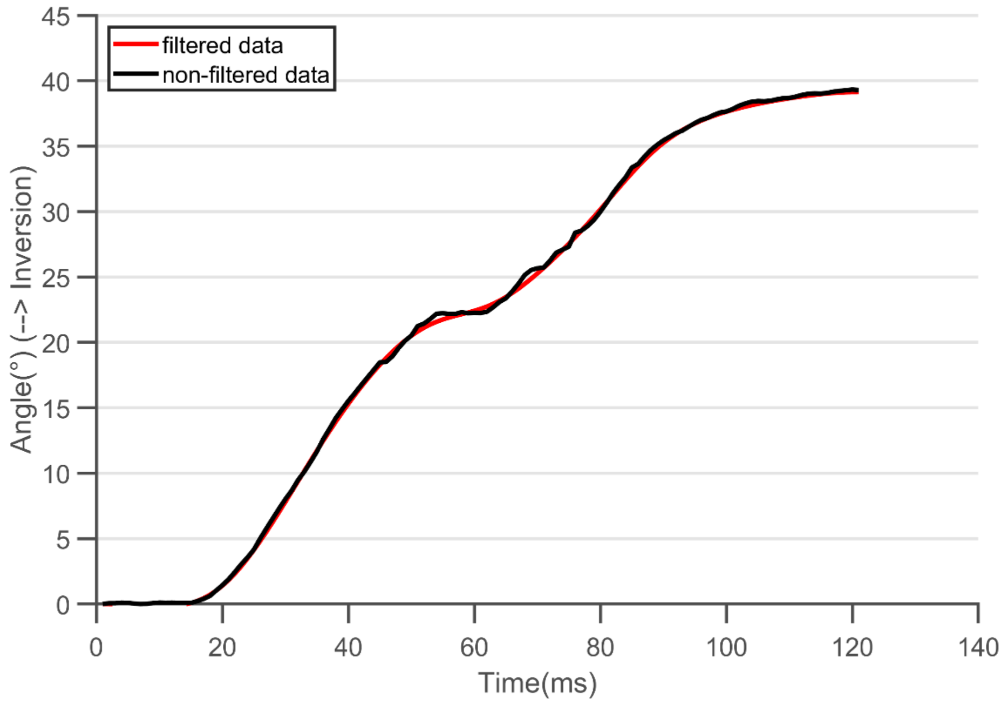

Figure 13: Filtered vs Non-filtered angle of a random subject

For the definition of the local coordinate systems on the segments of interest (shank and foot on the tested side), different marker sets were tested for accuracy, as visibility was difficult, and a threshold for marker numbers needed to be determined.

First, to determine which set offers the most accuracy, a set of six, five, four and three markers for each segment was used and compared. We observed that the more markers used, the smoother and more accurate the ankle line produced was. However, they were also more prone to a marker disappearing during the capture, resulting in a part of the angle being completely off. A three markers segment construction was then decided.

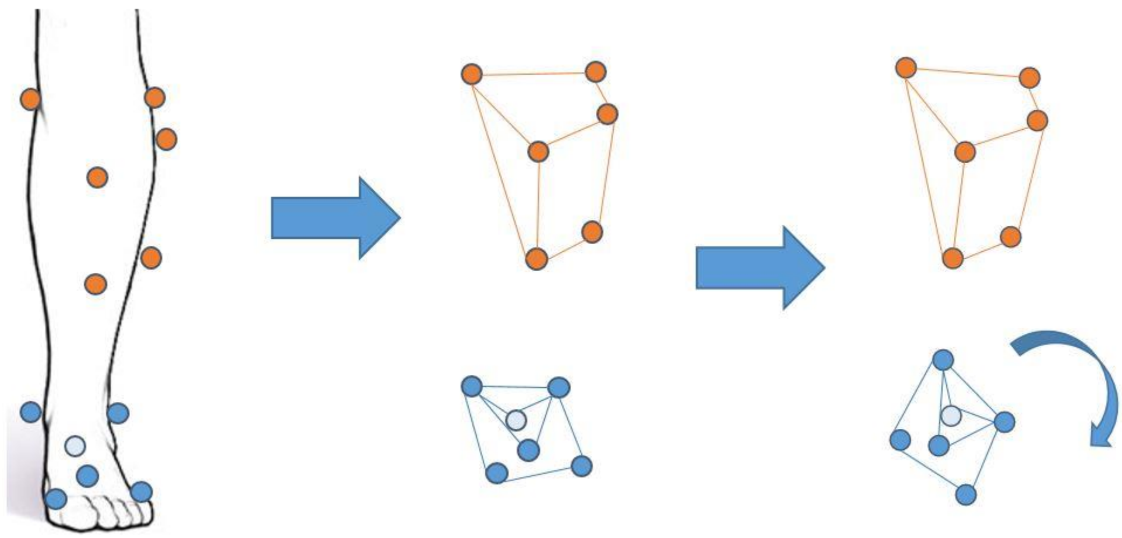

Figure 14: Two segments construction

After that, three required markers were chosen based on palpable bony landmarks. First, the international standards for the segments were used as described by Vaughan, Davis, and Jeremy (1999) and Taylor et al. (2010). The markers are set as:

- For the Shank: TUTI (tuberosity of tibia), MMA (medial malleolus), LMA (lateral malleolus)
- For the Foot: HEEL, MET01 (1^{st} metatarsal), MET05 (5^{th} metatarsal)

This standardized definition was then compared with the Oxford Foot Model (Stebbins et al., 2006):

- For the Shank: TUTI (tuberosity of tibia), MMA (medial malleolus), LMA (lateral malleolus)
- Foot: HEEL, HFM (hind-foot medial), HFL (hind-foot lateral) - (posterior, medial, and lateral calcaneus markers).

The angle produced was almost identical for both standard and Oxford model. Due to better visibility of the markers near the ankle, it was decided to use the lateral one as standard for all patient measurements.

To counteract when a marker from the defined model was not visible, the following procedure was used for choosing a substitute:

- In case TUTI marker is not usable, CAFI is used.
- In case HEEL marker is not usable, TOE is used.
- In case HFL marker is not usable, TOE05 is used or MET05.
- In case HFM marker is not usable, MET01 is used.

A visualization/decision tree of this can be seen at Figure 15.

