Design of a vibrotactile stimulus paradigm for a biofeedback device to improve gait rehabilitation of lower limb amputees

Ana Margarida do Vale

UMinho | 2022

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Master's Dissertation
Integrated Master's In Biomedical Engineering

Specialization in Biomaterials Rehabilitation and Biomechanics

Work conducted under the supervision of
Professor Doctor Cristina Manuela Peixoto dos Santos
Professor Doctor Eurico Augusto Rodrigues de Seabra
PhD Student Joana Alves

October 2022

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ACKNOWLEDGEMENTS

The most challenging year of my academic path comes to an end, but it was also my best year and the one I am most proud of. In this sense, I want to thank all those who crossed my path and helped me, either directly or indirectly, to achieve this project.

To my supervisors, and especially to Cristina Santos, I would like to express my gratitude for all the wisdom transmitted, for the rigour with which she guided me throughout this journey and without her I would never have had the experience of living in Madrid. I would also like to thank Professor Cecilia for all the assistance and time dedicated during the Erasmus + Internship and Professor Lino Costa for all the help in the statistical analysis.

I would also like to thank the whole team involved in data collection, namely Rui from Padrão Ortopédico and Gonçalo from Ortoadapta. Thank you for sharing your interest in this project and for all your help in its accomplishment.

To my colleagues at the BiRDLab, I thank you for the warm welcome and total availability to help me in whatever was necessary. The people where we work are what make the place a good space to work. A special thanks to Joana, for all the time she spent with me, she was my mentor and my right arm in this work, without her it would not be possible.

To Rita and Carolina, my support at all times, and my friends of forever, Margarida, Simão, and the Chávena group, thank you for making me believe in all my potential and for supporting me whenever I needed it. To my Ana, Guida and all the Terras crew, thank you for putting up with all my frustrations but also experiencing all my happiness, you are the most precious part that I take from this degree. To Nunes, Bea, Patricia, and Inês thank you for being my home in Madrid and for calming me down when I felt things were not going well.

Last but certainly not least, my family, especially my parents and brother, who always worked extremely hard, did everything so that I would never be deprived of anything and always encouraged me to become the best version of myself. Thank you for raising me and for passing on all the values that make me very proud of the person I am today.

STATEMENT OF INTEGRITY

I hereby declare having conducted this academic work with integrity. I confirm that I have not used plagiarism or any form of undue use of information or falsification of results along the process leading to its elaboration.

I further declare that I have fully acknowledged the Code of Ethical Conduct of the University of Minho.

ABSTRACT

A lower limb amputation not only affects locomotion, but also the amputee's somatosensory system, body perception, and mental health and, naturally, the fear of falling is more pronounced. Consequently, the patient is faced with the challenge of developing motor strategies that allow him to carry out daily activities since the use of the prosthesis does not fully compensate for the deficiencies acquired by a prosthetic gait, such as, for instance, asymmetry and variation in the duration of the gait events. Faced with the absence of effective treatments that restore locomotor functionality, the BioWalk project presents a rehabilitation solution: a biofeedback system that assists amputees during gait training sessions. This system consists in applying a vibrotactile stimulus on the skin of the affected leg. This stimulus can be activated at different moments of the prosthetic gait, allowing the patient to have a better perception and awareness of his body and locomotion to be able to detect any abnormal motor behaviours during the rehabilitation sessions and, in the future, to establish an adequate and healthy gait pattern.

Consequently, there is a need to analyse muscular and kinematic data of the gait of amputees to detect which events are critical in prosthetic gait, which muscles are activated or most required in gait, how the centre of mass behaves in the gait of an amputee, among other parameters.

Thus, in this dissertation, the main goal is to investigate and propose the best way (i.e., paradigm) to apply a vibrotactile stimulus to be used in a biofeedback device during rehabilitation sessions.

Keywords: Gait, Lower limb amputees, Biomechanics Analysis, Biofeedback, vibrotactile stimulus.

Resumo

Uma amputação do membro inferior não afeta apenas a locomoção, mas também o sistema somatosensorial do amputado, a sua perceção corporal, a sua saúde mental e, naturalmente, o medo de cair encontra-se mais acentuado. Consequentemente, o paciente é confrontado com o desafio de desenvolver estratégias motoras que lhe permitam a realização de atividades diárias dado que o uso da prótese não compensa totalmente as deficiências adquiridas por uma marcha protética, como por exemplo, a assimetria e a variação na duração dos eventos de marcha. Perante a ausência de tratamentos eficazes que restaurem a funcionalidade locomotora, o projeto *BioWalk* apresenta uma solução de reabilitação: um sistema de *biofeedback* que auxilie a pessoa amputada durante sessões de treino de marcha. Este sistema consiste na aplicação de um estímulo vibrotátil sobre a pele da perna afetada. Este estímulo pode ser ativado em diversos momentos da marcha protética permitindo ao paciente uma melhor percetibilidade e consciência sobre o seu corpo e locomoção para que seja capaz de detetar algum comportamento motor anormal durante as sessões de reabilitação e para, futuramente, estabelecer um padrão de marcha adequado e saudável.

Consequentemente, surge a necessidade de analisar dados musculares e cinemáticos da marcha de amputados de forma a detetar quais os eventos críticos na marcha protética, quais são os músculos ativados ou os que são mais requeridos na marcha, como se comporta o centro de massa na marcha de um amputado, entre outros parâmetros. Assim, nesta dissertação, o objetivo é propor um paradigma de estímulos vibrotáteis para serem usados num dispositivo de *biofeedback* durante sessões de reabilitação.

Palavras-chave: Marcha, Amputação dos membros inferiores, Análise Biomecânica, Biofeedback, Estímulo Vibrotáctil.

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LIST OF ABBREVIATIONS AND ACRONYMS

ASF	Artificial Sensory Feedback
BiRDLab	Biomedical Robotic Devices Lab
CAR	Centre of Automation and Robotics
CMEMS	Centre for MicroElectroMechanical Systems
CNS	Central Nervous System
COM	Centre of Mass
DFS	Diabetic Foot Syndrome
EMG	Electromyography
ERM	Eccentric Rotating Mass
FA	Feet Adjacent
FD	Forward Dynamics
FF	Foot Flat
GRF	Ground Reaction Force
HO	Heel Off
HR	Heel Rise
HS	Heel Strike
IC	Initial Contact
ID	Inverse Dynamics
IK	Inverse Kinematics
IMU	Inertial Measurement Unit
KPI	Key Performance Indicator
LLA	Lower Limb Amputation
MIEBIOM	Integrated Master's in Biomedical Engineering
MMST	Mid-Stance
MMSW	Mid-Swing
NHS	National Health Service
OI	Opposite Initial Contact
OT	Opposite Toe Off

RQ	Research Questions
TFA	Transfemoral Amputees
TO	Toe Off
TTA	Transtibial Amputees
TV	Tibia Vertical
UM	University of Minho
UPM	University Polytechnic of Madrid
VR	Virtual Reality
VT-S	Vibrotactile Upper Leg Socket

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1. INTRODUCTION

This project was developed as part of the Integrated Master's in Biomedical Engineering (MIEBIOM) in Biomedical Robotic Devices Lab (BirdLab) at the Center for MicroElectroMechanical Systems (CMEMS), a research center from the University of Minho (UM). Part of this project was, also, done in collaboration with the CAR-Centre of Automation and Robotics, a research center from the Polytechnical University of Madrid (UPM).

This work addresses the field of biofeedback systems for human gait rehabilitation. The ultimate goal of this dissertation is to develop a vibrotactile stimulus paradigm for a biofeedback device, intended to be used by lower-limb amputees. This device directly affects gait stability and trains the user to rectify his/her gait pattern in specific gait events, leading to a more natural and healthier gait. In this current chapter, the subject of this dissertation is contextualized, and the problems are stated, as well as the goals of this dissertation and the manuscript outline. Besides, all the methodologies, analyses and conclusions are detailed in this document.

1.1 Motivation

Lower Limb Amputation (LLA) remains a major problem worldwide despite the advancement in the diagnostic and therapeutic procedures [1]. Most of the underlying cause is vascular disease, namely diabetes [2].

An amputation not only affects locomotion, but also the amputee's somatosensory system, body perception, and mental health. Naturally, the fear of falling is more pronounced. Accordingly to [3], unilateral lower limb amputees are more prone to falling when compared to able-bodied individuals, with a reported incidence of 52.4% to 58% among community-dwelling amputees. As claimed by [4], in the USA, in 2005 was estimated that 1.6 million people had lost their lower limbs. Correspondingly, it is anticipated that in 2050 this number doubles to around 3.6 million people. In comparison, in European countries, the average annual incidences of major lower limb amputations is lower. In Central and Eastern European countries, the amputee population are around 30 per 100 000 population. In Western European countries, where Portugal is included, the major amputation incidence data is about

20 per 100 000 [5]. Thus, in northern Europe, in England, between 2003 and 2008, the major amputation rate was 51 per 100 000 population and did not change over the next 5 years [6]. Accordingly, this epidemiological study it was confirmed what was previously stated, in other words, most leg and foot amputations occur due to peripheral arterial disease and diabetes (80%). In Portugal, annually occur from 1.200 to 1.500 amputations, due to Diabetic Foot Syndrome (DFS), according to [7, 8] making Portugal the top European country with the most amputations caused by diabetes. In **Figure 1-1** is graphically represented the total number of lower limb amputations due to diabetes, in Portugal, between the years 2009 and 2018.

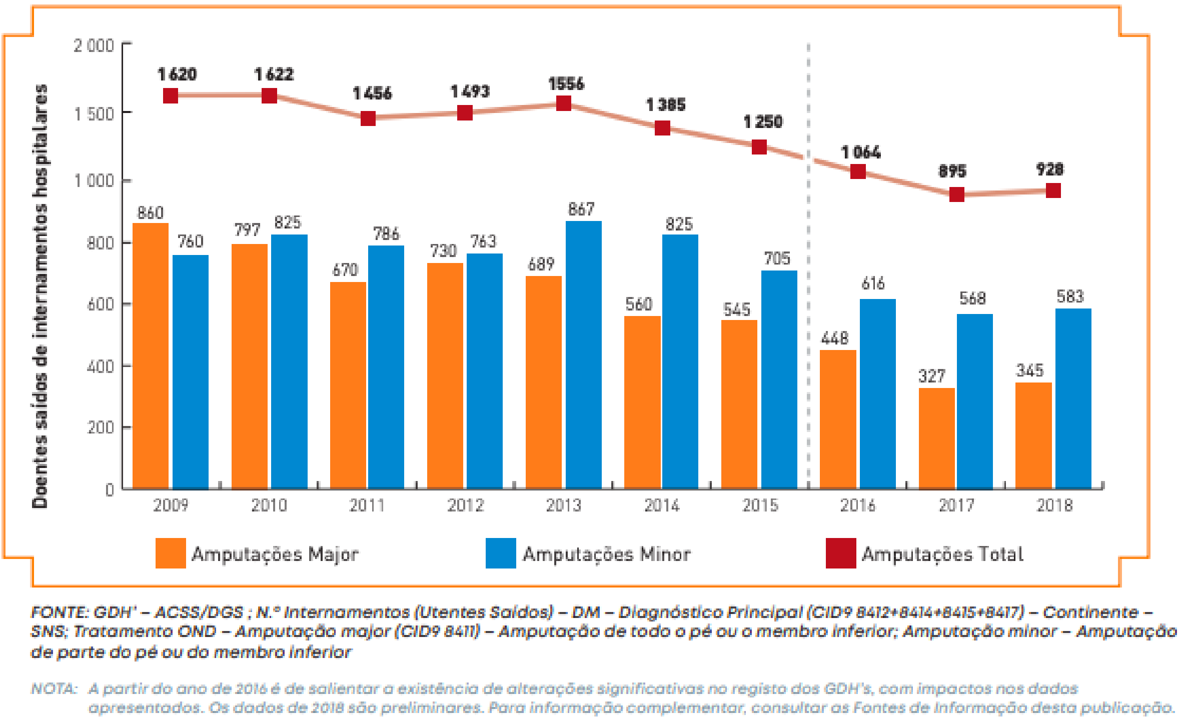


Figure 1-1: Number of lower limb amputations due to diabetes, in Portugal, between the years of 2009 and 2018 [8].

Above-knee amputations (i.e., transfemoral) and below-knee (i.e., transtibial) are the most performed major amputations [2] and the ones that require more medical attention since an entire joint and limb segment must be replaced. Transtibial amputees require an artificial ankle, a foot, and the missing part of the shank. Additionally, transfemoral amputees require an artificial knee and the missing part of the thigh [4]. The impact on gait for patients with major amputations is more pronounced than in patients with minor amputations [9].

Additionally, to all the severe emotional and psychological effects that an amputation causes, the financial costs can, also, be hard to manage. A lot of times, amputees may not be able to work or continue in their prior line of work following an amputation. Moreover, changes in their homes are often needed to accommodate their new limited mobility.

Non-traumatic lower amputation represents a substantial economic burden to any healthcare system. Regarding the costs, the annual cost of lower extremity amputation in the USA is estimated at 4.3$ billion dollars [10]. Corresponding data from the National Health Service (NHS) in England estimates an expenditure of 972 to 1.13 billion pounds [11]. In [12], the cost for the patients who had undergone amputation was 509,275$ US dollars. In line with Johns Hopkins Centre for Injury Research and Policy estimated that the lifetime total cost for a typical amputation was, also, around 509,272$ US dollars. This estimate includes the initial costs of hospitalization, follow-up hospitalization costs, inpatient rehab services, outpatient physician visits, occupational and physical therapy, and prostheses costs.

Consequently, there is a need, and room for research, to find and develop affordable assistive solutions that ensure an efficient and almost automatic response to the locomotor impairment of lower limb amputees. This type of patient, to live their daily lives, require an adequate gait support solution. As mentioned above, mechanical support is mandatory to reinstate their ability to move freely through the surrounding space by enabling the coordination of the healthy and prosthetic lower limbs and trunk. Besides the physical removal of the limb, amputation leads to significant neural reorganization within the central nervous system (CNS) mostly due to the loss of the sensorimotor function caused by this medical intervention [13]. Hence, amputated people need considerable walking training to adopt a series of compensatory motor strategies involving both prosthetic and sound limbs [14]. Indeed, transtibial (TTA) and transfemoral amputees (TFA) require long-term therapy and gait training [15]. Studies evaluating the activity of the final motor effectors, the muscles, revealed a higher and longer compensatory activity of the residual muscles in the prosthetic limb [16], and altered activation of all muscle synergies in the sound limb before and after the prosthetic heel strike, during the gait. These compensatory mechanisms in the sound limb consist of increasing muscle activation, spending more time on the ground, and developing a greater and longer force production [14].

One of the key characteristics of normal gait is how energy is conserved through several optimizations. Abnormal gait patterns involve a loss of these optimizations, which may result in excessive energy expenditure and consequently fatigue. The measurement, during gait, of energy transfers at individual joints and the overall energy consumption is an important component of scientific gait analysis [17]. It is well acknowledged that individuals with lower limb amputations, who ambulate with prosthetic limbs, have an increased metabolic cost of locomotion compared with non-amputated individuals. Besides, LLA exhibits asymmetric gait patterns that can increase the movement of the Centre of Mass (COM) and interfere with the smoothness of limb coordination [18, 19]. It has, also, been postulated that one of the main factors that improve the metabolic efficiency of gait is minimizing the movement of the COM. Although this mechanism likely does not completely account for the increased metabolic costs of prosthetic ambulation, improvements in gait symmetry will likely result in a more metabolically efficient gait [19,21].

Individuals living with an amputation characteristically present an asymmetrical gait pattern characterized by a prolonged stance phase (temporal asymmetry) and greater limb loading on the intact side as compared to the prosthetic side (limb loading asymmetry) [22]. A persistent asymmetrical gait may influence the appearance of health problems, such as knee or hip osteoarthritis of the intact side, back pain, and balance impairments [23], hence an increased risk of falling [24] Indeed,50% of people with TTA report one or more falls each year [25].

Asymmetrical movement patterns, as previously stated, usually manifest as compensations, in consequence, to post amputation and are characterized by the preferential use of the intact limb, evidenced by abnormal gait biomechanics including asymmetric ground reaction forces, muscle activation patterns, and knee joint kinetics (i.e., forces and torques) between the intact and residual limbs [26–28]. Therefore, identification and consequent treatment of gait asymmetries in people with LLA could reduce long-term health effects associated with amputation while improving mobility and overall well-being of the patients in need [22].

Another important aspect of human gait, and human senses in general, is proprioception. The proprioceptive senses include the senses of position and movement of our limbs and trunk, the sense of effort, the sense of force, and the sense of heaviness [29]. Bodily perception permits control of posture and movement, and it is based on the integrative processing of multiple sensory information located in skin, muscles, and joints [30].

As previously mentioned, due to the definitive loss of a body segment individuals with lower limb amputation experience loss of sensory function, and therefore its somatosensory afferents can profoundly affect the internal body representation (e.g., embodiment) and the sense of position, as well as the loss of support and mobility [30]. However, since mechanoreceptors (sensory neurons located within joint capsular tissues, ligaments, tendons, muscle, and skin) can detect a wide range of mechanical stimuli from the external environment- tactile, visual and auditory- this characteristic could be used as an advantage, since it is possible to apply a stimulus to the skin of the amputated limb, for instance, and the mechanoreceptors present can recognize it could, thus restore the loss of proprioceptive information [29,31].

Additionally, due to the loss of sensory function amputees use more cognitive resources while walking than healthy subjects 49% of individuals with LLA have reported that they must concentrate on every step while walking [9]. Then, as walking requires attention, it is difficult to walk with a concurrent task.

Moreover, as prosthesis use relies on the same cortical areas as those involved in the movement of an intact limb, long periods of prosthesis use may reinforce the preservation of the innate representation of the missing limb in the body schema, possibly through the conscious incorporation of the prosthesis into the body image [9]. This is why it is so important that patients have a prosthesis that is suitable for them, in which they feel comfortable and do not feel the need to remove it immediately after performing the required task.

1.2 Goals and Research Questions

As aforementioned, the goal of this dissertation is to propose a vibrotactile stimulus paradigm to be implemented in a biofeedback device. The purpose is that this device would be worn by LLA around the remaining limb of the amputated side. The apparatus is equipped with vibrotactile motors whose vibration may influence gait stability. That is, through its use during rehabilitation and physiotherapy sessions, accompanied by a specialized technician, the reaction to the vibrotactile stimulus may instruct the user to adjust gait motion in specific gait events, enhancing gait rehabilitation and correcting gait patterns of lower limb amputees.

To accomplish this, it is proposed the following set of objectives:

Goal 1: Gather knowledge about: **I)** Body movement and understand the importance of healthy locomotion in human mobility; **II)** Relevant biomechanical features that characterize motor disorders and abnormal walking patterns in lower limb amputation; **III)** Biofeedback mechanisms and gait monitoring systems used in the literature**.**

Goal 2: Analyse which type of data (kinematic, electromyographic, gait events, variability of the angular range of motion of joints) is the most considered for the analysis and recognition of patterns in human gait in different locomotor situations.

Goal 3: Collection and analysis of data of amputees in specific situations (treadmill and regular ground, with and without obstacles).

Goal 4: Propose vibrotactile patterns according to the locomotor behaviour of healthy and amputee patients and appropriate to the critical gait event to assist in the gait rehabilitation of amputee patients.

Following this, Key Performance Indicators (KPI) were also defined for each proposed goal:

KPI 1: Reports of **I)** Importance of human locomotion; **II)** Biomechanical features that characterize motor disorders and abnormal walking patterns in lower limb amputation; **III)** Biofeedback mechanisms and gait monitoring systems used in the literature**.**

KPI 2: Report on which type of parameters are considered for the analysis and recognition of patterns in human gait in different locomotor situations.

KPI 3: Collection of data from at least five subjects in each condition and execution of a statistical analysis.

KPI 4: Suggestion of a vibrotactile stimulus paradigm for a biofeedback device in which is disclosed the location and moment, within the gait cycle, the stimulus should be applied, as well as the frequency applied, the duration of the stimulus and the type of gait training that should be carried out.

Subsequently, the following research questions (RQ) are raised and will be addressed in Chapter 4 of this dissertation:

RQ 1: What are the main challenges encountered by amputees during their daily lives?

RQ 2: How do spatiotemporal parameters, kinematic and electromyography of the amputee's lower body differs from the healthy lower body, in specific conditions (e.g., the centre of mass, joint angles, joint angular velocity, limb segments position)?

RQ 3: What should be the parameterization of a vibrotactile stimulus to be applied effectively as artificial feedback, during specific gait events?

1.3 Dissertation Outline

Chapter 2 introduces some general concepts as a means to a better understanding of this research project. A State of the art is, also, presented containing the current biofeedback devices reported in the literature.

Following, **Chapter 3** points out the methodologies used during this dissertation, detailing which and how the biomechanical data was acquired. Additionally, it presents the statistical analysis and the way quantitative data was processed and organized. The results from this investigation are revealed as well as the respective critical analysis are, too, presented in this section.

Lastly, **Chapter 4** states the main conclusions, and possible challenges related to this project will be pointed out. This section also answers the RQ made and addresses the future directions that must be followed.

2. Human Locomotion and Artificial Sensory Feedback Solutions

The surgical removal of a lower limb, or part of a lower limb, from the rest of the body, is called a lower limb amputation. Thus, to reinstate the patient's full mobility an artificial limb (i.e., a prosthesis), is needed. The prosthesis must be designed to match the mechanical properties of the missing limb and restore the human gait as the main requisite. Likewise, due to the experience of losing sensory function and degeneration of residual nerves because of the loss of the limb, as previously mentioned, the prosthesis is not able to compensate for the lack of sensory feedback.

As stated earlier, in section 1.2, this dissertation aims to implement a biofeedback system that assists amputees during gait training sessions. The underlying idea of this system is the application of a vibrotactile stimulus on the skin of the affected limb to compensate for the loss of gait functions. For instance, improve symmetry and variation in the duration of the gait events and provide the missing proprioception. In this manner, we anticipate that the patients gain their independency back and can have an active life again.

Subsequently, there are two main problems to tackle to achieve our ultimate goal. Being the first problem does respond to the question “When?”. When should the stimulus be given along the amputee’s gait cycle, so that the user compensates for his/her uneven walking manner? The second problem is “How?” can the missing proprioception and sensory embodiment be restored? We hypothesize that by providing external afferent sensory information during locomotion through an artificial substitution of the natural feedback (e.g., tactile, visual or auditory) we can reduce gait abnormalities (e.g., asymmetry, imbalance) and pain experienced by the amputees. Hence, in this chapter, to seek available solutions that answer the two disclosed problems, we performed a concise state-of-the-art. In this review, a comparison between the prosthetic gait and the healthy gait will be conducted for understanding which moments, of the gait cycle, the amputee gait differs from a healthy one, so we can infer the event or phase of gait it is possible and desired to provide the stimulus, on the skin, to compensate the loss of gait functions, as previously stated.

Furthermore, it will be investigated technical and training solutions providing biological information to patients in real-time regarding gait events with the purpose of not only improving the gait parameters, and stability in symmetry in prosthetic gait, but also increasing the amputee's body perception. It is important to note that for most of the sensorial feedback solutions, the proposed concepts have not yet exceeded the clinical studies.

2.1 General Overview of the Gait Cycle

Walking is a purposeful act. It is a complex activity involving the central and peripheral nervous system and the entire musculoskeletal system to achieve movement with postural stability and equilibrium.

Human gait can be broken down into a sequence of repeated phases and events in a cyclic pattern. According to Perry et al. [32], the stance and swing phases are the two main phases of the gait cycle, correspondingly to 60% and 40%, respectively, as illustrated in **Figure 2-1**. The stance phase integrates Heel Strike (HS), Foot Flat (FF), Mid-Stance (MMST) and Heel Off (HO). During this phase, the foot is mostly on the ground. The swing phase consists in: Toe Off (TO), Mid-Swing (MMSW). The pre-swing coincides in part with the end of the stance phase. In terms of events, Heel Strike (HS) and Toe Off (TO) mark the beginning of a stance and swing phase, respectively. Based on these two events, as main markers, it is possible to evaluate stance time, swing time, cycle duration and gait asymmetry. There are also two moments in the walking gait cycle, designated ‘double support periods’, that account for approximately 10% of one gait cycle, which occur at the beginning and end of the stance phase and are when both feet are in contact with the ground [33].

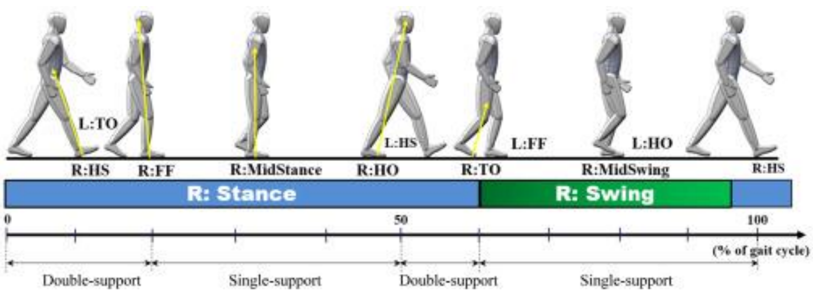


Figure 2-1: Human walking gait cycle, and stance and swing phases of the right leg. Adapted from [34].

The activity of major muscle groups during the gait cycle, presented in **Figure 2-2**, is an aspect very important being noted in this dissertation. This is due to the significance of knowing where the vibrotactile stimulus should be applied, accordingly to the investigation of different biomechanical data.

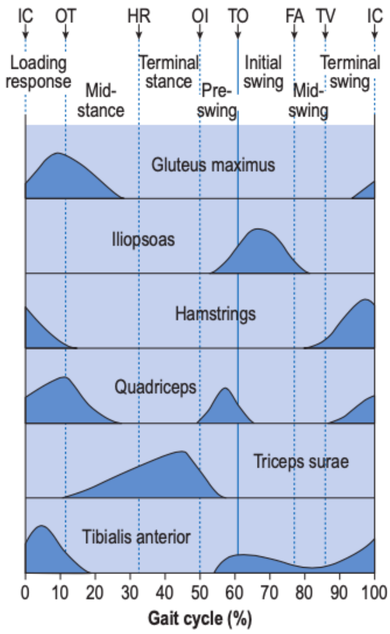


Figure 2-2: Typical activity of major muscle groups during the gait cycle. The timings of the events of the gait cycle are typical and not derived from a single subject. Adapted from [17].

Gait parameters such as stride, step, stride length, step length, cadence, cycle time and walking speed are, also, important to human gait analysis since they allow us to compare biomechanical indices of healthy subjects to pathological ones. A stride, or a gait cycle, consists of two successive steps from both feet. Stride length is the distance between two consecutive heel contacts of the same foot. Whereas step length is the distance between the point of initial contact of one foot and the point of initial contact of the opposite foot. Cadence is the number of steps taken in a given time, the usual units being steps per minute. In a single gait cycle, there are two steps, so the cadence is a measure of half-cycles. Cycle time can be referred to as ‘stride time’ as well. The speed of walking is the distance covered by the whole body in a determined amount of time. It should be measured in meters per second. The average duration of one gait cycle for a human individual ranges from 0.98 to 1.07 s [35]. The cadence is around 91 to 135 steps per minute, 1.25 to 1.85meters of stride length and a walking speed is between 1.10 to 1.82 meters per second, this to a male subject between the age of 18 to 49 years [17].

More detailed aspects of each phase of the gait cycle are presented in the following **Table 2-1**.

Table 2-1: Phases of the gait cycle summary.

