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FEASIBILITY AND VALIDATION OF SAGEMOTION, AN IMU-BASED BIOFEEDBACK SYSTEM FOR GAIT RETRAINING AND MODIFICATION

A COMPARATIVE ANALYSIS WITH OPENCAP ON THE EXECUTION OF GAIT RETRAINING TECHNIQUES

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Abstract

This master's thesis work is the result of six months of research conducted alongside the Human Movement Biomechanics Research Group at the KU Leuven University (Belgium), within a collaboration with the Human Movement Bioengineering laboratory at the University of Padova (Italy).

The aim of this study is to test and validate SageMotion, a new wearable IMU-based haptic feedback system for real-time movement assessment and training; the main goal is to establish SageMotion's suitability as a gait retraining and modification tool for patients affected by knee osteoarthritis.

Knee osteoarthritis (OA) is a chronic degenerative joint disease that affects millions of people worldwide, causing joint stiffness, pain during gait and movement restrictions.
Many studies have highlighted a correlation between a higher knee adduction moment (KAM) and the presence, severity and progression of medial compartment knee OA; for this reason, the KAM is an often investigated biomechanical variable for assessing the disease occurrence and progression.
Among the possible treatments for knee OA, gait retraining has recently emerged as a non-invasive conservative strategy aiming at decreasing joint loading, thanks to the implementation of gait retraining techniques which, through the modification of the patient's gait kinematics, allow a reduction of the KAM.

For this study, a group of four healthy individuals took part to the data collection. Each participant performed three different gait retraining strategies (trunk leaning, toe-in walking and toe-out walking), which were collected simultaneously by SageMotion and OpenCap, the reference system chosen for assessing SageMotion's validity.
OpenCap is a markerless video-based system that enables 3D kinematic and dynamic analysis of human movement using videos captured with iOS devices, which already proved its reliability and suitability for rehabilitation purposes.

After the acquisition, for each analyzed technique the data underwent filtering, resampling and synchronization, in order to make them comparable.
The last step into the data processing consisted of a statistical analysis, which included the root mean square errors (RMSE) and coefficient of multiple correlation (MCM) calculation, a normality assessment for the groups under comparison and the computation of statistical tests, followed by a false discovery rate (FDR) correction for minimizing the rate of false positives. The analysis covered both a inter-subject comparison and a comprehensive overview concerning the whole system's validity, regardless of the distinction between subjects.

The analysis revealed comparable results between the two systems for the trunk leaning strategy, suggesting the system's suitability as a gait retraining tool within this technique.
The most controversial results occurred from the toe-in and toe-out techniques, resulting in highly significant discrepancies between the two systems for the toe-out walking, while suggesting a much better comparability between SageMotion and OpenCap for the toe-in.
This contradictory outcome, together with the lack of an explained calibration procedure, recurrent connection issues during the data collection and imprecise structure of some user apps, led to the conclusion that the SageMotion system, despite its strengths and novelty, still needs to be improved and investigated before being used as a gait retraining and modification tool for patients affected by knee OA.
However, this study provided a first insight into SageMotion's capabilities, highlighting some of its limitations, that could be further analyzed in the future, ideally through a comparison against a gold standard marker-based system.

Sommario

Il presente lavoro di tesi magistrale è il risultato di un progetto di ricerca della durata di sei mesi, svolto presso il gruppo di ricerca di Human Movement Biomechanics dell'Università KU Leuven (Belgio), in collaborazione con il laboratorio di Bioingegneria del Movimento presso l'Università di Padova (Italia).

Questo studio si pone come scopo quello di testare e validare SageMotion, un innovativo sistema di acquisizione indossabile con feedback tattile, per la valutazione e la riabilitazione del movimento in tempo reale; in particolare, l'obiettivo primario è quello di decretare l'adeguatezza di SageMotion come strumento di riabilitazione all'andatura per pazienti affetti da osteoartrite di ginocchio.

L'osteoartrite (OA) del ginocchio è una malattia articolare cronica degenerativa, che colpisce milioni di persone in tutto il mondo, causando rigidità articolare, dolore durante la deambulazione e restrizioni nel movimento.
Molti studi hanno evidenziato una correlazione tra un momento di adduzione del ginocchio più elevato e la presenza, gravità e progressione dell'OA del compartimento mediale del ginocchio; per questo motivo, il momento di adduzione del ginocchio costituisce una variabile biomeccanica spesso investigata al fine di valutare l'incidenza e la progressione della malattia.
Tra i possibili interventi atti a rallentare la progressione e i sintomi dell'OA del ginocchio, la riabilitazione all'andatura (*gait retraining*) è recentemente emersa come strategia conservativa e non invasiva, volta a ridurre il carico articolare, grazie all'implementazione di tecniche di riallineamento dell'andatura che, attraverso la modifica della cinematica della deambulazione del paziente, consentono una riduzione del momento di adduzione del ginocchio (KAM).

In questo studio, un gruppo di quattro individui sani ha preso parte all'acquisizione dati. Ciascun partecipante ha eseguito tre diverse strategie di riallineamento dell'andatura (inclinazione del tronco o *trunk leaning*, camminata *toe-in*, e camminata *toe-out*), che sono state acquisite simultaneamente da SageMotion e da OpenCap, il sistema di riferimento scelto per decretare

l'idoneità di SageMotion.
OpenCap è un sistema di acquisizione *markerless* (non prevede l'applicazione di *markers* riflettenti sul corpo del soggetto), che consente l'analisi cinematica e cinetica del movimento umano servendosi solamente di registrazioni video acquisite con dispositivi iOS, le cui afidabilità e idoneità a scopo riabilitativo sono già state testate e dimostrate.

Dopo l'acquisizione, per ciascuna delle tecniche di riabilitazione dell'andatura analizzate i dati sono stati sottoposti a filtraggio, campionamento e sincronizzazione, al fine di renderli confrontabili.
L'ultimo passaggio nell'elaborazione dati, costituito da un'analisi statistica, includeva il calcolo degli errori quadratici medi (RMSE) e del coefficiente di correlazione multipla (MCM), una valutazione della normalità della distribuzione dei dati per ciascuno dei gruppi confrontati e l'esecuzione di alcuni test statistici, seguito da una correzione *false discovery rate* (FDR) atta a minimizzare il numero falsi positivi nei risultati. L'analisi, dopo un primo confronto intra-soggetto, ha fornito una panoramica completa riguardante la validità del sistema, indipendentemente dalla distinzione tra i soggetti. L'analisi dati ha rivelato risultati comparabili tra i due sistemi per la strategia di *trunk leaning*, suggerendo l'idoneità del sistema come strumento per la riabilitazione all'andatura per quanto concerne questa specifica tecnica di *gait retraining*.
I risultati più controversi sono emersi invece dalle tecniche di *toe-in* e *toe-out*, evidenziando discrepanze altamente significative tra i due sistemi durante l'esecuzione del *toe-out*, e suggerendo invece una discreta comparabilità tra SageMotion e OpenCap per la tecnica di *toe-in*.
Questo risultato contraddittorio, unito all'assenza di una spiegazione dettagliata della procedura di calibrazione, a problemi di connessione ricorrenti durante l'acquisizione dati e a una struttura poco intuitiva di alcune delle *app* previste nell'interfaccia del sistema, ha condotto alla conclusione che il sistema SageMotion, nonostante le sue caratteristiche innovative, necessiti di ulteriori miglioramenti e indagini prima di essere utilizzato come strumento di *gait retraining* per pazienti patologici affetti da OA di ginocchio.
Tuttavia, questo studio ha permesso di fornire una prima panoramica sulle potenzialità di SageMotion, evidenziandone al contempo alcune limitazioni, che potrebbero essere ulteriormente analizzate e migliorate in futuro, preferibilmente in un confronto con un sistema *marker-based*, le cui accuratezza e precisione sono state ampiamente testate e accertate.

Contents

List of Figures

List of Tables

Abbreviations

COP Center of Pressure

COM Center of Mass

HS Heel Strike

TO Toe Off

OA Osteoarthritis

MEMS Micro-Electro-Mechanical Systems

MIMUs Magneto-Inertial Measurement Units

IMUs Inertial Measurement Units

KAM Knee Adduction Moment

GRF Ground Reaction Forces

STA Soft Tissue Artifact

SG Strain Gauge

MMC Markerless Motion Capture

RMSE Root Mean Square Error

SM SageMotion

OC OpenCap

FPA Foot Progression Angle

TSA Trunk Side Angle

FDR False Discovery Rate

CMC Coefficient of Multiple Correlation

SPM Statistical Parametric Mapping

1

Introduction

1.1 Introduction to the study

Knee Osteoarthritis (OA) is a chronic degenerative joint disease that affects millions of people worldwide, especially adults and elderly people.
Aging is considered as the main cause of knee osteoarthritis, but factors such as excessive weight, heredity, gender and repetitive stress can increase the risk of developing osteoarthritis also for younger people. Due to their condition, osteoarthritic patients suffer from pain during gait, joint stiffness and limitation of the range of movement; all these symptoms can affect an individual's daily activities and quality of life [1].
More specifically, the knee's medial compartment is usually affected more often than the lateral one, probably due to the higher loads acting on the medial compartment during gait [2].
Many studies have observed a correlation between a subject's higher knee adduction moment (KAM) (especially the first peak of the curve representing the KAM over time) and the presence, severity, progression and pain caused by medial compartment knee OA. For this reason, the KAM represents a biomechanical variable which is often examined and taken into consideration for assessing the disease progression [2] [3].
There are different possible treatments for knee OA, which should suit the needs and specific condition of the individual. Clinical guidelines and scientific studies provide a comprehensive

overview of the available options [4]. Among the others, rehabilitation is strongly recommended in both national and international guidelines for the management of OA within primary care settings, being emphasized by the OA Research Society International (OARSI) as the cornerstone of OA treatment and advised for all patients [5] [6].
Rehabilitation for OA typically comprises various interventions, such as land-based and water-based exercise therapy, strength training, weight management, self-management and regular physical activity.
Gait retraining has been recently proposed as a non-invasive conservative treatment strategy aiming to address the biomechanical gait dysfunction observed in osteoarthritic individuals. This intervention's main goal is to reduce joint loading and decrease the pain level using different strategies and tools. In particular, in the case of osteoarthritic patients, the main strategy consists in modifying their gait kinematics in order to affect and reduce their KAM.
Several gait modification techniques proved to have an effective influence on the reduction of the KAM; the most common techniques include the lateral leaning of the trunk towards the stance leg during walking (trunk leaning), the modification of the foot progression angle by intra- or extra-rotating the feet during walking (toe-in or toe-out), and the medialising of the knee during the stance phase (medial thrust). These methods are usually employed by a therapist, aiming at helping the patient in changing in his gait pattern through verbal, visual or haptic feedback; in fact, biofeedback is presented by researchers as a promising tool which can be combined with gait retraining, providing the patients with real-time data regarding their gait patterns, helping them to adjust their gait in a faster and easier way [7].
In order to acquire gait data from the patients, the gold standard solution is represented by optical marker-based motion capture (MoCap). This technology employs reflective markers placed on the subject's body in order to track his movements in three-dimensional space. Multiple cameras record the markers' positions in real-time, providing highly detailed and accurate data.
Despite the high accuracy, as a drawback these systems limit the subjects to the controlled laboratory environment, they're very expensive and the maintenance of an accurate calibration is challenging.
In order to overcome the need for a laboratory environment, several methods were developed for motion analysis; a promising approach is represented by inertial measurement units (IMUs)

wearable sensors: they combine accelerometers, gyroscopes, and magnetometers, providing real time information on the subject's movement. IMUs employment is increasing due to their low production costs, small size and weight and portability, which allows to acquire data in any environment [8].

The purpose of this thesis project is to test and validate SageMotion, a new wearable IMU-based haptic feedback system for gait retraining and modification, that aims at providing biofeedback based on IMU data, verifying the feasibility of the feedback for adjusting individual gait patterns [9].
This goal translates into a comparison between SageMotion and OpenCap [10], an open-source software which enables 3D kinematic and dynamic analysis of human movement, through the use of videos captured with *iOS* devices. OpenCap combines computer vision, machine learning and musculoskeletal simulation to provide a cost-effective and accessible alternative to traditional motion capture systems. As its strength, it's already been validated [11] against the gold standard stereophotogrammetric MoCap (motion capture) acquisition systems, which makes it a suitable solution for the comparison with SageMotion in this study.
The key aim is therefore to conduct a meaningful comparison regarding the acquisition of different gait retraining strategies between the two systems, in order to assess SageMotion's accuracy and precision, which would verify its suitability as a wearable biofeedback system for gait retraining and modification for patients affected by knee OA.

1.2 Thesis Outline

Chapter 1 of this thesis provides an introduction to the study, aiming to describe the work and define its objectives.

Chapter 2 presents and examines the background information necessary to understand the development of the project, going deep into the topics of human motion analysis, gait analysis, motion capture instrumentation and gait retraining techniques; moreover, this chapter provides a detailed introduction to SageMotion and OpenCap, the two acquisition systems employed for the data collection.

Chapter 3 portrays a description of the participants involved in the study, and underlines the methods and materials employed during the data collection; moreover, it goes through the steps of the data processing and statistical analysis.

The results of the study are outlined in Chapter 4, where they're divided into three sections: Trunk Leaning results, Toe-in results and Toe-out results.

Chapter 5 provides a comprehensive discussion regarding the obtained results, also comprising an analysis of the limitations of the study, and possible future developments.

Finally, Chapter 6 consists of an overview of the thesis work, summarizing the achievements reached and including some final statements.