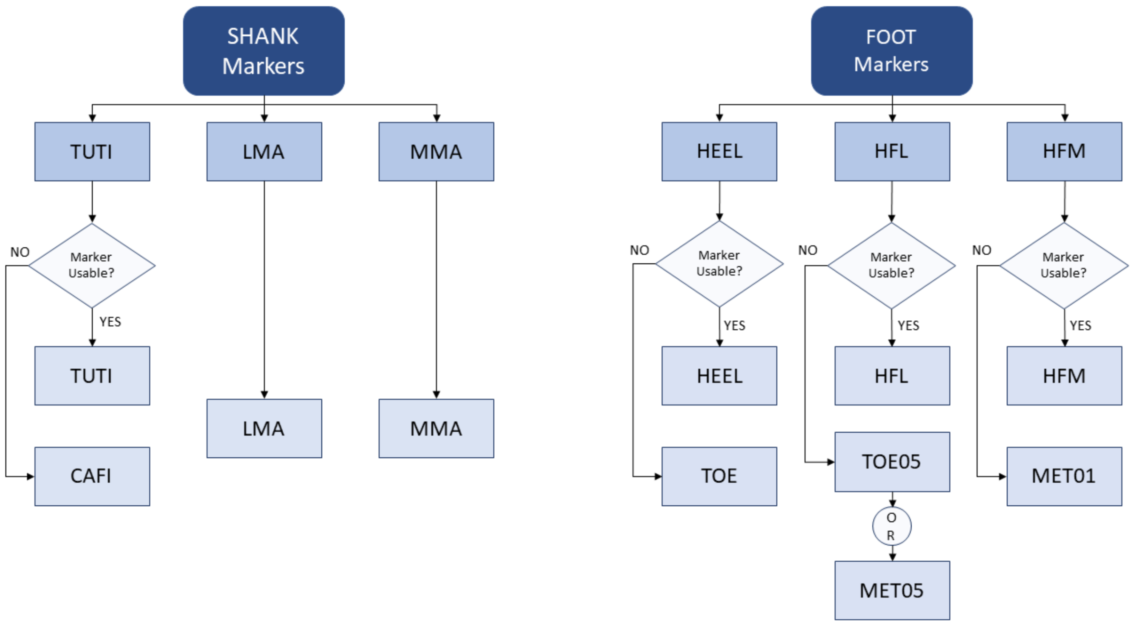

Figure 15: Decision tree for the markers

All combinations were tested and almost the same angle was produced each time. Such example is shown in Figure 16; a graph with the angle produced using different marker setups. A small deviation exists, but this occurs after ~170ms, when the movement has already been completed.

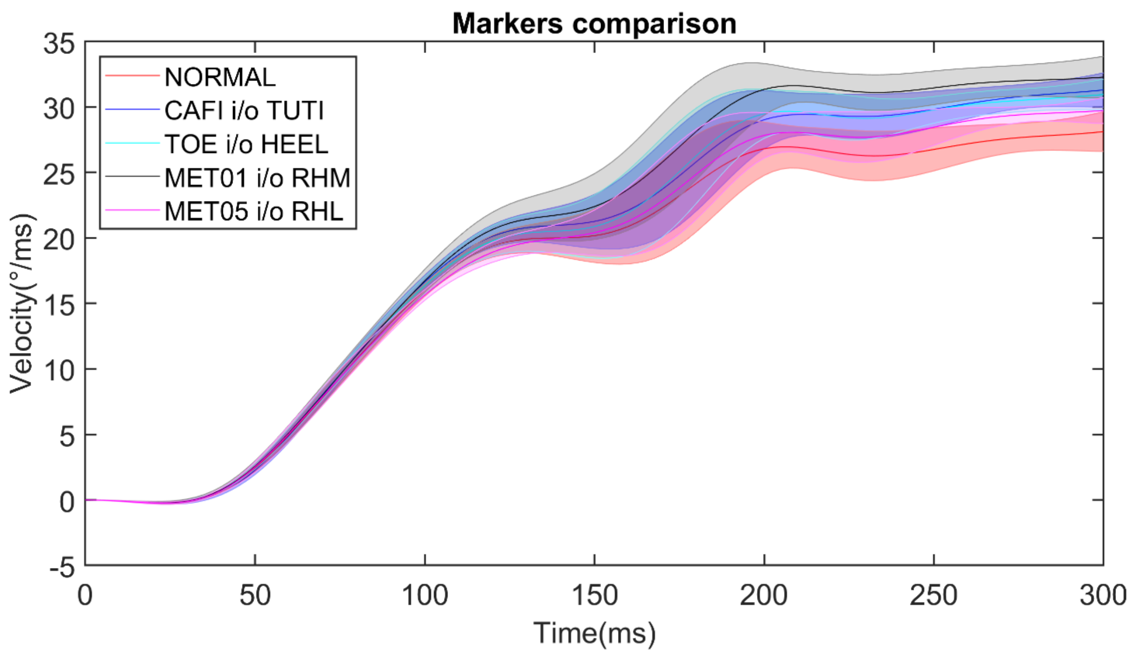

Figure 16: Different marker setups tested for similarities

Previous standards, with regard to calculations using markers that they were placed on anatomical landmarks, have always been performed with direct access to the foot. However, in our setup, the markers were not placed directly on the participants' feet, but on their shoes, since patients had to wear socks/shoes for the orthosis to be strapped on. Meaning that these positions are purely estimations of anatomical landmarks on the foot – but no anatomical landmarks were actually used, as the shoe has its own kinematics.

When the calculation was finished, the first derivative was used to get the velocity of the ankle. The angles were then normalized to zero. A time frame of 200ms was used, as the movement was already finished by then. Since the data were captured using 400Hz, 200ms corresponded to 81 captured frames.

The data (angles and velocities) were exported to an Excel file with an excel tab for each stored angle .mat file. The mean value and the standard deviation of the five trials was also calculated and exported.

2.9. Statistics

It was expected that the active module would reduce inversion angle during simulated inversion sprain and also to test the placebo effect of the passive placebo module. The hypotheses are then formulated as follows:

H0: Wearing an orthosis (active or placebo) restricts the inversion movement of the ankle regardless its capacity to protect/ resist.

H1: Wearing an orthosis (active or placebo) does not restrict the inversion movement of the ankle regardless its capacity to protect/ resist.

The statistical model chosen to test the abovementioned hypotheses was a paired t-test. This statistical procedure was used to determine whether the mean difference between two sets of observations is zero. The dependent variable in these tests was always the measured ankle-shank angle.

Four paired t-tests were conducted:

- all the patients at Day01 WithOut orthosis and all the patients at Day02 WithOut orthosis
- all the patients WithOut orthosis and all the patients when wearing Orthosis A
- all the patients WithOut orthosis and all the patients when wearing Orthosis B
- all the patients when wearing Orthosis A and all the patients when wearing Orthosis B.

To test the repeatability of the system and the MIP platform, the mean value of the five trials of each patient WithOut orthosis for Day01 was compared against the same trials of Day02, using SPM analysis.

To double check this, an Intraclass Correlation Coefficient (ICC) was used. ICC describes how strongly outputs in the same group resemble each other. Unlike most other correlation tests, ICC views data structured as groups, rather than data structured as paired observations. (Koch, 1982).

Three variables are needed when performing an ICC:

Decision of which model of ICC is need

If raters are not consistent but changing randomly then "One-way Random" is used. If a fixed population of raters exist, then "Two-Way Mixed" is needed. Lastly, if a sample of rates exists then "Two-Way Random" is used.

Determine which value will be ultimately use.

If only a single individual rater existed, then the "Single Measure" output is considered. Otherwise, the output "Average Measures".

Determine which set of values the reliability is needed.

For subsequent values, "consistency" is used. For reliability of individual scores, an "absolute agreement".

In this case the data were analyzed using a single-measurement, absolute-agreement, 2-way mixed-effects. The point chosen for the ICC was at 80ms because at that time point all curves reach their highest point and the patient cannot react yet and influence the angle. ICC was analyzed using SPSS (IBM SPSS Version 25.0).

Koo and Li (2016) define the ICC output as follows:

- Less than 0.40—poor reliability.
- Between 0.40 and 0.59—moderate reliability.
- Between 0.60 and 0.74—good reliability.
- Between 0.75 and 1.00—excellent reliability.