<table>
<tr><td rowspan="4">Stance Period
(60% of the gait cycle)</td><td rowspan="2">Weight Acceptance</td><td>Heel Strike</td><td>The beginning instant of the gait cycle is represented as initial contact of one foot with the ground. Initial contact is frequently called heel strike.</td></tr>
<tr><td>Foot Flat</td><td>The instant that the rest of the foot comes down to contact the ground and usually is where full body weight is being supported by the leg. During this period, the foot is lowered to the ground by plantarflexion of the ankle.</td></tr>
<tr><td rowspan="2">Monopodial support time</td><td>Mid-stance</td><td>Is the period of the gait cycle between opposite toe off and heel rise. Is defined when the centre of mass is directly above the ankle joint centre. This is also used as the instant when the hip joint centre is above the ankle joint. The function of this event is to advance on the supported limb and to maintain stability.</td></tr>
<tr><td>Heel Off</td><td>Heel-off occurs when the heel begins to lift off the ground in preparation for the forward propulsion of the body or push-off. It occurs when the foot loses the last contact with the ground. This event ends the stance phase.</td></tr>
<tr><td rowspan="3" colspan="2">Swing or flight period
(40% of the gait cycle)</td><td>Pre-swing</td><td>This coincides in part with the conclusion of the stance phase. It positions the body and the limb for take-off. It begins with the beginning of the stance of the other limb and ends with the toe-off.</td></tr>
<tr><td>Toe Off</td><td>It happens just after the toe-off event when the foot starts to accelerate in the forward direction.</td></tr>
<tr><td>Mid-Swing</td><td>It occurs when the foot passes its contralateral foot. Ends when the swinging foot is in front of the supported foot and the tibia is vertical.</td></tr>
</table>

In this way, it was analysed the normal gait before examining the gait of an amputee, to understand and assess the differences between the two. Based on this, the next subsection will indicate the altered aspects related to a prosthetic gait.

2.2 Prosthetic Gait

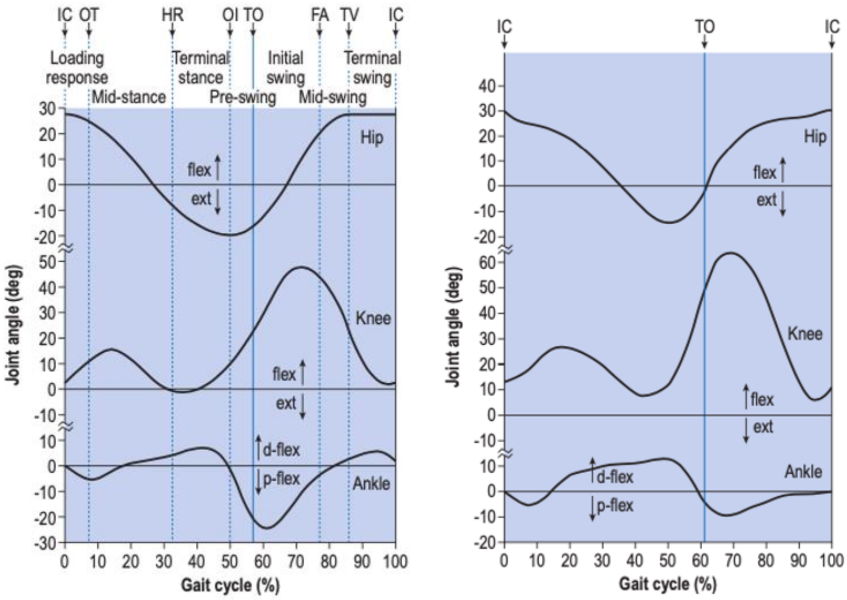
Naturally, an individual with lower limb amputation will have an altered gait cycle, notably in several gait parameters (spatiotemporal and biomechanical). Pathological gait may be viewed as compensation to try to preserve as low a level of energy consumption as possible. The compensations are seen in the activity of the lower limb muscles in both the sound and residual limbs [36].

Amputees tend, for instance, to shift more weight to the sound limb and for that reason have a prolonged stance phase on this limb and longer swing on the prosthetic side creating an asymmetrical gait pattern [37]. The ability to plantarflex (i.e., extension) and dorsiflex (i.e., flexion) of the ankle and/or the knee is lost after an amputation, despite the use of a prosthesis. This means that muscle power cannot be used to provide an active push off [36]. According to [38], the path of the centre of gravity is relatively normal after a below-the-knee amputation because the hip and knee can compensate for the loss of the ankle joint. The two main factors influencing the gait in people with amputation are related to the level of the amputation and the type of prostheses. People with TFA when compared with people with TTA present a more pronounced asymmetric gait, due to the loss of a foot, ankle and knee, therefore the gait patterns of transfemoral amputees are known to be less efficient [39]. In **Figure 2-3**, a comparison between the ankle, knee and hip joint angle degrees is done.

In general, according to [17,40], the gait cycle of an amputee has the following characteristics:

- Increased cycle time (1.13 seconds), decreased cadence (106 steps per min), however, the increased cycle time led to a decreased speed;
- Decreased gait speed (1.37 meters per second);
- Longer stance duration (0.85 vs. 0.67 s), on the sound limb;
- The duration of the swing phase is longer on the amputated side;
- The prosthetic side presents lower horizontal ground reaction forces (GRF) than the sound limb;
- Accented Hip abduction due to the lack of knee range of motion at the prosthetic leg in the knee zone;
- The prosthetic limb shows a longer stride than the intact limb;

• Earlier heel rises in the stance phase than in healthy individuals because of a reduction in the ability to dorsiflex the prosthetic ankle.



(I) **(II)**

Figure 2-3: Sagittal plane joint angles (degrees) during a single gait cycle of the right hip (flexion positive), knee (flexion positive) and ankle (dorsiflexion positive) in a healthy subject **(I)** and a lower limb amputee **(II)**. IC = initial contact; OT = opposite toe

2.3 Sensorial Perception In Lower-Limb Amputees

As stated in section 1.1, proprioception is an extremely important and fundamental aspect of human gait. It grants control of posture and movement and is established on the integrative processing of multiple sensory information [41]. Consequently, due to amputation, other sensory adaptations come into place that could restore the loss of body perception information, for example, vision and sensory sensibility at the stump.

In this investigation, are projected interventions to diminish gait deviations, and re-establish proprioception and embodiment of the patient, this involves an assistive sensorial feedback therapy for gait training, improving in this way the quality of life for lower limb amputees.

2.3.1 Artificial Sensory Feedback (ASF) Solutions for Gait Rehabilitation

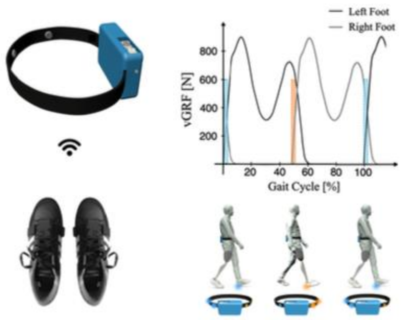
A biofeedback method is based on a biomedical variable that can be a biomechanical or a physiological measurement [41]. Biofeedback research has steadily increased in recent decades, representing a growing interest in this topic [42]. As reported by the literature, a proven way to improve the quality of the rehabilitation treatment and to reduce the time spent in recovery is integrating a biofeedback system for the rehabilitation gait training sessions of amputees [43]. In this way, for an effective system, it is important to understand how humans sense, interpret and respond to the feedback that would be provided by [44].

In the classical rehabilitation program, the patients learn how to wear the prosthesis, how to load and unload the body weight on the prosthesis and then how to develop a dynamic postural control enough to walk over several surfaces [43]. After the learning curve, gait retraining includes the observation of gait deviations or atypical movement patterns and the delivery of corrections. However, these conventional methods have several limitations, such as limited and inadequate gait training sessions [45]. One of them also is that the detection of gait deviations is narrowed to a subjective assessment of gross movement patterns [42], hence, the importance of including augmented sensory feedback in rehabilitation programs. This is due to the activation of sensitive and motor systems during this therapy motivates brain plasticity, promoting the recovery of motor skills [43] and can effectively mitigate spatiotemporal gait irregularities [46]. This is, also, extremely important because poor mobility is one of the main causes of eventual device abandonment [47].

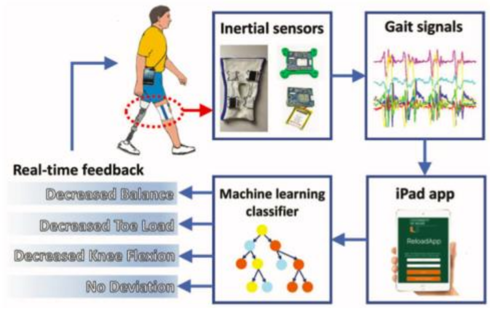
There are a variety of biomechanical variables to be used as a codification of the biofeedback signal. For example, inertial-based sensing biofeedback is the most widely researched biomechanical biofeedback method [42], with several studies showing it to be effective in improving measures of balance in several populations. Other types of biomechanical biofeedback include force plate systems, electro goniometry, pressure biofeedback and camera-based systems however the evidence for these is limited. The physiological systems of the body which can be measured to provide biofeedback are the neuromuscular system, the respiratory system and the cardiovascular system [41].

Biofeedback therapy for the treatment of movement, postural control, balance, and asymmetries has been the most focused issues described in biofeedback research. The stimulus can be delivered using Visual, Auditory or Tactile feedback. However, recently virtual reality (VR) or exergaming technology has been used in rehabilitation as biofeedback signals [48]. It is defined as a simulation of a real-world environment that is generated through computer software and is experienced by the user through a human-machine interface [49]

Following, a summary of the artificial sensory feedback solutions, their type of feedback, body placement, therapeutic focus, and outcomes, found in the literature are presented in **Table 2-2** to **Table 2-4** and **Figure 2-4**.



(I)



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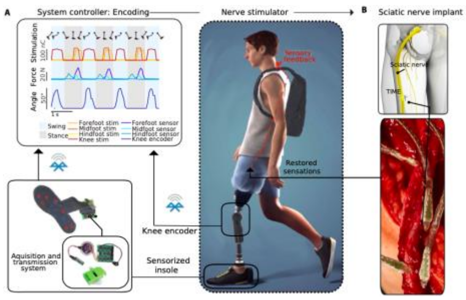

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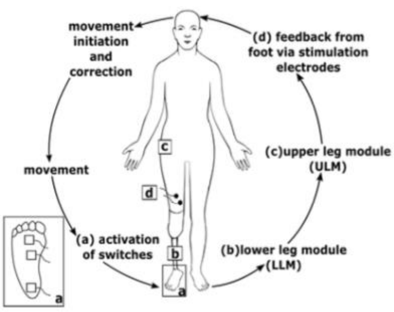

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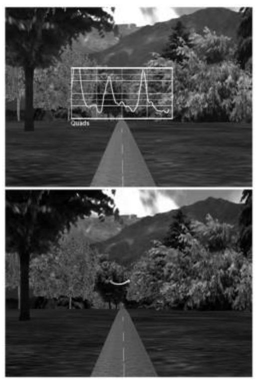

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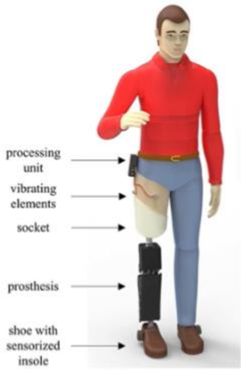
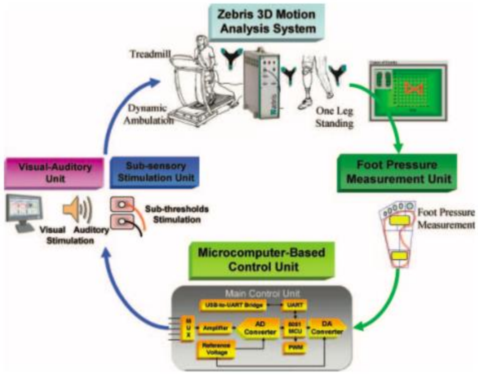


(VII)



(VIII)

Figure 2-4: **(I)** Tactile biofeedback system to improve temporal gait symmetry of lower-limb amputees [46]. **(II)** Auditory biofeedback system to improve strength, mobility, and gait quality [50]. **(III)** Tactile system feedback for mobility, fall prevention, and agility [47]. **(IV)** Visual biofeedback system to improve gait symmetry [51]. **(V)** Tactile system to reduce phantom limb pain and increase ambulation [52]. **(VI)** Visual display of example real-time feedback for COM and EMG, within CAREN [53]. **(VII)** Concept of biofeedback with vibrating elements [37]. **(VIII)** Visual-auditory biofeedback system for static balance and gait performance of single leg quiet standing [54].

In this segment, it was summarized some studies that conducted research in biofeedback systems with a therapeutic focus for lower limb amputees. We described eight feedback solutions and research proposals in the literature. However, the majority of the studies included research in tactile stimulus [37, 45, 46, 51], as seen in **Figures 2-4 (VII)**, **(I)**, **(III)**, **(V)**. Subsequently in [47], illustrated in **Figure 2-4 (III)**, the tactile biofeedback system presented involved surgery, implanting four transversal intraneural electrodes in the distal section of the tibial nerve. Although this invasive method communicates through somatotopic feedback and presents elevated accuracy and repeatability, it is considered less safe than non-invasive systems, as [37, 45, 51], represented in **Figure 2-4 (VI)**, **(I)** and **(V)**. Proprioceptive information delivered by auditory and visual biofeedback are very important to the human sensorial system, and despite the positive outcomes achieved by the presented studies, illustrated in **Figure 2-4 (IV)**, **(VI)** and **(VIII)**, they did not offer a compact display that is small and portable (e.g., earbuds or small monitor) restricting the applicability of those feedback devices to laboratory or clinical settings [50, 52, 53]. Hence, this presents a disadvantage, as these two systems are not considered wearable devices. Nonetheless, one system [50], based on auditory feedback, used a mobile sensor system that is connected to an app on an iPad, providing real-time gait assessment, and through earbuds, the auditory biofeedback for gait correction is delivered, being able to be classified a wearable device. Furthermore, this type of feedback information is considered less important than the somatosensory feedback provided by muscle and skin receptors in the leg, which is responsible for the proprioception [55]. Besides, haptic feedback systems have been shown to operate without overloading sensory systems already occupied during locomotion and activities of daily living promoting wearable usage, since they present a high spatial resolution [46], as shown in **Figure 2-4 (I)**.

Related to the encoding, five of the eight studies exhibited in **Figures 2-4 (VI)**, **(I)**, **(III)**, **(V)** and **(VIII)** used pressure-sensitive sensors that were embedded into insoles [37, 45, 46, 51, 53]. Pressure sensors were positioned under the foot of the residual and sound limb and were activated considering the percentage of body weight loading or by the combination of body weight loading and specific gait cycle phase. This sensor is very common since most of the works focus on stability, balance, and gait symmetries of the patient that can be calculated from the force that the lower limb amputee exerts on the ground. It is, also, very useful since it is widely used in gait event detection. When the therapeutic focus is mainly kinematic enhancements then motion capture, illustrated in **Figures 2-4 (IV)** and **(VI)**, is preferred by [50, 52]. In [50] it was the only study that used Inertial Measurement Unit (IMU)sensors.

Lastly, concerning the clinical experiments, the majority of the studies are in a preliminary evaluation of their system. An example is a study of *Simona Crea* in *Scuola Superiore Sant'Anna* [37]. This work only conducted tests in healthy people to test if subjects were able to detect vibrations applied and to test if subjects learn to associate gait-phase transitions not only temporally but spatially. No main outcomes were evaluated, so it does not prove if the system will improve or not gait parameters, as they conjectured in their therapeutic focus.

At the moment, to the author's knowledge, there are almost no studies conducted regarding biofeedback systems applied in rehabilitating the prosthetic gait considering disturbances in locomotion, such as obstacle crossing, stumble correction and stability in uneven ground. Nevertheless, there is one study, displayed in **Figure 2-4 (V)**, worth noticing, since it was the only one in which the tactile biofeedback was applied to lower limb amputees considering un uneven terrain with obstacles, the therapeutic focus was not improving gait stability or asymmetries, but reducing phantom limb pain, this is, also, important as most amputees suffer from this [52]. In this other study [56] was performed applying real-time visual and auditory Lower-Limb motion feedback while obstacle crossing, but too mild cognitive impairment subjects, not to lower amputees. Hence, this dissertation work will be relevant since it will use a vibrotactile feedback system to assist lower limb amputees when their gait is disturbed by obstacles or uneven ground.

Table 2-2: Summary of the artificial sensory feedback solutions for lower limb amputees.

Authors-Research Lab	Figure	Sensors & System	Body Placement	Therapeutic Focus	Encoding	Clinical Studies	
						Subjects	Protocol
Elena Martini et all. (Scuola Superiore Sant'Anna) 2021 [46]	**Fig. 2-4 (I)**	Pressure-sensitive insoles/ Bidirectional Interface (wearable haptic feedback device)	Waist	Temporal gait symmetry of LLA	Time-discrete vibrotactile stimuli (100 ms duration) provided synchronously with the occurrence of heel-strike event of both limbs during ground-level walking, detected by the insoles. The feedback induces a walking rhythm to the participants to improve symmetry by balancing the feedback cadence between the two limbs	3 LLA. Limited sample size represented a main limitation.	The patients were asked to wear the BI and perform several ground-level walking trials with and without the feedback, to evaluate the effects of the BI on their gait before and after the training sessions. On the pre-and post-assessment sessions, the gait of the participants was assessed in five different walking conditions, all performed overground: (i) natural walking (NW), (ii) symmetrical walking (SW), (iii) symmetrical walking with sensory feed- back (SF), (iv) symmetrical walking with a concurrent cognitive task (SW+ce) and (v) symmetrical walking with sensory feedback and a cognitive task.
Ignacio Gaunaurd et all. (University of Miami) 2020 [50]	**Fig. 2-4 (II)**	IMU sensors/ Wearable auditory feedback system	Medially on each shank, laterally on each thigh. Secured on knee sleeves for the sound limb and prosthetic limb (or directly onto the prosthesis or socket) Also, worn at the sacrum.	Strength, mobility, and gait quality	The ReLOAD system consists of an app stored on an iPad and five wearable sensors, either embedded within knee sleeves, a waist belt, or directly on the prosthesis. The mobile app receives and processes the kinematic data transmitted from the sensors during walks; the participant's gait characteristics are compared through a machine learning classifier with instant real-time auditory biofeedback via earbuds providing verbal commands designed to correct selected gait deviations.	17 participants with LLA	Subjects were trained to use ReLOAD. After baseline testing, prosthetic gait and exercise training, participants took ReLOAD home and completed an 8-week walking and home exercise program. Home visits were conducted every 2 weeks to review gait training and home exercises. Significant improvements in hip extensor strength, basic and high-level mobility, musculoskeletal endurance, and gait quality were found at the completion of the 8-week intervention.

Table 2-3: Summary of the artificial sensory feedback solutions for lower limb amputees (Continuation).

Authors-Research Lab	Figure	Sensors & System	Body Placement	Therapeutic Focus	Encoding	Clinical Studies	
						Subjects	Protocol
Francesco Maria Petrini et all. 2019 (Institute for Robotics and Intelligent Systems, Zürich, Switzerland) [47]	**Fig. 2-4 (III)**	Knee encoder and sensorised soles/ Wearable Real-time tactile feedback device	Knee encoder	Mobility, fall prevention, and agility	LLA wear prosthesis with a system for restoring sensory feedback. An encoder is in the prosthetic knee indicating the flexion of the device and a sensorized insole is under the prosthetic foot. The information is transmitted via Bluetooth as input to an external controller, which translates it into the language of the nerve. These instructions drive the activity of an external stimulator, which is connected to four transversal interfascicular multichannel electrodes (TIMEs), previously implanted. Improved mobility, ease of cognitive effort, and increased embodiment of prosthesis with feedback.	3 TFA	Nine 5 m walking trials with/without feedback over a straight line (one foot after the other without stepping outside the line)
Caroline Dietrich et al. (Friedrich Schiller University) 2018 [52]	**Fig. 2-4 (V)**	-	Residual's limbs thigh	Reduce phantom limb pain and increase ambulation	Sensors at the prosthesis foot detect ground contact and send signal to lower leg module. LLM sends information to upper leg module (ULM) via Bluetooth connection. ULM generates electrocutaneous stimulation signals that are applied via stimulation electrodes at the thigh inset bottom view of the prosthesis foot with three sensors.	14 TTA	0 days of training (walking at level ground and uneven terrains) over 2 weeks, 2 sessions per day, 2 h per session with 30–60 min of rest between daily sessions.
Andrea Brandt et all. 2019 (The University of North Carolina) [51]	**Fig. 2-4 (IV)**	Computer monitor and Instrumented treadmill (dual belt) with force plates, motion capture system/ Visual feedback display	-	Gait symmetry	Custom code for the real-time visual feedback display and displayed it on a computer monitor at eye-level, 1 m in front of the treadmill. Amputated-limb stance time was averaged it over the previous five strides and updated it after each stride. The targets remained on the centre screen. The subject's preferred stance time on each limb was extracted during the first trial, and a no-feedback trial, and used to set three visual feedback targets. Level 1 corresponded with the typical stance time of the prosthetic-limb. Level 3 corresponded with the stance time of the intact-limb. Level 2 was set at the midpoint between L1 and L3. Stance time symmetry and peak propulsion symmetry significantly improved with both prosthesis by increasing prosthetic stance time via feedback	5 TFA	Twelve 1.5 min walking trials at SS speed with 2 min of rest between trials over 3 sessions of 3 h each. Fitting and training provided during prior sessions.

Table 2-4: Summary of the artificial sensory feedback solutions for lower limb amputees (Continuation).

Authors-Research Lab	Figure	Sensors & System	Body Placement	Therapeutic Focus	Encoding	Clinical Studies	
						Subjects	Protocol
Caroline Dietrich et al. (Friedrich Schiller University) 2018 [52]	**Fig. 2-4** (V)	Insole pressure sensors/ Wearable tactile feedback device	Residual's limbs thigh	Reduce phantom limb pain and increase ambulation	Sensors at the prosthesis foot detect ground contact and send signal to lower leg module. LLM sends information to upper leg module (ULM) via Bluetooth connection. ULM generates electrocutaneous stimulation signals that are applied via stimulation electrodes at the thigh inset bottom view of the prosthesis foot with three sensors.	14 TTA	0 days of training (walking at level ground and uneven terrains) over 2 weeks, 2 sessions per day, 2 h per session with 30–60 min of rest between daily sessions.
Elizabeth Russell Esposito et al. (Brooke Army Medical Center) 2017 [53]	**Fig. 2-4** (VI)	Bipolar surface electrodes +motion capture system/ Visual feedback display	-	Reduce centre of mass sway and metabolic consumption during gait retraining	Two separate bouts of real-time visual feedback were provided during a single session of gait retraining. Baseline and post-intervention data were collected. Metabolic rate, heart rate, frontal plane centre of mass sway, quadriceps, and hamstrings muscle activity, and co-contraction indices were evaluated during steady state walking at a standardized speed.	Study group: 8 TTA; Control group:8 H	Baseline: 10 min in seated position (VO2 baseline). Acclimation: 4 min practice receiving visual feedback and verbal cues (PT). Data collection: 8 min walking (with/without visual feedback) at standardized speed
Simona Crea et all. (Scuola Superiore Sant'Anna) 2015 [47]	**Fig. 2-4** (VII)	Pressure-sensitive insole/ Wearable tactlie feedback device	Upper part of the right thigh of the residual limbs	Designed to convey sensory information from a prosthetic foot sole to the individual.	Both shoes were equipped with pressure-sensitive insoles, vertical ground reaction and centre of planar pressures are acquired. These are recognized by the electronic board for the control of the VT units (3 vibrotactile round-shaped motors) placed in a belt. Only signals from right insole [were processed online to detect gait events and deliver VT stimulations;	10 H. No evaluation in amputees and main outcomes were evaluated.	The experimental procedures involved first, to test if subjects were able to detect vibrations applied on the thigh during walking and to what extent detection thresholds changed with increasing loss of synchronicity between the VT stimuli and specific gait-phase transitions. Second, to test if subjects learn to associate gait-phase transitions not only temporally but spatially, i.e., that specific VT units were associated with specific gait-phase transitions. No evaluation in amputees and main outcomes were evaluated.
Ming-Yih Lee et al. (Chang Gung University) 2007 [54]	**Fig. 2-4** (VIII)	Foot pressure sensors/ Visual-auditory bio-feedback display	Quadriceps muscle	Static balance and gait performance of single leg quiet standing	A computerized foot pressure biofeedback sensory compensation system using sub-threshold low-level electrical stimulation combined with visual- auditory biofeedback was developed. Two force sensing resistor FSR to detect the heel contact and toe push-off conditions. The foot-pressure signal is sent to the main control unit to generate the visual–auditory: beeping sound volume (three levels) and visualization of plantar foot-pressure distribution (range of colours indicated the intensity of the pressure exerted).	7 TTA	Subjects were asked to wear their prosthetic leg with two FSRs on the prosthetic foot and walk on treadmill while subjected to stimulus. Double Support Time Symmetry Index, Constant Time Step Number Index, Single Support Time Symmetry Index and Gait Phase Time Ratio Index were used as outcomes measures. In overall subjects showed improvement with visual–auditory biofeedback. ambulation performance for amputees

3. MULTIVARIATE BIOMECHANICAL DATA ANALYSIS

In this chapter, a multivariable biomechanical data analysis from the amputee and healthy subjects is presented. This includes the methods used to collect the data, the statistical plan and the post-processing tools that were used to undertake a careful and thorough examination. The results obtained will also be described with the respective critical analysis.

3.1 Methods

In this subsection, the procedures used to conduct this dissertation will be presented. This includes the data acquisition process to perform the biomechanical analysis of the retrieved data, as well as, the selection of participants, the protocol, the systems, and the devices used during it.

3.1.1 Participants

The evaluation proposed in this study included the participation of **eleven volunteers**, **six** (3 female, 3 male) of them were **healthy participants** (**Table 3-1**) from the University of Minho and **five** (2 female, 3 male) **amputee volunteers** (**Table 3-2**), regular customers of *Padrão Ortopédico* and *Ortoadapta*, to tune and optimize all the sub-systems of this project, as well as to evaluate their contributions and effects on locomotion.

A list of **inclusion and exclusion criteria** was outlined to select the participants. Participants were recruited if they had: **I)** Healthy locomotion**; II)** Full postural balance; **III)** Over 18 years old; **IV)** Body mass between 45 and 90 kg; **V)** Height between 1.50 and 1.90 m; **VI)** Able to use VT-S, active and commercial prosthesis devices with test adapter; **VII)** Signed informed consent. **Exclusion criteria** were: **I)** presence of comorbid disorders likely to affect gait, including stroke, orthopedic disease, rheumatologic disease, other neurological and musculoskeletal disorders, cardiovascular and pulmonary diseases; **II)** Difficulty locomotion on stairs, treadmill and/or ramps, on uneven terrain or with obstacles; **III)** Wounds or skin fragility in the areas of contact with the VT-S, or the prosthetic adapter; **IV)** Occurrence of fractures in the lower limbs; **V)** Use of inadequate clothing and footwear for gait and/or use of prosthetic and biofeedback devices. Error! Reference source not found. presents the participants detailed clinical characteristics and anthropometrics.

The subjects were approached to participate in the study via telephone or face-to-face contact, in which they were informed of **I)** the global objective of the project and possible impact on motor rehabilitation; **II)** the study protocol; **III)** the expected duration of the study and **IV)** justification of the absence of risks and use of non-invasive and safe systems, following the principles of the Declaration of Helsinki and the Oviedo Convention, by the ethical guidelines of the Ethics Committee in Life and Health Sciences (CEICVS 147/2021). All recruited participants agreed and signed informed consent before the study to participate in the current research, this document is available in **Appendix I**.

Table 3-1: Non-pathological participant's demographics.

ID	Sex	Age	Height (cm)	Weight (km)
1	M	24	170	75
2	F	28	157	53
3	M	24	162	95
4	M	25	170	76,9
5	F	25	151	50
6	M	31	173	67,5
7	F	28	164	68
8	F	25	170	61

Legenda: M = Masculine; F= Feminine.

Table 3-2: Pathological participant's demographics.

ID	Sex	Age	Height (m)	Weight (km)	Amputation Side	Amputation Level	Amputation Time	Etiology	Functional Capacity	Prosthesis Use	Falls	Prosthesis
1	M	58	1,7	91	L	TTA	30	A	K3	D	N/A	CDF
2	M	49	1,83	68,7	L	TTA	7	WA	K3	D	N/A	CDF
3	M	37	1,8	60,8	L	TFA	17	T	K3	D	N/A	HN
4	F	54	1,58	63	R	TFA	49	T	K3	D	N/A	HN
5	F	26	1,56	35	R	TFA	23	T	K3	D	N/A	HN, HA and CDF

Legenda: M = Masculine; F= Feminine; L = Left; R = Right; A = Accident; WA = Work Accident; T = Trauma; D = Daily; N/A= Not Applicable; CDF = Carbon dynamic foot; HN = Hydraulic Knee;

Despite the inclusion criteria defined, due to the limitation of patients, it was made an exception, emphasizing that the most important factor would be for the patients to be able to perform the tests and have a relatively normal gait. Since in the case of amputee patient 5, the weight did not limit his mobility, it was decided to include him/her anyway.