2

Movement analysis and gait retraining

2.1 Introduction to human motion analysis

Human motion analysis is a discipline that aims to obtain information regarding the movement of individual selected points, anatomical segments, joints, muscles, and the entire human body during the execution of specific predetermined tasks [12].
More specifically, we can distinguish kinematic analysis, which deals with the movement of a body in space and time without considering the causes that determine it, regardless of forces, and kinetic analysis, which instead investigates the cause that generates a specific movement and therefore takes into account all the forces and moments involved.

2.1.1 Reference systems

Kinematically describing the motion of a body means defining, at each instant, the position and orientation of an anatomical segment during the execution of a specific motor task [12].
In order to describe the motion of a body in motion analysis, it's essential to rely on the rigid body assumption. A rigid body is a body whose points move while maintaining unaltered distances relatively to a fixed observer. By observer, we mean an orthogonal Cartesian system

with a fixed orientation, and generally the laboratory's global reference system is considered as the fixed observer. It's also necessary to introduce a local reference system, attached to the moving body; with these assumptions, the rigid motion problem consists at defining, at each instant, the relative position of the local reference frame with respect to the absolute one of the laboratory. Motion analysis and the description of the examined quantities is therefore depending on the identification of appropriate reference systems. We can then introduce, in order to associate the anatomical segments with a reference system, the so-called "anatomical planes", three orthogonal imaginary planes, each one, as shown in [Fig. 2.1], dividing the human body into two parts:

- Sagittal plane: divides the human body into right and left part;
- Coronal plane: divides the human body into anterior and posterior part;
- Transverse plane: parallel to the ground, divides the human body into upper and lower part.

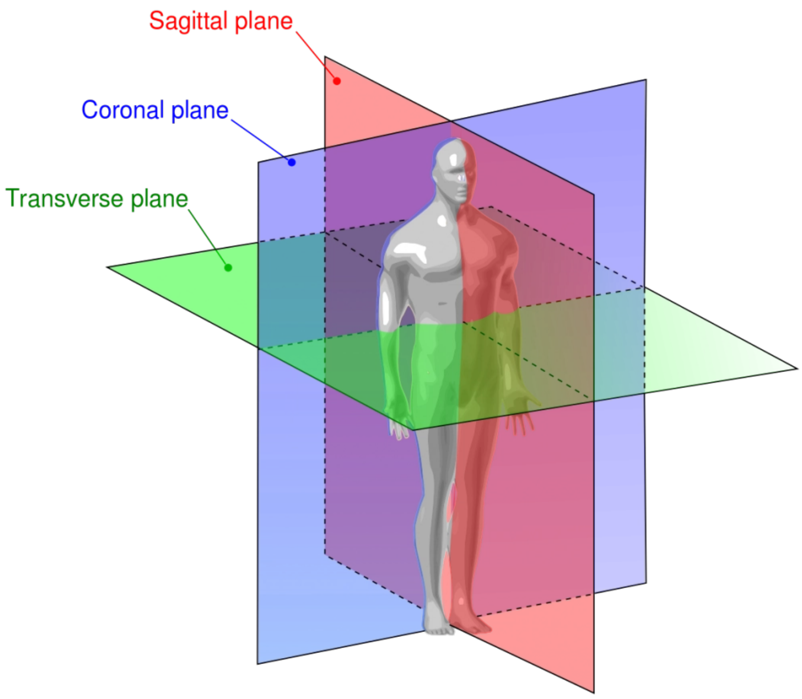

Figure 2.1: Anatomical reference planes

Referring to the above-described reference planes, internal and external rotation movements occur on the transverse plane, abduction and adduction movements occur on the coronal plane, and flexion-extension movements of the joints occur on the sagittal plane.

2.2 Gait analysis

Postural and movement analysis are practices of great scientific interest; posture and movement result from the interaction of different physiological systems, more specifically the musculoskeletal system and the nervous system.
The activity of walking is characterized by a cyclic motor activity pattern of the lower limbs and trunk, which allows to transfer the body weight onto the supporting limb and to move forward the contralateral limb [12]. Therefore, gait analysis, or computerized gait analysis, is a fundamental step within movement analysis in order to obtain a spectrum of information that accurately maps a subject's gait patterns.

It's important to underline that the analysis of postural and movement alterations can provide fundamental information in order to understand how restrictive a particular pathology can be at the motorial level, and how it may change over time. Moreover, in the rehabilitation field, gait analysis can be effective in assessing the feasibility of any interventions. Jacqueline Perry, physicist and researcher, one of the pioneers of movement analysis in clinical settings, and author of the reference text for clinical biomechanics enthusiasts [13], defined the process of walking as follows:

A series of rhythmic movements of the lower limbs, upper limbs, pelvis, and trunk that, by causing a forward displacement of the center of gravity, produces, through a series of translations and rotations of the bony segments and the joints involved, the forward movement of the body [13].

In order to carry out the locomotion process, it's necessary for the subject's body to exert an antigravitational function in order to counteract the oscillations of the center of gravity and maintain an upright position; furthermore, the subject must maintain balance and take steps, and in order to do this, the presence of a propulsive means in which it can move is also necessary.

2.2.1 The gait cycle

The period between two consecutive heel strikes of the same foot is defined as the ”gait cycle”. It represents the reference functional unit in gait analysis. The gait cycle is defined as a periodic cycle involving both lower limbs. During walking, the limbs repeat a sequence of movements that allow the center of pressure Center of Pressure (COP), which represents the ground projection of the body’s center of gravity, to shift from one foot to the other alternatively, in order to maintain dynamic balance [12]. Referring to one of the lower limbs, the most basic way to analyze the walking activity is to divide the gait cycle into two phases:

- *Stance phase*, or support phase, during which the foot of the reference limb remains in contact with the ground. In healthy deambulation, it occupies approximately the first 60% of the gait cycle. The stance phase can be further divided into:
  - *Double support*, the period during which the foot of the contralateral limb is also in contact with the ground. It occurs twice during the gait cycle: at the beginning and at the end of the support phases.
  - *Single support*, during which only the reference foot is in contact with the ground, corresponding to the swing phase of the contralateral limb.

  In healthy walking individuals, the first contact with the ground is made by the heel, and for this reason the starting point of the gait cycle (0%) is defined as Heel Strike (HS). The end of the stance phase, corresponding to the beginning of the swing phase, can be defined as the Toe Off (TO), the moment in which the foot leaves the ground.
- *Swing phase*, during which the reference foot lifts off the ground in order to advance. In a healthy subject, it represents the remaining 40% of the gait cycle.

More specifically, it’s possible to identify 8 phases during the gait cycle [12] [Fig. 2.2]; each of them has a specific functional objective and is characterized by a synergic movement pattern to be executed. The sequential combination of these phases allows the limb to perform three basic tasks: load acceptance, single support, and limb advancement.

- Load acceptance constitutes the first 10% of the gait cycle, and includes two phases:
  Initial contact , where the forward-projected foot makes contact with the ground; the knee is extended, the hip is flexed, and the ankle is dorsiflexed).
  Loading response, where heel the heel rolls and the weight is transferred onto the supporting limb, bringing the forefoot closer to the ground with consequent plantar flexion of the ankle and knee flexion.

- Single support occupies the period which goes from 10% to 50% of the cycle, consisting of two phases: *midtsance* (10-30% of the cycle, involving dorsiflexion of the ankle allowing the limb to advance beyond the supporting foot, and extension of the knee and hip) and *terminal stance* (30-50% of the cycle, where the heel lifts and hip extension allows limb advancement; the forefoot rolls and the initially extended knee flexes slightly)

- Limb advancement constitutes the remaining 50% of the gait cycle and can be divided into 4 phases:
  Pre-swing (50-60% of the cycle, contralateral limb begins the double support, while the reference limb increases plantar flexion of the ankle, the knee flexion increases, and the hip extension decreases);
  Initial swing (60-73% of the cycle, the foot is lifted and the limb advances, the hip and knee are flexed, and the ankle is partially dorsiflexed);
  Mid-swing (73-87% of the cycle, the hip flexes, the tibia continues the dorsiflexion, the knee extends due to gravity, and these movements cause the swinging limb to advance beyond the gravity line);
  Terminal swing (87-100% of the cycle, begins when the tibia is vertical; limb advancement is completed, the knee extends, the hip returns to the initial flexion, the ankle remains dorsiflexed until reaching a neutral position, and it ends when the foot touches the ground again).
  In each of these phases, the contralateral limb acts opposite to the ipsilateral limb (reference limb).

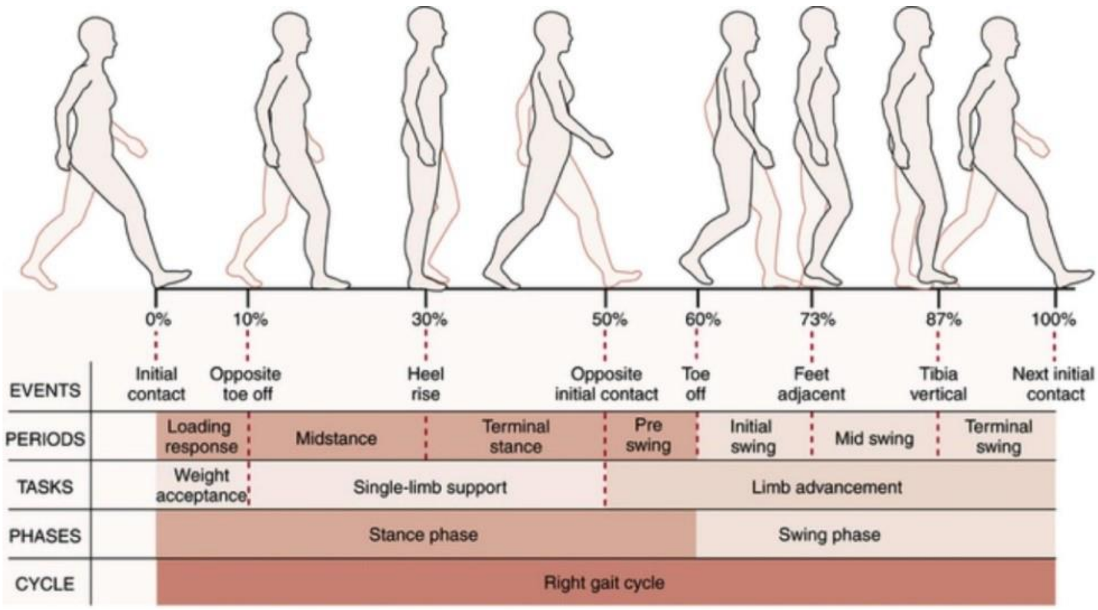

Figure 2.2: Phases of the gait cycle

2.2.2 Gait parameters

There are some significant instants identified within the gait cycle, that can be useful for calculating some parameters used in gait analysis in order to describe a subject's walking pattern. These instants include, for example, the HS, defined as the minimum vertical position of the heel, and the TO.

By knowing these instants, it's possible to calculate space-time parameters related to the gait cycle. The main temporal parameters include:

- Step duration [s]: the time interval between two heel-strikes of the same foot;
- Stance phase duration [s or % of step duration]: the time interval between heel strike and toe-off of the same foot;
- Swing phase duration [s or % of step duration]: the time interval between the toe-off and the subsequent heel strike of the same foot;
- Double support duration [s or % of step duration]: the time interval between the contralateral heel strike and the toe-off of the first foot.

The spatial parameters include:

- Stride length [m or % of subject's height]: the distance travelled by the heel in the walking direction between two successive heel strikes;
- Step width [m]: the distance between the right and left heels in successive steps, measured perpendicular to the walking direction.

Starting from these parameters, other derived measures can be obtained, such as:

- Walking speed [m/s or % of subject's height/s]: step length divided by step duration;
- Cadence [steps/min]: the number of steps at the minute.

2.2.3 Gait retraining strategies

Knee OA is a major cause of pain and physical disability. OA is the most common joint disorder worldwide, with symptomatic knee OA expected to rise due to population aging and the obesity epidemic. This condition affects all three compartments of the knee joint (medial, lateral, and patellofemoral), with a prevalence of the medial compartment (which is subjected to higher compressive loads), leading to limitations in daily activities. Initially perceived as a degenerative *wear-and-tear* disease only associated with aging, it is now recognized as multifactorial, with contributing factors including genetics, age, obesity, diabetes, systemic inflammation, lower limb alignment abnormalities and traumas. Regardless of the origin of the disease, OA is characterized by cartilage damage, subchondral bone sclerosis, and, in advanced stages, subchondral cysts, which lead to pain, stiffness and impaired movements. [14]
The external KAM has been proved to be a strong predictor of the presence, severity and rate of progression of knee OA. [15]
The KAM is calculated as the product of the Ground Reaction Forces (GRF) generated by the foot-ground interaction and the perpendicular distance in the frontal plane between this force vector and the knee center of rotation, also known as its lever arm. The KAM creates a tendency for the tibia to rotate inwards, such that a larger KAM concentrates higher compressive

loads on the medial tibiofemoral compartment. This uneven distribution of the loads imparted on the tibiofemoral joint due to KAM can be responsible for the higher prevalence of medial compartment knee OA.