Before putting the hypothesis in test, a repeated measures analysis of variance (ANOVA) was conducted to check whether an overall difference between the groups existed, but this does not tell which specific groups differed. Repeated measures ANOVA compares means across one or more variables that are based on repeated observations. A repeated measures ANOVA model can also include zero or more independent variables. The variables used were Orthosis A, Orthosis B and WithOut orthosis.

All curves for the different variables were compared using Statistical Parametric Mapping (SPM).

2.10. SPM

SPM refers to the construction and assessment of spatially extended statistical processes used to test hypotheses with time-based series (Penny, Friston, Ashburner, Kiebel, & Nichols, 2011). Spm1d is an open source program in Python and in MATLAB that uses Random Field Theory expectations regarding smooth, one-dimensional (random) Gaussian fields. According to Pataky (2012), the two main advantages of SPM over the summary-metric approach are:

- statistical results are presented directly in the original sampling space, so their spatiotemporal biomechanical context is immediately apparent
- there is no need for (potentially biasing) assumptions regarding the spatiotemporal foci of signals

SPM was chosen over other statistical analysis methods because of its ability to compare the calculated angle as an overall time-scale signal and not just at individual time points. Often only discrete parameters (such as max value, min value, or the difference between those two) are used to analyze such data. Another advantage is its ability to visualize the data, making it more intuitive and easier to see when and if any difference exists.

Considering that the orthosis was only meant to decelerate the ankle inversion, rather than completely restrict its motion, the start and end positions are likely very similar within the 250ms of measurement. Thus, a traditional min/max comparison would not show how the time dynamics of the movement are altered with the effect of the orthosis. SPM, on the other hand, allows for the time-region of interest to be identified, where there is a difference between orthosis/no orthosis conditions.

The analysis was performed using the SPM1D open-source package for MATLAB (spm1d version M.0.4.5 (2017.06.22), www.spm1d.org). and generated: map of t-values (SPM), t* limit, and areas whereas differences were found with relevant p-values (Di Marco, Rossi, Racic, Cappa, & Mazzà, 2016).

Some terminology clarifications are needed for a better understanding of the results:

<u>SPM vs SPM{t}</u>

SPM refers to the overall methodological approach (name) and SPM{t} to the scalar trajectory variable.

Supra threshold cluster

When adjacent points of the SPM{t} curve exceeds the critical threshold, this is called “supra-threshold clusters”.

Critical threshold

The value at which only α 5% of smooth random curves would be expected to cross.

p-value

A p-value is the probability that a completely random nD process will yield a particular result. P-value is not the probability that the null hypothesis is true but rather the probability of observing a value as "extreme" or more "extreme" than what was observed in the sample, given that the null hypothesis is true.

test

A SPM two-tailed paired sample t-test was used to compare all orthoses angles and also the WithOut orthoses angles. If the SPM{t} trajectory crosses the critical threshold at any time node, the null hypothesis is accepted. The critical threshold has a positive and a negative value because the tested orthosis can either be better or worse than the other, so it can go either way. Also, depending on the order of the inputs this can be flipped. The angles were calculated for the first 300ms of the movement. The time period for the main comparison was 0-200ms, since at this time main inversion movement is completed.

2.11. Unblinding data

Unblinding is the disclosure to the participant and/or the study team of which treatment the participant received during the trial. After all the data were processed and the statistical process was finished the blinding was lifted.

3. Results

3.1. Patients characteristics

Sixteen participants (7 females and 9 males) with a history of unilateral LAS were recruited for this study. Their characteristics were: (mean ± SD)

- age: 30.9 ± 4.7 years old
- body mass: 73.4 ± 11.9 kg
- body height: 176.4 ± 9.5 m

3.2. Repeatability

To test the repeatability of the system and the MIP platform the mean value of the five trials of each patient WithOut orthosis for Day 01 was compared against the same trials of Day 02 (Fig. 17). As can be seen, the critical threshold is not exceeded, therefore there is no significant statistical difference between the days. Also, an Intraclass Correlation Coefficient was conducted.

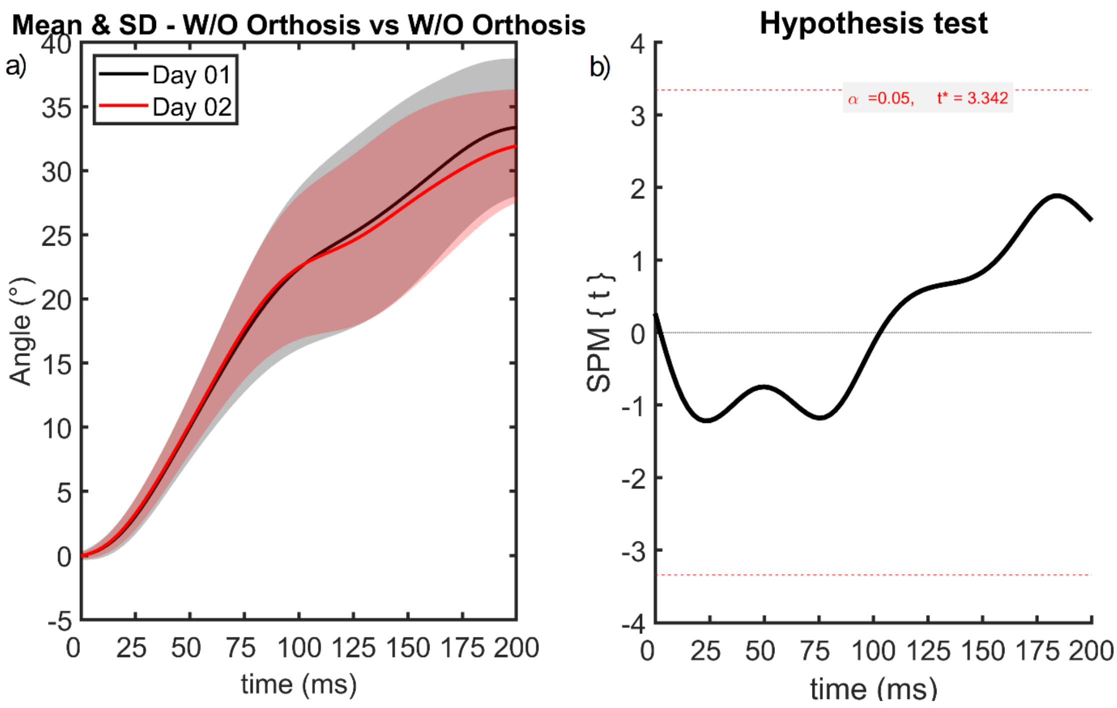

Figure 17: a) Mean trajectories of ankle angles WithOut orthosis for Day01 (black) and Day02 (red). b) The paired samples t-test statistic SPM{t}. (Graphs modified from (Agres et al., 2019))

3.2.1. ***Intraclass Correlation Coefficient***

	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.888[a]	.692	.963	16.126	13	13	.000

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.

b. Type A intraclass correlation coefficients using an absolute agreement definition.

Table 1: Intraclass Correlation Coefficient

Based on the ICC results, it is concluded that the test-retest reliability of the two days WithOut orthosis is “good” to “excellent”. The ICC result is ICC = 0.888 with 95% confident interval = 0.692 - 0.963.

3.3. ANOVA for repeated measures

Since the p-value between 60ms and 130ms is p: 1.1710e-04 ($p<0.001$) (Fig. 18) this means that there was a significant difference between the two orthoses or between an orthosis and WithOut orthosis. This test does not specify on which orthosis the difference was, and further analysis is required.