3.1.2 Biomechanical Data Acquisition

To accomplish the objectives defined in this research project, a quantitative methodology characterized by a systematic process of collecting measurable and quantifiable data by precise collection instruments, with a focus on sensory systems was chosen. Afterwards, data, from healthy participants and lower limb amputees, were collected and analyzed. The data acquisition of the amputee patients was done in collaboration with *Padrão Ortopédico* and *Ortoadapta*.

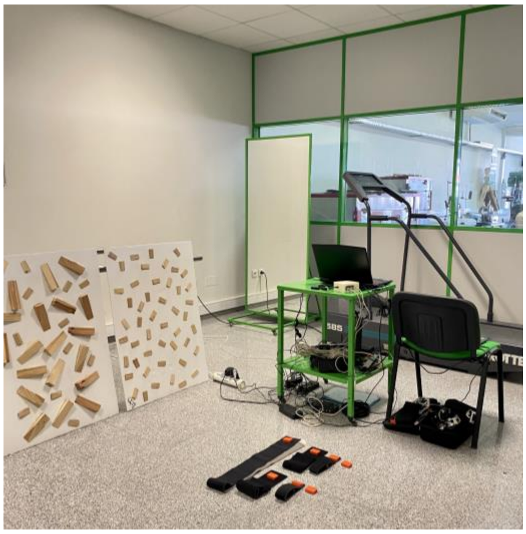
In this protocol it was performed the collection and application of biomechanical and physiological data regarding healthy and prosthetic locomotion, using **Gait Shoes** made by BiRDLab, **Xsens MVN Awinda ®** (Enschede, The Netherlands) in **Figure 3-1 (I)**, **Delsys Trigno ®** (Natick, MA, USA) in **Figure 3-1 (II)** and video recording using Microsoft Kinect Xbox One, in different daily locomotion environments, all of them are non-invasive sensory systems.

(I) (II)

Figure 3-1: Sensory Systems used during Biomechanical Data acquisition: **(I)** Xsens MVN Awinda ® and (**II)** Delsys Trigno ®.

These different environments include the use of a treadmill with three different speeds, and forward walking in three settings: ground floor, obstacles base and irregular terrain, specified information can be found in **Appendix II**. **Figure 3-2 (I)** shows the collection of biomechanical data in irregular terrain and **Figure 3-2 (II)** the setup of the different components used in the acquisition. The protocol for data collection of pathological patients suffered some alterations, detailed information about both protocols can be found in **Appendix III**.

(I)



(II)

Figure 3-2: **(I)** Collection of biomechanical data in an irregular terrain and **(II)** Setup of the different components used in Biomechanical Data acquisition.

3.1.3 Sensory Systems

All sensory systems that will be mentioned are already developed and properly validated, being suitable for use in gait tracking.

Gait Shoes were used to collect biomechanical data and they will be used as a gait event detection device. The device worn by the participants is a restructuring model of the wearable system proposed in [57] and is represented in **Figure 3-3**.

The proposed device is a wearable inertial sensory system that was designed for ambulatory human gait sensing in diverse walking situations. It includes two inertial units and two distance sensing sensors VL53L0X, placed on the instep of each foot and a central processing unit. Each inertial unit is fixed to the feet by adjustable ribbons, and it is based on the MPU6050, a low-cost IMU that combines a tridimensional accelerometer (± 8 g) and a tridimensional gyroscope (±2000 °/s) for the acquisition of feet kinematic data and foot clearance. For data acquisition, represented in **Figure 3-3**, it was used radio-frequency modules (NRF24L01+) to transmit the data acquired by each system to the motherboard (Arduino Mega). Subsequently, the communication from the motherboard to the computer was done using a Bluetooth module (HC06 Serial Bluetooth Brick) to be displayed by a user interface [58].

Figure 3-3: Sensory systems used, Gait Shoes and Xsens MVN Awinda ®.

MVN Analyze Pro® was the **Xsens MVN Awinda ®** software used and integrates seven miniaturized compact inertial sensors (IMUs) on textile straps, which are placed on the user's clothing, on the lower limbs and waist. The **Delsys Trigno ®** system includes surface electrodes to be placed in contact with the skin surface of the lower limb muscles. Muscular data were retrieved and analysed with **EMGworks® Acquisition** and **EMGworks® Analysis**. For the synchronization of all sensory devices, it was used Hardware, **SyncLab**, developed at BiRDLab, which was able to ensure that all the systems were synchronized and started and stopped, at the same time. The synchronization was done in microseconds. The calibration of both systems is done according to the company's instructions.

All the sensorial equipment will allow us to assess the patient's performance during the execution of the study sessions.

The following **Table 3-3** presents the sensory systems that will be used in this dissertation, as well as the resulting data collected. Only wearable and non-invasive systems will be used (illustrated in **Figure 3-1** and **Figure 3-2**)

Table 3-3: Identification of sensory systems and their location to collect the data indicated.

Sensorial System	Location	Data
GaitShoes	Foot	**Biomechanical Data:** Gait Events Foot Clearance
Xsens MVN Awinda ®	IMUs placed in the lower segments (thigh, skin and foot) and lumbar area	**Biomechanical Data:** 3D acceleration 3D angular velocity Angles of the segments and joints 3D position and orientation of the segments Gait events Walking speed Location of the centre of mass
Delsys Trigno ®	Superficial electrodes placed on muscles of the lower limbs (*tibialis anterior, gastrocnemius, soleus, vastus lateralis, bicep femoris*)	**Physiological data – EMG:** Muscle activity MVC normalised muscle activity Muscle envelope signal

3.2 Vibrotactile Socket

In this research, the main goal is to propose a paradigm of vibrotactile stimulus to be used in a biofeedback device during rehabilitation sessions. Therefore, it is intended that in the future, an experimental protocol must be conducted to test the proposal paradigm, through a Vibrotactile Socket, with healthy and pathological patients. This future experimental protocol will assess the proprioception of patients when their gait is disturbed by obstacles or uneven ground while receiving artificial sensory feedback. Thus, for this investigation, subjects in some trials, only wore a sensory feedback socket, **Vibrotactile Upper Leg Socket (VT-S)**, to test its wearability, as presented in **Figure 3-4**, no stimulation was applied.

Figure 3-4: Devices worn by the participants in the research study. Vibrotactile Upper Leg Socket (VT-S) **(I)** and the subjects also wore on the feet Gait Shoes **(II)**.

The **Vibrotactile Upper Leg Socket** will provide vibratory sensations according to gait information (i.e., biofeedback approach), such as gait events, and distance to the obstacle and/or foot clearance.

The vibrotactile technology consists of coin-shaped Eccentric Rotating Mass (ERM) DC motors with a 2 cm diameter each. The motor, rotating an eccentric mass at different angular velocities, allows the generation of various amplitudes and thus, frequencies, of vibrations. The eccentric vibration stimulates the Pacinian corpuscles, which are encapsulated mechanoreceptors located in the subcutaneous tissue, specialized in providing information to the CNS about touch, pressure, vibration, and cutaneous tension. Pacinian corpuscles are referred to as high-sensitivity mechanoreceptors because even weak mechanical stimulation of the skin induces them to rapidly produce action potentials [59]. These receptors allow frequencies from 30-300 Hz, and a peak at 250 Hz, their stimulation induces a sensation of vibration or tickle. Since ERM coin-shaped actuators range from 125-300 Hz, it was decided the range of the actuation of the device was between 125-250 Hz.

The **VT-S**, intended to be located at the upper leg uses 12 vibrator modules, the vibrators are organized in four rows. Each row has three modules equidistant 10 cm from each other's. Using the circumference of the thigh each row is distributed one-fourth of the total circumference equidistant around the thigh, 90° apart (Lateral, Medial, Anterior and posterior). In **Figures 3-5** and **3-6**, the device is represented.

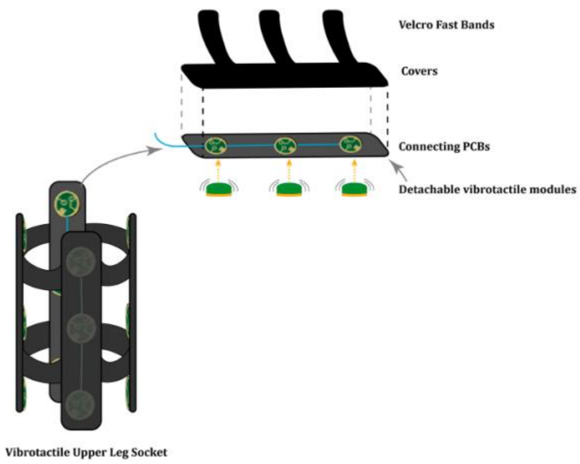


Figure 3-5: VT devices for the upper leg. Three vibrators are aligned in each cloth, adjusted through Velcro fast bands.

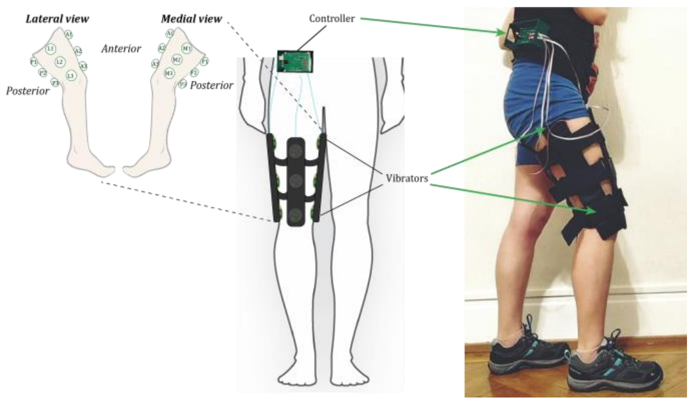


Figure 3-6: Placement of the Vibrotactile Upper Leg Socket, (VT-S) with a total of 12 vibrators aligned along the user's thigh circumference. The identification for each ERM motor is also included.

3.3 Use of Biomechanical Modelling in Gait Analysis

Movement Science is driven by observation, but observation alone can not elucidate the principles of human movement [60]. Biomechanical modelling and computer simulation complement observations and are useful tools to evaluate complex biomechanical problems, simulate and evaluate injuries, estimate the muscle-tendon forces, and joint the torques during motion and predict, for instance, a fall or the effect of a prosthetic limb [61].

During the course of this year, for six months, the work was mainly focused on the curricular internship at the CAR-Centre of Automation and Robotics. In this traineeship, the main objective was to analyse the Human gait affected by a disease condition, in OpenSim. With this internship, knowledge in the field of biomechanics and gait analysis was acquired to be applied to this dissertation.

With the knowledge gained from the internship, an interesting aim would be to combine a biomechanical model of human gait with data collected from healthy subjects and amputees. Thus, it would be possible to simulate or even predict biomechanical behaviours and accomplish a more careful and scientific analysis of the prosthetic gait.

Over the past decades, many tools have been developed for biomechanical simulation and analysis. OpenSim is one of the virtual human modelling software that has been widely used. It is an open-source platform that gives easy access to biomechanical analysis, especially of muscles [62].

Various models are publicly available and are often reused for multiple investigations because they provide a rich set of behaviours that enables different lines of inquiry [60].

OpenSim enables the construction of musculoskeletal models, the visualization of their motion, and a set of tools for extracting meaningful information [60]. It has multiple capabilities such as the ability to create and edit a broad range of models of musculoskeletal structures and many other mechanisms. It is widely used to analyse and simulate models and motions. OpenSim, also, has the ability and the tools to Import Experimental Data, such as marker data, joint kinematics, and external forces, from, for example, XSens and Vicon. Additionally, this software is capable of performing Inverse Kinematics (IK), Inverse Dynamics (ID), and Static Optimization that solves the muscle redundancy problem based on algorithms in the literature, Forward Dynamics (FD), and so on. All the information about OpenSim can be found in [63].

The collection of biomechanical data did not allow us to obtain the forces and moments of the joints. Therefore, the main objective of using OpenSim would be to utilize the ground reaction force (GRF) obtained by the Gait Shoes to calculate the forces and moments of the joints to carry out a more detailed biomechanical analysis.

In this dissertation, it was used the model entitled 3DGaitModel2392 with 23 degrees of freedom and actuated by 76 muscles, as a generic musculoskeletal model. Detailed information about the model can be found on the Gait2392 [64].

Flowing, IK was performed using OpenSim's tool. The purpose of IK is to estimate the joint angles of a particular subject from experimental data. It is possible to compare experimental marker data with inverse kinematics results obtained. The virtual markers should correspond closely to the experimental marker locations as the animation proceeds. After IK is performed it is possible to acquire the markers errors and model coordinate errors (e.g., joint angle errors) associated with the last frame of the motion.

Lastly, the final step was to perform an ID analysis, which objective was to estimate the forces and moments that affect the gait. The obtained results can be used to instigate how muscles are utilized in that motion. To perform ID it was necessary to use the joint angles from IK and experimental GFR data, in order to obtain the net reaction forces and net moments at each of the joints [61, 62]. A detailed explanation of the ID Tool can be found on the ID page of the documentation [67].

With OpenSim it is possible to view the GRF with the inverse dynamics results. Green arrows shown represent GRF vectors collected from a force plate in the following **Figure 3-7**.

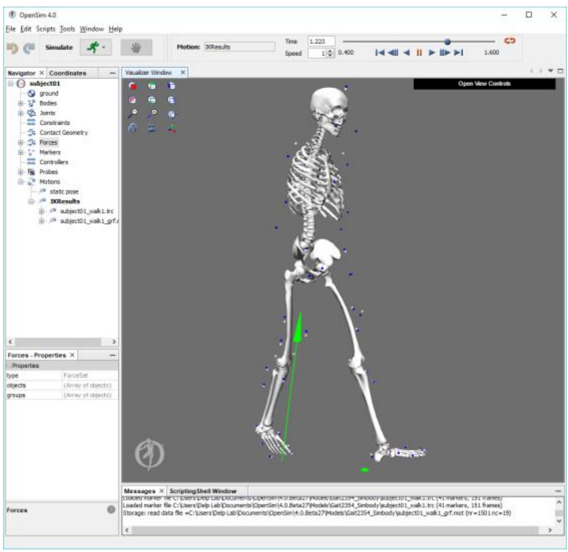


Figure 3-7: Representation of GRF vector, shown as green arrows (OpenSim Example).

After doing all these procedures, it was possible to obtain the forces and moments during each motion. However, the values were very low, almost null, and not consistent. This may have happened because of two distinct reasons: (i) the experimental GRF data were not acquired with force plates but with embedded Force Resistive Sensors and during data collection, the foot of each patient when striking the ground must not have been properly recognized by the device, and since (ii) IK and ID solutions are very sensitive to the accuracy of the scaling and marker registration it can be inferred that there have been some mistakes during these steps. Consequently, it was decided not to include these forces and moments, in this investigation.

3.4 Data Processing

Quantitative data will be processed by filtering algorithms (i.e., interpolation, signal alignment, and removal of offsets), using Matlab® software (R2021a, The Mathworks, Natick, MA, USA). After post-processing, the data was stored in*.mat* format files, from which they were subsequently normalized per gait cycle, considering the average signal, for each test condition.

Next, it was necessary that the data from all subjects was organized in a way that then could be statistically analyzed in SPSS software (IBM Corp. Released 2019. IBM SPSS Statistics for Macintosh, Version 28.0. Armonk, NY: IBM Corp). Thus, the data was segmented by gait event, in each cycle, and labelled as: Heel Strike (HS), Foot Flat (FF), Mid-Stance (MMST), Heel Off (HO), Toe Off (TO), Mid-Swing (MMSW). Then, data was stored by subject, trial, cycle, gait event, amputated side (left or right), speed (FO, 1.6, 2.7, 3.6), floor (Ground, Obstacles, Irregular), perturbation (Obstacles 1, 2,3 or 4 and Type 1 or 2), condition (Healthy or Amputee), and by sensory data. In the end, files from Spatiotemporal parameters, Kinematic data, Range of motion, and Amplitude Analysis of Muscle Activity were obtained.

Finally, after all the processing has been done, the data was ready to be statistically analysed. In total 590 trials of Spatiotemporal parameters were analysed, 108 339 samples of kinematic parameters (being 16 530 gait cycles of ROM parameters and 91 809 gait events) and 91 809 gait events of muscular data.

3.5 Data Set Statistical Plan

After retrieving the required data, from healthy subject and amputees, the next step was to analyse this information. To perform the data analysis, was necessary a descriptive statistical analysis of socio-demographic data, namely age, gender, body mass, and height. It was also necessary to categorize quantitative data in dependent or independent data, in order to be able to perform the statistical analysis.

Therefore, types of floors, speeds and perturbations were defined as independent data, as well as the condition of the subject, in other words, if the subject has a pathological gait or not. Being a pathological subject means that the patient has lost one of their lower limbs. All of the biomechanical parameters were considered as dependent data in the matter that they may or may not vary according to the statistical analysis that was carried out. Succeeding, in **Table 3-4** and **3-5** it is described each category and correspondent data.

Table 3-4: Independent data.

<table>
<tr><td rowspan="18">Independent Data</td><td rowspan="4">Gait speeds</td><td rowspan="3">Treadmill</td><td>1.8 km/h</td></tr>
<tr><td>2.7 km/h</td></tr>
<tr><td>3.6 km/h</td></tr>
<tr><td colspan="2">Forward walking GO (Ground)</td></tr>
<tr><td rowspan="6">Types of Floors</td><td colspan="2">Treadmill</td></tr>
<tr><td colspan="2">Ground</td></tr>
<tr><td colspan="2">Obstacle terrain</td></tr>
<tr><td colspan="2">Irregular terrain</td></tr>
<tr><td colspan="2">Type 1</td></tr>
<tr><td colspan="2">Type 2</td></tr>
<tr><td rowspan="4">Perturbations</td><td colspan="2">Obstacle 1 (3cm)</td></tr>
<tr><td colspan="2">Obstacle (7cm)</td></tr>
<tr><td colspan="2">Obstacle (10cm)</td></tr>
<tr><td colspan="2">Obstacle (15 cm)</td></tr>
<tr><td rowspan="2">Patient Condition</td><td colspan="2">Healthy</td></tr>
<tr><td colspan="2">Amputee</td></tr>
<tr><td rowspan="2">Patient Foot</td><td colspan="2">Left</td></tr>
<tr><td colspan="2">Right</td></tr>
</table>

Table 3-5: Dependent data.

Dependent Data		
Kinematic Data	**SpatioTemporal**	**Muscular Activity**
Ankle_AngleX Ankle_AngleY Ankle_AngleZ Hip_AngleX Hip_AngleY Hip_AngleZ Knee_AngleX Knee_AngleY Knee_AngleZ Shank__position_Z Thigh__position_Z ROM (ankle, knee and hip) (per step) ROM of the Centre of mass)	Cadence Double Support Duration Foot Clearance Mean Per Stance Mean Per Swing Single Support Duration Step Duration Step Length Stride Duration Stride Length Stride Per Minute Stride Velocity	Rectus Femoris (RF) Vastus Laterallis (VL) Gluteus Maximus (GMax) Gluteus Medius (GMed)

After all the data being categorized, the next step was focused on idealizing and deciding the best and most adequate statistical analysis for this kind of data, in order to accomplish our objectives and answer the research questions proposed. Hence, some statistical questions were set in order to guide the analysis: **I)** What is the role of each of the parameters (Dependent Data) when analysing the gait of a lower limb amputee?; **II)** Is the contribution of the parameters significant when comparing a healthy gait with the gait of an amputee?; **III)** Is it possible to correlate muscle activity and the parameters to be analysed?; **IV)** What is the influence of the irregular and obstacle pavement in the amputated leg during the walk?; **V)** Are the parameters significantly relevant and should they be considered in the application of the given stimulus, by the VT-S?; **VI)** Are all parameters selected significant for this analysis?

Spatiotemporal, Kinematic Parameters and Muscular Activity were analysed using SPSS statistics for IOS 28. In order to verify whether there is a significant difference between the means and whether the factors exert influence on any dependent variable, it is necessary to perform a variance analysis. for multiple variables, as was the case of this multivariate data analysis, a MANOVA must be used since it considers the effects of several dependent variables. To be able to perform MANOVA it is necessary to fulfil some statistical assumptions, such as: **1)** Multivariate normality; **2)** Absence of multivariate outliers and **3)** multicollinearity; **4)** Linear relationship between dependent and independent variables; **5)** Homogeneity of the matrices of variances and covariances. Lastly, MANOVA assumes that the observations are independent of one another, there is not any pattern for the selection of the sample, and that the sample is completely random.

Normality of the data was verified using the Kurtosis and Skewness, Mahalanobis distance was used to test the presence of multivariate outliers. A Pearson correlation coefficient was calculated to detect potential correlations between the different parameters in the various conditions. Levene's Test of Equality of Variance was used to examine whether or not the variance between independent variable groups is equal. Non-significant values of Levene's test indicate equal variance between groups.

In general, MANOVA only permits to infer whether or not there is a difference, to determine where the difference is evidenced and how it evolves between groups (i.e., which specific independent variable level significantly differs from another), post hoc tests, usually univariate, are executed. But in this work, it preferred to perform post hoc tests of the factor's interaction. In this investigation, it was used the Tuckey post hoc test.

Moreover, it is, usually, helpful, when there is a large dataset and several variables, to plot a line graph, it allows to visualize if there are depressions and considerable variations of the means. However, it is necessary to be extremely cautious when analysing this kind of graph, as it is very easy to jump to misleading conclusions. This is because, by default, SPSS when plotting, changes the scaling, depending on the mean of a parameter and on the specific condition. This results in the graph sometimes being misleading, in the sense that analysing the graph it may seem that there is a significant variation, however there is not. It may look like this because the scale may be too short or the opposite. Hence, it is always better to draw conclusions only from the Post Hoc results.

To evaluate the effect size for the MANOVA model it is used Partial *eta* square ($\eta 2$), it shows how much variance is caused by the independent variable. The value for Partial *eta* squared ranges from 0 to 1, where values closer to 1 indicate a higher proportion of variance that can be explained by a given variable in the model after accounting for variance explained by other variables in the model.

Even though some assumptions were not satisfied, it was not an impossibility to perform MANOVA. Of the four tests that MANOVA performs, Pillai's Trace is the most robust and was the one used.

3.6 Outcomes

In this subsection, the results from the statistical analysis performed will be presented. Primarily, the Spatiotemporal Parameters will be presented, then it will be evaluated the alterations Kinematic Parameters suffer, this includes the ROM and joint angles. Last but not least, the results from the muscular activity will be disclosed.

3.6.1 Spatiotemporal Parameters

Spatiotemporal parameters statistically analysed included Cadence, Double Support Duration, Foot Clearance, Mean Per Stance, Mean Per Swing, Single Support Duration, Step Duration, Step Length, Stride Duration, Stride Length, Stride Per Minute and Stride Velocity.

The normality of the data was verified using Kurtosis and Skewness. It was confirmed the presence of some multivariate outliers, but they were found not significant. The absence of multicollinearity was, also, established. The only assumptions that were not fulfilled were linearity and homogeneity, however, the MANOVA was still performed, given that a more robust analysis was performed.

From all of the spatiotemporal parameters mentioned above, and based on [68, 69], it was decided to analyse only the following parameters: Cadence, Foot Clearance, Double Support Duration, Single Support Duration, Step Length, Stride Length and Stride Velocity.

After calculating the Pearson Correlation coefficient, it was detected correlations between the parameters such as Stride Length, Step Length and Stride Velocity, as shown in **Figure 3-8** below.

Correlations

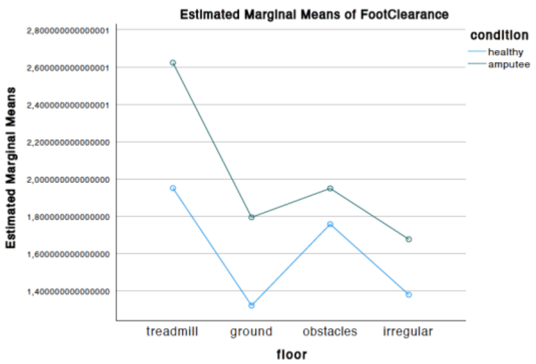
		StepLength	StrideLength	StrideVelocity
StepLength	Pearson Correlation	1	,614**	,747**
	Sig. (2-tailed)		<,001	<,001
	N	590	590	590
StrideLength	Pearson Correlation	,614**	1	,837**
	Sig. (2-tailed)	<,001		<,001
	N	590	590	590
StrideVelocity	Pearson Correlation	,747**	,837**	1
	Sig. (2-tailed)	<,001	<,001	
	N	590	590	590

**. Correlation is significant at the 0.01 level (2-tailed).

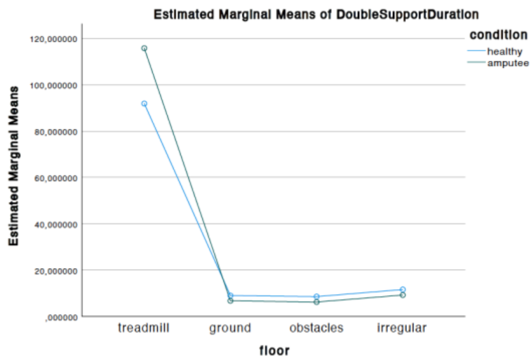
Figure 3-8: Table of Pearson Correlation coefficient, obtained with SPSS.

Since the sample number, N, is elevated, as verified in **Figure 3-8**, it is possible to consider that there is a correlation every time Pearson Correlation > 0,6. It is, then, possible to contemplate that these three parameters are correlated, and, therefore, to make this investigation faster and not repetitive, only one parameter was analysed, that being Stride Length. The behaviour of the step length and stride velocity can be inferred by the performance of Stride Length.

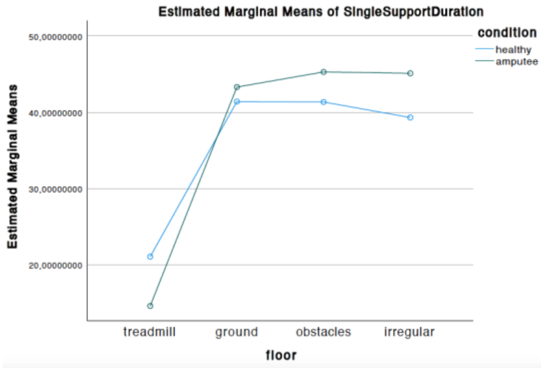
MANOVA showed that there is no effect on the condition of the subject regarding the Spatiotemporal parameters [Pilai's trace = 0,010; F (5,578) = 1,214; p > 0.001]. However, there is the floor's effect [Pilai's trace = 0,464; F (15,1740) = 21,248; p < 0.001] and the interaction between the floor and condition [Pilai's trace = 0,076; F (15,1740) = 3,002; p < 0.001] on the Spatiotemporal parameters. Subsequent univariate ANOVAs showed that there is only an effect of the condition on one parameter, Foot Clearance [F (1, 590) = 4,592; p<0.05]. While the floor produces an effect on Cadence [F (3, 590) = 43,402; p<0.05], on Foot Clearance [F (3,590) = 3,704; p>0.05], on Single Support Duration [F (3,590) =19,208; p<0.05] and on Stride Length [F (3,590) = 40,463; p<0.05], contrary to Double Support Duration [F (3,590) = 1,441; p>0.05] there is no effect of the floor. Univariate ANOVAs, also, presented that the interaction between the floor and condition only makes a significant effect on Cadence [F (3,590) = 5,240; p<0.05] and on stride length [F (3,590) = 7,036; p<0.05].