The KAM typically exhibits 2 peaks during the stance phase of gait, that correspond to the peaks in the vertical GRF [Fig. 2.3]. The larger initial peak occurs during the load-acceptance phase of gait, and the second peak occurs in late stance. A higher first peak in KAM has been previously reported in patients with medial compartment knee OA. [16]

For this reason, the KAM is a biomechanical variable which is often investigated in order to evaluate the disease progression. [3]

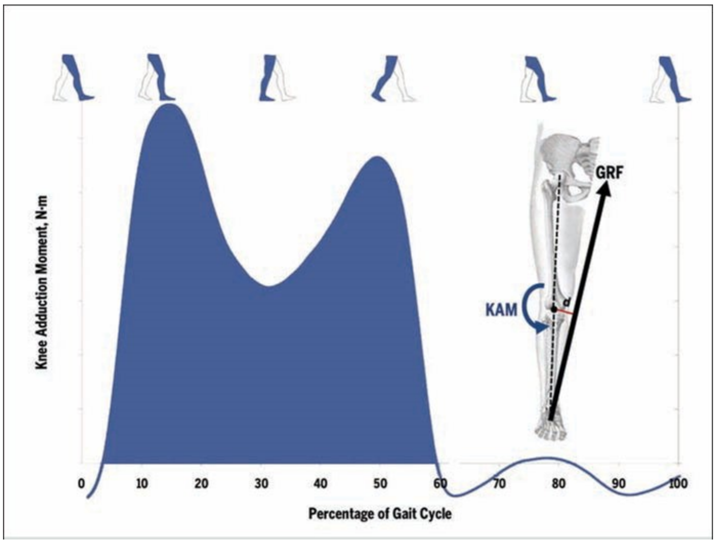

Figure 2.3: Schematic representation of the KAM during gait

Gait retraining is a conservative intervention which has recently been proposed as a non-invasive treatment strategy aiming to address biomechanical gait dysfunction experienced by individuals with osteoarthritis. The main goal of gait retraining is to reduce joint loading and decrease the pain level using different strategies and tools. In particular, in the case of osteoarthritic patients, it can be used for modifying their gait kinematics in order to reduce the KAM.

Several gait modification techniques have been tested and shown to effectively reduce the KAM; the most common techniques include leaning the trunk in the direction of the stance leg (trunk leaning), medialising the knee during the stance phase (medial thrust), and modifying the foot

progression angle (toe-in or toe-out) [17]; in particular, the Foot Progression Angle (FPA) is defined as the angle between the line from the calcaneous to the second metatarsal and the line of progression averaged from heel strike to toe-off during the stance phase of walking for each step (the toe-in angle is conventionally considered to be positive, while the toe-out angle is negative) [18].
These methods are usually employed by a therapist, and help the patient to make changes in his gait through verbal, visual or haptic feedback. In fact, research suggests biofeedback to be a promising tool used to complement gait retraining, since it provides individuals with real-time data on their gait patterns, and helps them to make the necessary adjustments more easily and faster [7].

2.3 Motion Capture instrumentation

Modern laboratory motion analysis systems often consist of multiple interconnected instruments, each aimed at investigating a specific aspect of movement itself.
These systems can be used alone or combined, and they can provide a detailed analysis of movement and gait, which is essential for the diagnosis and treatment of many disease conditions related to posture and movement.

In order to perform motion analysis, different types of instrumentation can be used, including:

- Stereophotogrammetric systems: these systems measure the three-dimensional coordinates of anatomical landmarks on the subject using markers;
- Force platforms: these platforms measure the interaction forces between the subject's foot and the ground;
- Pressure sensors: these systems measure the distribution of pressure from the subject's foot on the ground; they can be pressure platforms or pressure insoles;
- Electromyographs: these devices measure the electrical potentials developed in a muscle during contraction using different types of electrodes;

- Inertial Measurement Units (IMUs) wearable sensors: these systems provide information about angular velocities and linear accelerations using accelerometers and gyroscopes.

Within this research project, stereophotogrammetry and force platforms are going to be further investigated, as they represent the gold standard techniques; moreover, IMU wearable sensors' functioning is also going to be explained in detail, since IMUs constitute the basic components of the SageMotion system.

2.3.1 Stereophotogrammetry

Optoelectronic stereophotogrammetric systems exhibit high accuracy in the measurement of human motion kinematics, and are regarded as the gold standard when compared to other motion capture systems [19].
A stereophotogrammetric system [fig. 2.4] refers to a system with two or more cameras equipped with infrared sensors, positioned at known points in the laboratory space. By using the two-dimensional local coordinates of a point on the image plane of each camera, it's possible to process the information obtained through a method called *triangulation*, resulting in 3D trajectories [12].

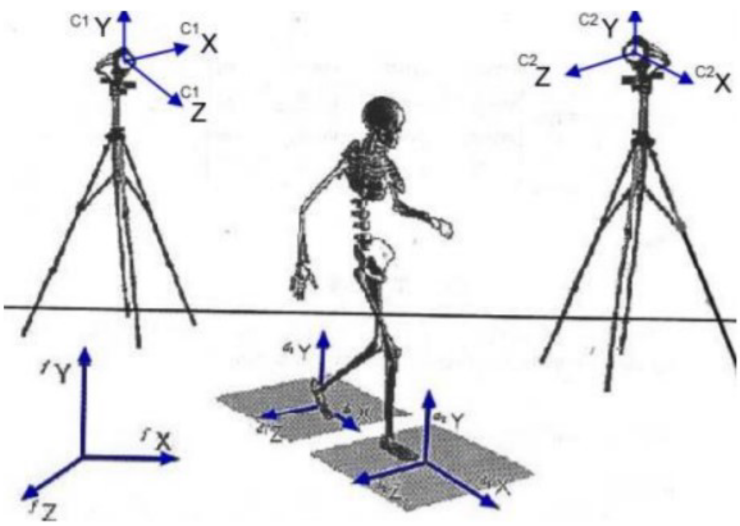

Figure 2.4: Optoelectronic stereophotogrammetric system

This process involves the application of two algorithms: the first is *thresholding*, which retains data from stuff coated with infrared-reflective material, calculating the centroid of points corresponding to pixels with values exceeding a certain threshold. The second is *blob analysis* (where *blob* refers to groups of pixels in an image with shared properties): through this algorithm, it's possible to retain data from spherical objects named *markers*, coated with infrared-reflective material placed on specific points on the subject's body.

Markers can be of two different types: active diodes emitting infrared light, or passive, spherical markers which reflect infrared light; spherical passive markers, made from plastic and coated with reflective film, are most used due to their geometry, that ensures accurate and complete visualisation.

Knowing that the marker's projection occupies an ellipsoidal area on the image plane of the cameras, it's possible to calculate the centroid. In order to align the trajectories of the markers with their projections on the image planes of the individual cameras, and then use the *triangulation* procedure, it's also necessary to assume that the camera can be approximated by a *pin-hole* model. This model assumes that all optical rays contributing to the formation of the image pass through a single point, known as the projection center [12].

A crucial step to be carried out before each acquisition, in order to obtain accurate measurements in stereophotogrammetry, is the calibration of the system, which involves measuring and recording the geometric properties of the cameras, such as intrinsic parameters (lens distortion) and extrinsic parameters (position and orientation of the cameras with respect to a global coordinate system). This ensures that the coordinates of the same point, expressed on the image planes of two or more different cameras, are expressed with respect to the same reference system.

Despite its reliability, this technique presents some limitations [20] [21]; it's really expensive, it requires a laboratory environment to be performed, the application of the markers onto the subject's body is time-consuming and requires expertise to be performed, and the calibration needs to be very accurate.

Moreover, the precision and accuracy of the reconstructed kinematics can be affected by three different types of errors:

1. Instrumental errors: errors related to the system, they can be both *systematic* (for example, related to an inaccurate calibration procedure, or a wrong choice of the model parameters)

or *random* (for example, related to the electronic noise, *flickering*);

2. Incorrect marker placement on the anatomical reference points: the identification of the anatomical landmarks can be challenging and imprecise;

3. Soft Tissue Artifact (STA): it's the most critical error source in terms of markers' trajectory reconstruction; it's caused by a relative sliding between the marker and the underlying bone, due to the presence of skin, muscles and adipose tissue.

2.3.2 Force platforms

The study of human movement aims to obtain precise and quantitative information not only in terms of the kinematics, but also on the kinetics of these movements. The human body operates under the influence of internal forces generated by muscular actions, respecting joint constraints, while also experiencing external forces exchanged between the body and the environment.
Force platforms, also known as dynamometric platforms, are devices consisting of an instrumented platform that allows for the measurement of ground reaction forces when a subject applies weight to them. The platforms can measure the three components of ground reaction force and the three components of moments along the three coordinate axes, thus providing six outputs [fig. 2.5]; additionally, the use of force platforms enables the estimation of the COP, which is the point of force application. Each platform comprises 4 triaxial load cells at the four corners, and each cell has three transducers, each one aiming at detecting one of the three force components [12].

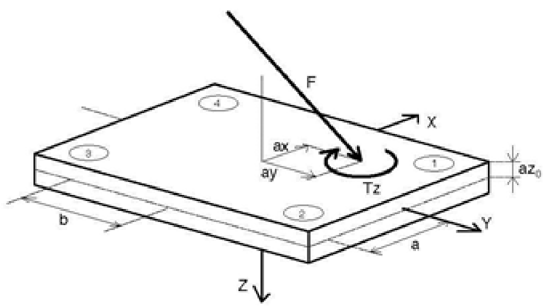

Figure 2.5: Force platform

The two most commonly used types of transducers are:

- Strain Gauge (SG): Forces and moments are measured using SG associated with four load cells placed near the four corners of the platform. The cells consist of an insulating layer and a measuring grid to which the strain gauges are bonded, converting elongation or compression into a change in the electrical resistance. Since the induced variations are often minimal, additional circuits are generally required in order to amplify the resistance variations. The most commonly used circuit configuration in a load cell is called a ”Wheatstone bridge”. The operating principle of the strain gauge sensor is presented in [fig. 2.6].

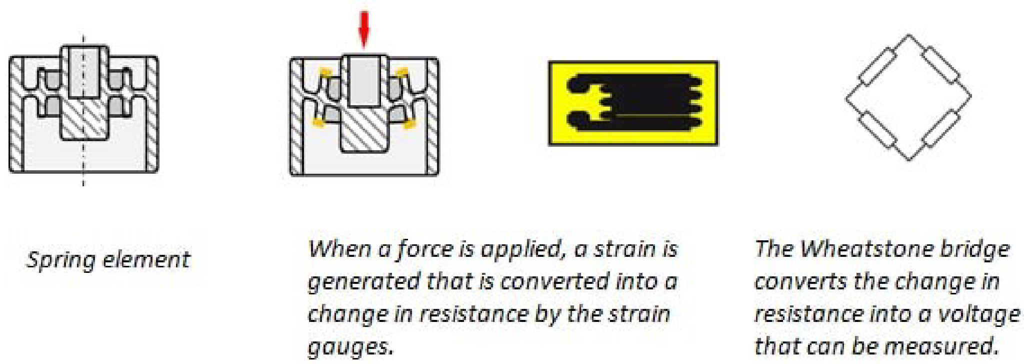

Figure 2.6: Strain gauges working principle

- Piezoelectric sensors: piezoelectric sensors consist of crystals of piezoelectric materials, which change their orientation in response to stress variations, thereby generating an electric charge proportional to the mechanical stress. Usually, a charge amplifier is used to make the variations measurable (typically in a range of 0-10V). Platforms with piezoelectric sensors have the advantage of being able to measure a wide range of force values; however, they are subject to drift for prolonged static loads, meaning that when applying a constant force, after a certain period of time, no change in orientation is detected. Therefore, strain gauge platforms are generally preferred in posturography, while piezoelectric sensor platforms are preferred for dynamic measurements at high frequencies.

2.3.3 Inertial Measurement Units (IMUs)

As already explained, despite being to date the most accurate motion capture system, optical stereophotogrammetry needs sophisticated calibration, it's space-limited, expensive and not easy to deploy, since it needs the use and application of markers; moreover, it's also easily affected by occlusion and the presence of reflective objects [19].
Micro-Electro-Mechanical Systems (MEMS) inertial sensors, also known as IMUs, are an increasingly popular and widespread technology for movement analysis and training, due to their low cost, customization, flexible application, and comfort in wearing. IMUs have the capability to capture motion in the three planes of space. This technology generally puts together two different types of sensors, accelerometers and gyroscopes, eventually associated with magnetometers (in this case Magneto-Inertial Measurement Units (MIMUs)).
The complementary information of acceleration, angular velocity, and magnetic field can be exploited by means of a sensor fusion algorithm in order to estimate the absolute orientation and displacement of the MIMU (and the body segment which it's attached to) [22].
Thanks to their small size and portability, these sensors are proving to be an optimal option for human motion analysis, and more specifically for gait analysis.
The purpose of inertial sensors is to translate a physical phenomenon, inertia, into a measurable signal.

Accelerometers can measure linear acceleration along their sensitive axis [23]. The general principle they are based on is a mass-spring-damper system; more specifically, a known seismic mass (which generates the inertial force) is coupled to a spring, which induces a kinematic movement in the mass, oscillating along an axis (called the sensitivity axis); furthermore, there must be a damper to obtain favorable frequency response values, and a method to convert the mass displacement into an electrical output.
Accelerometers can be single-axial, as described above, or triaxial; in the latter case, they allow the reconstruction of linear acceleration values along the three axes x, y, z, although it is important to avoid cross-talk phenomena between the different axes.
There are three common types of accelerometers: piezoelectric, piezoresistive, and capacitive.

Gyroscopes generate and measure angular acceleration values; more specifically, they exploit

the Coriolis acceleration phenomenon to estimate angular acceleration. The gyroscope rotates around the y-axis perpendicular to the x-axis around which a mass rotates; in this way, an angular momentum around z is generated, which is measured with a force or torque sensor.
MEMS gyroscopes do not have rotating parts and measure acceleration through the Coriolis force, an apparent force to which a body is subjected when its motion is observed from a reference system that is in circular motion with respect to an inertial reference system. In this situation, the observer, located in the rotating reference system, sees the object moving with a curved trajectory.