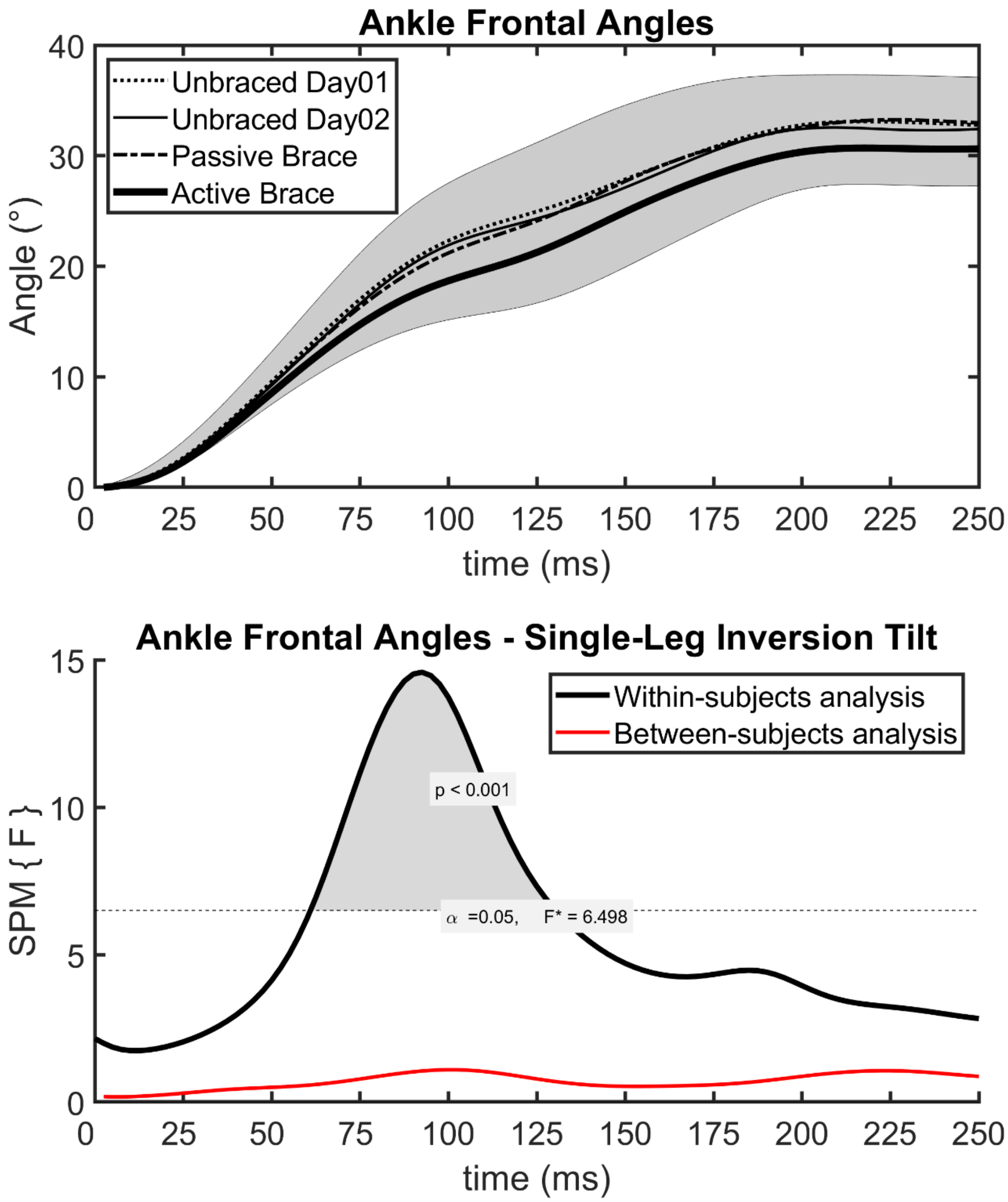

Figure 18: ANOVA repeated measures curve containing Orthosis A, Orthosis B and Day 01 WithOut Orthosis data (Graphs taken from (Agres et al., 2019))

Post hoc analysis can then be conducted with paired t-tests to examine specific group differences.

3.4. Orthosis A vs WithOut orthosis

The critical threshold is not exceeded (Fig. 19), meaning there is no significant statistical difference between Orthosis A and WithOut Orthosis. The greatest difference can be seen around 100ms.

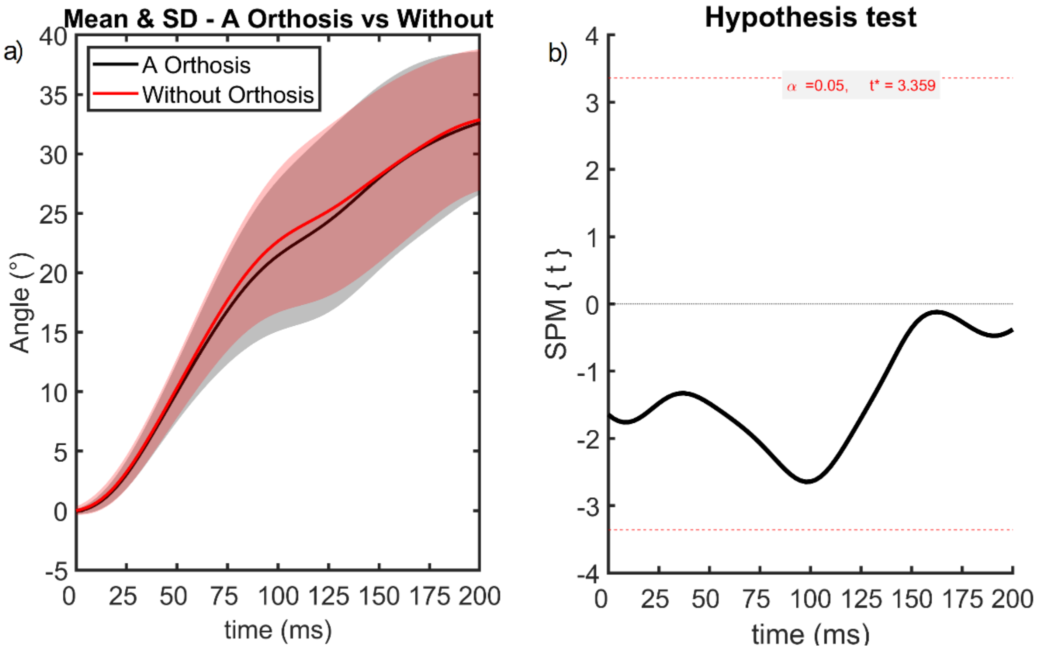

Figure 19: a) Mean trajectories of ankle angles for Orthosis A (black) and WithOut Orthosis (red). b) The paired samples t-test statistic SPM{t}. A Orthosis, active orthosis. (Graphs modified from (Agres et al., 2019))

3.5. Orthosis B vs WithOut Orthosis

The critical threshold of SPM{F} = 3.487 (red dashed line) was exceeded two times (Fig. 20), first at 65 to 150ms with a supra-threshold cluster probability of $p<0.001$ indicating a significantly lower angle on the ankle with the orthosis B and also after 175ms with a supra-threshold cluster probability of $p=0.013$ indicating also the same.