(I)



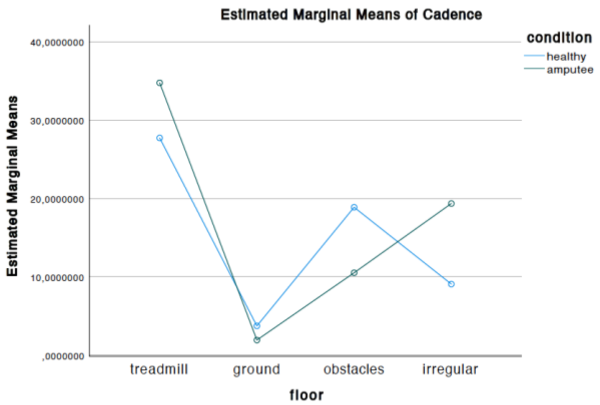
(II)



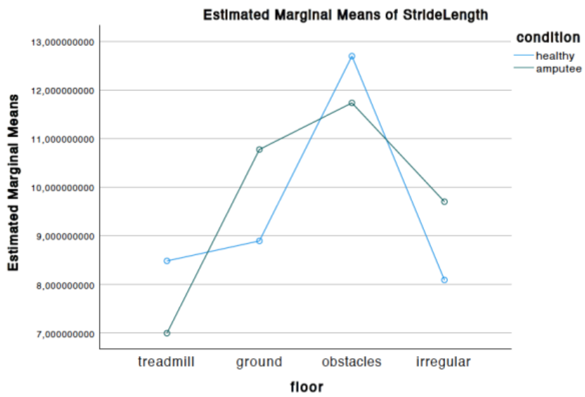
(III)

Figure 3-9: Comparison, among healthy and amputee patients during walking on different types of floors, of **(I)** Foot Clearance, **(II)** Double Support Duration and **(III)** Single Support Duration.

Analysing these graphs, **Figure 3-9**, it is possible to confirm what was said before, that conjugating the independent variables, floor and condition, there are no significant differences among the lines, since they have a very similar shape.



(I)



(II)

Figure 3-10: Comparison among healthy and amputee patients during walking in different types of floors, of **(I)** Cadence and **(II)** Stride Length.

While analysing the interaction between the floor and condition, in healthy subjects, post-hoc and Tuckey showed, as verified in **Figure 3-10 (I)**, that there are significant differences in **Cadence** among the treadmill, ground, obstacles and irregular terrain, as well as between ground and obstacles, and among obstacles and irregular floor. **Stride Length**, it is mainly affected by the obstacles and irregular floor, **Figure 3-10 (II)**.

In amputees, on **Cadence,** there is only a significant difference between the treadmill, ground floor and irregular floor, plus among treadmill and obstacles. On **Stride Length,** it is only verified, in **Figure 3-10 (II)**, that there exist differences between treadmill and ground and between obstacles and irregular.

3.6.2 Kinematic Parameters

From all the kinematic parameters mentioned above, in section 3.3 Statistical Analysis, and based on [69] it was decided to analyse only the parameters in the sagittal plane,

The normality of the data was verified using Kurtosis and Skewness test. It was confirmed the absence of significant multivariate outliers. The nonexistence of multicollinearity was established, and only two parameters showed a strong correlation. Thus, only two suppositions were not fulfilled, including linearity and homogeneity, however, the MANOVA was still performed, given that a more robust analysis was performed.

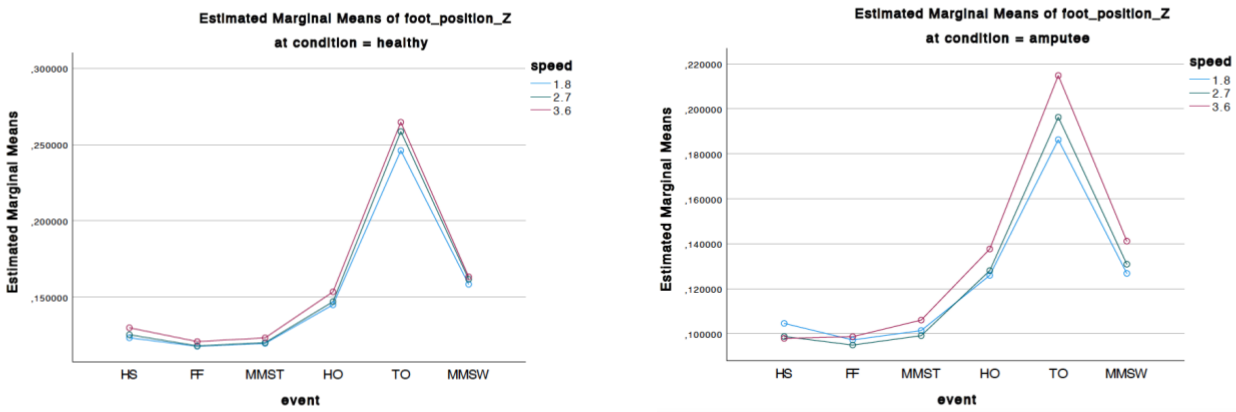
Primarily, the kinematic parameters retrieved from Xsens were analysed, this includes how speed and gait events produce an effect or not on the parameters while walking on a treadmill. Then, it was studied the effect that types of floors have on gait events in the required parameters.

Subsequently, it was evaluated the significance of varieties of floors on ROM parameters.

Influence of Speed on Treadmill walking

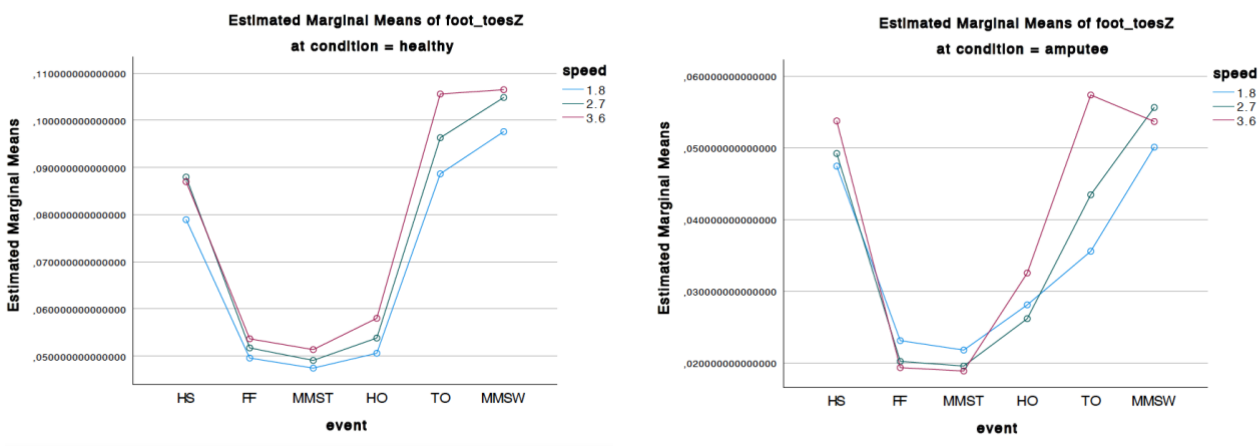
Firstly, the kinematic parameters were analyzed on the treadmill, and how speed and gait events produce an effect or not on the parameters.

MANOVA showed that there is an effect of the interaction between the condition and speed on the kinematic parameters [Pilai's trace = 0,036; $F (14, 163790) = 211,454$; $p < 0.001$]. Additionally, there is an effect of the interaction between the condition and event [Pilai's trace = 0,227; $F (35, 409490) = 556,698$; $p < 0.001$] and the interaction between speed and event [Pilai's trace = 0,119; $F (70, 573300) = 141,560$; $p < 0.001$] on the parameters. Furthermore, the interaction amid these three factors [Pilai's trace = 0,029; $F (70, 573300) = 33,715$; $p < 0.001$], also, displays effects on the dependent variables. Subsequent univariate ANOVAs showed the same results, that condition, speed, gait event and the interactions between all of them produce an effect on these parameters.



(I) (II)

Figure 3-11: Behaviour of gait events of Foot Position in Z during walking on a treadmill with different paces among **(I)** healthy and **(II)** amputee patients.

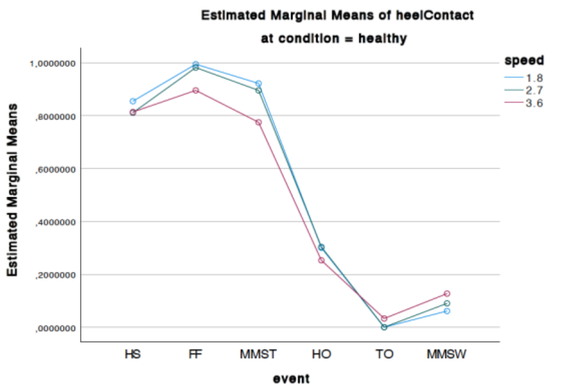


(I) (II)

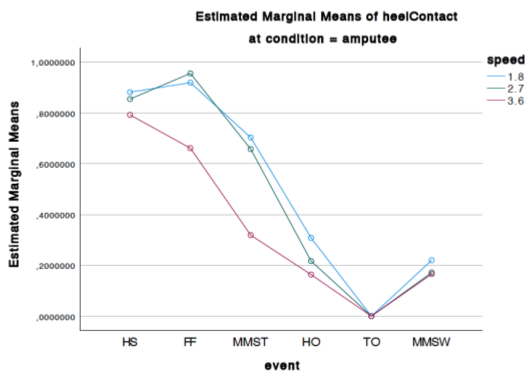
Figure 3-12: Behaviour of gait events of Toes Position in Z during walking on a treadmill with different paces among **(I)** healthy and **(II)** amputee patients.

Post-hoc and Tuckey tests showed that all gait events were affected by the three velocities on **Foot Position**, in healthy participants, as presented in **Figure 3-11 (I)**. The same occurs to the parameter **Toes Position**, with the exception that there were no differences between TO and MMSW in speed 3.6 km/h, as it is verified in **Figure 3-12 (I)**, by the straight red line among these events.

As to the amputee subjects, on **Foot Position**, **Figure 3-11 (II)**, there are no differences: in speed 1.8 km/h, between HO and MMSW events; in speed 2.7 km/h, amid HS-MMST and in speed 3.6 HS-FF events, in the conjunction differences between the group are demonstrated. In **Figure 3-12 (II)**, on **Toes Position** there are differences in all gait events, excluding, in the speed 2.7 km/h between FF-MMST and on speed 3.6 km/h among HO-MMSW, HS-MMSW and FF-MMST.



(I)

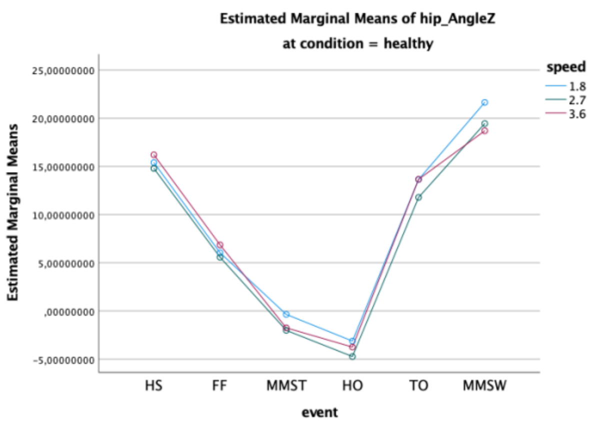


(II)

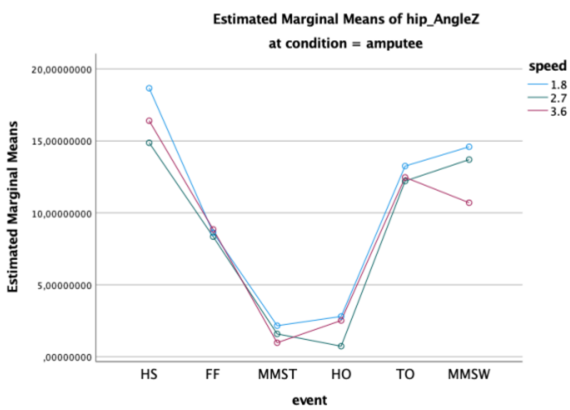
Figure 3-13: Behaviour of gait events of Heel Contact in Z during walking on a treadmill with different paces among **(I)** healthy and **(II)** amputee patients.

Concerning **Heel Contact**, all gait events were affected by the three paces, both in healthy and amputee subjects, as it is presented above in **Figure 3-13 (I)** and **(II)**, respectively.

Similar behaviour for the **Hip Angle** can be verified bellow for healthy people, in **Figure 3-14 (I)** and for amputated patients, in **Figure 3-14 (II)**.



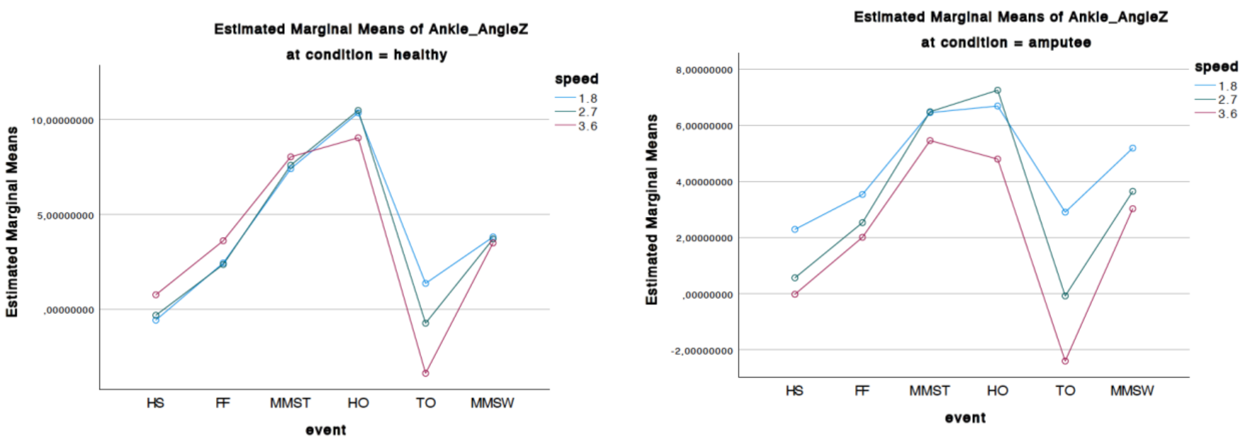
(I)



(II)

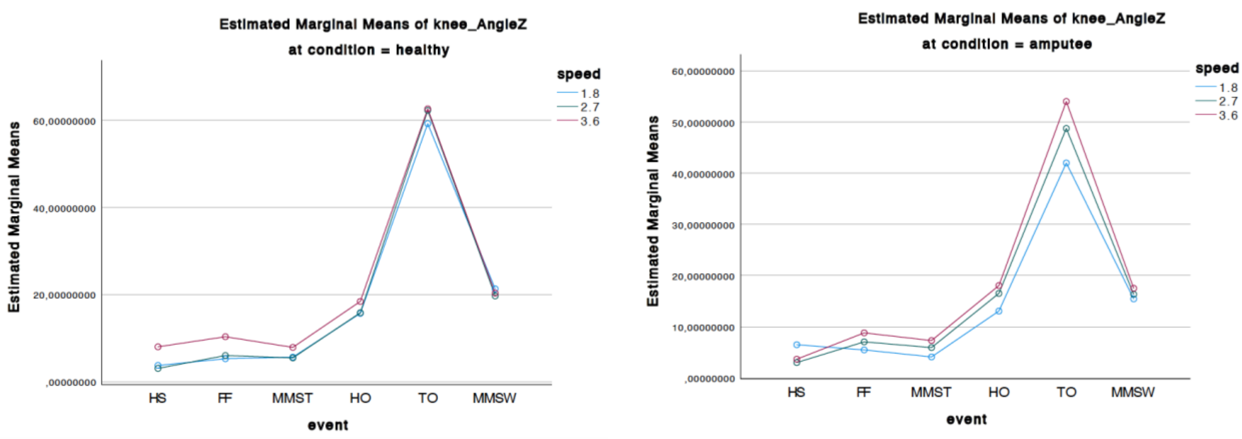
Figure 3-14: Behaviour of gait events of Hip Angle in Z during walking on a treadmill with different paces among **(I)** healthy and **(II)** amputee patients.

As it is represented in **Figure 3-15 (I)**, in healthy subjects, there are significant differences to **Ankle Angle** among all gait events during speed 1.8 km/h and 2.7 km/h. However, amid FF-MMSW, during pace 3.6 km/h, there is not any differences. Instead, on amputees, **Figure 3-15 (II)**, the only absence of disparities occurs during pace 1.8 km/h between HS-TO and MMST-HO.



(I) (II)

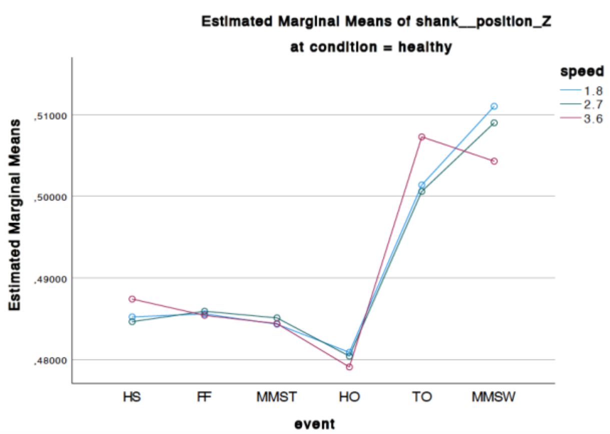
Figure 3-15: Behaviour of gait events of Ankle Angle in Z during walking on a treadmill with different paces among **(I)** healthy and **(II)** amputee patients.



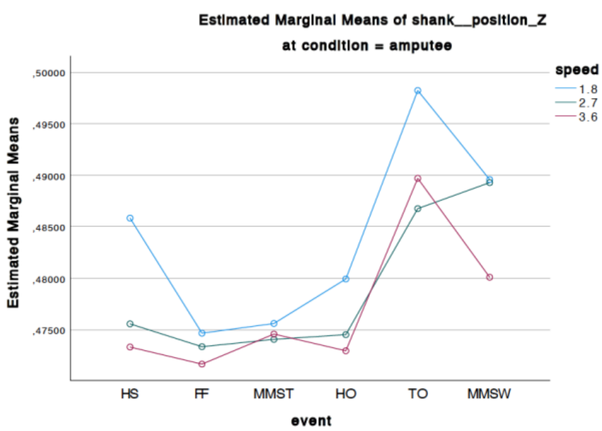
(III) (IV)

Figure 3-16: Behaviour of gait events of Knee Angle in Z during walking on a treadmill with different paces among **(I)** healthy and **(II)** amputee patients.

Concerning **Knee Angle**, in **Figure 3-16 (I)**, it is mainly identical to the previous parameter, that all gait events are affected by the three speeds, except speed 1.8 km/h, and speed 3.6 km/h, which there is no difference, between FF-MMST and HS-MMST, correspondingly. In amputees, in **Figure 3-16 (II)**, the same pattern is followed, are significant differences to Knee Angle among the gait events, as well as the speed, excluding speed 2.7 km/h amid these, HO-MMSW.



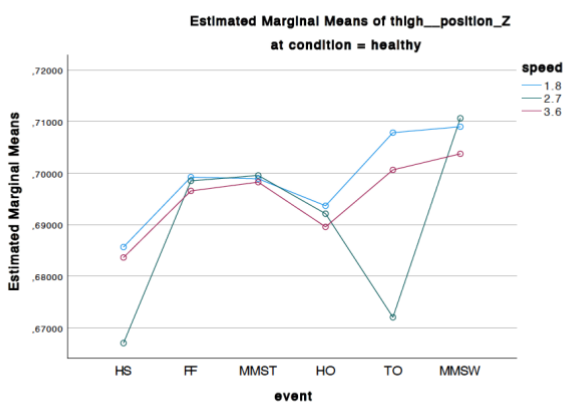
(I)



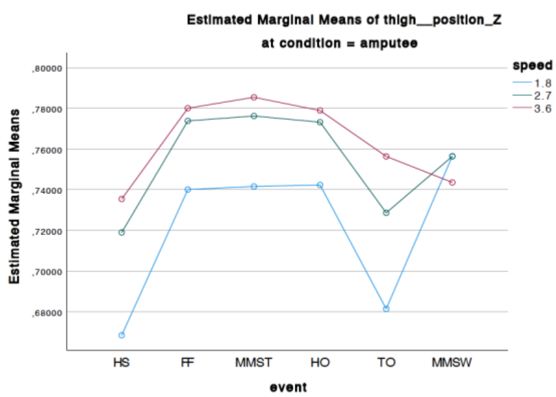
(II)

Figure 3-17: Behaviour of gait events of Shank Position in Z during walking on a treadmill with different paces among **(I)** healthy and **(II)** amputee patients.

Concerning the **Shank Position**, in **Figure 3-17 (I)**, in healthy participants, speed produces an effect mainly in all gait events. Both on speed 1.8 km/h and 2.7 km/h there are not any differences between HS-FF e MMST and on speed 3.6 km/h among HO-MMSW. As to amputees, in **Figure 3-17 (II)**, the velocity 1.8 km/h only does not produce an effect between FF-MMST events as well as the speed 2.7 km/h. Additionally, it also does not produce an effect amid HS-MMST-HO, FF-MMST-HO and MMST-HO. At speed 3.6 km/h, there is no difference between HS, MMST and HO, as well as among FF-MMST.



(I)



(II)

Figure 3-18: Behaviour of gait events of Thigh Position in Z during walking on a treadmill with different paces among **(I)** healthy and **(II)** amputee patients.

About the parameter **Thigh Position**, disclosed in the **Figure 3-18 (I)**, concerning the non-pathological patients, the speed 1.8 km/h only created an influence between HS and these gait events: TO and MMSW. On the opposite, the speed 2.7 km/h only did not produce any differences between HS and TO, and between FF and MMST-HO-MMSW, as well as among MMST and HO-MMSW. In amputees, in the Figure 22 (II), the speed 1.8 km/h only affects the events HS and TO, the same pattern occurs to the speed 2.7 km/h, as is perceived by the straights blue and green lines on the graph. The velocity 3.6 km/h has only caused an alteration between MMST-MMSW.

The Partial Eta Squared value for condition was [$\eta2 = 0{,}603$], for speed was [$\eta2 = 0{,}040$] and for gait events was [$\eta2 = 0\ {,}364$]. This means that whether a subject is an amputee or not it is the gait event he/she is what influences these kinematic parameters the most, in these circumstances, since condition and gait event present the two highest values of η2, being the condition higher. On the other hand, speed does not influence the parameters as much, like it possible to verify as well in all of the graphs evaluated, **Figure 15-22**, as the speed lines do not show a distinctive shape among them.

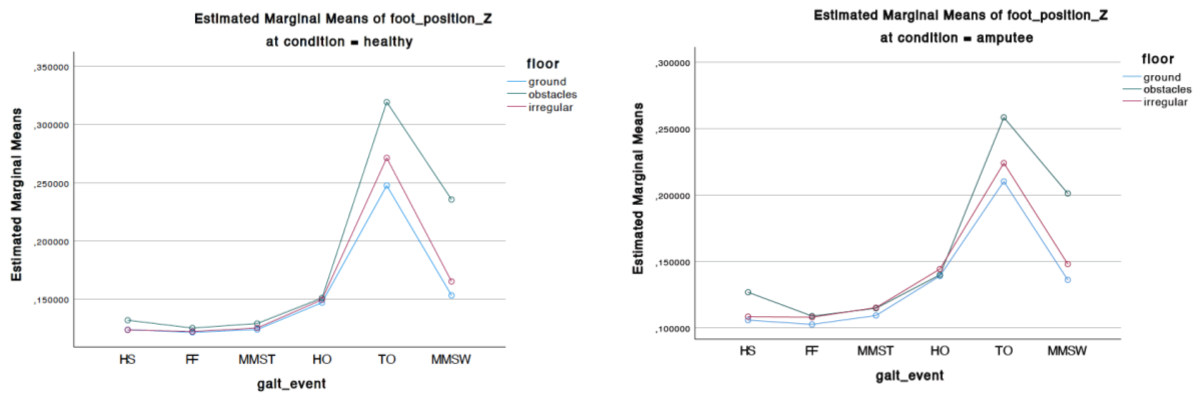
Influence of Type of Floor on Gait Events

The influence that the floor types have or not on gait events, considering the kinematic parameters, were analyzed in the different conditions, pathological or non-pathological.

MANOVA showed that there is an effect of the interaction between the condition and floor on the kinematic parameters [Pilai's trace = 0,021; $F\ (16, 19662) = 13{,}199$; $p < 0.001$]. Additionally, there is an effect of the interaction among the condition and event [Pilai's trace = 0,096; $F\ (40, 49170) = 24{,}188$; $p < 0.001$] and the interaction between floor and event [Pilai's trace = 0,204; $F\ (80, 78696) = 25{,}693$; $p < 0.001$] on the parameters. Furthermore, the interaction amid these three factors [Pilai's trace = 0,038; $F\ (80, 78696) = 25{,}693$; $p < 0.001$], also, displays effects on the dependent variables. Subsequent univariate ANOVAs showed that there is only effect of the interaction between condition and floor on three parameters, Foot Position [$F\ (2{,}9873) = 6{,}830$; $p < 0.05$], Heel Contact [$F\ (5, 9873) = 0{,}174$; $p<0.05$] and Shank Position [$F\ (2, 9873) = 26{,}243$; $p < 0.05$]. While interaction between condition and gait event it just does not perform an effect on Hip Angle [$F\ (5, 9873) = 43{,}402$; $p>0.05$] and on Thigh Position [$F\ (5, 9873) = 0{,}793$; $p>0.05$]. Whereas interaction between floor and gait event plays an effect on Foot Position [$F\ (10, 9873) = 128{,}402$; $p < 0.05$], Toes Position [F (10, 9873) =

190,798; $p < 0.05$], Heel Contact [F (10, 9873) = 4,758; $p < 0.05$] and Shank Position [F (10, 9873) = 76,641; $p < 0.05$]. Similarly, univariate ANOVAs, presented the interaction between the three factors, condition, floor and gait event, and also makes a significant effect on Foot Position [F (10, 9873) = 5,910; $p < 0.05$], Toes Position [F (10, 9873) = 7,282; $p < 0.05$], Heel Contact [F (10, 9873) = 7,487; $p < 0.05$] and Shank Position [F (10, 9873) = 4,481; $p < 0.05$].

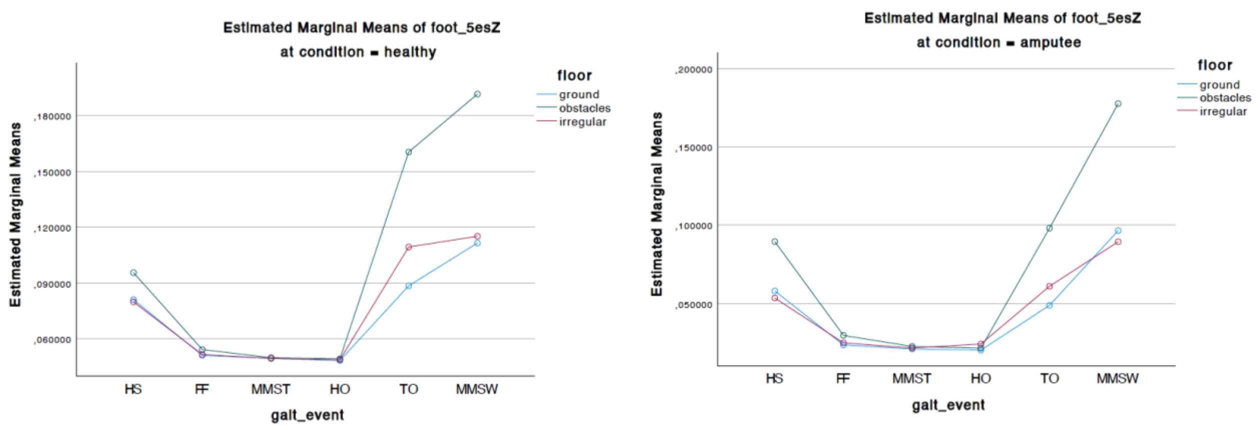
First, we will focus on the parameters that are similar between the MANOVA results and the univariate ANOVA results, when combining the three key factor.



(I) **(II)**

Figure 3-19: Behaviour of gait events of Foot Position in Z during walking on a different floor among **(I)** healthy and **(II)** amputee patients.