The combination of the different elements results in IMUs, which consist of three accelerometers, three gyroscopes, a battery, an hardware for data processing, and a small box acting as a container.
Typically, a magnetometer is also added to the system, because the obtained measurements are often subjected to drift, meaning that the trajectory of the sensor's position, due to the Earth's magnetic field, turns out to be curved and non-linear. The magnetometer allows detecting the offset due to the magnetic field and subtracting it from the obtained measurements. With the addition of the magnetometer, we speak of MIMUs. This technology presents some great advantages: their small size, light weight and portability, in addition to their ability to provide real-time measurements, makes them an suitable solution for various acquisition environments. Moreover, compared to traditional motion capture systems, they're less influenced by occlusion, and, since they can be directly attached to the body or clothing, they allow the subject's movements to be more natural and unrestricted, which makes IMUs not only ideal for rehabilitation, but also in the world of sports and biomechanic research.
However, it's important to know that this technology also presents some drawbacks [22]: first of all, they can be subjected to drift, which consist in a progressive misalignment of the sensor over time, which can cause errors in the estimation of the sensor orientation, and the magnetometer's measurements can be affected by ferromagnetic disturbances. In addition, IMUs require a careful and time-consuming calibration, and they can present some errors due to limited accuracy, repeatability, sensitivity to the magnetic field interference, and integration (errors can accumulate while integrating acceleration in order to obtain velocity and position).
Overall, wearable inertial sensors represent a suitable solution for tracking the movement of the

human body, especially when conventional gait analysis is too expensive, or the analysis needs to be carried out of the laboratory environment. [24]

2.3.4 Markerless motion capture

Markerless Motion Capture (MMC) is a technique which is still not fully recognized as an application in clinical settings. There are various approaches to it, and the one which will be here explained, called *Visual Hull Based Markerless Motion Capture*, represents one of the few whose clinical applications are recognized, since it's been validated against a stereophotogrammetric system. [25]

It's based on the premise that it's possible to reconstruct human movement without using markers, which would overcome some of the limitations related to the use of the gold standard optical stereophotogrammetric technique: it's time-consuming, expensive, it can introduce errors due to STA, and needs a laboratory setting; MMC aims to reconstruct motion, using non-invasive measurements of body segments kinematics through video sequences of the subject taken from multiple views, acquired synchronously, and with each camera calibrated to the same calibration object.

This methodology is very advantageous because the subject can perform a "natural walk" without perceiving the encumbrance due to marker application. Furthermore, markerless technique allows for acquisitions even in uncontrolled environments, such as outside and even underwater.

The procedure of Visual Hull MMC involves retaining only the silhouette of the subject from the visible image, and then projecting and assembling the shapes from individual views. It's also necessary to create a model, which will then be tracked by the dynamic visual hull.

There are two methods in order to create a model: the optimal method acquires the volume of the subject with a body scanner and then assimilates each body segment to a known solid, in order to obtain the anatomical axes and position the joint centers; the non-optimal method, due to the lack of a body scanner, acquires a static visual hull of the subject in the laboratory; subsequently, using machine learning algorithms, for each acquired visual hull, it searches a database (which contains laser scans performed on various subjects) for the model which is the most similar to the one found in static, which already contains the anatomical axes. Static acquisitions are then

associated with dynamic visual hulls frame by frame.
Obviously, this technique needs to be validated through synchronous acquisition with a stereophotogrammetric system. Based on the offsets identified between markerless and marker-based acquisitions, whose acceptability needs to be evaluated considering the range of motion of each joint, it can be concluded that markerless technique can be used to reconstruct hip, knee, and ankle angles for the sagittal plane, while its use must be excluded for the coronal and transverse planes [25].

2.4 Haptic wearables and SageMotion

Haptic wearables can be defined as untethered, ungrounded body-worn devices that interact with the subject's skin, directly or through clothing, and can be used in natural environments outside a laboratory.
The clinical interest in the haptic wearables area is progressively increasing; in fact, depending on the level of impairment of a subject (total impairment, partial impairment or no impairment), haptic wearables can act, respectively, as sensory replacement, sensory augmentation or trainers [26] [Fig. 2.7].

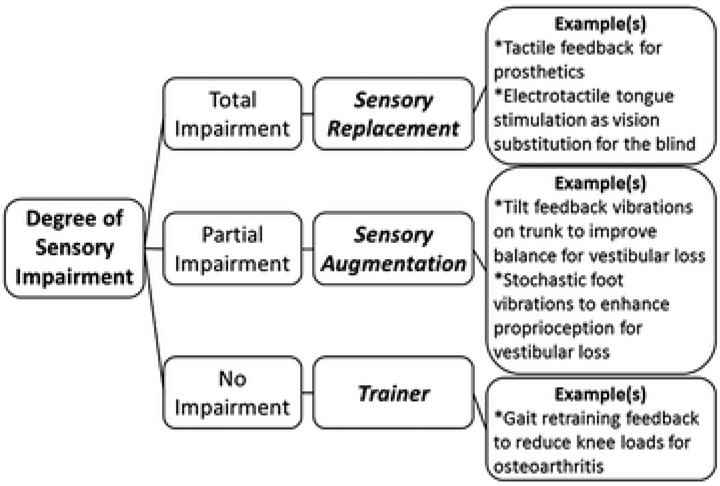

Figure 2.7: Haptic wearable applications classified by degree of sensory impairment

Focusing now on the area of rehabilitation and the use of haptic wearables as trainers, they can train human motion by stimulating mechanoreceptors in the skin; they can be applied across multiple locations on the body, in order to simultaneously train one or more movement parameters.

One of the applications of haptic wearables allows to reduce knee loads by providing information directly to the subject, allowing him to self-select a new gait pattern. This solution, which can be effective in short-term, as a drawback risks to make the subject adopt gait patterns that could be awkward and difficult to maintain long-term.

Another approach which overcomes this issue is to explicitly train gait kinematics in order to reduce knee loading. In two studies carried out by Shull et al. [27] [28], vibration pulses on the lateral shank, just below the knee, have been used with the aim of training individuals affected by knee OA to internally rotate their toes, resulting in reduced knee loading and reduced knee pain over time.

Another solution that has been tried is the training of multiple kinematic parameters simultaneously [29], which could present challenges in terms of cognitive and motorial processing, due to the need to respond to multiple streams of information simultaneously. Lurie et al. [30] conducted a study where subjects were trained to adjust different gait parameters, such as trunk sway, tibia angle and foot progression angle, and they either received error correction feedback on all parameters simultaneously or one parameter at a time. Results showed that perception accuracy was lower when all three feedback cues were given simultaneously, but surprisingly, the subject performance was similar regardless of receiving all feedback simultaneously or one feedback parameter at a time, despite the latter scenario transmitting less feedback information.

Although haptic wearables' primary target was addressing existing issues, there's also a shift towards preventive medicine, which could allow a greater impact on clinical applications. For example, in knee osteoarthritis, tactile feedback has already been proved to be effective in re-training gait patterns to reduce knee loads, potentially slowing down the progression of the osteoarthritis. Moreover, haptic wearables could also be used to correct sitting posture to forestall back and neck injuries, as well as refining athletic movements to mitigate risks of ligament tears or bone fractures. This shift towards prevention could significantly enhance the depth and impact of the use of haptic wearables in the healthcare field.

SageMotion [9] is the first wearable haptic feedback system with full customization and open algorithm code, for real-time movement assessment and training. As previously explained, the use of haptic biofeedback represents a powerful solution in order to train human movement, by stimulating one or multiple body locations, with the aim of training one or more movement parameters.
As its strength, SageMotion is a wearable and portable system, which eliminates the need for a laboratory environment; moreover, the use of haptic biofeedback instead of visual or auditory feedback allows the system not to interfere with the visual/audio information input that are usually necessary for rehabilitative movement sessions. In addition, the customization allows to perform subject-specific research for a specific movement training application; SageMotion sensors can be placed in any configuration across any location of the human body, which also allows to use just the necessary number of sensors, without being forced to wear a full body suit or a complicated configuration of unnecessary sensors.

SageMotion System The system is composed by 8 (or 16) nodes, one wifi Hub to which the nodes get connected, a battery, 14 node straps with three different lengths for fixing the nodes to the body, two cables for connecting the hub to the battery (or the laptop) and charge the sensors, and a node charging station [Fig. 2.8].

Figure 2.8: SageMotion system's components

Each node contains a MIMU, and can perform both sensing and vibrating biofeedback.
The sampling rate of the nodes is 100 Hz, their size is 58 x 38 x 19 mm, and the weight is 43 g.
SageMotion interface software is fast and easy to use, it's supported on *Windows*, *Mac*, *Linux*, *iOS* and *Android*, and the output measures given during the data collection depend on which App the user decided to select for that specific acquisition. In fact, the system provides plenty of different Apps that can measure and train different parts of the human body.
The Apps that were used in this research work were:

- *Standing Balance Trunk Side Angle App*: measures and trains trunk side angle during walking.
- *Walking Foot Progression Angle App*: measures and trains foot progression angle during walking.

2.5 OpenCap

OpenCap is an open-source, video-based and web-based software presented in 2023 by a research group from Stanford University, Stanford, California, USA, which allows to obtain both 3D kinematics and dynamics of human movement, by using videos captured with at least two *iOS* devices (*iPhone, iPad or iPod*).
OpenCap allows movement analysis to become widely available without specialized hardware, software or expertise, through the combination of computer vision, machine learning and musculoskeletal simulation.
Compared to the gold standard marker-based stereophotogrammetric motion capture, the system presents an important reduction in terms of cost, time of the acquisition, and expertise barriers for the movement analysis, as shown and explained in the figure below [fig. 2.9]. In fact, OpenCap allows to obtain musculoskeletal dynamics data in less than 10 minutes of hands-on time, with an equipment worth less than $700, which is 200 times cheaper than traditional motion capture laboratory equipment, and it does not require a dedicated laboratory space. Moreover, the system can be used almost anywhere, since it just requires a working internet connection and a minimum of two *iOS* devices.

The experimental setup for an OpenCap data acquisition just requires the use of a device for running the OpenCap web application, two tripods in order to fix the *iOS* devices, and a printed calibration checkerboard provided on the OpenCap website [10]. After pairing the devices to the application, the user is guided through the calibration, the data collection and the visualization of three-dimensional (3D) kinematics.

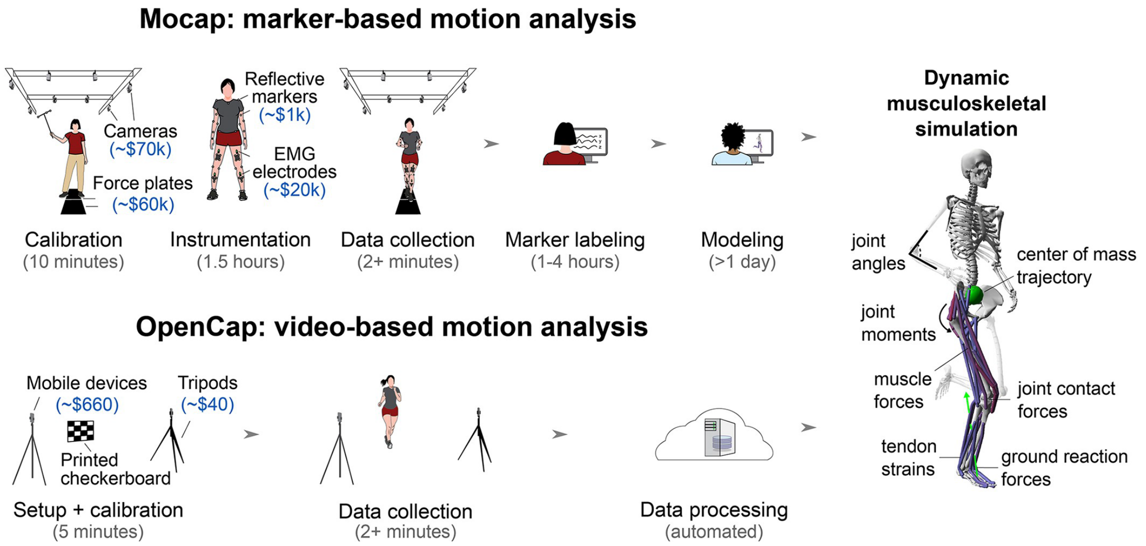

Figure 2.9: Marker-based motion capture (Mocap) vs. video-based (OpenCap) analysis of human movement dynamics

The OpenCap system includes a smartphone application, a web application and a cloud computing; in order to obtain kinematic data, the user must link the smartphone application on the *iOS* devices to the OpenCap web application on a laptop, which allows to visualize the three-dimensional (3D) kinematics simultaneously to the video recording on the iOS devices. In the cloud, 2D keypoints are obtained from the multi-view videos through an open-source pose estimation algorithm, and subsequently synchronized and triangulated in order to obtain 3D keypoints. With the use of two long short-term memory (LSTM) networks, starting from the position of the triangulated video keypoints, it's possible to predict the position of 43 anatomical markers, corresponding to the ones commonly used in marker-based motion capture, in order to determine more precisely the 3D joint kinematics.

OpenCap uses the anatomical markers' position to scale the subject's anthropometry through

OpenSim's Scale tool, by using the musculoskeletal model from Lai et al. [31], which comprises 33 degrees of freedom. After the scaling, it's possible to compute joint kinematics through the OpenSim's *Inverse Kinematics* tool; finally, OpenCap estimates dynamics using tracking simulations of joint kinematics. All the process is resumed in [fig. 2.10].