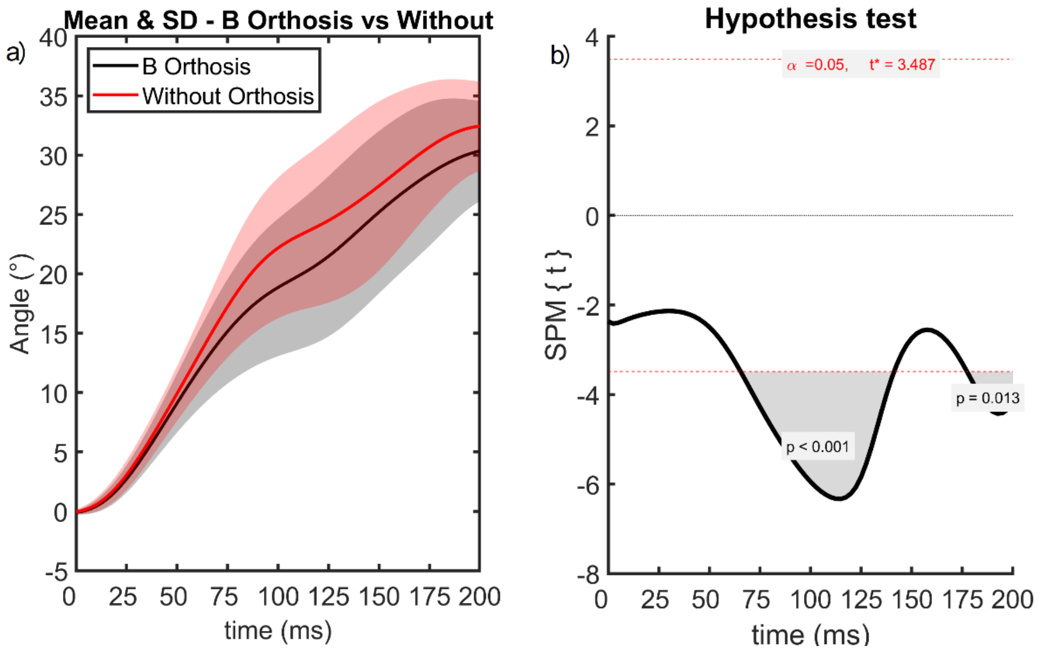

Figure 20: a) Mean trajectories of ankle angles for Orthosis B (black) and WithOut Orthosis (red). b) The paired samples t-test statistic SPM{t}. B orthosis, passive orthosis. (Graphs modified from (Agres et al., 2019))

3.6. Orthosis A vs Orthosis B

Mean ankle angles during MIP trials for Orthosis A and Orthosis B were highly similar for the majority of time (Fig. 21). However, one supra-threshold cluster (75-150ms) exceeded the critical threshold of SPM{F} = 3.401 (red dashed line) as the angle difference of the Orthosis B is significantly lower than Orthosis A. The precise probability that a supra-threshold cluster of this size would be observed in repeated random samplings was p=0.024. The null hypothesis was therefore partially proven.

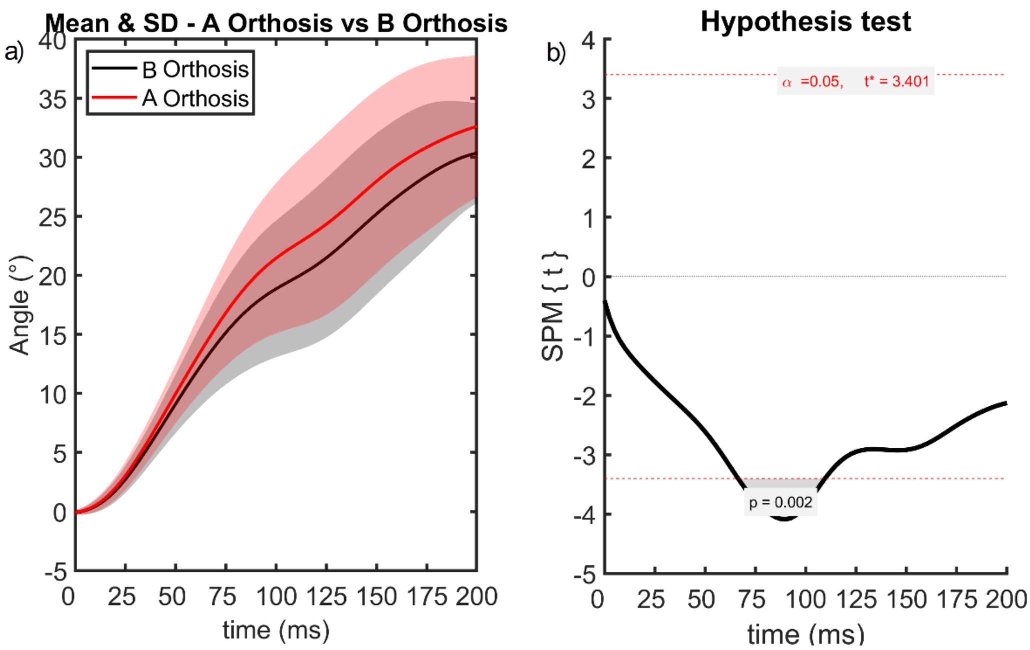

Figure 21: a) Mean trajectories of ankle angles for Orthosis A (black) and for Orthosis B (red). b) The paired samples t-test statistic SPM{t}. A orthosis, active orthosis; B orthosis, passive orthosis

Data for 150°/s were also calculated but no significant statistical differences were found. Furthermore, the speed is slow enough that the active module does not stiffen to prevent inversion of the ankle. Graphs for 150°/s can be found in APPENDIX B.

After the analysis was ended the blinding was lifted.

A orthosis = Passive Placebo Orthosis

B orthosis = Novel Active Orthosis

4. Discussion

Angle instability is a condition characterized by a recurring “giving way” of the outer part of the ankle. Patients after experiencing an ankle sprain, are often faced with chronic ankle instability with stretched or torn ligaments. Practically this means that their ability to balance is often compromised, thus when faced with a sudden inversion (either through motion or uneven surface), they are unable to react fast enough. This often leads to recurrent ankle sprain injuries. To compensate these problems, patients tend to wear an orthosis that restricts the overall movement of the ankle. Considering the high occurrence of unilateral ankle sprains in athletic populations, this can have heavy consequences for athletes wishing to continue their career in high-impact sports after suffering an ankle sprain.

Herein, we tested the effect of a novel selectively restrictive ankle orthosis (brace) on sagittal kinematics during simulated sprain using a titling platform, in patients with a previous unilateral ankle sprain, while also accounting for a possible placebo effect. The aim of this study was to investigate the effect of both orthoses (i.e. newly active orthosis containing shear thickening fluid module and an elastic-band placebo orthosis) on the frontal plane ankle joint angle during an unexpected ankle inversion. All subjects were also tested without wearing an orthosis (unbraced).