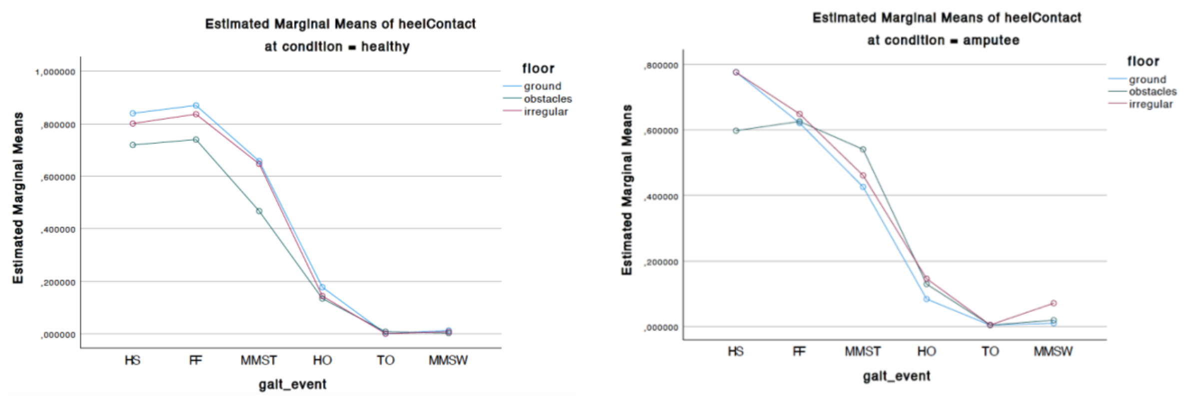
Post-hoc and Tuckey tests showed that all gait events were affected by the three types of floors, on **Foot Position**, excluding HS, FF and MMST where it was not verified significant differences, in healthy participants, presented in **Figure 3-19 (I)**. As to the amputated subjects, on these parameters, **Figure 3-19 (II)**, there are only no differences on the ground and irregular pavement, between HS, FF and MMST, as well as, amid HO and MMSW. Contrary, on the obstacles floor between FF and MMST events there were not demonstrated any differences.



(III) **(IV)**

Figure 3-20: Behaviour of gait events of Toes Position in Z during walking on different floors among **(I)** healthy and **(II)** amputee patients.

The parameter **Toes Position**, in **Figure 3-20 (I)**, all gait events were affected, with the exception that there were no differences between FF, MMST and HO, plus on irregular floor among TO and MMSW, also, the are not substantial alterations. The same occur to the amputees, **Figure 3-20 (II)**, there are only no differences between these gait events, FF, MMST and HO, for all types of floors, and additionally, in the obstacle floors there are not, also, any alterations among HS and TO.

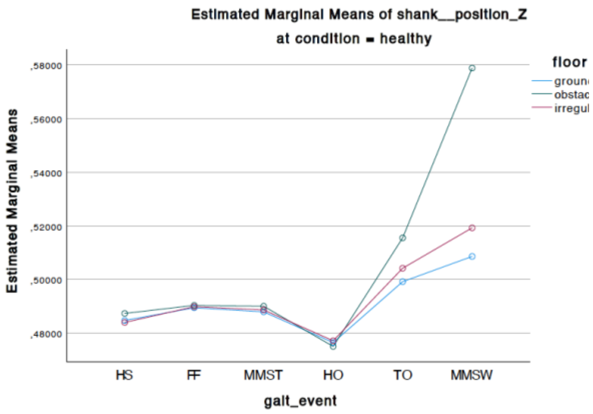


(I) **(II)**

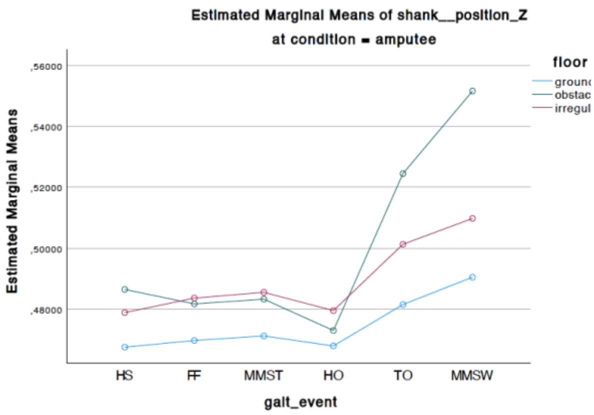
Figure 3-21: Behaviour of gait events of Heel Contact during walking on different floors among **(I)** healthy and **(II)** amputee patients.

Concerning **Heel Contact**, all gait events were affected by the three grounds, excluding between HS and FF and between TO and MMSW, where there were no differences verified, as the straight blue, green and red lines show in **Figure 3-21 (I)**.

In amputee subjects, illustrated in **Figure 3-21 (II)**, identically ground and irregular floor do not produce an effect between the gait event HO, TO and MMSW, with the exception the on irregular floor there is a difference between TO and MMSW. The obstacles floor does not reveal changes between HS, FF, and MMST, among HO and MMSW, and, lastly, as the irregular floor between TO and MMSW.



(I)



(II)

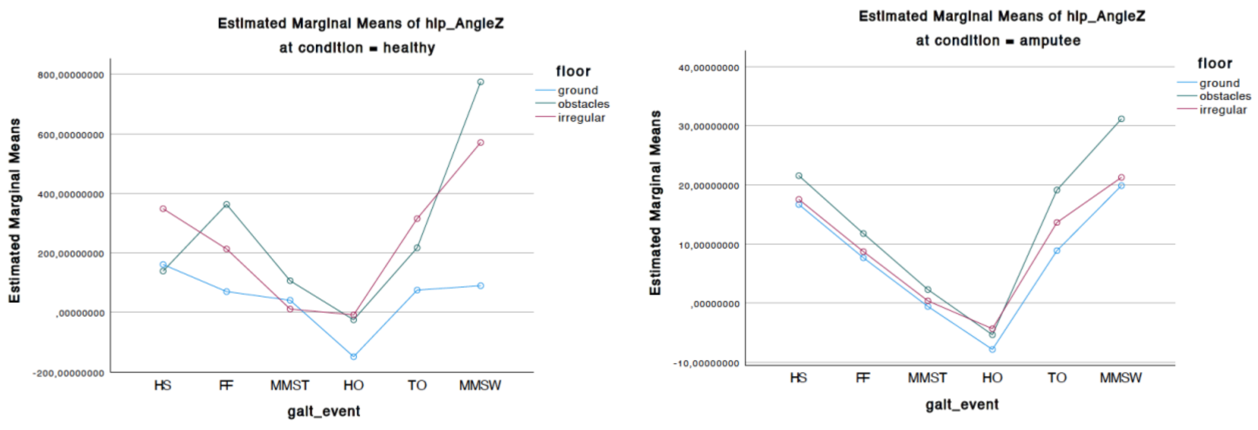
Figure 3-22: Behaviour of gait events of Shank Position in Z during walking on different floors among **(I)** healthy and **(II)** amputee patients.

Regarding **Shank Position**, in healthy participants, all gait events were affected by the ground, obstacles and irregular pavement, excluding between HS, FF and MMST, as an almost straight blue, green and red line are formed, in **Figure 3-22 (I)**. In amputees, the situation differs, since during the walk on the three floors, there were significant differences between HS, TO and MMSW. Also, there are changes among HO and TO and MMSW. However, there are no substantial differences between FF and MMST.

Although, in the following parameters, Hip, Ankle and Knee Angles, according to the univariate ANOVAs, no differences were found when combining the three factors, since they represent the behaviour of the angles of the three most important joints in locomotion, they are quite relevant, and by the MANOVA, significant differences were found.

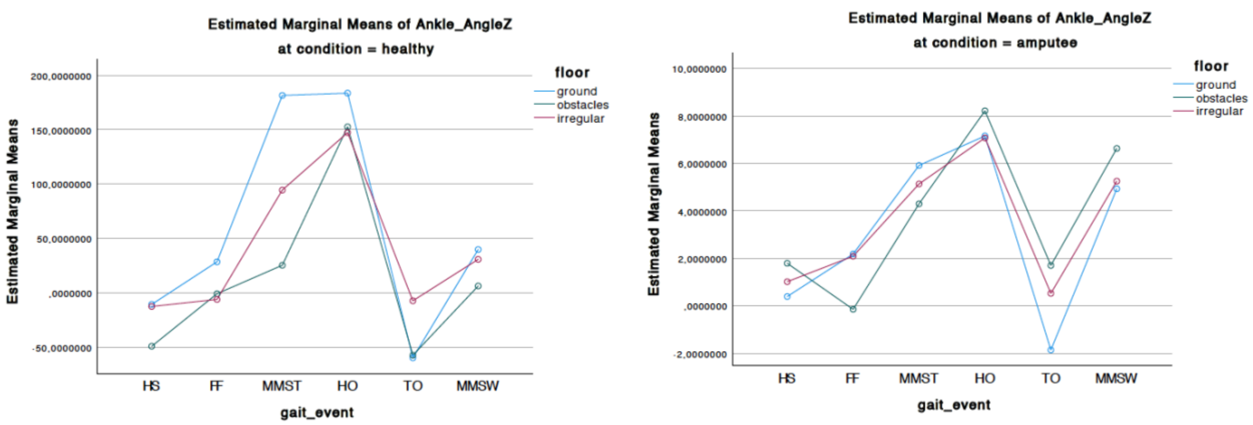
In healthy subjects, in **Figure 3-23 (I)**, post-hoc and Tuckey showed that to **Hip Angle**, are only significantly differences between HS-HO, FF-HO and TO-MMSW on the ground floor. In obstacles, there are no differences in the gait events, with the exception of MMSW. As to the irregular terrain, there are substantial differences between MMSW and MMST, and among HO and MMSW.

Regarding amputee patients, in **Figure 3-23 (II)**, the irregular floor and the obstacles only not made an impact between HS and TO, while on the ground floor it is between FF and TO.



(I) (II)

Figure 3-23: Behaviour of gait events of Hip Angle in Z during walking on different floors among **(I)** healthy and **(II)** amputee patients.



(I) (II)

Figure 3-24: Behaviour of gait events of Ankle Angle in Z during walking on different floors among **(I)** healthy and **(II)** amputee patients.

Concerning **Ankle Angle**, there is only difference between HS and MMST-HO, and also among HO and TO, on the ground floor. To the obstacles terrain, every event compared with TO suffers a significant difference. As to the irregular floor, every event compared with HO suffers a significant difference, excluding the event MMST. The behaviour of healthy subjects to this parameter is illustrated in **Figure 3-24 (I)**. In amputees, **Figure 3-24 (II)**, the ground did not show any differences, between these pairs: HS-FF, HS-TO, FF-MMSW, MMST-HO and

MMST-MMSW. As to the obstacle course, all gait events suffered changes, with the exception among HS and TO. On the opposite, gait events on the irregular floor, only suffered alteration amid these sets: HS-FF, HS-TO and MMST-MMSW.

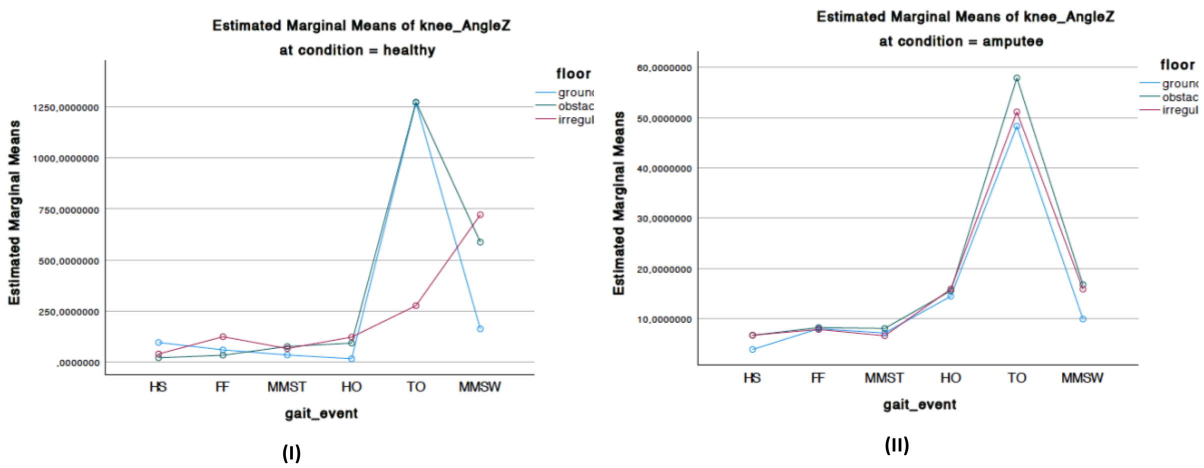


Figure 3-25: Behaviour of gait events of Knee Angle in Z during walking on different floors among **(I)** healthy and **(II)** amputee patients.

About the behavior of the **Knee Angle** on healthy volunteers, in **Figure 3-25 (I)**, both on ground and obstacles, TO is the only event affected. Similarly, on irregular floor all MMSW is the only event disturbed. As to the pathological subjects, **Figure 3-25 (II)**, in all types of floors, there are no differences among these pairs: FF-MMST, FF-MMSW, MMST-MMSW, HO-MMSW.

These statistic tests revealed that for **Thigh Position**, the floor type did not influence the gait events for both healthy and amputees, being that the reason it is not included.

Range of Motion Influence

Lastly, the influence that the four types of floors exerted on Range of Motion parameters were analysed.

MANOVA showed that there is effect of the condition of the subject on the ROM parameters [Pilai's trace = 0,019; F (4,16519) = 80,228; p < 0.001]. Additionally, there is effect of the floor [Pilai's trace = 0,154; F (12,49563) = 223,994; p < 0.001] and the interaction between the floor and condition [Pilai's trace = 0,034; F (12,49563) = 47,007; p < 0.001] on the parameters. Subsequent univariate ANOVAs showed the exact same results that condition, floor and the interaction between both produce an effect on these parameters.

Moreover, in **Figure 3-27 (I)-(III)**, it is possible to verify that the ROM of Hip, Ankle and Knee have a very identical graph, which agrees with the Pearson Correlation results, presented in **Figure 3-26**. This way, one of the three parameters can be used to infer results about the others and that parameter will be the Hip angle ROM, bearing in mind that there are amputees who do not have knee and ankle joint. Also, the Hip Joint it is the one that most contributes to the walking in obstacles.

Correlations

		RangeAngleHipZ	RangeAngleAnkleZ	RangeAngleKneeZ	RangeCOMposZ
RangeAngleHipZ	Pearson Correlation	1	,691**	,922**	,826**
	Sig. (2-tailed)		,000	,000	,000
	N	16530	16530	16530	16530
RangeAngleAnkleZ	Pearson Correlation	,691**	1	,808**	,699**
	Sig. (2-tailed)	,000		,000	,000
	N	16530	16530	16530	16530
RangeAngleKneeZ	Pearson Correlation	,922**	,808**	1	,791**
	Sig. (2-tailed)	,000	,000		,000
	N	16530	16530	16530	16530
RangeCOMposZ	Pearson Correlation	,826**	,699**	,791**	1
	Sig. (2-tailed)	,000	,000	,000	
	N	16530	16530	16530	16530

**. Correlation is significant at the 0.01 level (2-tailed).

Figure 3-26: Table of Pearson Correlation coefficient among ROM parameters, obtained with SPSS.

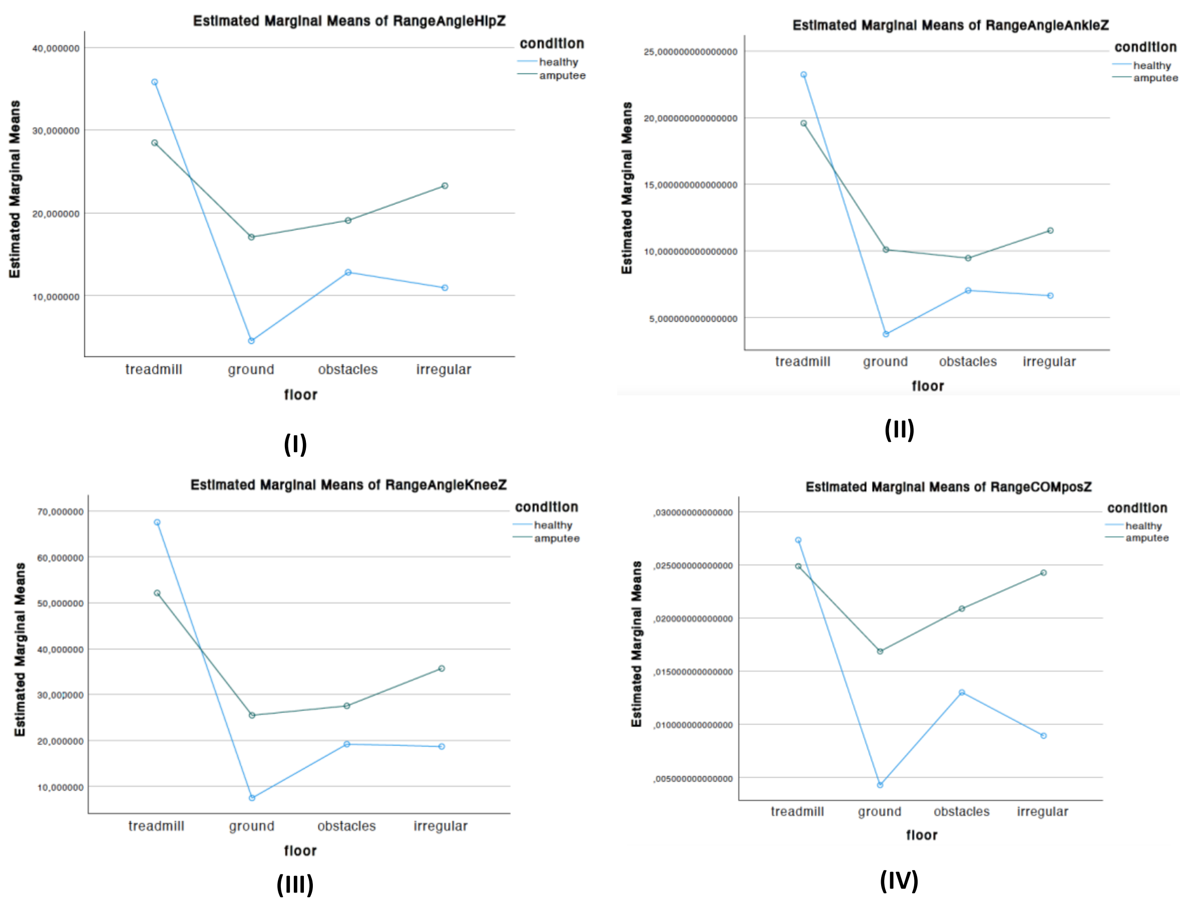


Figure 3-27: Comparison, among healthy and amputee patients during walking in different types of floors, of **(I)** Hip Angle ROM **(II)** Ankle Angle ROM, **(III)** Knee Angle ROM and **(IV)** COM position in Z ROM.

Thus, when analysing the post-hoc tests of the interaction between the floor and condition it will be only focusing the Hip Angle and COM ROM parameters. In healthy subjects, post-hoc and Tuckey showed, as is verified in **Figure 3-27 (I)** by the blue line, that there are significant differences to **Hip Angle ROM** among the treadmill, ground, obstacles, and irregular terrain, as well as between ground, obstacles, and irregular floor, however, amid obstacles and irregular floor there is not. With regard to **position of COM ROM**, the blue line in the **Figure 3-27 (IV)**, it is mainly identical to the previous parameter with the exception that between obstacles and irregular floor there is a significant difference.

In amputees, the green line in **Figure 3-27 (I)**, there are significant differences to **Hip Angle ROM** among the treadmill, ground, obstacles, and irregular terrain, as well as between ground and irregular floor plus obstacles and irregular. However, amid ground and obstacle it is not verified a significant difference. The same differences occur to Ankle and Knee Angle ROM. Regarding **position of COM ROM**, the green line in **Figure 3-27 (IV)**, there are substantial differences among the treadmill, ground, and obstacle terrain, as well as between ground, obstacles, and irregular floor, however, amid obstacles and irregular floor plus treadmill and irregular floor there is not. Additionally, this parameter is higher in amputees then in healthy participants.

Analysing these graphs, **Figure 3-27**, it is possible to endorse what was aforementioned, that conjugating the independent variables, floor, and condition or only the factor condition, in other words being healthy or an amputee it is significant, and creates an effect on these parameters among, as the lines show a distinctive shape.

3.6.3 Muscular Activity

The analyses of the muscular activation include these muscles: *Rectus Femoris*, *Biceps Femoris*, *Gluteus Medius* and *Gluteus Maximus*

Normality of the data was verified using the Kurtosis and Skewness. It was confirmed the presence of some significant multivariate outliers, but they were found not significant, since the sample is so large. The absence of multicollinearity was, also, established. The only assumptions that were not fulfilled were linearity and homogeneity, however, the MANOVA was still performed, given that a more robust analysis was performed.

Since it was found in the kinematic parameter analysis that the speed of the treadmill was not such a significant factor, it was decided for the muscles not to analyse the effect that speed would have on them.

Therefore, first it was analysed, both on healthy and amputee patients, the influence of types of floors during gait events on muscle activity. It is noteworthy that for muscles *Rectus Femoris* and *Biceps Femoris*, when they emerge in amputees, it refers to their non-paretic leg.

Secondly, it was focused solely on amputees, and were disclosed the results of the interaction between the legs of an amputee and the floor type.

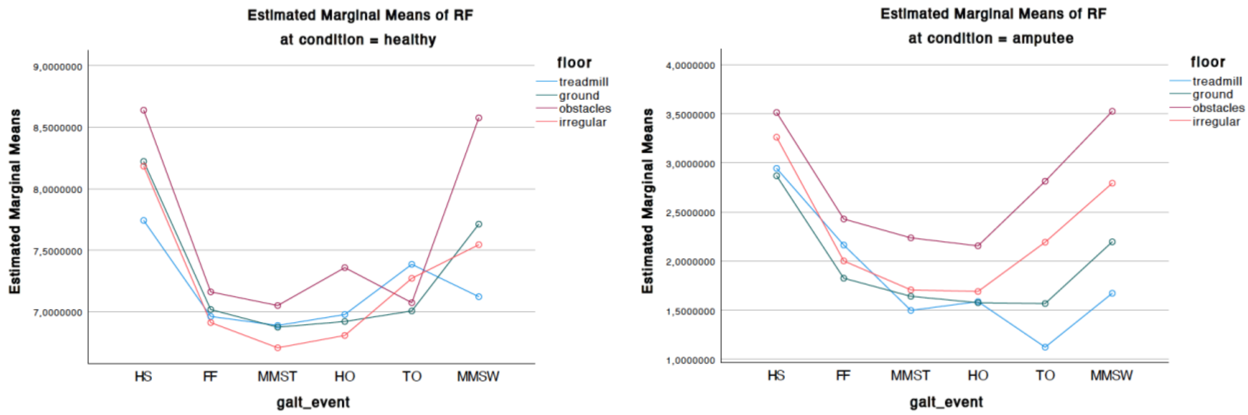
Lastly, for the muscles considered most relevant, were also presented at which moment of the gait they were most affected on each floor.

Influence Of Types Of Floors During Gait Events On Muscle Activity

Subsequently, the influence floor types disturb or not gait events on the kinematic parameters were analysed in the different conditions, pathological or non-pathological.

MANOVA showed that there is an effect of the interaction between the condition and floor on the kinematic parameters [Pilai's trace = 0,016; F (12, 219354) = 97,909; $p < 0.001$]. Additionally, there is an effect of the interaction among the condition and event [Pilai's trace = 0,007; F (20, 292476) = 24,079; $p < 0.001$] and the interaction between floor and gait event [Pilai's trace = 0,009; F (60, 292476) = 10,626; $p < 0.001$] on the parameters. Furthermore, the interaction amid these three factors [Pilai's trace = 0,004; F (60, 292476) = 5,376; $p < 0.001$], also, displays effects on the dependent variables. Subsequent univariate ANOVAs showed that there is an effect of the interaction between condition and floor on *Rectus Femoris* [F (3,73119) = 3,892; $p < 0.05$], *Biceps Femoris* [F (3,73119) = 3,791; $p < 0.05$] *Gluteus Max*imus [F (3,73119) = 119,814; $p < 0.05$] and *Gluteus Medius* [F (3,73119) = 224,262; $p < 0.05$]. While interaction between condition and gait event it just does not perform an effect on Rectos Femoris [F (5,73119) = 0,513; $p>0.05$]. Whereas interaction between floor and gait event, it only does not play an effect on *Gluteus Maximus* [F (15,73119) = 1,549; $p > 0.05$]. Univariate ANOVAs, combining the three factors, condition, floor, and gait event, presented a significant effect on *Rectus Femoris* [F (15,73119) = 1,757; $p < 0.05$], *Biceps Femoris* [F (15,73119) = 4,767; $p < 0.05$] and *Gluteus Medius* [F (15,73119) = 8,345; $p < 0.05$].

First, it was focused on the parameters that coincided between the MANOVA results and the univariate ANOVA results, when combining the three key factor.

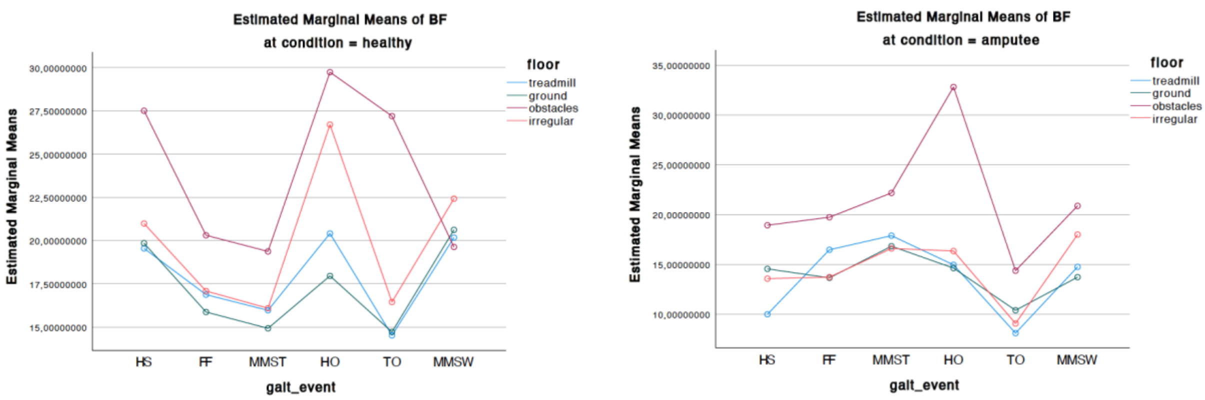


(I) **(II)**

Figure 3-28: Behaviour of gait events of *Rectus Femoris* during walking on different floors among **(I)** healthy and **(II)** amputee patients.

Post-hoc and Tuckey tests showed that the muscle ***Rectus Femoris*** are not affected during the FF, MMST and HO events, and between HO and MMSW, by the treadmill since it was not verified any significance differences, in healthy participants, presented in **Figure 3-28 (I)**. As to the ground floor, there is only difference between the event HS and the others, with the exception, that among HS and MMSW, there is not, also, any significant difference. The obstacle floor only did not cause alteration among HS and MMSW plus amid FF, HO and TO. On the opposite, in the healthy subjects, the irregular floor only provoked differences between HS and these events: FF, MMST and HO.

As to the amputated subjects, on these parameters, **Figure 3-28 (II)**, there are only substantial differences on obstacles and irregular pavement, between HS, FF and MMST, and, additionally, on obstacles floor amid HS and HO. On the contrary, treadmill has an effect on all gait events, excluding between MMST and HO, as well among HO and MMSW, where there were not demonstrated any differences. The ground floor just produced an effect between HS and MMSW, among FF and the following events: MMST, HO and TO.

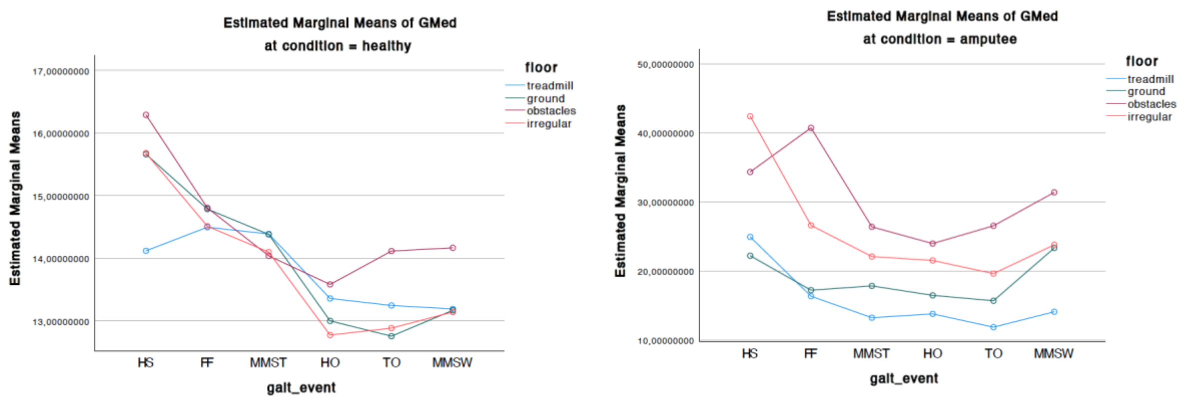


(I) (II)

Figure 3-29: Behaviour of gait events of *Biceps Femoris* during walking on different floors among **(I)** healthy and **(II)** amputee patients.