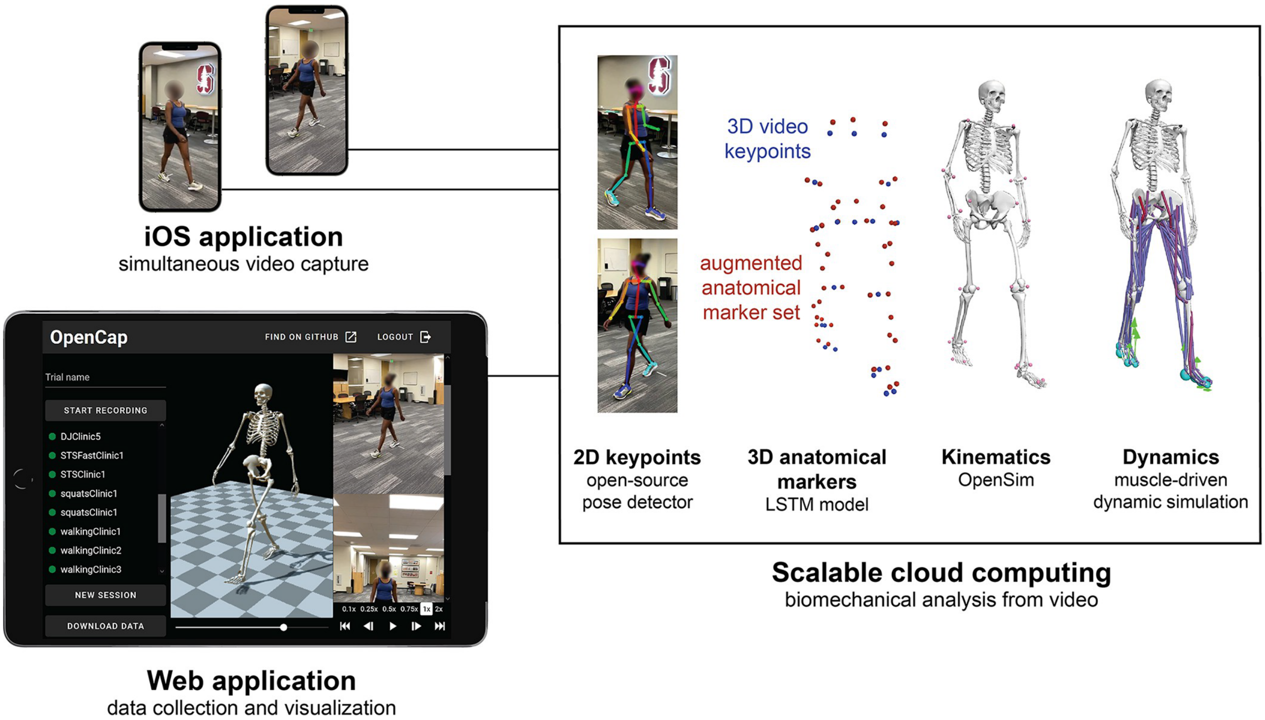

Figure 2.10: OpenCap data collection and analysis workflow

The system has been validated against the gold standard marker-based motion capture and force platform analysis, with a group of ten healthy subjects performing different tasks, such as walking, squatting, rising from a chair and drop jumping; OpenCap demonstrated to accurately estimate changes in dynamic measures with statistical power ranging between 0.65 and 0.92, which is comparable to the gold standard technique (0.77-0.89). The system also predicted adverse outcomes related to osteoarthritis and fall risk with values ranging from 0.65 to 0.80. Furthermore, OpenCap provided dynamic measures that can inform rehabilitation decision-making with classification accuracies between 75% and 89% [11].

Moreover, the system's kinetics is comparable to inertial measurement unit-based approaches, with root mean square errors (RMSE) and joint moments predictions comparable to the ones obtained by using a 17-sensor IMU suit [32].

2.6 Musculoskeletal modeling

Musculoskeletal modeling represents an increasingly popular approach that aims at determining how the elements of the musculoskeletal system interact with each other in order to produce movement. A musculoskeletal model consists of a mechanical description of bones, muscles and joints, and it's usually created in order to estimate the internal forces (muscle and joint reaction forces) that can't be experimentally measured in vivo; plus, these models can be scaled and customized according to the parameters related to the individual, which makes them subject-specific [12].
According to this type of approach, the human body is assumed to be an *articulated multi-body system*, which means that it's represented as a kinematic chain between anatomical segments, which transfer motion through joints; the single bones are typically modeled as rigid bodies, as the bone deformations are assumed not to contribute significantly to the joint articulations or estimations of muscle forces. The segments' lengths are corresponding the anatomical lengths, measured as distances between anatomical landmarks. Masses are considered as if they were concentrated on the Center of Mass (COM) of each segment, and their inertial features are known [33].

2.6.1 Opensim

OpenSim is a freely-available, open-source, user extensible software system for biomechanical modelling, simulation and analysis, which allows the development of musculoskeletal structures' models and the creation of dynamic simulations of movement [34].
The first version of the system was released in 2007 by *Simbios*, a NIH Center for Biomedical Computation at Stanford University.
OpenSim enables the implementation of musculoskeletal models, the visualization of their motion, and a set of tools for extracting meaningful information. These tools include the *Inverse Kinematics*, to resolve internal coordinates from available spatial marker positions correspond-

ing to known landmarks on rigid segments; *Inverse Dynamics*, to determine the set of generalized forces necessary to match estimated accelerations; *Static Optimization*, to decompose net generalized forces amongst redundant actuators (muscles); and *Forward Dynamics*, to generate trajectories of states by integrating system dynamical equations in response to input controls and external forces. Moreover, specialized tools are provided in order to generate patient-specific simulations. These include the scaling of an existing model to match patient-specific measurements, and the determination of dynamic muscle activations that cause the model to track experimental data [35].

OpenSim models consist of several elements (components) that have computational counterparts in the underlying *Simbody* multibody system. These include: bones (rigid bodies), joints (mobilizers, constraints and forces), contact elements (rigid constraints and compliant forces), as well as ligaments and muscle actuators (forces).

The OpenSim pipeline is displayed in the figure below [fig. 2.11].

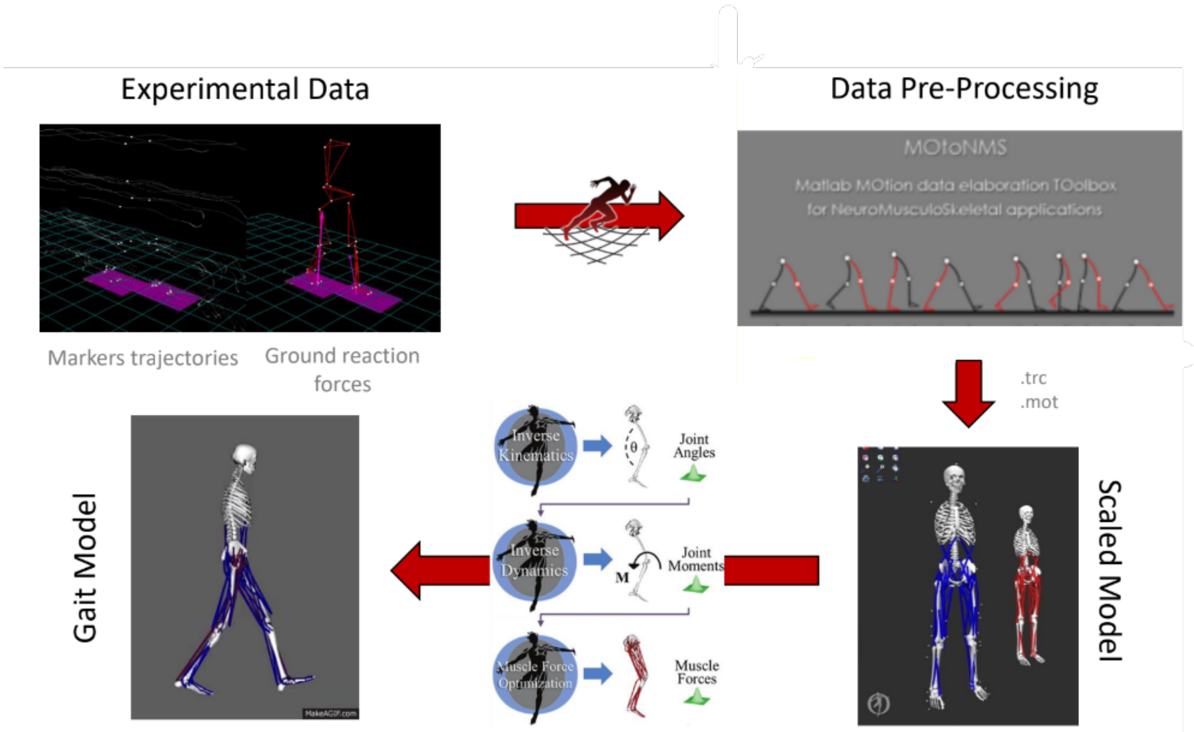

Figure 2.11: OpenSim elaboration pipeline

3

Materials and Methods

3.1 Data collection

The data collection took place at the *Movement and Posture Analysis Laboratory Leuven (MALL)*, at the Department of Movement Science of the KU Leuven University in Leuven, Belgium.

3.1.1 Participants

A total number of four healthy subjects, with no history of musculoskeletal or neurological disorders, volunteered for the study (3 males and 1 female, age 27.7 ± 2.2 years, height 181.4 ± 6.3 cm, weight 76.6 ± 4.7 kg).
Tab. 3.1 displays all the subjects' demographics.

All the participants were asked to wear tight clothing, in order to create contrast with the background, and shoes that made contrast with both the floor and the pants, which was helpful for the OpenCap video-based data collection.

Subject	Gender	Age	Height	Weight	BMI
H01	M	27	178 cm	78 kg	24,62
H02	M	31	186 cm	76 kg	21,97
H03	M	28	189 cm	83 kg	23,24
H03	F	25	173 cm	70 kg	23,39

Table 3.1: Participants' demographics

3.1.2 Experimental setup

OpenCap The OpenCap system requires to record the videos of the subject using at least two cameras from *iOS* devices. For the data collection, two *iPad Pro 11"* were used; there was no need for a third camera, since the two devices allowed to avoid body segment occlusions.
The *iPad Pro 11"* were fixed to the tripods, and the cameras were positioned in order to see every body segment at all times during the data acquisition. As suggested on the OpenCap website, the cameras were orientated at approximately 45° with respect to the walking direction of the acquired subject.

Calibration The calibration took place through the use of a checkerboard provided by OpenCap [fig. 3.1], which was printed on A4 paper, with 35x35 mm black and white squares.
The checkerboard was positioned at the center of the desired capture volume, at less than 5m far from the cameras, visible by all the cameras. As specified on the OpenCap instructions, the line pointing out of the checkerboard didn't point straight at one of the cameras, but it bisected the cameras' arches.

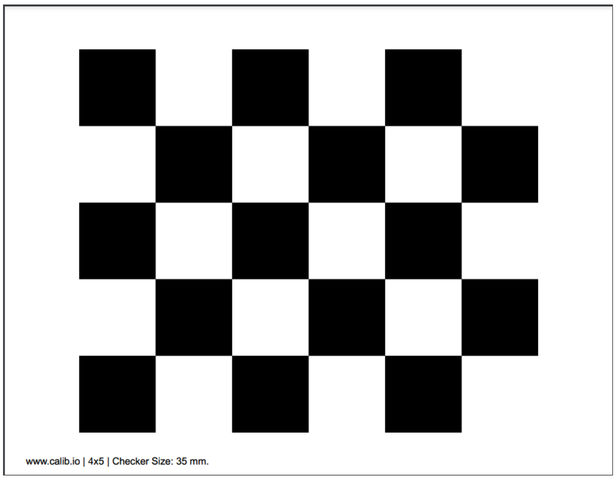

Figure 3.1: OpenCap calibration checkerboard

After the calibration, the checkerboard could be removed.
It was fundamental not to move the cameras after the calibration; if this happened, a new session had to be started, and it was necessary to perform the calibration again.

3.1.3 Data collection

Sensors placement

Each of the eight SageMotion nodes, displayed on the back of the sensor, presented its own reference system, and a code which was supposed to identify the sensor [fig. 3.2].

Figure 3.2: Reference system and identification code of a SageMotion node

Using the node straps, the eight nodes were fixed onto the subjects' bodies, and positioned as follows [36]:

- one sensor on the upper trunk
- one sensor at the middle of the left and right posterior superior iliac spines (pelvis) [fig. 3.3]
- two sensors, one for each thigh, at the middle of the greater trochanter and the lateral epicondyle of the knee (left/right thighs)
- two sensors, one for each shank, at the middle of the lateral epicondyle of the knee and the lateral malleolus of the ankle (left/right shanks)
- two sensors, one for each foot, at the middle of the heel and the toe (left/right feet) [fig. 3.4]

Figure 3.3: Nodes' positioning on the back

Figure 3.4: Nodes' positioning on the lower limbs

3.1.4 Acquisition protocol

The data were collected by both systems (SM and OC) simultaneously.
Each time a new subject started the acquisition, the OpenCap web app asked as an input his/her weight, height and date of birth, in order to create a profile for the subject, and required the subject to stand in a "neutral pose" (standing with arms along the trunk and the distance between the feet comparable to the shoulder width), which allowed the system to scale the model and adapt it to the individual's features.
As suggested on the OpenCap website, each recording was started at least 1s before the participant beginned the movement, in order to allow the system to set, and to be sure that the measured values were more precise and reliable.
Since SageMotion presented some issues related to the Wi-Fi connection between the hub and the nodes, it was decided to ask the subject to make some extra steps at the beginning of each acquisition, in order to facilitate the setting of the system, and, since the space in the laboratory and the cameras setting didn't allow to walk straight for a longer distance, the subjects had to make a 90° turn during walking.
For this reason, during the data processing it was necessary to cut the part of the acquisition relative to the steps taken before the turn, because in that part of the task the cameras were not orientated at 45° with respect to the subject's walking direction as requested by OpenCap, and due to occlusion, the data were not very precise.