Based on our results, the main hypothesis (H0, i.e. an orthosis restricts the inversion movement of the ankle regardless its capacity to protect/resist) was partially confirmed. Specifically, the active orthosis (**B orthosis**) was able to significantly reduce angles during a sudden inversion, whereas the placebo orthosis (**A orthosis**) did not exhibit any differences when compared with the unbraced (no orthosis) condition. Therefore, it is suggested that the novel orthosis design being tested, effectively protects the ankle from inversion while allowing unrestricted sagittal movements of the ankle. In addition, these observations do not support any protective effect of the plain act of ankle-bracing (placebo). Since no significant statistical difference was observed in the placebo condition, we suspected that the elastic band added no substantial physical aid on the ankle support, apart maybe from a sense of security. (Fig. 19)

The active orthosis module clearly restricted the movement of the ankle and helped restrain it during an inversion. The active module was designed and optimized especially around reaction time. Numerous fluids were tested inside the module, in order to achieve a balance between allowing the ankle to move freely but being able to stiffen up and restrict movement, when a certain speed is reached. As shown in Figure 20, the module influences the angle from 65ms -

150ms. As already discussed, this is partially explained by the prolonged reaction time of the injured ankle, being unable to react earlier than the first 70ms of the movement. Then as the patient reacts, the angle drops. This is also the case at 175ms.

Study limitations were mainly in regard to the MIP design. The platform was used in two different speeds, 150°/s and 400°/s. As seen in the Appendix B, 150°/s does not show any difference in angle inversion, regardless of wearing the active module or the passive placebo. A third, increased speed could have also been tested for example, to investigate the minimum required speed for the active module to work (stiffen up) and then test how the angle is influenced. Additionally, by having a different person operating the platform and another the VICON Nexus, may have introduced some errors. The external force plate, mounted on the MIP, was producing a lot of analog noise, so accurately reading the force plate value was tricky.

Our findings that an active module orthosis resists the inversion angular movement, are in line with similar finding on the effectiveness of a semi-rigid and a softer lace-up ankle brace in restricting inversion angular displacement (Alfuth, Klein, Koch, & Rosenbaum, 2014; Cordova, Dorrough, Kious, Ingersoll, & Merrick, 2007; Tang, Wu, Liao, & Chan, 2010). In addition, our finding on the lack of a placebo effect, is also in agreement with a similar study investigating the placebo effect of ankle taping in ankle instability, by comparing using real tape, placebo tape and no tape (control) (Sawkins, Refshauge, Kilbreath, & Raymond, 2007).

However, the double-blind, placebo-controlled design of our study ensured that neither the patients nor the investigators knew, who was getting a placebo and who was getting the active orthosis, thus avoiding any bias that could taint the results. Besides, this design allowed for an internal control group, meaning that the patients served as their own control group for each trial, making the comparison between groups and conditions more accurate. Furthermore, the two conditions (active and placebo) were tested in different days, to allow the subjects some time to “forget” the trial process and get more authentic data on the next measurements.

Similar reports did not control the weight distribution between legs (Alfuth et al., 2014; Cordova et al., 2007). But since we ensured that participants always placed 80% of their body weight on the tested limb, we could ensure that the inversion tilt was performed similarly across patients and measurement days. Additionally, this reduced the variability among the participants and measuring days, and help produce more robust, comparable, and reproducible data. In addition, most of the previous reports were performed with healthy participants and not participants with previous LAS injury (Alfuth et al., 2014; Cordova et al., 2007; Tamura et al., 2017). All participants in this study, however, had a history of LAS, reported recurrent episodes of ankle instability, and continued to participate in athletic activities regularly. The orthosis design, allowed direct markers placement, ensuring that the kinematics data of the ankle were collected and not those of the orthosis, as reported by previous studies. By controlling these parameters, we can be confident in the kinematic results presented here.

The herein presented results highlight the possibility of successfully integrating shear thickening fluid in modern orthosis technology. Our results can be a starting point for future designs of orthosis. Further studies are needed to establish the exact speed and time needed, for the shear thickening fluid material to react. However such information, will help design a new era of exoskeletons, were an active orthosis will allow the person wearing it to move freely, but still ensure the exoskeleton (e.g. orthosis) will have enough time to react and adapt in a sudden ankle inversion motion.

5. Conclusion

Athletes with functional ankle instability or a history of ankle sprain, could benefit from this newly developed active module orthosis containing a shear thickening fluid. A sudden ankle inversion could be avoided by reducing the inversion velocity and preventing the possibility of re-spraining the ankle. An active orthosis that stiffens when a specific velocity is reached while allowing the foot to move freely in lower velocities, can be critical among professional athletes, as it will provide stability without compromising their performance.

The results presented in this study, indicate that there is no placebo effect for patients with previous lateral ankle sprain, during a sudden inversion movement, and that only an actively protecting orthosis protects the joint. It is therefore suggested that patients implement the use of an orthosis of known efficacy, as part of their rehabilitation program after an ankle sprain, and particularly the ones participating in high impact activities like sport.