The muscle ***Biceps Femoris*** is not affected during the HS, HO and MMSW, by the treadmill and ground floor since it was not verified any significance differences, in healthy participants, presented in **Figure 3-29 (I)**. As to the ground floor, there are only differences between the event HS and the others, with the exception, that among HS and MMSW, there is not any significant difference. The obstacle floor only did not cause any alterations among HS, HO and MMSW plus amid FF, MMST and MMSW. Also, in the healthy subjects, the irregular floor only provoked differences between HO and all other gait events.

Regarding pathological patients, **Figure 3-29 (II)**, there were not revealed substantial differences, while walking on a treadmill, only on amid HO and MMSW. On the contrary, walking the ground did not cause an alteration on all gait events. The obstacle floor just produced an effect on the event HO. Finally, irregular floor created differences between the following events MMST-TO-MMSW.



(I) (II)

Figure 3-30: Behaviour of gait events of *Gluteus Medius* during walking on different floors among **(I)** healthy and **(II)** amputee patients.

Concerning, the ***Gluteus Medius*** muscle, in healthy people, **Figure 3-30 (I)**, while walking on a treadmill, ground or irregular floor there were only demonstrated differences between HS and the other events. On the opposite, obstacles course just do not reveal variances between FF and MMSW and TO and MMSW. In lower limb amputees, **Figure 3-30 (II)**, this muscle is only affected amid HS and MMST during a treadmill walk. As to walking in the ground, there were not demonstrated any significant differences among all gait events. Furthermore, on obstacles or uneven floors, changes were only revealed in among FF and HS, respectively, and all the other gait events.

Although the univariate ANOVA indicated no differences for the ***Gluteus Maximus*** muscle, the MANOVA test did, so it was decided to analyse it as well. Thus, this muscle, in healthy patients, the following **Figure 3-31 (I)**, on a treadmill it does not show among this sets: HS-MMST; HS-MMSW; FF-TO; and MMST-HO. As to walking in the ground or on an irregular pavement, there were not demonstrated any significant differences among all gait events. Furthermore, on obstacles floors, changes were only revealed in the following gait events: HS, MMST and TO.

The situation is slightly different for amputees, **Figure 3-31 (II)**, there are only no differences between these gait events, FF, MMST and MMSW, for the ground floor, and additionally, on the ground floor there were not verified any alterations. The floors, obstacle and uneven, have a very similar behavior since amid the event HS and these events: MMST, HO and TO there are significant differences.

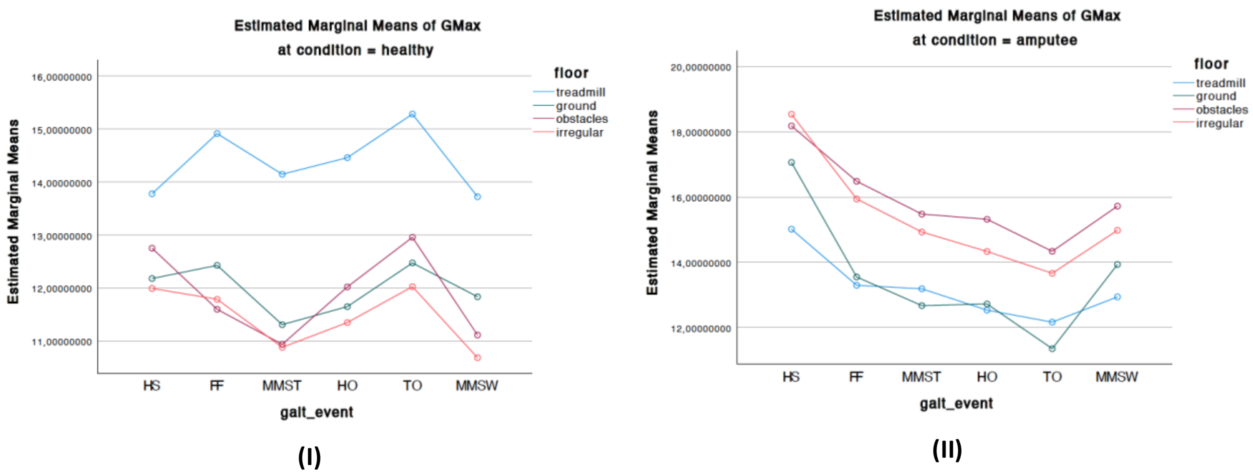


Figure 3-31: Behaviour of gait events of *Gluteus Maximus* during walking on different floors among **(I)** healthy and **(II)** amputee patients.

Observing the following figure, presented below, it is possible to affirm that the ***Gluteus Medius*** muscle, **Figure 3-32 (I)-(II)**, between it and the ***Gluteus Maximus***, **Figure 3-32 (III)-(IV)**, is the one that presents a greater muscular activation, in both healthy and amputees subjects. It is also possible to note that in both muscles there is greater muscle activation in the amputee subjects than in the healthy ones.

The ***Gluteus Medius*** muscle, reaches its maximum in the obstacle floor, **Figure 3-32 (I)**, during the HS event, **Figure 3-32 (II)**. The ***Gluteus Maximus*** muscle reaches its maximum on the ground floor, during the event HS as well, **Figure 3-32 (IV)**.

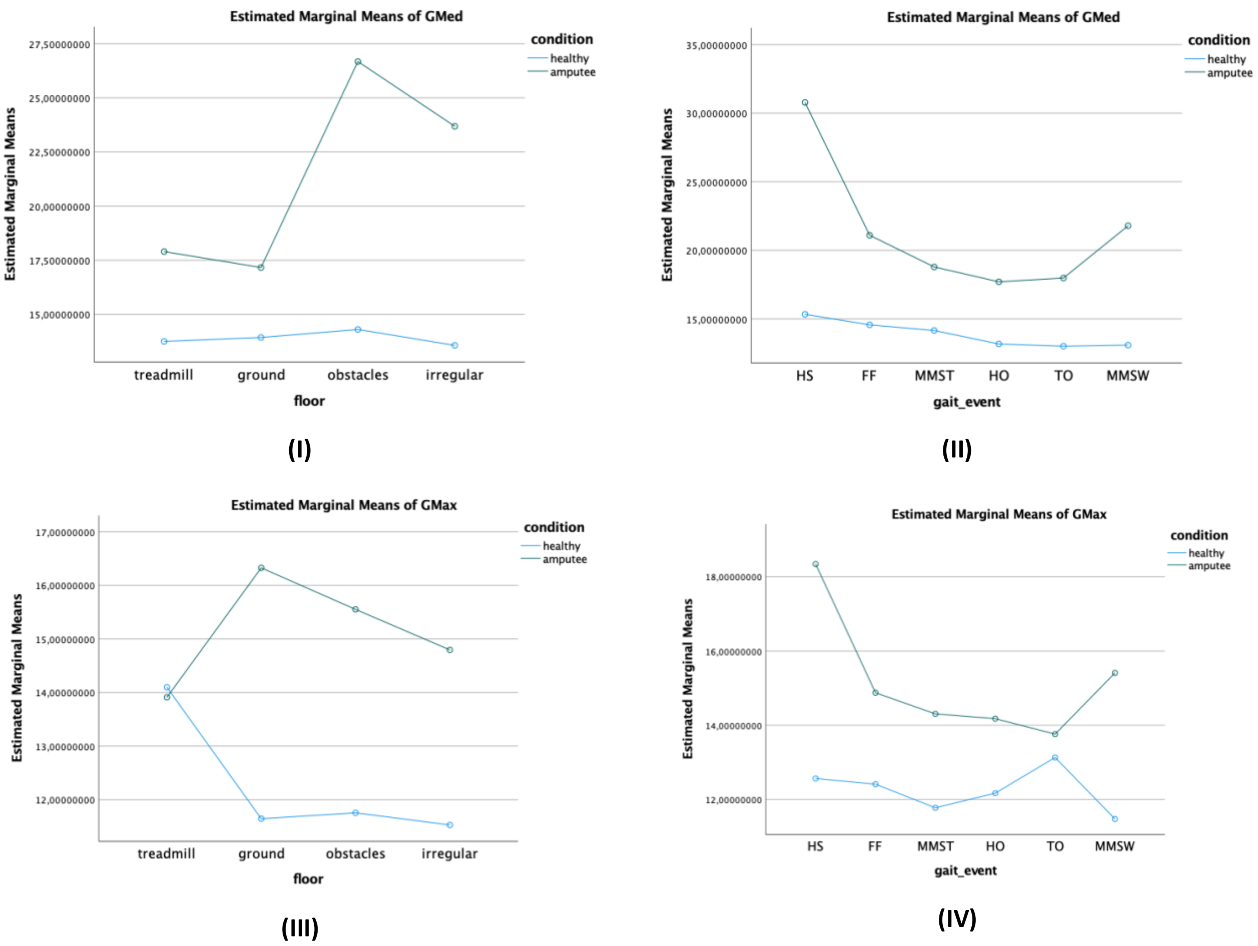
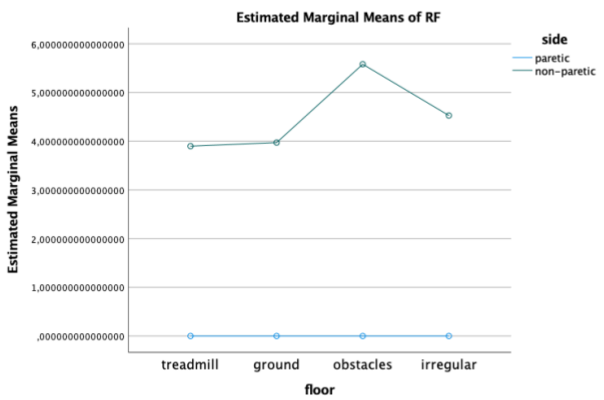


Figure 3-32: Comparison, among healthy and amputee patients, in a single gait cycle: in different types of floors of **(I)** *Gluteus Medius*, **(II)** *Gluteus Maximus*, **(III)** *Gluteus Medius* and **(IV)** *Gluteus Maximus*.

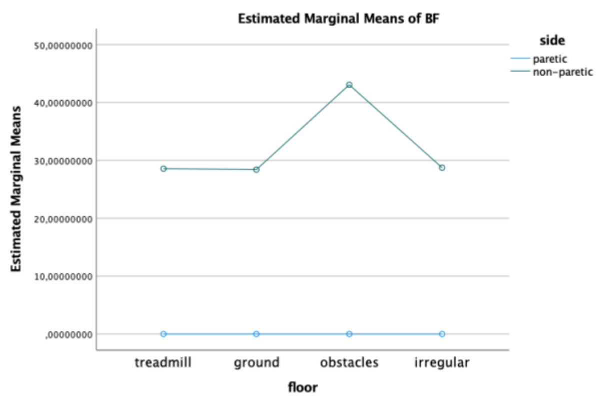
Influence of Paretic Leg on an Amputee

The results of the interaction between the side of an amputee's leg and the floor type were presented first. Afterwards, for the muscles considered most relevant, were also presented at which moment of the gait they were most affected on each floor.

MANOVA showed that there is effect of the side of the amputee on the muscular activation [Pilai's trace = 0,568; F (4,21827) = 7161,425; p < 0.001], an effect of the floor [Pilai's trace = 0,066; F (12,65487) = 122,620; p < 0.001] and an effect of the gait event [Pilai's trace = 0,058; F (20,87320) = 64,503; p < 0.001]. Additionally, there is an influence of the interactions on the parameters between: side and floor [Pilai's trace = 0,057; F (12, 65487) = 105,001; p < 0.001]; side and gait event [Pilai's trace = 0,055; F (20, 87320) = 60,708; p < 0.001]; floor and gait event [Pilai's trace = 0,032; F (60, 87320) = 11,820; p < 0.001] and among all factors [Pilai's trace = 0,032; F (60, 87320) = 11,628; p < 0.001]. Subsequent univariate ANOVAs showed the exact same results that side, floor, gait event and all of the interactions produces an effect on the four muscles. The results of the post hoc and Tuckey tests will be presented next.



(I)

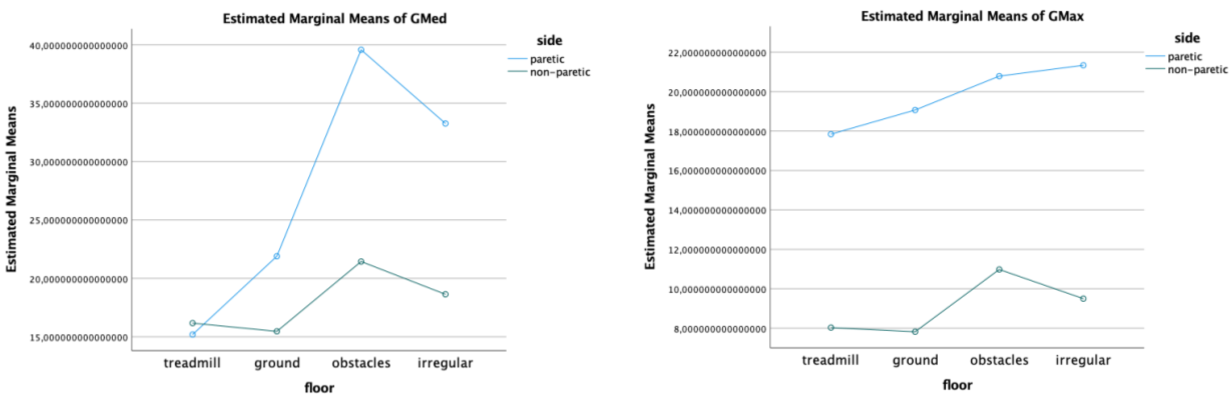


(II)

Figure 3-33: Comparison, among paretic and non-paretic leg, during walking in different types of floors, of **(I)** *Rectus Femoris* **(II)** *Biceps Femoris*.

Since four of the five amputees included in this analysis were TFA, they do not have a ***Rectus Femoris*** neither a ***Biceps Femoris***. Only one patient was a TTA and in that way it had a *Biceps Femoris*, but because it was the single one it was not considered. Therefore, muscle activation is null, blue lines in **Figure 3-33 (I)** and **(II)**, for paretic leg.

Post-hoc and Tuckey tests showed that for both muscles there were not significant differences among the treadmill, ground and irregular, green lines in **Figure 3-33 (I)** and **(II)**. There are significant between the ground and obstacle floors, and between obstacles and irregular floors.



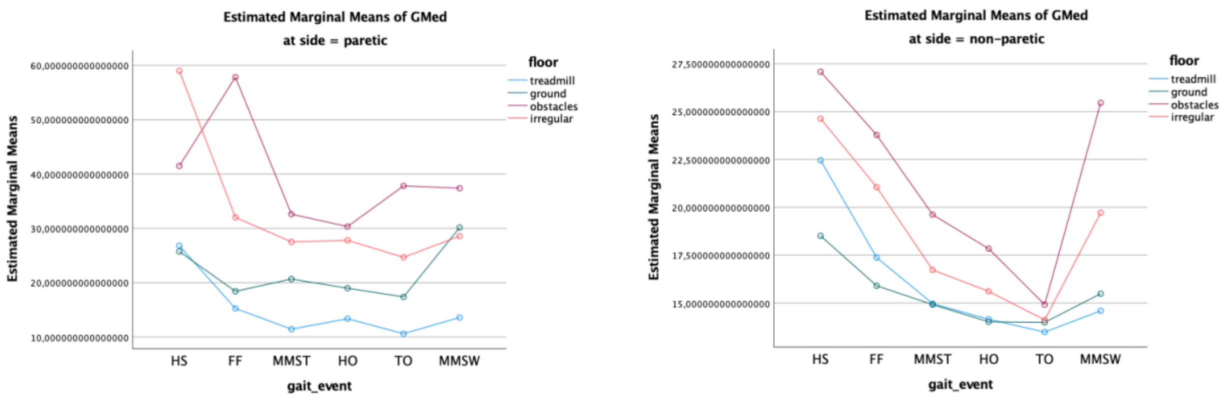
(I) **(II)**

Figure 3-34: Comparison, among paretic and non-paretic leg during walking in different types of floors, of **(I)** *Gluteus Medius* **(II)** *Gluteus Maximus*.

Concerning, ***Gluteus Medius*** in amputees, the paretic leg, the blue line in **Figure 3-34 (I)**, presents that there are significant differences among all types of floors. Identically, concerning the ***Gluteus Maximus***, the same occurs, blue line in **Figure 3-34 (II)**, excluding between obstacles and irregular floor. As can be seen in figure X, the scales of both graphs are very different, the *Gluteus Medius* shows twice as many values as the *Gluteus Maximus*, which indicates that the muscle activity of the *Gluteus Medius*, on the paretic leg, is much higher, reaching its maximum during obstacle walking.

Regarding the non-paretic leg, **both muscles**, green lines in **Figure 3-34 (I)** and **(II)**, there are significant differences among almost all types of floors with the exception that amid treadmill and ground, there were not verified any alterations.

After analysing these graphs, it is possible to corroborate what was aforementioned, that on amputees, the side of the leg, paretic or non-paretic is significant, and creates an effect on the muscles, as the lines show a distinctive shape, especially on the *Gluteus Medius*. This being the necessary reason to next assess in which gait events this muscle was most affected, considering the types of floors on each leg of the amputee.



(I) **(II)**

Figure 3-35: Behaviour of gait events of Gluteus Medius while walking on different floors among **(I)** paretic and **(II)** non-paretic leg.

On the paretic side, **Figure 3-35 (I)**, post hoc tests evidenced, that on treadmill, ***Gluteus Medius*** there is not only a difference between HS, FF and TO. The ground floor does not cause an effect on this muscle. Similarly, on the obstacle floor, also, there is not a difference among FF, MMST and HO.

As to the Irregular pavement, it is verified a significant difference between the event HS and the others**.**

On the contrary, **Figure 3-35 (II)**, the non-paretic side there is a substantial difference amid all gait event on the treadmill, obstacles, and irregular floor, with the exception that on obstacle floor there is not a difference between HS and MMSW. On the ground the is only a difference among the event HS and the others.

3.7 Critical Analysis

The crucial goal of this dissertation is to develop a vibrotactile stimulus paradigm for a biofeedback device, intended for use by LLA, this critical analysis will focus on the two main problems to be solved, When and Where/How should the stimulus be given.

Primarily, the statistical analysis of **Spatiotemporal Parameters** revealed that **Cadence** and **Stride Length** are the most significant parameters. This is consistent with the literature, since, in [69], these are the two most common as well. In healthy subjects, as the flooring is being modified, it is normal to alter the Cadence, **Figure 3-10 (I)**. In other words, the steps that are taken per second require an adjustment by the participants on the obstacle and uneven pavement as well as on the treadmill since there are different speeds. In amputees, it was verified that there were only substantial differences between flat (treadmill or ground floor) and uneven (obstacles or irregular) floors. However, it does not exist difference between obstacles and irregular. This may be because the minimum average age of amputation for this data set is 7 years, meaning that since they have been amputees for a long time, they have already acquired a gait pattern, and when faced with obstacles or uneven flooring, they behave in the same manner [70].

About **Stride Length**, both conditions, are mainly affected by the obstacles and irregular floor, **Figure 3-10 (II)**, this adds up, since, during data collection, there was a requirement that they had to step on the floor in regular intervals, especially during the obstacle course. The participants had to adapt their stride to some extent to be able to overcome obstacles with their right leg (healthy participants) or paretic leg (amputees). Since this was requested during data collection, the result was that these participants had to analyse their stride beforehand and anticipate it, as well as their stride length.

Secondly, after analysing the **Kinematic Data**, it is possible to generalize and postulate that the HS events and the TO/HO and MMSW events are more noteworthy differences, or in other words, the most disturbing phase of the movement is the swing phase. It was uncovered that speed does not influence the kinematic parameters as much as other factors, but the effect that presents is higher on amputees than on healthy patients. This is to be expected since the speed was always assessed on a treadmill, which can be considered a controlled environment in which strides are also regular. The effect being greater in amputees than in healthy patients, is consistent with the literature [17, 40], since as the speed increases, more steps per minute have to be taken, which can cause gait instability. The **Hip Joint** is the most worked and required joint for transfemoral amputees, since they do not have either the ankle or knee joint on the amputated leg, and therefore it is worth paying special consideration to it. From the observed graphs, **Figure 3-23 (I)-(II)**, and the statistical tests performed, it is possible to state that there were more variations in healthy subjects than in amputees during the gait events, regarding each type of floor. Since in **Figure 3-23 (II)** the tendencies are identical, regardless of the type of floor. This is in line with what was previously reported, in the sense that as they have been amputees for a long time, they have already acquired a gait pattern, behaving in the same way. Concerning the moment of gait, when it would be desirable to apply the stimulus, it was verified that the amputee's hip angle, on obstacles and uneven floor, only did not have a meaningful impact between HS and TO, and as it was also analysed beforehand that the pre-swing or swing phase is the most affecting moment in general, it might not be justifiable to apply the stimulus on both events, so it would be applied just on the gait event TO. Another important parameter to note, specifically for the obstacles crossing, is the **Foot Position** parameter, the statistical analysis confirmed that this floor is where amputees raise their feet more, as was expected. The results obtained revealed that the treadmill, in comparison with other types of floors, does not present so many distinctions, as well as the different speeds, and perhaps it is not justifiable to use a rehabilitation training session on the treadmill, but rather on the ground, on the irregular ground and with obstacles.

While analysing **Hip Angle ROM**, healthy participants showed that there are significant differences among all types of floors with the exception of obstacles and irregular floors, as for amputees all types of floors cause an effect. This is what it was hoped would happen since, as noted earlier, this is the most used joint by the TFA, so it was anticipated that different floors would have an influence.

With regard to the **position of COM ROM**, for healthy patients, all types of floors affected this parameter, on the contrary for amputees, amid obstacles and irregular floor plus treadmill and irregular floor there is not a substantial difference. This parameter refers to the variation in height from the ground to the centre of mass, therefore the significant discrepancies between the ground and the other floors made perfect sense, because a floor with obstacles or uneven floors implies lifting the leg more, and consequently the hip, to prevent stumbling. Between the obstacles and uneven floor, for amputees, not having significant differences is also in agreement with what was said before, given that the perception they should have of the height of the obstacles or the uneven floor should be the same, thus, amputees for both cases lift the leg the same height. Furthermore, between the treadmill and the uneven floor, there is also no substantial difference in the position of the COM ROM, which is curious and not entirely what was expected. However, by also taking into consideration the position of the foot, it can be corroborated that in amputees there is also almost no difference between a flat floor and the uneven floor, which indicates that this behaviour of the COM is valid. It should, also, be pointed out that in several videos recorded there was dragging of the feet, both on the treadmill and on uneven ground. Moreover, this parameter is higher in amputees than in healthy participants, being consistent with [19], hence LLA exhibit asymmetric gait patterns, increasing the movement of the COM. It has been postulated in [19, 21] that one of the main factors that improves the metabolic efficiency of gait is minimizing movement of the COM. Therefore, it would be logical to also propose a VT-S system on the waist, to potentiate the correction of the COM, in addition to the leg, thereby it being a versatile VT-S system.

Concerning the **Muscular Data Analysis**, it was revealed that for the ***Rectus*** and ***Biceps femoris*** muscles, among both types of subjects, the TO event was also significant. This difference between healthy and amputees, in the non-paretic leg, may indicate that a new paradigm of rehabilitation may be proposed, instead of biofeedback being applied solely to the paretic leg, it could also be applied to both, in order to rectify potential errors in the non-paretic leg. *Gluteus Medius*, on amputees, also revealed alterations between HS and HO/TO, for irregular floor, and among FF and HO/TO, amid others. The muscle Gluteus Maximus has a very similar behaviour as well, this is in line with what was stated previously.

It is possible to state that the ***Gluteus Medius*** muscle is the muscle that presents a greater muscular activation, in both healthy and amputees subjects, although there is a higher muscular activation for the amputees than for the healthy subjects, being consistent with [71]. This muscle reaches its maximum on the obstacle floor, which is appropriate since on this ground, amputees need to raise their legs more to cross the obstacles, demanding more of this muscle. The ***Gluteus Maximus*** muscle reaches its maximum in the ground floor, during the event HS as well, being the expected, as mentioned in the literature [17]. Afterwards, it was examined the sides of an amputee's leg and the same occur, *Gluteus Medius* showed double the muscular activation of Gluteus *Maximus*, and the muscle activity of the *Gluteus Medius*, on the paretic leg, is much higher, reaching its maximum, also, during obstacle walking. This muscle, on the paretic and non-paretic side, in the obstacle floor and irregular pavement presents, also, a difference to Gluteus Medius, among HS and other, including TO. Therefore, being this muscle the most important to TFA this could validate what was aforementioned, that the swing phase could be the ideal moment to apply the Vibrotactile stimulus.

The following **Table 3-6** presents a summary of the ideas for the Biofeedback System for the VT-S Vibrotactile Socket.

Table 3-6: Vibrotactile stimulus paradigm for a biofeedback device.

		Intention and purpose	**N. º of Motors**
Location	Gluteus Medius of Paretic Leg	Asymmetries	3
	Gluteus Medius of Non-Paretic Leg	Asymmetries	3
	Surroundings of Hip Joint	Deviations of COM	4
Moment of Gait Cycle	Pre-Swing (HO-TO events)		
Frequency	(125-250) Hz		
Duration	Time it takes to pass from TO-MMSW or from HO-TO		
Type of Gait Training	Ground, obstacles, and irregular floor		

4. CONCLUDING REMARKS

Biofeedback systems for human gait rehabilitation is the field addressed in this investigation. The ultimate goal of this dissertation was to develop a vibrotactile stimulus paradigm for a biofeedback device, intended to be used by lower limb amputees during gait training sessions. This device will directly affect, in real-time regarding gait events, the user to rectify his/her gait pattern, with the purpose to not only improve the gait parameters, stability in symmetry in prosthetic gait, but also increase the amputees body perception, leading to a more natural and healthier gait.

This work included a summary of the available artificial sensory feedback solutions for gait rehabilitation, it allowed to understand what is already done in this field and, furthermore, identify the main strategies to estimate the intended gait parameters from these sensors. Thus, in this review, a comparison between the prosthetic gait and the healthy gait was conducted for the purpose of understand which moments, of the gait cycle, the amputee gait differs from a healthy one.

A multivariable biomechanical data analysis from amputee and healthy subjects was presented, included the methodologies used to retrieve the biomechanical data, the statistical plan and post-processed tools that were used in order to perform a careful and complete examination.

From the outcomes of this research and the respective critical analysis, the paradigm to be implemented for this biofeedback system was proposed.

In light of the research questions placed at the beginning of this dissertation, they can be answered now:

RQ 1: What are the main challenges encountered by amputees during their daily lives? Lower limb amputees face challenges in day-to-day life since the use of the prosthesis does not fully compensate for the deficiencies acquired by a prosthetic gait such as asymmetry and variation in the duration of the gait events and does not address the deficit of sensorial mechanisms. They also have a higher risk of falling and fear of falling, more difficulty to keep balance and expend more metabolic energy than healthy individuals. When walking on uneven ground, crossing obstacles, and climbing stairs, for instance, are also conditions that affect them.

RQ 2: How spatiotemporal, kinematic, and electromyography of the amputee lower body differs from the healthy lower body (e.g., centre of mass, joint angles, joint angular velocity, limb segment's position)?