Each subject performed four different trials, and repeated each trial four times. The performed trials were:

1. Natural straight walking for a 5-10m length For the straight walking task, the SageMotion app used was the *Raw Data App*.
   As shown on the figure below, the required number of nodes was 8, so all the nodes were sensing during the acquisition of this task. In this case, there was no feedback going on.
   As an output, the system gave, for each sensor, the linear accelerations [m/s2], angular velocities [°/s] and the magnetometer data [µT] along each axis (X, Y, Z), and the quaternion

data.

2. Toe-in gait for a 5-10m length.

3. Toe-out gait for a 5-10m length.

   For the toe-in and toe-out walking tasks, the SageMotion app used was the *Walking Foot Progression Angle App*.

   In this case, the required number of nodes was 3, and there was just one sensing node [fig. 3.5], which was the one placed on the left foot of the subject (the one which was executing the toe-in or toe-out), and two feedback nodes, which could be put anywhere, because their function was just to vibrate whenever the FPA exceeded the maximum value set for the feedback (*foot-lateral*) node or was lower than the minimum value set for the feedback (*foot-medial*) node. [Fig. 3.6]

   The output values for this app were:

   - Step-Count: the number of steps of walking.
   - Gait-Phase: for the left foot, the system recognized the step phases, each corresponding to one number; 0 = *early stance*, 1 = *middle stance*, 2 = *late stance*, 3 = *swing*
   - FPA-This-Step [°]: the foot progression angle for each step, calculated, as explained on the SageMotion documentation, as the mean of the FPA between 15% and 50% of the stance phase.
   - For each sensor, the linear accelerations [m/s2], angular velocities [°/s] and the magnetometer data [μT] along each axis (X, Y, Z), and the quaternion data.

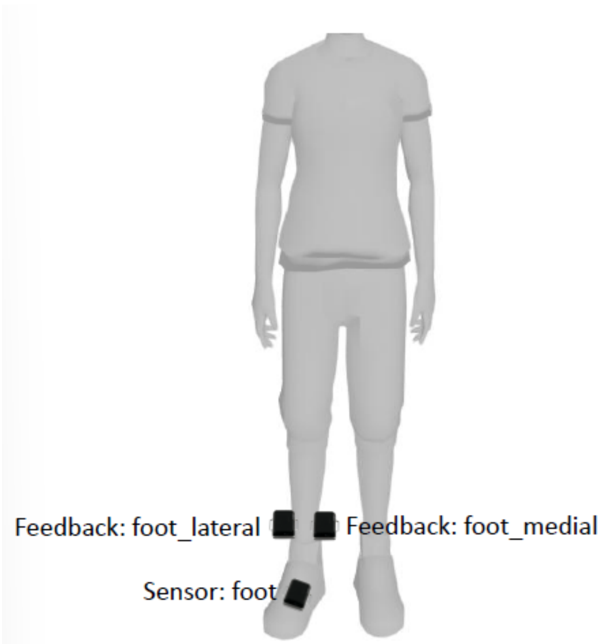

Figure 3.5: Nodes' positioning for the *Walking Foot Progression Angle App*

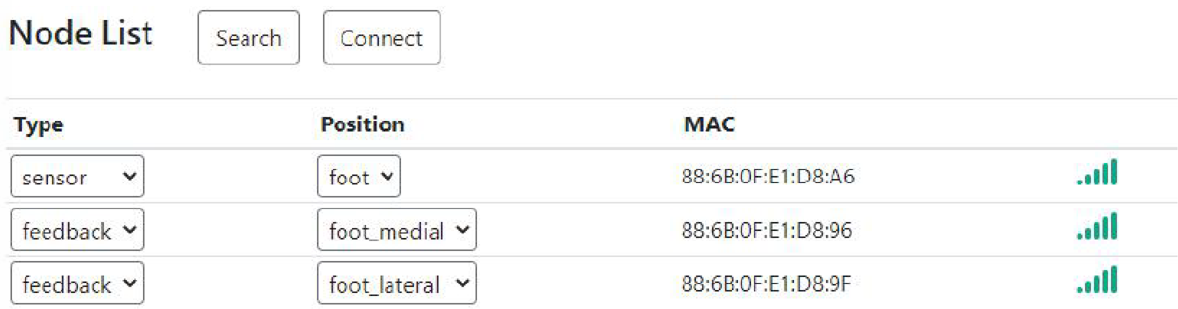

Figure 3.6: *Walking Foot Progression Angle App*'s interface on Sagemotion

4. Trunk leaning gait for a 5-10m length.

   For the trunk leaning walking task, the SageMotion app used was the *Standing Balance Trunk Side Angle App*.

   In this case, the required number of nodes was 3, and there was just one sensing node [fig. 3.7, which was placed on the back of the torso of the subject (which was executing the leaning), and two feedback nodes, which could be put anywhere, because their function was just to vibrate whenever the TSA exceeded the maximum value set for the feedback (*feedback-left* node) or was lower than the minimum value set for the feedback (*feedback-right* node). [Fig. 3.8]

   The output values for this app were:

   - Time [s]: time since the trial started
   - TSA [°]: the value of the trunk side angle (medial-lateral), with the TSA being positive when the subject was leaning to the right.
   - For each sensor, the linear accelerations [m/s2], angular velocities [°/s] and the magnetometer data [µT] along each axis (X, Y, Z), and the quaternion data.

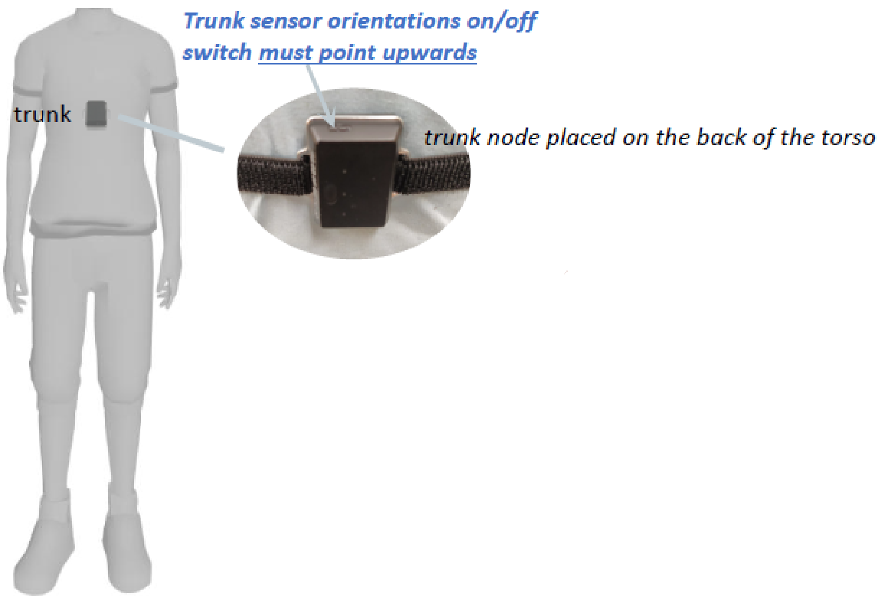

Figure 3.7: Nodes' positioning for the *Trunk Side Angle App*

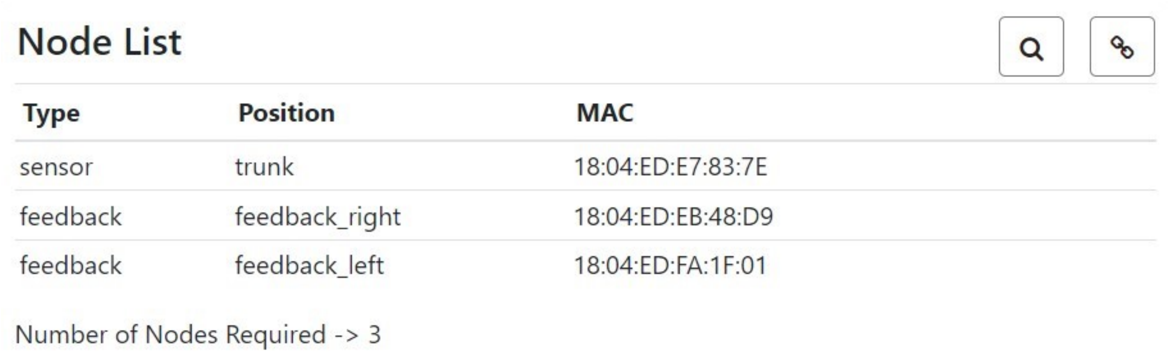

Figure 3.8: *Trunk Side Angle App*'s interface on Sagemotion

3.2 Data Processing

The main goal of the data analysis was to highlight eventual differences between the data obtained by OpenCap, which have already been proved to be reliable [11], and the SageMotion data, which need to be validated in order to understand if the system represents a suitable solution for the rehabilitation of patients affected by knee OA, through gait retraining and modification.
The analysis was conducted separately for the trunk leaning data and the toe-in and toe-out data.

Data processing was performed through the use of different tools, such as Matlab R2023a, OpenSim 4.4, and Microsoft Excel.

3.2.1 Trunk Leaning

For the trunk leaning technique, the variable of interest was the trunk side angle; for SM, the TSA values were extracted from the Excel files (outputs of the SM data collection), while for OC the output file was a *.mot*, and the value of the TSA was assumed to be equivalent to the

lumbar bending angle on OpenSim.
Some pre-processing procedures were implemented in order to reduce noise components without compromising the data integrity.
The data were filtered with a Butterworth lowpass filter, with filter order = 4 and cutoff frequency = 20 Hz.

As previously explained, due to internet connection issues, the subjects had to make a 90° turn while walking, so during the task execution, before the turn they were not totally visible by the OpenCap cameras, and the data were not reliable; for this reason, it was necessary to identify the instant of the turn for both the acquisition systems, in order to only retain the data from that instant onwards. For the OC data, this was possible thanks to the OpenSim reconstruction of the movement's kinetics, which allowed to identify the turn from the video; as for SM, the turn instant was corresponding to a peak of the angular velocity around the Y axis of the node placed on the back of the subject [fig. 3.9].
Once the instants corresponding to the turn were identified, the data were cut.

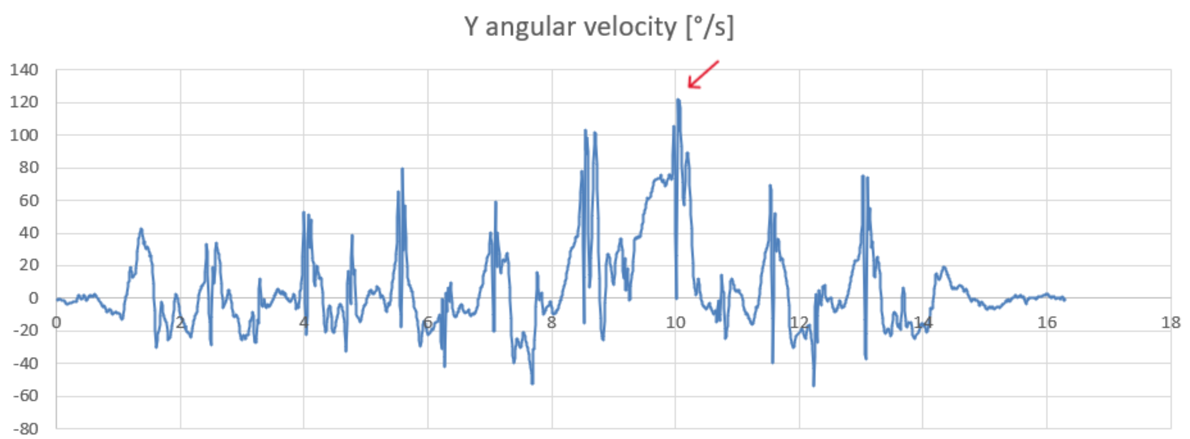

Figure 3.9: Peak of the angular velocity along the vertical axis, corresponding to the turning instant

The two systems collected data at different sampling rates (100 Hz for SageMotion, 60 Hz for OpenCap); for this reason, through the use of the Matlab function *resample*, the SM data were resampled at 60 Hz.
Moreover, in order to be comparable, the data needed to be synchronized; this happened through

the use of the Matlab function *alignsignals*, which aligns signals based on cross-correlation: it computes the cross-correlation between the two signals and finds the time shift that maximizes the correlation; afterwards, it applies this time shift in order to align the signals.

Once all these data processing techniques had been applied, the data were synchronized and comparable [fig. 3.10].