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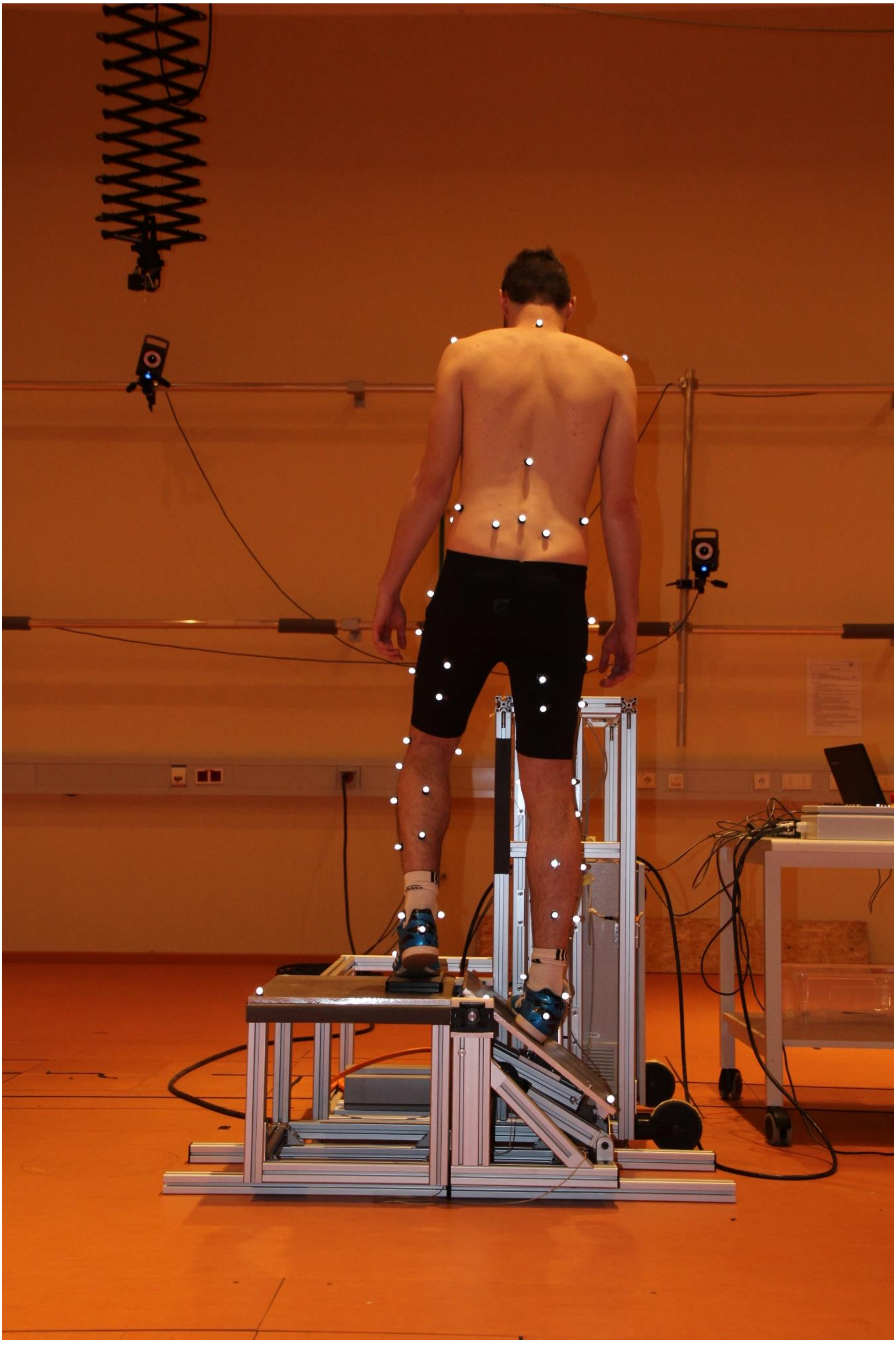
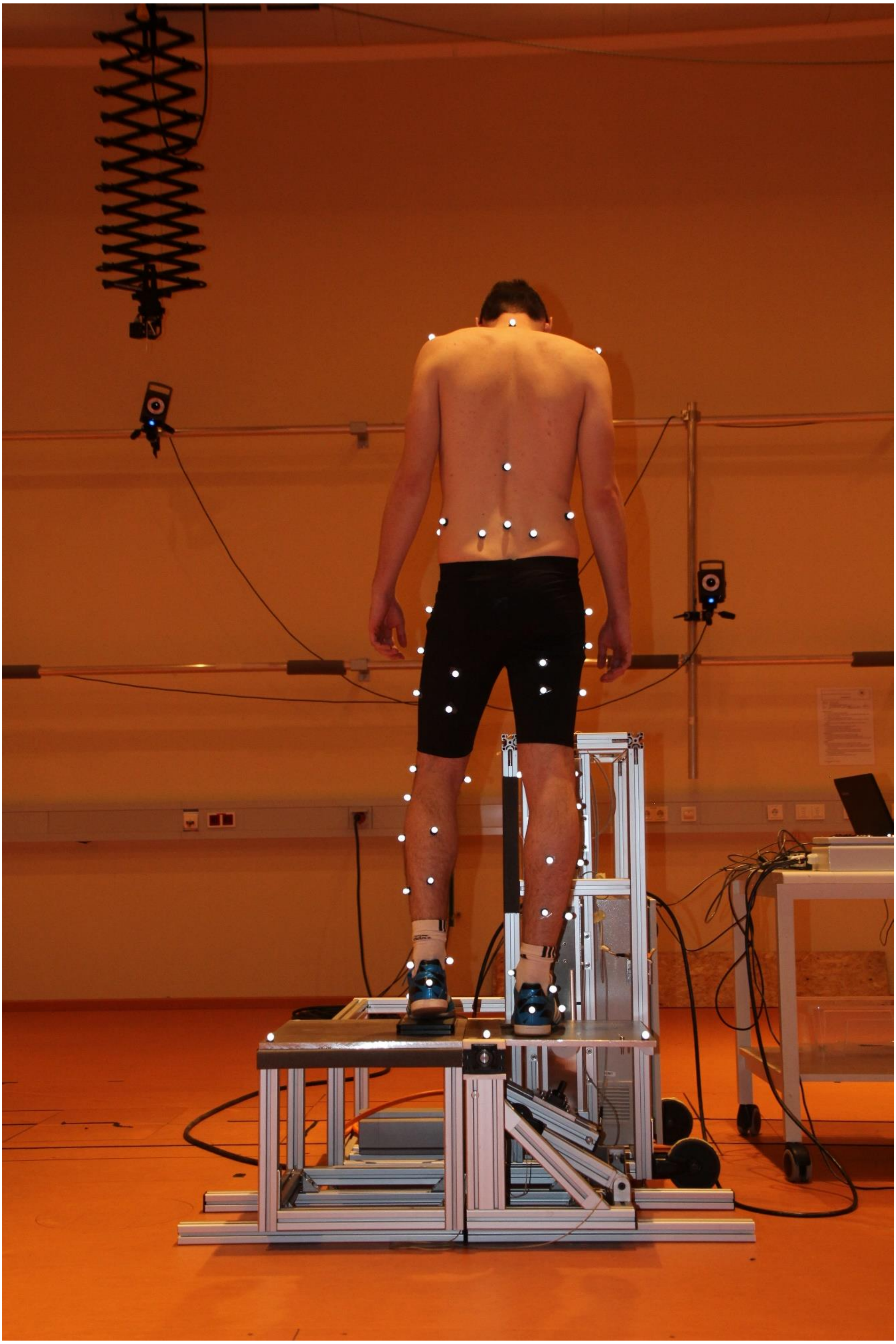
Appendix A





Appendix B

Graphs for *150°/s MIP speed.*

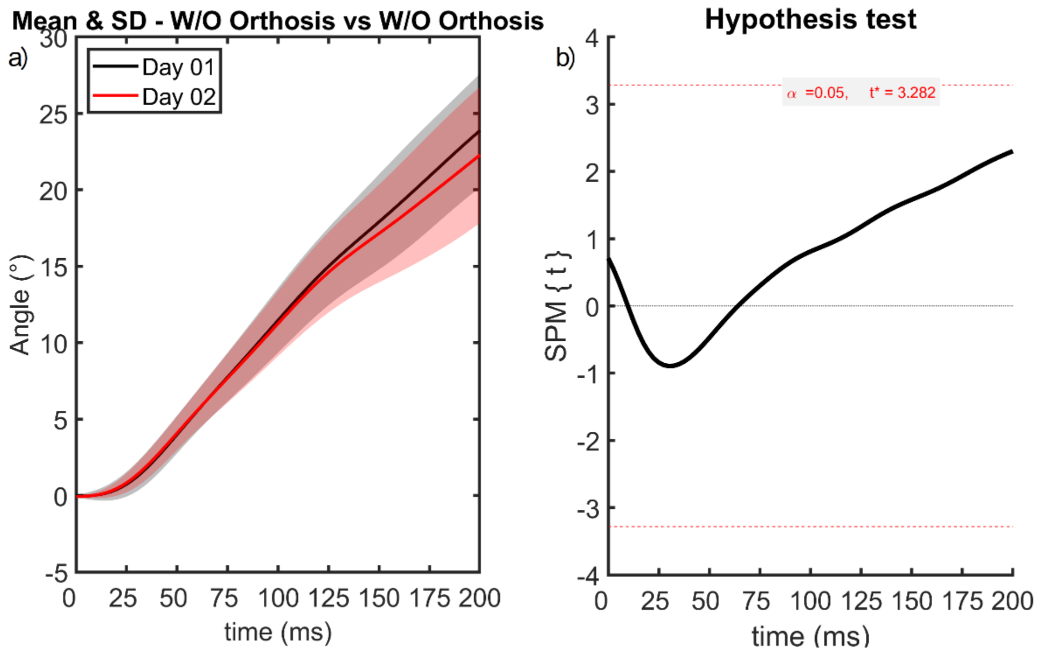


Figure 22: a) Mean trajectories of ankle angles WithOut orthosis for Day01 (black) and Day02 (red) – 150°/s. b) The paired samples t-test statistic SPM{t}.