Spatiotemporal parameters revealed that Cadence and Stride Length are the most significant parameters. **Cadence**, in healthy subjects, as the flooring is being modified, it is normal to alter the cadence, as to amputees, it was verified that there were only substantial differences between flat (treadmill or ground floor) and uneven (obstacles or irregular) floor. With regard to **Stride Length**, both conditions, are mainly affected by the obstacles and irregular floor

Regarding **Kinematic Parameters**, it was uncovered that speed does not influence them as much as other factors, but nonetheless the effect that presents it is higher on amputees then in healthy patients. The **Hip joint** is the most worked and required joint for the transfemoral amputees, since they do not have either the ankle or knee joint on the amputated leg, and therefore it is worth paying special consideration to it. It was possible to state that in healthy individuals there were more variations during the gait events, regarding each type of floor, than in amputees, since in the latter the tendencies are identical, regardless of the flooring. This is in line with what was previously reported, in the sense that as they have been amputees for a long time, they have already acquired a gait pattern, behaving in the same way. While analysing **Hip Angle ROM**, healthy participants showed that there are significant differences to among all types of floors with the exception amid obstacles and irregular floor there is not, as for amputees all types of floors cause an effect. With regard to **position of COM ROM**, for healthy patients, all types of floors were affected, on the contrary for amputees, amid obstacles and irregular floor plus treadmill and irregular floor there is not a substantial difference. Moreover, this parameter is higher in amputees then in healthy participants. Additionally, by also taking into consideration the **position of the Foot**, it can be corroborated that in amputees there is also almost no difference between a flat floor and the uneven floor, which indicates that this behaviour of the COM is valid.

Considering the muscular activation, it is possible to state that ***Gluteus Medius*** is the muscle that presents a greater muscular activation, in both healthy and amputees subjects. Although, there is a larger muscular activation for the amputees than for the healthy ones. Examining the sides of an amputee's leg and the same occur, *Gluteus Medius* showed double the of Gluteus *Maximus activation*, and that the muscle activity of the *Gluteus Medius*, on the paretic leg, is much higher, reaching its maximum, also, during obstacle walking.

RQ 3: What should be the parameterization of a vibrotactile stimulus to be applied in an effective way as artificial feedback, during specific gait events?

Considering the results of the biomechanical analysis carried out, in order to be applied effectively as artificial biofeedback, the parameterisation of the vibrotactile stimulus should be carried out between the pre-swing and swing phase, specifically between the HO and TO events. And instead of biofeedback being applied only to the paretic leg, it should also be applied to both legs, depending on the physiotherapy schedule and purpose, with the aim of rectifying potential errors in the non-paretic leg. Another body part that could be considered for the biofeedback stimulus application is the waist, since LLA present grater COM deviations than healthy subjects. The stimulus could be applied near the muscular zone of the Gluteus Medius and on the Hip Joint.

Therefore, each goal has been achieved, as evidence by the KPI, a quantifiable measure of performance over time for each proposed objective.

4.1 Future Work

Firstly, and as mentioned before, the amputees evaluated had already suffered the amputation more than 5 years ago, which implies that they had established gait patterns and that it was more difficult to correct the gait, so it would be interesting to increase the sample of amputees as well as to increase the sample of patients who had recently suffered the amputation. For healthy people, it would also be wise to expand the number of healthy people to be assessed, so that a more careful and complete comparison could be made.

Validating the paradigm proposed in the critical analysis would be a great addition, this being the application of biofeedback during the pre-swing and swing phases, more specifically in the HO and TO events. The results obtained revealed that it is not justifiable to use a rehabilitation training session on the treadmill, but rather on the ground, on uneven ground and with obstacles, since the treadmill, in comparison with other types of floors, does not present so many distinctions, as well as the different speeds. It was considered that the stimulus could only be applied in the surroundings of the Gluteus Medius muscle since it was the one with the highest activation and most influence on the different factors; moreover, this biofeedback would not only be applied to the paretic leg, but also the healthy leg of the amputee as well as and on the waist, as it was noted that were also affected.

Ultimately, to heighten the biomechanical analysis, it would be interesting to explore more of OpenSim and what it has to offer. It would be recommended that experimental GRF were acquired with force plates and performing a more careful and thorough scaling and marker registration of the biomechanical model used in OpenSim, so that net joint reaction forces and net joint moments could be computed to be able to accomplish a farther complete biomechanical analysis.

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APPENDIX I – INFORMED CONSENT FORM

Below is attached the Voluntary Informed Consent document participants signed, prior to involvement in this research.

CONSENTIMENTO INFORMADO, LIVRE E ESCLARECIDO

PARA PARTICIPAÇÃO EM INVESTIGAÇÃO

de acordo com a Declaração de Helsínquia[1] e a Convenção de Oviedo[2]

Por favor, leia com atenção a seguinte informação. Se achar que algo está incorreto ou que não está claro, não hesite em solicitar mais informações. Se concorda com a proposta que lhe foi feita, queira assinar este documento.

Título do estudo: *BioWalk* - Sistema vibrotátil e propriocetivo para a reabilitação e assistência da marcha em amputados do membro inferior
Enquadramento: *Center for MicroElectroMechnical Systems* (CMEMS), Escola de Engenharia da Universidade do Minho com a supervisão científica da Professora Doutora Cristina Manuela Peixoto dos Santos e do Professor Doutor Eurico Augusto Rodrigues Seabra. Este é o Estudo nº 1 de uma série de estudos a realizar no âmbito do projeto de investigação.
Explicação do estudo: Este estudo visa a recolha de dados biomecânicos (velocidade da marcha, amplitude do movimento articular, orientação e posicionamento, acelerações, velocidade angular) e fisiológicos (custo energético e atividade muscular) dos membros inferiores através de sistemas sensoriais vestíveis e não-invasivos. A recolha de dados foca-se na análise da marcha de voluntários amputados do membro inferior a caminhar a diferentes velocidades na passadeira, e a caminhar a velocidade confortável em terreno com obstáculos. O estudo segue um design repetitivo e terá uma duração aproximada de 3h. O investigador acompanhará o participante durante a realização da experiência, a qual decorrerá na Padrão Ortopédico. Os dados recolhidos contribuirão para o desenvolvimento de ferramentas inteligentes de análise de movimento.
Ao longo do estudo poderão ser recolhidos filmes e imagens, os quais serão apenas divulgados para fins académicos e científicos. Em ambos os casos, o rosto dos intervenientes não será visível para garantir o sigilo. Os resultados obtidos a partir da análise de dados biomecânicos e fisiológicos serão colocados em forma de gráficos, imagens e tabelas.

Condições e financiamento: Este é um estudo de carácter voluntário e não existem quaisquer prejuízos, caso não queira participar. A sua aceitação ou a sua recusa em participar, ou posterior abandono, não prejudicarão a sua relação com a equipa de investigação. Este estudo não é remunerado, mas não terá encargos monetários para o participante. Este estudo mereceu um parecer favorável da Padrão Ortopédico.

Confidencialidade e anonimato: As informações pessoais obtidas serão mantidas em sigilo e não poderão ser consultadas por pessoas leigas sem a prévia autorização por escrito do

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[1] http://portal.arsnorte.min-saude.pt/portal/page/portal/ARSNorte/Comiss%C3%A3o%20de%20%C3%89tica/Ficheiros/Declaracao_Helsinquia_2008.pdf

[2] http://dre.pt/pdf1sdip/2001/01/002A00/00140036.pdf

participante, de acordo com o Regulamento Geral de Proteção de Dados[3]. Como tal, os dados pessoais não serão compartilhados com terceiros, sendo totalmente confidenciais e apenas os investigadores poderão ter acesso aos mesmos.
Os dados biomecânicos e fisiológicos obtidas poderão ser usados somente para fins académicos ou científicos, sempre resguardando a privacidade e o anonimato do participante. Caso consinta, os dados biomecânicos e fisiológicos anonimizados poderão ser publicados numa base de dados online de forma a que outros investigadores possam fazer uso dos mesmos para os seus projetos de investigação. Note que a sua identificação nunca será tornada pública, pelo que ninguém conseguirá identificá-lo(a) através dos dados recolhidos.

Desde já, Professora Doutora Cristina Santos (cristina@dei.uminho.pt), Professor Doutor Eurico Seabra (eseabra@dem.uminho.pt) e Mestre Joana Alves (id7280@alunos.uminho.pt), e o investigador agradecem a sua colaboração.

Assinatura/s: … … … … … … … … … ... … … … …... … … … … … … … … … … …

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Declaro ter lido e compreendido este documento, bem como as informações verbais que me foram fornecidas pela/s pessoa/s que acima assina/m. Foi-me garantida a possibilidade de, em qualquer altura, recusar participar neste estudo sem qualquer tipo de consequências. Desta forma, aceito participar neste estudo e permito a utilização dos dados que de forma voluntária forneço, confiando em que apenas serão utilizados para esta investigação e nas garantias de confidencialidade e anonimato que me são dadas pelo/a investigador/a.

Nome: … … … … … … … …... … … … …... … … … … … … … … … … … …

Assinatura: … … … … … … … …... … … … … ... … … … … … … … … … … … …

Data: …… /…… /………..

ESTE DOCUMENTO É COMPOSTO DE 2 PÁGINA/S E FEITO EM DUPLICADO:
UMA VIA PARA O/A INVESTIGADOR/A, OUTRA PARA A PESSOA QUE CONSENTE

[3] Regulamento Geral de Proteção de Dados (RGPD) (Regulamento (UE) 2016/679 do Parlamento Europeu e do Conselho de 27 de abril de 2016 relativo à proteção das pessoas singulares no que diz respeito ao tratamento de dados pessoais e à livre circulação desses dados e que revoga a Diretiva 95/46/CE.), que entrou em vigor no passado dia 25 de maio de 2018, e vem substituir a atual diretiva e tem aplicação direta no quadro legal Português. Contudo, até haver legislação nacional de execução do RGPD que revogue a Lei 67/98 de 26 de Outubro (Lei de proteção de dados pessoais) nas matérias abrangidas pelo regulamento, a Lei 67/98 continua em vigor em tudo o que não contrarie o RGPD. Acesso via: https://eur-lex.europa.eu/legal-content/PT/TXT/?uri=celex%3A32016R0679

APPENDIX II – PROTOCOL OF HEALTHY PARTICIPANTS

Below is attached the complete protocol of biomechanical data collection for healthy participants.

Protocolo Experimental

Propósito e enquadramento

- Validação dos Sistemas Sensoriais e Respetivas Métricas (Estudo 1)
- Recolha e Aplicação de Dados Biomecânicos e Fisiológicos relativos à Locomoção Saudável (Estudo 2)
- Coletar e analisar dados biomecânicos e fisiológicos (Delsys – EMG e XSens) em diferentes ambientes de locomoção diária, utilizado sistemas sensoriais não invasivos, com vista à sintonização/criação de ferramentas computacionais avançadas e recolha de dados que constituirão uma base de dados *open-source*

Participantes

- **Número de participantes**: n = 30
- **População alvo**:

Critérios de Inclusão	Critérios de Exclusão
i. Locomoção saudável; ii. Total equilíbrio postural; iii. Mais de 18 anos; iv. Massa corporal compreendida entre 45 e 90 kg; v. Altura compreendida entre 1.50 e 1.90 m; vi. Apto para utilizar os dispositivos VT-S, VT-B, prótese ativa e comercial com adaptador de teste; vii. Consentimento informado assinado.	i. Doença ou défice ortopédico, cardíaco ou respiratório que afete a locomoção; ii. Dificuldade de locomoção em escadas, passadeira e/ou rampas, em terreno irregular ou com obstáculos; iii. Feridas ou fragilidade cutânea nas áreas de contato com a VT-S, VT-B ou com o adaptador protético; iv. Ocorrência de fraturas nos membros inferiores; v. Uso de roupa e calçado inadequados para a marcha e/ou uso dos dispositivos protéticos e de biofeedback.

Design estudo: ☐ Estudo Experimental ☐ Pré-Teste ☐ Estudo controlado ☐ Aquisiçãode dados ☐ Outro

Se **Outro** for selecionado, especifique:

Se **Estudo controlado** foi selecionado indique qual: ☐ Randomized ☐ Non-randomized ☐Se**randomized** foi selecionado, especifique o método:

Material

- Elétrodos EMG (Delsys Trigno^{TM} Avanti Platform, Massachussets, USA) nos músculos de ambas as pernas *Rectus Femoris* (*RF*), *Biceps femoris* (*BF*), *Vastus Laterallis (VL), Gluteus Maximus (GMax), Gluteus Medius (GMed), Tensor Fasciae Latae (TFL)*;
- IMUs da Xsens MTw Awinda (Lower limbs - trunk, thigh, shank, foot);
- Passadeira;
- Cadeira;
- Colchonete e almofada de fisioterapia;
- Câmara Kinect X-Box;
- SyncBox;
- GaitShoes;
- Dispositivo VT-S;
- Obstáculos de alturas 3, 7, 10 e 15 cm;
- Computador laboratório.
- Ligaduras para coxas;
- Fita adesiva hipoalergénica;
- Elástico CrossFit para abdução;
- Pano e Spray de desinfeção;
- Calções curtos e sapatilhas de cordões;
- Gilete com recargas;
- Tesoura;
- Fita métrica
- HUB Tp-Link

Aquisição de dados

- Sinal EMG para os músculos *RF, BF, VL, GMed, GMax, TFL* (frequência de amostragem: 2148 Hz);
- Dados cinemáticos dos membros inferiores (trunk, hip, thigh, shank e foot) (frequência de amostragem: 100 Hz);
- Dados visuais dos membros inferiores.

Análise e Tratamento de Dados (Resultados)

A análise dos dados inclui uma análise estatística descritiva dos dados sociodemográficos, nomeadamente de idade, género, massa corporal, e altura. Os dados quantitativos serão processados por algoritmos de filtragem (e.g. interpolação, alinhamento de sinais, e remoção de *offsets*), com recurso ao software Matlab® (2017b, The Mathworks, Natick, MA, USA). Após o pós-processamento, os dados serão armazenados em ficheiros no formato *.mat*, do qual posteriormente serão normalizados por ciclo de marcha, considerando o sinal médio, por cada condição de teste (i.e. tarefa, ver Tabela 2). Consecutivamente, os dados de todos os sujeitos serão armazenados por condição, e por sistema sensorial, e exportados para o formato .sav para serem analisados,estatisticamente, no software SPSS (IBM Corp. Released 2019. IBM SPSS Statistics forWindows, Version 26.0. Armonk, NY: IBM Corp).

A análise de *benchmarking* entre os dados monitorizados pelo sistema sensorial proposto e o sistema comercial baseia-se nos valores médios, *Range of Motion* (ROM) ede desvio padrão de métricas estatísticas. Assumindo uma amostra de dimensão inferior a 30, a seleção do teste estatístico, Paramétrico e Não Paramétrico, depende da verificaçãode três premissas: 1) Não existência de Outliers, 2) Normalidade e 3) Homogeneidade dos dados estudados. Desta forma, serão conduzidos os seguintes testes, para cada uma das premissas, respetivamente: 1) BoxPlot, 2) Shapiro-Wilk e Kolmonov-Smirnov, 3) Teste de Levine [1]. Para além disso, devemos sempre garantir que as observações são independentes.

Consoante os resultados obtidos, a análise dos dados seguirá a organização e etapas discriminadas na Tabela 1. Todos os testes estatísticos realizados são de HipóteseBilateral com nível de significância α=0.05 (probabilidade de rejeitar a H_0) em que:

H_0: $\mu_1=\mu_2$ (Não existem diferenças significativas entre os grupos 1 e 2)H_1:

$\mu_1 \neq \mu_2$ (Existem diferenças significativas entre os grupos 1 e 2)

[1] Almeida, Sofia. *Estadística aplicada à investigação em ciências da saúde: um guia com o SPSS*. Lusodidacta, 2017.
Ana Cristina Braga. *Quantitative and Qualitative Methods in Engineering – M2QE.* 2021

Tabela 1 – Distribuição dos Testes Estatísticos e discriminação do tipo

Objetivo	Equipamento sensorial	Parâmetros	Métricas Estatísticas	Testes Paramétricos	Testes Não-Paramétricos
Benchmarking **Grupos emparelhados**	• XSens • GaitShoe • Kinect (Condições C, D, F)	Pitch, Roll Toe Clearance Gait Event Detection	• Similaridade (Root Mean Square Error) • Correlação (i.e. performance do algoritmo de cálculo dos parâmetros) • Significância média (ROM) • Precisão (i.e. accuracy); • Sensibilidade; • Percentagem de ocorrências; • Duração de atrasos e avanços	**Paired T-Test Correlação de Pearson** **One-sample T-Test** (RMSE)	**Teste de Wilcoxon** (para1 ou 2 grupos emparelhados) **Correlação de Spearman**
Análise Inter-sujeito **Grupos Independentes**	• XSens • GaitShoe (i.e., Toe Clearance) • Kinect (Condições C, D, F) • Delsys (EMG)	Toe Clearance Ativação muscular (RMS) Parâmetros Espacio-Temporais (Step/Stride Length, Step/Stride Time, Step Width, Pelvis Range of Motion, Pelvis Height Displacement, Hip Range of Motion, Swing Time, Stance	• Média e desvio padrão de dados sociodemográficos de cada grupo • Similaridade de médias (Parâmetros Espacio-temporais, Ativação Muscular, Toe Clearance); • Similaridade de médias dos membros inferiores (Membro	**Unpaired T-Test** + RMSE (Valores de simetria para parâmetros espácio-temporaise comparação entre grupos)	**Teste de Mann-Whitney** (mesma abordagem se fosse testes paramétricos)

		Time, Symmetry, %Stance, %Swing, %Double Support)	saudável-membro amputado, Membro saudável – membro intacto); • Root Mean Square Error (Parâmetros Saudáveis Vs Amputados, e Diferenças entre membros inferiores)		
Análise Intra-sujeito **Grupos emparelhados**	• XSens • GaitShoe (i.e., Toe Clearance) • Kinect (Condições C, D, F) • Delsys (EMG)	Toe Clearance Ativação muscular (RMS) - % de ativação em obstáculos Parâmetros Espacio-Temporais (Step/Stride Length, Step/Stride Time, Step Width, Pelvis Range of Motion, Pelvis Height, Hip Range of Motion, Swing Time, Stance Time, Symmetry, %Stance, %Swing, %Double Support) Lead foot placement & Trail foot placement (Obstacle)	• Média e desvio padrão de dados sociodemográficos; • Similaridade/Simetria e significância de médias (Parâmetros Espacio-temporais, Ativação Muscular, Toe Clearance), para várias condições;	**Media e desvio padrão** (Parâmetros Espacio-Temporais) **Paired T-test** (Amputados - Membroprostético e saudável, Locomoção livre de obstáculos vs Locomoção comobstáculos) **ANOVA – RepeatedMeasures** - 3 velocidades distintas, mesmo sujeito (e.g. ativação	**Testes de Wilcoxon** **Testes de Friedman** (mesma abordagem se fosse testes paramétricos)

				muscular, parâmetros espácio-temporais) - 3 condições distintas (*Ground Level*, *Obstalces*,*Irregular Terrain*), mesmo sujeito (e.g. ativação muscular, parâmetros espácio-temporais) - % Ativação muscular de 4 músculos, mesmo sujeito (diferenças significativas entre as médias durante 1 GaitCycle) - 4 condições em marcha com obstáculos (diferenças significativas entre nos respetivos parâmetros para quatro obstáculos com alturas diferentes).	

Protocolo

!!Seguir atentamente as indicações abaixo discriminadas. Acompanhar as etapas com os seguintesdocumentos auxiliares: Dicas de utilização dos sistemas sensoriais e WALKTHROUGH SyncLab!!

T. 1 Anotar dados demográficos do participante: idade, altura, género, massa, e dados clínicos (Formulários de Recolha de Dados);

T. 2 Limpar a área da pele, com álcool, onde irão ser colocados os elétrodos EMG;

T. 3 Colocar fita-cola nos sensores EMG e emparelhar com a *Base Station*. Registar no software os músculos para cada sensor respetivamente:

Right RF → Sensor 1	Left RF→ Sensor 5
Right *BF*→ Sensor 2	Left *BF*→ Sensor 6
Right *GMax* → Sensor 3	Left *GMax*→ Sensor 7
Right *GMed* → Sensor 4	Left *GMed* → Sensor 8

T. 4 Colocar os elétrodos EMG nos músculos *RF, BF, GMed, GMax*. Usar cintas paramelhor fixação dos sensores à pele.

T. 5 Registar a contração voluntária máxima (MVC) para normalização do envelope EMG. Realizar 3 tentativas durante 5 segundos para cada músculo, com 15 segundos de repouso. Participantes devem-se colocar de acordo com as figuras no documento "Dicasde utilização dos sistemas sensoriais", usando a cadeira ou a colchonete;

T. 6 Clicar em "Next Task", e seguidamente em "Start". O software EMG Acquisitionirá ficar em modo de espera pelo *trigger*;

T. 7 Registar os dados antropométricos do participante e guardá-los na aplicação do software da XSens;

T. 8 Colocar os sensores XSens nos membros inferiores de acordo com o documento "Dicas de utilização dos sistemas sensoriais";

T. 9 Seguir indicações de conexão e funcionamento do software XSens presentes no documento "Dicas de utilização dos sistemas sensoriais";

T. 10 Selecionar uma sincronização/trigger: **Start Recording (in) → IN 2 → Rising Edge → Skip Factor 0 → Skip First 0** + **Stop Recording (in) → IN 2 → Rising Edge → Skip Factor 0 → Skip First 1**;

T. 11 Calibrar o Xsens, guardar o processo e seguidamente conectar o cabo BNC parasincronização;

T. 12 Posicionar a câmara Kinect conforme a localização do teste e conectar ao computador pessoal (excepto T6);

T. 13 Calçar os GaitShoes em cada pé, posicionar as powerBanks nos tornozelos e fixara PCB-Master à cinta do participante;

T. 14 Conectar o cabo BNC de sincronização da XSens, da Delsys e dos GaitShoes à SyncBox;

T. 15 Ligar a SyncBox ao computador do laboratório, ou computador pessoal, e abrir a aplicação SyncLab (*GUI_SYNC_v5*)[2] selecionado os 4 equipamentos sensoriasi: Labsystems, XSens, Delsys, Kinect;

T. 16 Abrir a aplicação *GUI_VibrotactileSocket* e ativar a aquisição de dados do GaitShoe ("GaitShoe Acquistion"), clicar na opção "SyncLab", e introduzir o identificador do trial (ver tabela abaixo). Clicar em "Start Trial" (o software fica em *stand-by*);

T. 17 Pedir ao participante para se colocar na posição inicial em *N-Pose* e fazer *load* da calibração. Iniciar a aquisição de dados da XSens colocando o sistema em modo de espera;

T. 18 Clicar em "Start" na aplicação SyncLab e iniciar a aquisição dos dados para os diferentes *trials* de tarefas motoras, seguindo a tabela:

Tabela 2 - Descrição das tarefas a realizar no presente protocolo

	Tarefa	**Tempo/Distância**	**Velocidades**	**Trials**	**Repouso**
ParteI	A. Treadmill 0%	3 min	a. 1.8 km/h	3	60 s
			b. 2.7 km/h	3	
			c. 3.6 km/h	3	
Parte II	B. Forward walking GO (Ground)	10 m (10-15 s)	Confortável (dia-a-dia)	7	1 min
	C. Forward walking GO (obstacles)[3]	10 m (10-15 s)	Confortável (dia-a-dia)	7	1 min

[2] Assegurar que a frequência do sinal está entre 500 e 999 Hz

[3] Obstáculos: 3 cm, 7 cm, 10 cm, 15 cm (30 cm de altura), distanciados de 1 metro. Incremental comperna dominante

	D. Forward walking GO (Irregularterrain)	10 m (10-15 s)	Confortável (dia-a-dia)	7	1 min
	E. Forward walkingGO VT-S (Ground)	10 m (10-15 s)	Confortável (dia-a-dia)	3	1 min
	F. Forward walking GO VT-S (obstacles) [4]	10 m (10-15 s)	Confortável (dia-a-dia)	3	1 min

Follow-up standard

1. Sujeito inicia cada trial na posição neutra (N-pose);
2. Calibração dos FSR dos GaitShoes;
3. Iniciar aquisição dos dados;
4. Correr o trial consoante a condição[5];
5. Clicar em Stop na GUI do SyncLab e aguardar que todos os sistemas parem;
6. Clicar em Stop na GUI_VibrotactileSocket[6] -> Reset -> Reintroduzir dados e alterar o nome ID do trial;
7. Repetir processo.

Nota: Entre cada trial verificar o tamanho do ficheiro guardado no cartão SD do dispositivo VT-S, tirar a XSens de modo de espera e fazer load da calibração antes do início do próximo trial. Iniciar e terminar os testes em posição estática/neutra durante 10segundos.

Número de *trials* total:
9 × Treadmill 0% + 9 × Treadmill 10% + 7 × Forward walking (Ground) + 7 × Forward walking (Obstacles) + 7 × Forward walking GO (Irregular terrain) + 3 × Forward walkingGO VT-S (Ground) + 3 × Forward walking GO VT-S (obstacles) = 45 Trials/sujeito

Tempo estimado por sujeito:

1. Limpar a área para colocar os elétrodos: 20 minutos;
2. Realizar o MVC: 30 minutos;
3. Colocar os sensors XSens: 15 minutes;
4. Realizar a calibração da XSens: 10 minutos;
5. Colocar a camera KINECT enquadrada na zona de teste: 10 minutos;
6. Colocação dos GaitShoes e sistemas anexos: 15 minutos;

7. Treadmill 0% = 35 minutos (9 × 3 + 1 × 8);
8. Forward walking GO (Ground) = 8 minutos (7 × 15 s + 60 s × 6);
9. Forward walking GO (obstacles) = 8 minutos (7 × 15 s + 60 s × 6);
10. Forward walking GO (Irregular terrain) = 8 minutos (7 × 15 s + 60 s × 6);
11. Forward walking GO VT-S (Ground) = 3 minutos (3 × 15 s + 60 s × 2);
12. Forward walking GO VT-S (obstacles) = 3 minutos (3 × 15 s + 60 s × 2);
13. Tempo extra (ex: transição de trials, colocação de obstáculos, verificação de dados armazenados, quebras/falhas de comunicação, outros) = 30 minutos;

Tempo total: 20 + 30 + 15 + 10 +10 +15 +35+8 +8 +8 +3 +3 + 3 +30 = 195 minutos/sujeito (aproximadamente 3,5 horas)

Calendarização

Iniciar recolha de dados: **Terminar** recolha de dados:

Maximo de sujeitos por dia: 1

[4] Obstáculos: 3 cm, 7 cm, 10 cm, 15 cm (30 cm de altura), distanciados de 1 metro. Incremental. VT-S emmodo passivo.
[5] Verificar que os dados estão a ser enviados para o cartão através da luz LED do módulo SD card
[6] Optar pelo modo "Debug" colocando um breakpoint na função do botão Stop, assim poderei verificar seo ficheiro foi criado e qual o seu tamanho

Formulários de Recolha de Dados

Título do projeto: *BioWalk* - Sistema protético, inteligente e propriocetivo para a reabilitação e assistência da marcha em amputados do membro inferior

Investigadores: Mestre Joana Elisa Ferreira Alves, Professora Doutora Cristina Manuela Peixoto dos Santos

Enquadramento: *Center for MicroElectroMechnical Systems* (CMEMS), Escola de Engenharia da Universidade do Minho com a supervisão científica da Professora Doutora Cristina Manuela Peixoto dos Santos. Este instrumento de recolha de dados visa recolher os dados sociodemográficos dos participantes, informações do estudo e situações inesperadas que ocorram ao longo do estudo. Garante-se o anonimato e rigorosa confidencialidade dos dados recolhidos.