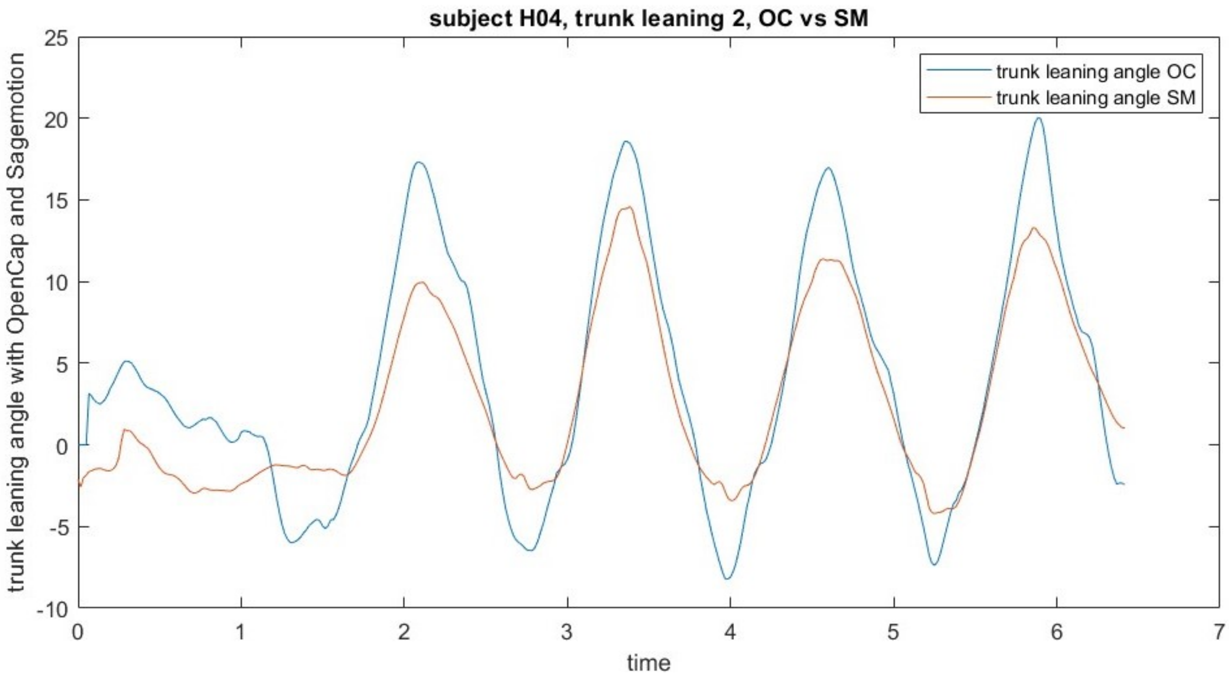

Figure 3.10: Example of the processed data: subject H04, trunk leaning OpenCap vs SageMotion

For each task, the peak values of the trunk side angle were extracted with the use of the MatLab function *findpeaks*; moreover, the Root Mean Square Error (RMSE) [formula 3.1] , which represents one of the most commonly used measures for evaluating the quality of predictions, was calculated, as well as the variance and standard deviation of the TSA for each task and each repetition.
Moreover, the mean value and the standard deviation of the RMSE were calculated.

$$RMSE = \sqrt{\frac{1}{n}\sum_{i=1}^{n}(sm_i - oc_i)^2} \tag{3.1}$$

Moreover, it was decided to compute the Coefficient of Multiple Correlation (CMC) [37], which allows to assess the similarity between kinematic waveforms acquired synchronously through different protocols or measurement systems. The CMC provides an index of the similarity among the curves, clearing it from the ”gait cycle to gait cycle” variability, which is related to the subject’s kinematics’ changes and the measurement system’s performance variability.
The CMC’s absolute value ranges between 0 (indicating great discrepancies between the systems’ measurements), and 1 (suggesting greater consistency between the measures obtained from the two systems).

For all the analyzed gait retraining techniques, a statistical analysis was performed, in order to understand if the differences between the data acquired with SM and OC were significant or non significant, which would have meant that SageMotion represents a suitable system for gait retraining and modification for patients affected by knee OA.
First of all, it was decided to perform one-dimensional Statistical Parametric Mapping (SPM) in order to evaluate the trunk side angle values measured by the two systems, for all the subjects, among all the trials.

One-dimensional Statistical Parametric Mapping (SPM1D) SPM, which was initially developed for statistical inference on neuroimaging data, was subsequently introduced in the biomechanics and human movement science, and used for the analysis of kinematic and kinetic data [38].
SPM, employing the Random Field Theory, takes into account the fact that, since biomechanical data are typically smooth, neighboring time samples are not independent [39]; through the leverage of the local correlation between adjacent time points, SPM mitigates the multiple testing problem, controlling Type I errors when testing correlated field data.
Rather than computing a *p-value* at each time sample, SPM calculates a *p-value* for clusters of statistics that cross a critical threshold [40].

In a second moment, it was decided to perform an additional analysis, only considering the peak values of the TSA for each subject, under the assumption that for rehabilitation purposes the most relevant aspect is the maximum angle value reached by the patient on each step, while the

intermediate values can be considered less significant.
An initial assessment for normality was conducted through the computation of a normality test, the *Shapiro-Wilk test*, aiming to evaluate the distribution characteristics of the acquired data.

Shapiro-Wilk test The Shapiro-Wilk test is a hypothesis test used for small samples. Its null hypothesis assumes that the sample originates from a normal distribution, while the alternative hypothesis contends that it deviates from normality.
It assesses the degree of conformity between the sample data and a normal distribution by ordering and standardizing (setting a mean (μ) of 0 and a standard deviation (σ) of 1) the sample.

Due to the prevalence of normal distribution of both the OC and SM datasets, the chosen test for the statistical analysis was a *two-sample t test*.

Two-sample t test The *two-sample t test*, also known as the *independent sample t test*, is a statistical method used to determine whether the unknown means of two groups' populations are equal or not.
This test is applicable when data values are independent and randomly sampled from two normal populations with equal variances.
The null hypothesis of the *t test* assumes that the mean values of the populations underlying the two groups are equal (or that their difference is null), while the alternative hypothesis contends that their difference is nonzero.
The assumptions for a valid *t test* include the independence of the data values, a random sampling from populations, a normal distribution of data in each group, the continuity of the data values, and equal variances of the two groups.
In order to compare the two groups of data, it was necessary to establish a level of significance. In this case, the significance level was set at 5% (*alpha* was set at 0.05), meaning that any *p-value* lower than *alpha* was considered to be significant. In fact, the *p-value* represents a measure of the likelihood of the null hypothesis, based on the observed result in the sample: the higher the *p-value*, the more likely the null hypothesis is true, and therefore confirmed by observations, meaning that it's compatible with the empirical result. On the contrary, the lower the *p-value*, the less likely the null hypothesis is true: the observed result is too (significantly)

different from the expected.
Overall, the *two-sample t test* represents a valuable tool for comparing means between two independent groups, providing insights into whether observed differences are statistically significant or can be attributed to chance.

For each subject two vectors were initialized:

- all the peak values reached during the four tasks' repetitions measured by OpenCap
- all the peak values reached during the four tasks' repetitions measured by SageMotion

The two vectors, constituting the two groups used to perform the *t test* for each subject, are displayed below [tab. 3.2], with T representing the task number, and P representing the peak number; for the sake of clearness, the first element of the first vector displays the first peak value (P1) measured by OpenCap (OC) during the first repetition of the trunk leaning task (T1), for the first subject (H01).

H01OC	**H01SM**
T1P1	T1P1
T1P2	T1P2
T1P3	T1P3
T2P1	T2P1
T2P2	T2P2
T3P1	T3P1
T3P2	T3P2
T3P3	T3P3
T4P1	T4P1
T4P2	T4P2
T4P3	T4P3
T4P4	T4P4

Table 3.2: Peak TSA values' vectors for subject H01, trunk leaning task, OC vs SM

The *t tests* were performed for each subject, resulting in four *p-values*, allowing to test the inter-subject variability.

Moreover, it was decided that in order to compare the accuracy and precision of SageMotion's measures, it would have been significant to compute another *t test*, considering as the two groups under comparison the two vectors containing all the peak values measured for all the subjects during the trunk leaning technique acquisition, respectively for OpenCap and SageMotion.
This resulted in another *p-value*.

Once the *p-values* were obtained, for both the tests comparing the TSA for each instant and the ones only considering the peak values of the TSA, it was decided to apply a False Discovery Rate (FDR) correction, due to the need to address the issue of multiple testing, which consists in an increased risk of a type I error when making multiple statistical tests.

False Discovery Rate correction When conducting multiple statistical tests, the likelihood of obtaining false positives increases.
The FDR correction technique allows for controlling the rate of false positives while simultaneously identifying significant results [41].
The application of FDR correction allows to maintain a balance between the identification of true significant findings and the minimization of the risk of false positives. This correction adjusts the significance thresholds of individual tests to account for the multiple comparisons being made, ensuring that only a small proportion of significant results are likely to be false discoveries.
Consequently, the resulting *q-values* provide a more reliable measure of significance, indicating the probability that a given result is a false positive within the context of multiple testing.
For this reason, the computation of the *q-values* through the use of FDR enhances the reliability and interpretability of the performed statistical analysis.

3.2.2 Toe-in and Toe-out

Since the SageMotion App used was the *Walking Foot Progression Angle App* for the execution and acquisition of both the toe-in and toe-out tasks, the steps performed for the data processing were the same for both these gait retraining techniques, and for this reason they will be presented and explained together.
The variable of interest for these techniques was the foot progression angle; for SM, the FPA values were extracted from the Excel files (outputs of the SM data collection), while for OC the output file was a *.mot*, and the value of the FPA was assumed to be equivalent to the *subtalar angle* on OpenSim.
Some pre-processing procedures were implemented in order to reduce noise components without compromising the data integrity.
As previously explained, the output value for the FPA on the SageMotion *Walking Foot Progression Angle App* was the mean of the FPA between 15% and 50% of the stance phase. In fact, the system was able to detect the gait phases from each step performed by the subject, and it provided just one value of FPA for each step. For this reason, since the system didn't provide the value for each time sample, in order to compare the data and perform the statistical analysis, it was necessary to calculate the mean value between the 15% and 50% of the stance phase also for the OC data.
Moreover, as in the trunk leaning acquisition, due to internet connection issues, the subjects had to make a 90° turn while walking, so during the task execution, before the turn they were not totally visible by the OpenCap cameras, and the data were not reliable; for this reason, it was necessary to identify the instant of the turn for both the acquisition systems, in order to keep only the data from that instant on. For the OC data, this was possible thanks to the OpenSim reconstruction of the movement's kinetics, which allowed to identify the turn from the video; the number of steps made by the subject after the turn was counted, and same number of steps was kept from the SM output values, starting to count from the last value.

Afterwards, the next step was to detect all the stance phases of the left foot (which was the one where the sensing node was applied); this objective translated into the need of identifying the Heel Strikes (HS) and Toe-Offs (TO) for each step of the task execution acquired by OpenCap.

The research literature presents various different strategies for the detection of the gait events during walking; the ones chosen for the development of this work are explained below [42]:

- the time instant corresponding to the left HS was detected as the maximum displacement, along the subject's walking direction (which, for the OpenCap/OpenSim reference system, was the X axis), between the heel and the sacrum.

$$t_{HS} = (\mathrm{X}_{\text{heel}} - \mathrm{X}_{\text{sacrum}})_{\max} \tag{3.2}$$

  Once the time instants corresponding to the HS were found, the heel and sacrum coordinates along the walking direction (X) were extracted from the *.trc* files relative to the markers' data, respectively from the *X-Lheel* and the *X-LASIS* (where ASIS stands for Anterior Superior Iliac Spine) columns [fig. 3.11].
  Once the data was extracted, the displacement was calculated, and the peaks (corresponding to the heel strikes) were extracted using the MatLab function *findpeaks* [fig. 3.12].

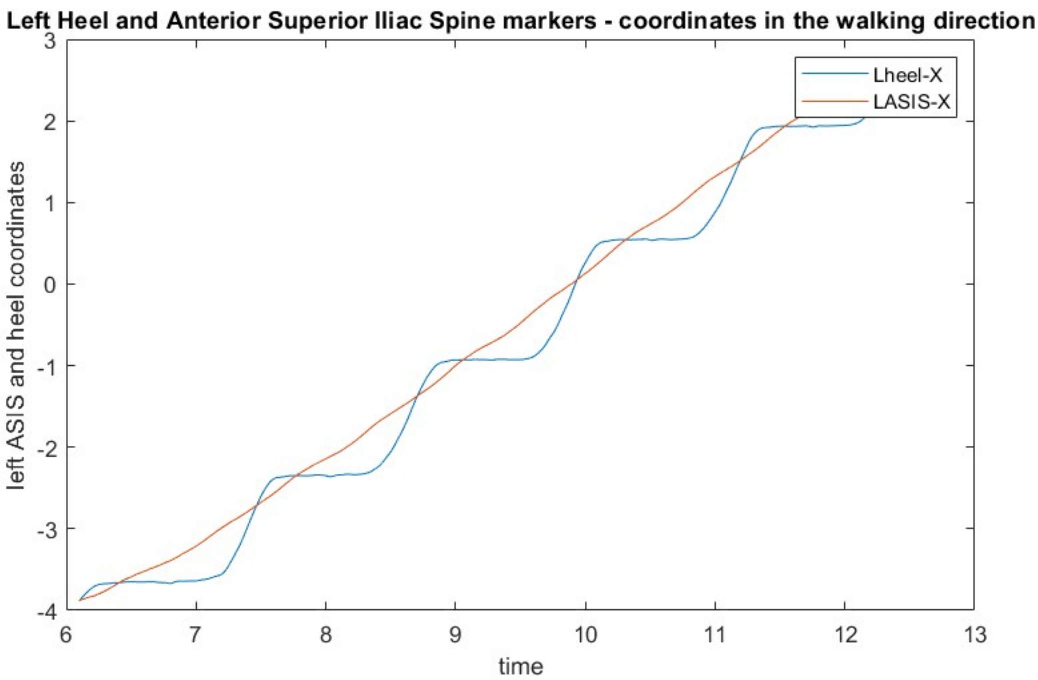

Figure 3.11: Example of the plot of the left heel marker (blue) and the left ASIS marker (orange) coordinates along the X axis