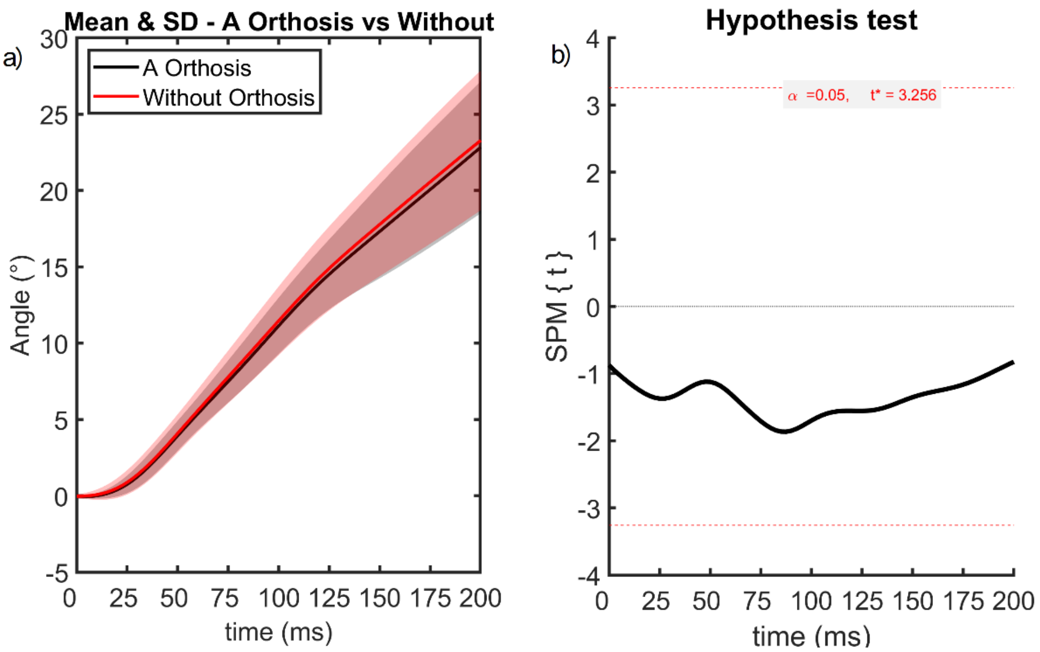


Figure 23: a) Mean trajectories of ankle angles for Orthosis A (black) and WithOut Orthosis (red) - 150°/s. b) The paired samples t-test statistic SPM{t}.

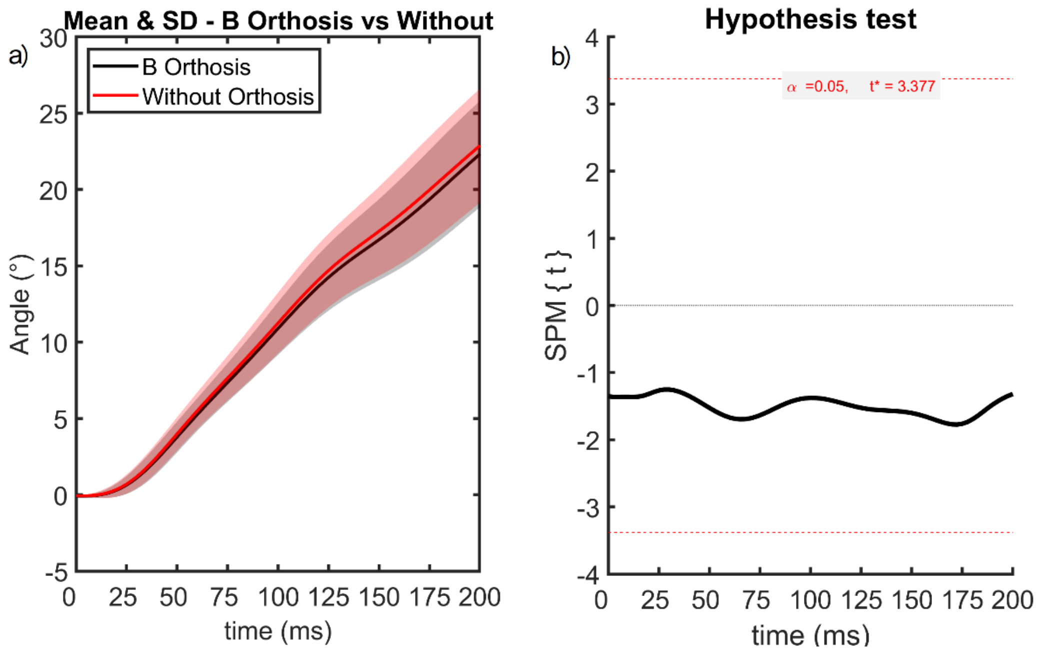


Figure 24: a) Mean trajectories of ankle angles for Orthosis B (black) and WithOut Orthosis (red). b) The paired samples t-test statistic SPM{t}.

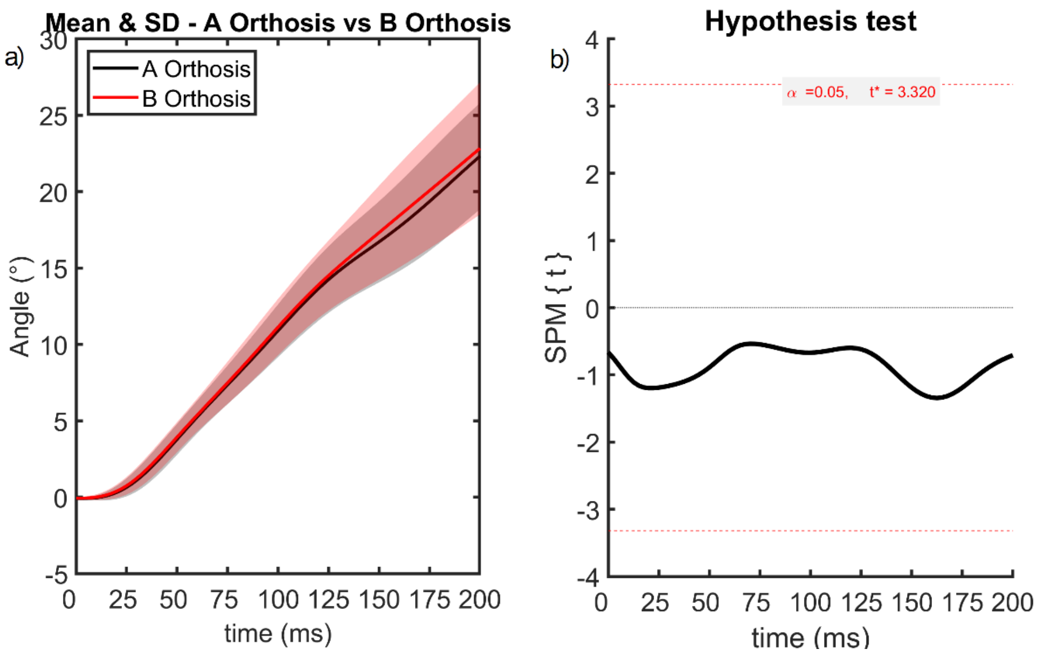


Figure 25: a) Mean trajectories of ankle angles for Orthosis A (black) and for Orthosis B (red) - 150°/s. b) The paired samples t-test statistic SPM{t}.