Participante nº: ____________

Data da Recolha:___________/____/____

Local da Recolha: ____

Investigador responsável pelo estudo: ____________________________________

1. Dados Sociodemográficos

Sexo: M____________F_______Indiferenciado__________

Idade: ___________________ Altura (m):_____________ Massa Corporal (kg): _______________

2. Dados Clínicos e Anatómicas

	Dimensões anatómicas	
	Membro Direito (cm)	Membro Esquerdo (cm)
Comprimento do pé (i.e., marcando a distância do calcanhar ao dedo grande)		
Comprimento do fémur (i.e., distância do trocânter maior ao epicôndilo lateral do fémur)		
Comprimento da tíbia (i.e., distância do Maléolo medial ao côndilo medial da tíbia)		
Comprimento total do fémur à tíbia (i.e., distância do Maléolo medial da tíbia ao trocânter maior do fémur)[7]		

[7] Pelo lado lateral

Altura da perna (i.e., altura do trocânter maior do fémur)	
Altura da cintura ao pé (i.e., altura *Sacrum*)	

Tamanho de calçado (34 - 50): ______________________________

Tratamentos/Cirurgias realizadas: Quais? ____

Onde?____

Medicação:____

Fraturas:____

Ocorrência recente de quedas: ____

3. Dados do Estudo

Estudo Marcha Saudável nº: ____________

Sistema Sensorial Utilizado*			
GaitShoe		Plataforma da AMTI	
InertialLAB		Trigno^{TM} Avanti (Delsys)	
MyoLAB		3D motion capture (Qualysis)	
Obstacle-Detection		MVN BIOMECH (Xsens)	
k4b2 (COSMED)		respiBAN (biosignalsplux)	

*Assinalar com X

Sistema de *Biofeedback* (se aplicável) *			
Vibrotactile Socket (VT-S)		Vibrotactile Belt (VT-B)	

*Assinalar com X

Dispositivos Protéticos (se aplicável) *			
Prótese Inteligente (estratégia passiva)		Prótese Inteligente (estratégica c/ sinais EMG)	
Prótese Inteligente (estratégia adaptativa)		Prótese *Standard* Qual? __________________________	

*Assinalar com X

Situações Inesperadas: ____

____

____

____

ANOTAÇÕES EXPERIMENTAIS

			GaitShoes	**XSens**	**Delsys**	**Kinect**
PARTE I[8]	**A**	Tread0Slow-1				
		Tread0Slow -2				
		Tread0Slow-3				
		Tread0Med-1				
		Tread0Med-2				
		Tread0Med-3				
		Tread0Fast-1				
		Tread0Fast-2				
		Tread0Fast-2				
PARTE II[9]	**B**	FwdGnd -1				
		FwdGnd -2				
		FwdGnd -3				
		ForwdGnd -4				
		FwdGnd -5				
		FwdGnd -6				
		FwdGnd -7				
	C	FwdObs -1				
		FwdObs -2				
		FwdObs -3				
		FwdObs -4				
		FwdObs -5				
		FwdObs -6				
		FwdObs -7				
	D	FwdIrr-1				
		FwdIrr-2				
		FwdIrr-3				

[8] Esperados ficheiros na ordem dos 1000 kb
[9] Esperados ficheiros entre 50 a 200 kb

		FwdIrr-4				
		FwdIrr-5				
		FwdIrr-6				
		FwdIrr-7				
	E	FwdGndVTS-1				
		FwdGndVTS-2				
		FwdGndVTS-3				
	F	FwdObsVTS-1				
		FwdObsVTS-2				
		FwdObsVTS-3				

Anexos

Sistema Sensorial	Localização	Dados
MVN BIOMECH (Xsens)	IMUs colocado nos segmentos inferiores (coxa, canela e pé) e zona lombar	<u>Dados Biomecânicos</u> - Aceleração 3D - Velocidade angular 3D - Ângulos dos segmentos e das articulações - Posição e orientação 3D dos segmentos - Eventos da marcha - Velocidade da marcha - Localização do centro de massa
Trigno^{TM} Avanti (Delsys)	Elétrodos superficiais dispostos sobre músculos dosmembros inferiores (*tibialis anterior, gastrocnemius, soleus, vastus lateralis, bicep femoris/semitendinous*)	<u>Dados fisiológicos – EMG</u> - Atividade muscular - Atividade muscular normalizada MVC - Sinal do envelope muscular
GaitShoe	Pés	<u>Dados Biomecânicos</u> - Eventos da marcha - Simetria da marcha - Parâmetros espácio-temporais (velocidade, comprimento do passo e da passada, duração do passo e da passada) - *Foot Clearance*
RespiBAN Professional (biosignalsplux)	Cinta de peito vestível para medição em tempo real do ritmo respiratório	<u>Dados fisiológicos – Custo metabólico</u> - Ciclos respiratórios - Monitorização do ritmo respiratório

MVN BIOMECHA (Xsens)

Trigno™ Avanti (Delsys)

Outros materiais importantes:

1	Protocolo impresso
2	Fichas para protocolo (saudáveis + amputados)
3	Questionários para preeenchimento
4	Consentimento informado para Estudo 1 Padrão ou Estudo 2 Uminho
5	Telemóvel/câmara amadora
6	Obstáculos *handmade*
7	Acessórios extra - velcro, fitas, cola, fita cola grossa, tiras de velcro, cabos USB, fita cola de papel
8	Fita métrica ou fita Xsens
9	Regras de utilização dos sistemas sensoriais

[10] Usar nos protocolos com o Sistema VT-S (Estudo 3)

Appendix III – Protocol of Amputee Participants

Below is attached the complete protocol of biomechanical data collection for amputee participants.

Protocolo Experimental

Propósito e enquadramento

- Validação dos Sistemas Sensoriais e Respetivas Métricas (Estudo 1)
- Recolha e Aplicação de Dados Biomecânicos e Fisiológicos relativos à Locomoção Saudável (Estudo 2)
- Coletar e analisar dados biomecânicos e fisiológicos (Delsys – EMG, XSens, GaitShoe-Sensor de distância) em diferentes ambientes de locomoção diária, utilizado sistemas sensoriais não invasivos, com vista à sintonização/criação de ferramentas computacionais avançadas e recolha de dados que constituirão uma base de dados *open-source*
- Recolha de dados foto e filmográficos (Kinect e Telemóvel) em diferentes ambientes de locomoção diária, com vista à posterior análise e complementaridade de dados.

Participantes

- **Número de participantes**: n = 30
- **População alvo:**

Critérios de Inclusão	Critérios de Exclusão
i. Locomoção saudável; ii. Total equilíbrio postural; iii. Mais de 18 anos; iv. Massa corporal compreendida entre 45 e 90 kg; v. Altura compreendida entre 1.50 e 1.90 m; vi. Apto para utilizar os dispositivos VT-S, VT-B, prótese ativa e comercial com adaptador de teste; vii. Consentimento informado assinado.	i. Doença ou défice ortopédico, cardíaco ou respiratório que afete a locomoção; ii. Dificuldade de locomoção em escadas, passadeira e/ou rampas, em terreno irregular ou com obstáculos; iii. Feridas ou fragilidade cutânea nas áreas de contato com a VT-S, VT-B ou com o adaptador protético; iv. Ocorrência de fraturas nos membros inferiores; v. Uso de roupa e calçado inadequados para a marcha e/ou uso dos dispositivos protéticos e de biofeedback.

Design estudo: ☐ Estudo Experimental ☐ Pré-Teste ☐ Estudo controlado ☐ Aquisição de dados ☐ Outro

Se **Outro** for selecionado, especifique:

____

Se **Estudo controlado** foi selecionado indique qual: ☐ Randomized ☐ Non-randomized

Se **randomized** foi selecionado, especifique o método:

____

Material

- Elétrodos EMG (Delsys Trigno™ Avanti Platform, Massachussets, USA) nos músculos de ambas as pernas *Rectus Femoris* (*RF*), *Biceps femoris* (*BF*), *Vastus Laterallis (VL), Gluteus Maximus (GMax), Gluteus Medius (GMed), Tensor Fasciae Latae (TFL)*;
- IMUs da Xsens MTw Awinda (Lower limbs - trunk, thigh, shank, foot);
- Passadeira;
- Cadeira;
- Colchonete e almofada de fisioterapia;
- Câmara Kinect X-Box;
- SyncBox;
- GaitShoes;
- Dispositivo VT-S;
- Obstáculos de alturas 3, 7, 10 e 15 cm;
- Computador laboratório.
- Ligaduras para coxas;
- Fita adesiva hipoalergénica;
- Elástico CrossFit para abdução;
- Pano e Spray de desinfeção;
- Calções curtos e sapatilhas de cordões;
- Gilete com recargas;
- Tesoura;
- Fita métrica
- HUB Tp-Link

Aquisição de dados

- Sinal EMG para os músculos *RF, BF, VL, GMed, GMax, TFL* (frequência de amostragem: 2148 Hz);
- Dados cinemáticos dos membros inferiores (trunk, hip, thigh, shank e foot) (frequência de amostragem: 100 Hz);
- Dados visuais dos membros inferiores.

Análise e Tratamento de Dados (Resultados)

A análise dos dados inclui uma análise estatística descritiva dos dados sociodemográficos, nomeadamente de idade, género, massa corporal, e altura. Os dados quantitativos serão processados por algoritmos de filtragem (e.g. interpolação, alinhamento de sinais, e remoção de *offsets*), com recurso ao software Matlab® (2017b, The Mathworks, Natick, MA, USA). Após o pós-processamento, os dados serão armazenados em ficheiros no formato *.mat*, do qual posteriormente serão normalizados por ciclo de marcha, considerando o sinal médio, por cada condição de teste (i.e. tarefa, ver Tabela 2). Consecutivamente, os dados de todos os sujeitos serão armazenados por condição, e por sistema sensorial, e exportados para o formato .sav para serem analisados, estatisticamente, no software SPSS (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp).

A análise de *benchmarking* entre os dados monitorizados pelo sistema sensorial proposto e o sistema comercial baseia-se nos valores médios, *Range of Motion* (ROM) e de desvio padrão de métricas estatísticas. Assumindo uma amostra de dimensão inferior a 30, a seleção do teste estatístico, Paramétrico e Não Paramétrico, depende da verificação de três premissas: 1) Não existência de Outliers, 2) Normalidade e 3) Homogeneidade dos dados estudados. Desta forma, serão conduzidos os seguintes testes, para cada uma das premissas, respetivamente: 1) BoxPlot, 2) Shapiro-Wilk e Kolmonov-Smirnov, 3)

Teste de Levine [4]. Para além disso, devemos sempre garantir que as observações são independentes.

Consoante os resultados obtidos, a análise dos dados seguirá a organização e etapas discriminadas na Tabela 1. Todos os testes estatísticos realizados são de Hipótese Bilateral com nível de significância α=0.05 (probabilidade de rejeitar a H_0) em que:

H_0: $\mu_1=\mu_2$ (Não existem diferenças significativas entre os grupos 1 e 2)

H_1: $\mu_1 \neq \mu_2$ (Existem diferenças significativas entre os grupos 1 e 2)

[4] Almeida, Sofia. *Estadística aplicada à investigação em ciências da saúde: um guia com o SPSS*. Lusodidacta, 2017.
Ana Cristina Braga. *Quantitative and Qualitative Methods in Engineering – M2QE.* 2021

Tabela 1 – Distribuição dos Testes Estatísticos e discriminação do tipo

Objetivo	Equipamento sensorial	Parâmetros	Métricas Estatísticas	Testes Paramétricos	Testes Não-Paramétricos
Benchmarking **Grupos emparelhados**	• XSens • GaitShoe • Kinect (Condições C, D, F)	Pitch, Roll Toe Clearance Gait Event Detection	• Similaridade (Root Mean Square Error) • Correlação (i.e. performance do algoritmo de cálculo dos parâmetros) • Significância média (ROM) • Precisão (i.e. accuracy); • Sensibilidade; • Percentagem de ocorrências; • Duração de atrasos e avanços	**Paired T-Test** **Correlação de Pearson** **One-sample T-Test** (RMSE)	**Teste de Wilcoxon** (para 1 ou 2 grupos emparelhados) **Correlação de Spearman**
Análise Inter-sujeito **Grupos Independentes**	• XSens • GaitShoe (i.e., Toe Clearance) • Kinect (Condições C, D, F) • Delsys (EMG)	Toe Clearance Ativação muscular (RMS) Parâmetros Espacio-Temporais (Step/Stride Length, Step/Stride Time, Step Width, Pelvis Range of Motion, Pelvis Height Displacement, Hip Range of Motion, Swing Time, Stance	• Média e desvio padrão de dados sociodemográficos de cada grupo • Similaridade de médias (Parâmetros Espacio-temporais, Ativação Muscular, Toe Clearance); • Similaridade de médias dos membros inferiores (Membro	**Unpaired T-Test** + RMSE (Valores de simetria para parâmetros espácio-temporais e comparação entre grupos)	**Teste de Mann-Whitney** (mesma abordagem se fosse testes paramétricos)

		Time, Symmetry, %Stance, %Swing, %Double Support)	saudável-membro amputado, Membro saudável – membro intacto); • Root Mean Square Error (Parâmetros Saudáveis Vs Amputados, e Diferenças entre membros inferiores)		
Análise Intra-sujeito **Grupos emparelhados**	• XSens • GaitShoe (i.e., Toe Clearance) • Kinect (Condições C, D, F) • Delsys (EMG)	Toe Clearance Ativação muscular (RMS) - % de ativação em obstáculos Parâmetros Espacio-Temporais (Step/Stride Length, Step/Stride Time, Step Width, Pelvis Range of Motion, Pelvis Height, Hip Range of Motion, Swing Time, Stance Time, Symmetry, %Stance, %Swing, %Double Support) Lead foot placement & Trail foot placement (Obstacle)	• Média e desvio padrão de dados sociodemográficos; • Similaridade/Simetria e significância de médias (Parâmetros Espacio-temporais, Ativação Muscular, Toe Clearance), para várias condições;	**Media e desvio padrão** (Parâmetros Espacio-Temporais) **Paired T-test** (Amputados - Membro prostético e saudável, Locomoção livre de obstáculos vs Locomoção com obstáculos) **ANOVA – Repeated Measures** - 3 velocidades distintas, mesmo sujeito (e.g. ativação	**Testes de Wilcoxon** **Testes de Friedman** (mesma abordagem se fosse testes paramétricos)

				muscular, parâmetros espácio-temporais) - 3 condições distintas (*Ground Level*, *Obstalces*,*Irregular Terrain*), mesmo sujeito (e.g. ativação muscular, parâmetros espácio-temporais) - % Ativação muscular de 4 músculos, mesmo sujeito (diferenças significativas entre as médias durante 1 GaitCycle) - 4 condições em marcha com obstáculos (diferenças significativas entre nos respetivos parâmetros para quatro obstáculos com alturas diferentes).	

Protocolo

!!Seguir atentamente as indicações abaixo discriminadas. Acompanhar as etapas com os seguintes documentos auxiliares: Dicas de utilização dos sistemas sensoriais e WALKTHROUGH SyncLab!!

T. 1 Anotar dados demográficos do participante: idade, altura, género, massa, e dados clínicos (Formulários de Recolha de Dados);

T. 2 Limpar a área da pele, com álcool, onde irão ser colocados os elétrodos EMG;

T. 3 Colocar fita-cola nos sensores EMG e emparelhar com a *Base Station*. Registar no software os músculos para cada sensor respetivamente:

Right RF → Sensor 1	Left RF→ Sensor 5
Right *BF*→ Sensor 2	Left *BF*→ Sensor 6
Right *GMax* → Sensor 3	Left *GMax*→ Sensor 7
Right *GMed* → Sensor 4	Left *GMed* → Sensor 8

T. 4 Colocar os elétrodos EMG nos músculos *RF, BF, GMed, GMax*. Usar cintas para melhor fixação dos sensores à pele.

T. 5 Registar a contração voluntária máxima (MVC) para normalização do envelope EMG. Realizar 3 tentativas durante 5 segundos para cada músculo, com 15 segundos de repouso. Participantes devem-se colocar de acordo com as figuras no documento "Dicas de utilização dos sistemas sensoriais", usando a cadeira ou a colchonete (Delsys Channel 400, 2000 Hz);

T. 6 Clicar em "Next Task", e seguidamente em "Start". O software EMG Acquisition irá ficar em modo de espera pelo *trigger*;

T. 7 Registar os dados antropométricos do participante e guardá-los na aplicação do software da XSens;

T. 8 Colocar os sensores XSens nos membros inferiores de acordo com o documento "Dicas de utilização dos sistemas sensoriais";

T. 9 Seguir indicações de conexão e funcionamento do software XSens presentes no documento "Dicas de utilização dos sistemas sensoriais";

T. 10 Selecionar uma sincronização/trigger: **Start Recording (in) → IN 2 → Rising Edge → Skip Factor 0 → Skip First 0** + **Stop Recording (in) → IN 2 → Rising Edge → Skip Factor 0 → Skip First 1**;

T. 11 Calibrar o Xsens, guardar o processo e seguidamente conectar o cabo BNC para sincronização;

T. 12 Posicionar a câmara Kinect conforme a localização do teste e conectar ao computador pessoal (excepto T6);

T. 13 Calçar os GaitShoes em cada pé, posicionar as powerBanks nos tornozelos e fixar a PCB-Master à cinta do participante;

T. 14 Conectar o cabo BNC de sincronização da XSens, da Delsys e dos GaitShoes à SyncBox;

T. 15 Ligar a SyncBox ao computador do laboratório, ou computador pessoal, e abrir a aplicação SyncLab (*GUI_SYNC_v5*)[5] selecionado os 4 equipamentos sensoriasi: Labsystems, XSens, Delsys, Kinect;

T. 16 Abrir a aplicação *GUI_VibrotactileSocket* e ativar a aquisição de dados do GaitShoe (“GaitShoe Acquistion”), clicar na opção “SyncLab”, e introduzir o identificador do trial (ver tabela abaixo). Clicar em “Start Trial” (o software fica em *stand-by*);

T. 17 Pedir ao participante para se colocar na posição inicial em *N-Pose* e fazer *load* da calibração. Iniciar a aquisição de dados da XSens colocando o sistema em modo de espera;

T. 18 Clicar em “Start” na aplicação SyncLab e iniciar a aquisição dos dados para os diferentes *trials* de tarefas motoras, seguindo a tabela:

Tabela 2 - Descrição das tarefas a realizar no presente protocolo

	Tarefa	**Tempo/Distância**	**Velocidades**	**Trials**	**Repouso**
Parte I	A. Treadmill 0%	3 min	a. 1.8 km/h	3	60 s
			b. 2.7 km/h	3	
			c. 3.6 km/h	3	
	B. Forward walking GO (Ground)	10 m (10-15 s)	Confortável (dia-a-dia)	3	60 s

[5] Assegurar que a frequência do sinal está entre 500 e 999 Hz

Parte II	C. Forward walking GO (obstacles) [6]	10 m (10-15 s)	Confortável (dia-a-dia)	3	60 s
	D. Forward walking GO (Irregular terrain)	10 m (10-15 s)	Confortável (dia-a-dia)	3	60 s
	E. Forward walking GO VT-S (obstacles) [7]	10 m (10-15 s)	Confortável (dia-a-dia)	3	1 min

NOTA! (Forward Walking GO (obstacles) & Forward walking GO (Irregular terrain))– Considerando que se irá usufruir do máximo espaço possível, e por forma a reduzir a variabilidade de testes em saudáveis com testes em amputados, propõe-se a redução para 3 trials no percurso com obstáculos e piso irregular. Esta solução pressupõe, ainda, que iremos considerar 2 ciclos antes e no fim do percurso para que possam ser rejeitados na análise.

NOTA 2! – Uma segunda proposta, para melhor análise dos percursos com obstáculos seria considerar que em cada trial o participante percorreria um caminho com 2 obstáculos com a mesma altura. Para obstáculos com a mesma altura repetiria 3 vezes. Como temos 4 alturas diferentes de obstáculos ficaria 3 trials por cada altura, ou seja, 12 trials. Esta alteração implicaria um aumento de cerca de 20 minutos no protocolo já alterado para 2h 30.

NOTA 3! – O teste E. Forward Walking GO VT-S (Ground) iria ser útil para analisar a influência do uso do sistema VT-S na marcha do participante. Por exemplo, se existem desvios da marcha quando comparado com a sua não-utilização (uso do sistema VT-S em modo passivo). Contudo, por forma a reduzir os tempos dos testes, consideramos apenas a influência do uso durante trials com obstáculos por ser este o foco do estudo e aplicação do sistema VT-S. Por outro lado, aquando uma possível futura recolha de dados com o

[6] Obstáculos: 3 cm, 7 cm, 10 cm, 15 cm (30 cm de altura), distanciados de 1 metro. Incremental com perna dominante
[7] Obstáculos: 3 cm, 7 cm, 10 cm, 15 cm (30 cm de altura), distanciados de 1 metro. Incremental. VT-S em modo passivo.

sistema de biofeedback poderemos considerar melhor esta análise da influência do uso numa marcha livre de obstáculos.

Follow-up standard

1. Sujeito inicia cada trial na posição neutra (N-pose);
2. Calibração dos FSR dos GaitShoes;
3. Iniciar aquisição dos dados;
4. Correr o trial consoante a condição[8];
5. Clicar em Stop na GUI do SyncLab e aguardar que todos os sistemas parem;
6. Clicar em Stop na GUI_VibrotactileSocket[9] -> Reset -> Reintroduzir dados e alterar o nome ID do trial;
7. Repetir processo.

Nota: Entre cada trial verificar o tamanho do ficheiro guardado no cartão SD do dispositivo VT-S, tirar a XSens de modo de espera e fazer load da calibração antes do início do próximo trial. Iniciar e terminar os testes em posição estática/neutra durante 10 segundos.

Número de *trials* total:

9 × Treadmill 0% + 3 × Forward walking (Ground) + 3 × Forward walking (Obstacles) + 3 × Forward walking GO (Irregular terrain) + 3 × Forward walking GO VT-S (obstacles) = 39 Trials/sujeito

Tempo estimado por sujeito:

1. Limpar a área para colocar os elétrodos: 20 minutos;
2. Realizar o MVC: 30 minutos;
3. Colocar os sensors XSens: 15 minutes;
4. Realizar a calibração da XSens: 10 minutos;
5. Colocar a câmera KINECT enquadrada na zona de teste: 10 minutos;
6. Colocação dos GaitShoes e sistemas anexos: 15 minutos;

[8] Verificar que os dados estão a ser enviados para o cartão através da luz LED do módulo SD card
[9] Optar pelo modo "Debug" colocando um breakpoint na função do botão Stop, assim poderei verificar se o ficheiro foi criado e qual o seu tamanho

7. Treadmill 0% = 35 minutos (9 × 3 + 1 × 8);
8. Forward walking GO (Ground) = 3 minutos (3 × 15 s + 60 s × 2);
9. Forward walking GO (obstacles) = 3 minutos (3 × 15 s + 60 s × 2);
10. Forward walking GO (Irregular terrain) = 3 minutos (3 × 15 s + 60 s × 2);
11. Forward walking GO VT-S (obstacles) = 3 minutos (3 × 15 s + 60 s × 2);
12. Tempo extra (ex: transição de trials, colocação de obstáculos, verificação de dados armazenados, quebras/falhas de comunicação, outros) = 30 minutos;

Tempo total: 20 + 30 + 15 + 10 +10 +15 +35+3 +3 +3 +3
= 147 minutos/sujeito (aproximadamente 2 horas e 30 minutos)

Calendarização

Iniciar recolha de dados: **Terminar** recolha de dados:

Máximo de sujeitos por dia: 1

Formulários de Recolha de Dados

Título do projeto: *BioWalk* - Sistema protético, inteligente e propriocetivo para a reabilitação e assistência da marcha em amputados do membro inferior

Investigadores: Mestre Joana Elisa Ferreira Alves, Professora Doutora Cristina Manuela Peixoto dos Santos

Enquadramento: *Center for MicroElectroMechnical Systems* (CMEMS), Escola de Engenharia da Universidade do Minho com a supervisão científica da Professora Doutora Cristina Manuela Peixoto dos Santos. Este instrumento de recolha de dados visa recolher os dados sociodemográficos dos participantes, informações do estudo e situações inesperadas que ocorram ao longo do estudo. Garante-se o anonimato e rigorosa confidencialidade dos dados recolhidos.

Participante nº: ______

Data da Recolha: _____/____/____

Local da Recolha: ____

Investigador responsável pelo estudo: ________________________________

Dados Sociodemográficos

Sexo: M______ F______ Indiferenciado________
Idade: ______________ Altura (m):____________ Massa Corporal (kg): ______________

Dados Clínicos e Anatómicas

	Dimensões anatómicas	
	Membro Direito (cm)	Membro Esquerdo (cm)
Comprimento do pé (i.e., marcando a distância do calcanhar ao dedo grande)		
Comprimento do fémur (i.e., distância do trocânter maior ao epicôndilo lateral do fémur)		

Comprimento da tíbia (i.e., distância do Maléolo medial ao côndilo medial da tíbia)	
Comprimento total do fémur à tíbia (i.e., distância do Maléolo medial da tíbia ao trocânter maior do fémur)[10]	
Altura da perna (i.e., altura do trocânter maior do fémur)	
Altura da cintura ao pé (i.e., altura *Sacrum*)	

Tamanho de calçado (34 - 50): ________________________
Lado amputação: ☐ Direito ☐ Esquerdo
Nível de amputação: ☐Transtibial ☐ Transfemoral ☐ Outro. Qual? _______________
Tempo de amputação (anos): _____________
Etiologia da amputação? ____
Capacidade funcional (Nível K da Medicare): ☐ K1 ☐ K2 ☐ K3 ☐ K4 ☐ K5
Tempo médio diário de uso da prótese? (Horas) _________________________________
Tratamentos/Cirurgias realizadas: Quais? _____________________________________
Onde? _____________________________________
Medicação: ____
Fraturas: ____
Ocorrência recente de quedas: ____

Dados do Estudo

Estudo Marcha Protética nº: ______

Sistema Sensorial Utilizado*			
GaitShoe		Plataforma da AMTI	
InertialLAB		Trigno™ Avanti (Delsys)	
MyoLAB		3D motion capture (Qualysis)	
Obstacle-Detection		MVN BIOMECH (Xsens)	
k4b2 (COSMED)		respiBAN (biosignalsplux)	

*Assinalar com X

Sistema de *Biofeedback* (se aplicável) *			
Vibrotactile Socket (VT-S)		Vibrotactile Belt (VT-B)	

*Assinalar com X

[10] Pelo lado lateral

Dispositivos Protéticos (se aplicável) *			
Prótese Inteligente (estratégia passiva)		Prótese Inteligente (estratégica c/ sinais EMG)	
Prótese Inteligente (estratégia adaptativa)		Prótese *Standard* Qual? ____________________________	

*Assinalar com X

Situações Inesperadas:

____

____

____

____

ANOTAÇÕES EXPERIMENTAIS

			GaitShoes	**XSens**	**Delsys**	**Kinect**
PARTE I[11]	**A**	Tread0Slow-1				
		Tread0Slow -2				
		Tread0Slow-3				
		Tread0Med-1				
		Tread0Med-2				
		Tread0Med-3				
		Tread0Fast-1				
		Tread0Fast-2				
		Tread0Fast-2				
PARTE II[12]	**B**	FwdGnd -1				
		FwdGnd -2				
		FwdGnd -3				
		ForwdGnd -4				
	C	FwdObs -1				
		FwdObs -2				

[11] Esperados ficheiros na ordem dos 1000 kb
[12] Esperados ficheiros entre 50 a 200 kb

		FwdObs -3				
		FwdObs -4				
	D	FwdIrr-1				
		FwdIrr-2				
		FwdIrr-3				
		FwdIrr-4				
	F	FwdObsVTS-1				
		FwdObsVTS-2				
		FwdObsVTS-3				

Sistema Sensorial	**Localização**	**Dados**
MVN BIOMECH (Xsens)	IMUs colocado nos segmentos inferiores (coxa, canela e pé) e zona lombar	Dados Biomecânicos - Aceleração 3D - Velocidade angular 3D - Ângulos dos segmentos e das articulações - Posição e orientação 3D dos segmentos - Eventos da marcha - Velocidade da marcha - Localização do centro de massa
Trigno^{TM} Avanti (Delsys)	Elétrodos superficiais dispostos sobre músculos dos membros inferiores (*tibialis anterior, gastrocnemius, soleus,*	Dados fisiológicos – EMG - Atividade muscular - Atividade muscular normalizada MVC - Sinal do envelope muscular

	vastus lateralis, bicep femoris/semitendinous)	
GaitShoe	Pés	Dados Biomecânicos - Eventos da marcha - Simetria da marcha - Parâmetros espácio-temporais (velocidade, comprimento do passo e da passada, duração do passo e da passada) - *Foot Clearance*
RespiBAN Professional (biosignalsplux)	Cinta de peito vestível para medição em tempo real do ritmo respiratório	Dados fisiológicos – Custo metabólico - Ciclos respiratórios - Monitorização do ritmo respiratório

Anexos

MVN BIOMECHA (Xsens)

Trigno™ Avanti (Delsys)

RespiBAN Professional (biosignalsplux)[13]

[13] Usar nos protocolos com o sistema VT-S (Estudo 3)

Outros materiais importantes:

1	Protocolo impresso
2	Fichas para protocolo (saudáveis + amputados)
3	Questionários para preeenchimento
4	Consentimento informado para Estudo 1 Padrão ou Estudo 2 Uminho
5	Telemóvel/câmara amadora
6	Obstáculos *handmade*
7	Acessórios extra - velcro, fitas, cola, fita cola grossa, tiras de velcro, cabos USB, fita cola de papel
8	Fita métrica ou fita Xsens
9	Regras de utilização dos sistemas sensoriais