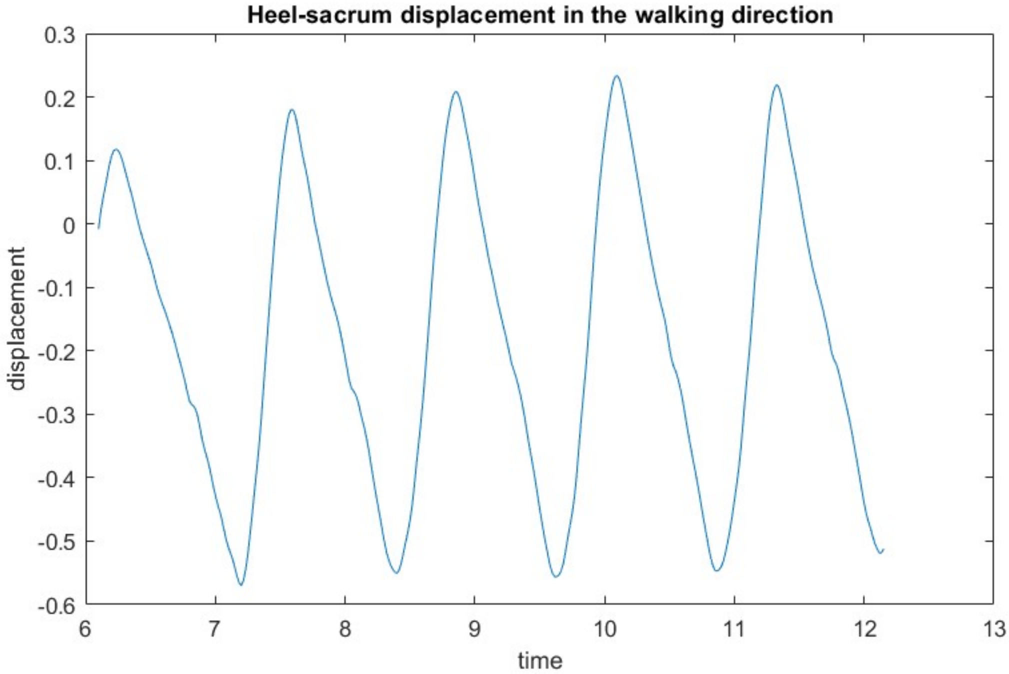

Figure 3.12: Example of the plot of the heel-sacrum displacement

- the time instant corresponding to the left TO was detected as the maximum vertical position of the left heel (which, with respect to the OpenCap/OpenSim reference system, corresponded to the Y axis).

  Once the time instants corresponding to the TO were found, the heel marker's coordinates along the vertical axis (Y) were extracted from the *.trc* files relative to the markers' data, in particular from the *Y-Lheel* column [fig. 3.13].

  Once the data was extracted, the peaks (corresponding to the toe-offs) were extracted using the MatLab function *findpeaks*.

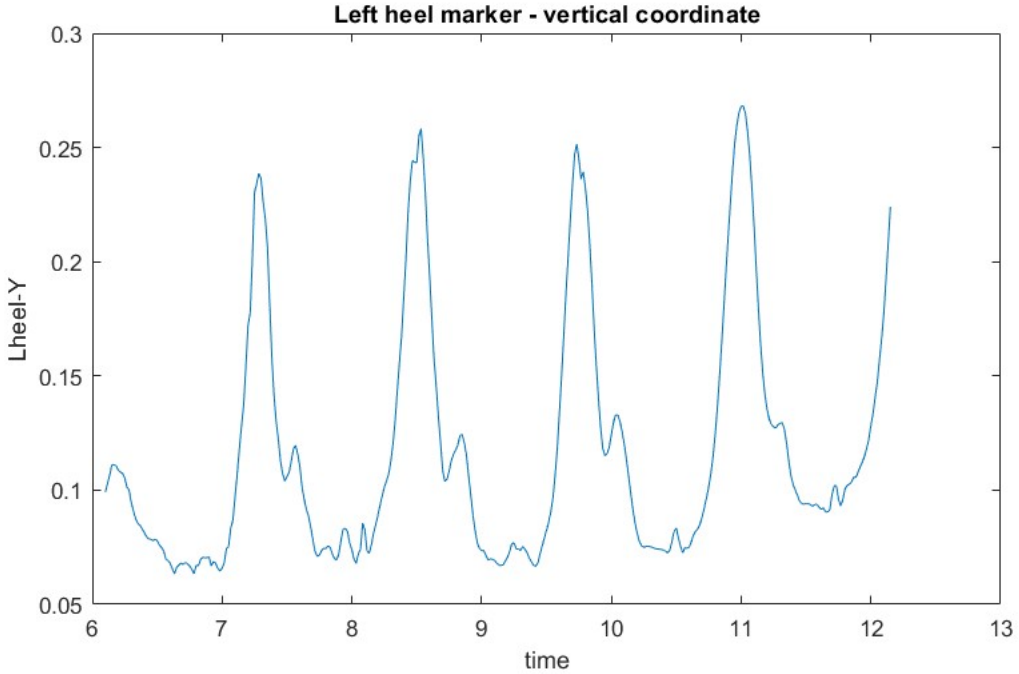

Figure 3.13: Example of the plot of the left heel marker coordinate along the Y axis

Since the calculation of the RMSE wouldn't have been extremely significant when considering mean FPA values, in order to provide a first insight on the results, it was decided to calculate the mean value of the FPA for all the steps, for all the subjects, for each system, with the corresponding standard deviation.
Subsequently, as well as for the trunk leaning task, an initial assessment for normality was conducted through the computation of a normality test, the *Shapiro-Wilk test*, aiming to evaluate the distribution characteristics of the acquired data.
In this case, due to the prevalence of non-normal distribution of the data (especially SM's data), it was decided to extract the *p-values* computing the *Wilcoxon-Mann-Whitney test*, which is a non-parametric test suitable for non-normally distributed data.

Wilcoxon-Mann-Whitney test The *Wilcoxon-Mann-Whitney test*, also called *Mann-Whitney-U* test, is a non-parametric statistical method that involves ordering the data in each group from the lowest to the highest values. Subsequently, the entire dataset undergoes ranking. The summation of ranks is then computed for each group, leading to the determination of

U by the formula:

$$U = \min(U', U'') \tag{3.3}$$

where U' stands for the Mann-Whitney statistic for one group (OpenCap data), while U" is the Mann-Whitney statistic for the other one (SageMotion data).
In order to compare the two groups of data, it was necessary to establish a level of significance. In this case, the significance level was set at 5% (*alpha* was set at 0.05), meaning that any *p-value* lower than *alpha* was considered to be significant [43].

In order to perform the test, for each subject two vectors were initialized:

- the mean FPA value for each step calculated for the left foot during the four tasks' repetitions measured by OpenCap
- the mean FPA value for each step calculated for the left foot during the four tasks' repetitions measured by SageMotion

The two vectors, constituting the two groups used to perform the test for each subject, are displayed below [tab. 3.2], with T representing the task number, and S representing the left foot's stance phase number; for the sake of clearness, the first element of the first vector displays the TSA mean value during the first left foot's stance phase (S1) measured by OpenCap (OC) during the first toe-in/toe-out task repetition (T1), for the first subject (H01).

H01OC	**H01SM**
T1S1	T1S1
T1S2	T1S2
T1S3	T1S3
T2S1	T2S1
T2S2	T2S2
T3S1	T3S1
T3S2	T3S2
T3S3	T3S3
T4S1	T4S1
T4S2	T4S2
T4S3	T4S3
T4S4	T4S4

Table 3.3: Mean TSA values' vectors for subject H01, toe-in/toe-out tasks, OC vs SM

The tests were performed for each subject, resulting in four *p-values* for each technique (Toe-in and Toe-out).

As well as for the trunk leaning, once the tests had been computed, for both the techniques' resulting *p-values* it was decided to apply a FDR correction, due to the need to address the issue of multiple testing, which consists in an increased risk of a type I error when making multiple statistical tests.

Moreover, as for the trunk leaning data, it was decided that in order to compare the accuracy and precision of SageMotion's measures, it would have been significant to compute another *Wilcoxon-Mann-Whitney test*, considering as the two groups under comparison the two vectors containing all the FPA values measured for all the subjects during the toe-in and toe-out techniques acquisition, respectively for OpenCap and SageMotion.
This resulted in other two *p-values*, one for the Toe-in technique and one for the Toe-out technique.

4

Results

The performed statistical analysis, coupled with the generation of graphic representations that facilitated the results' visualization, aided in making a distinction between the compared groups. This assisted the detection of significant differences, providing a clear understanding of the obtained results, which will be exposed and subsequently discussed within the following chapters. The achieved findings will be presented and further discussed through the division into three sections: Trunk Leaning results, Toe-in results and Toe-out results.

4.1 Trunk leaning

In the trunk leaning section of the study, the data were collected from 4 participants, each of whom performed the trunk leaning technique 4 times, for a total number of 16 tasks' repetitions.

The first step performed on the processed data was the calculation of the Root Mean Square Error (RMSE), which was computed for each task repetition for each subject, as a representation of the discrepancy between the OC and the SM data.
The RMSEs, as well as the standard deviation for each acquisition, are displayed in the following table [tab. 4.1].

	RMSE [°]	std OC [°]	std SM [°]
H01 TL1	3.71	7.81	8.67
H01 TL2	4.13	7.07	6.85
H01 TL3	3.71	8.92	10.35
H01 TL4	10.49	11.41	13.69
H02 TL1	2.56	6.29	6.96
H02 TL2	2.68	5.73	6.24
H02 TL3	6.16	9.86	14.59
H02 TL4	4.90	9.55	13.66
H03 TL1	6.77	6.32	8.01
H03 TL2	5.69	5.96	7.52
H03 TL3	8.03	8.33	10.45
H03 TL4	9.02	8.36	11.81
H04 TL1	3.60	7.39	5.38
H04 TL2	3.32	7.35	5.28
H04 TL3	5.06	8.66	7.53
H04 TL4	3.87	9.18	7.09

Table 4.1: Statistical analysis: Root Mean Square Error and standard deviations, trunk leaning technique, OC vs SM

In order to obtain more significant information, the mean of the RMSE was calculated for each subject, which allowed to establish an inter-subject comparison and to highlight eventual differences between subjects.

Finally, the mean RMSE value referred to all the acquisitions, which represents the most intuitive and immediate result in terms of comparison between the two acquisition systems, was calculated; the resulting information was that the two acquisition systems exhibit an average discrepancy of $4.80° \pm 2.25°$.

The RMSE mean values for each subject are displayed in the table below [tab. 4.2], and a visual representation is provided through the bar plot in [fig. 4.1].

Moreover, in [fig. 4.2] is displayed the mean RMSE value calculated over all the trials, for each frame, represented over the percentage of the trials.

	RMSE [°]
H01	4.94 ± 2.88
H02	3.79 ± 1.52
H03	7.27 ± 1.26
H04	3.91 ± 0.66

Table 4.2: Statistical analysis: mean Root Mean Square Error and standard deviations for each subject, trunk leaning technique, OC vs SM

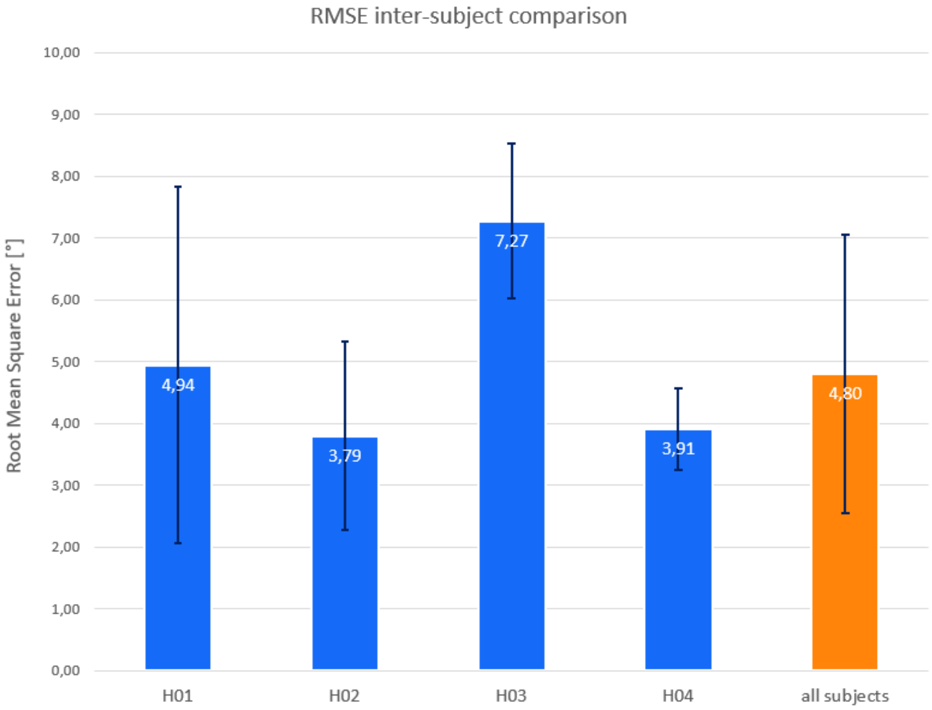

Figure 4.1: Inter-subject trunk leaning Root Mean Square Error comparison

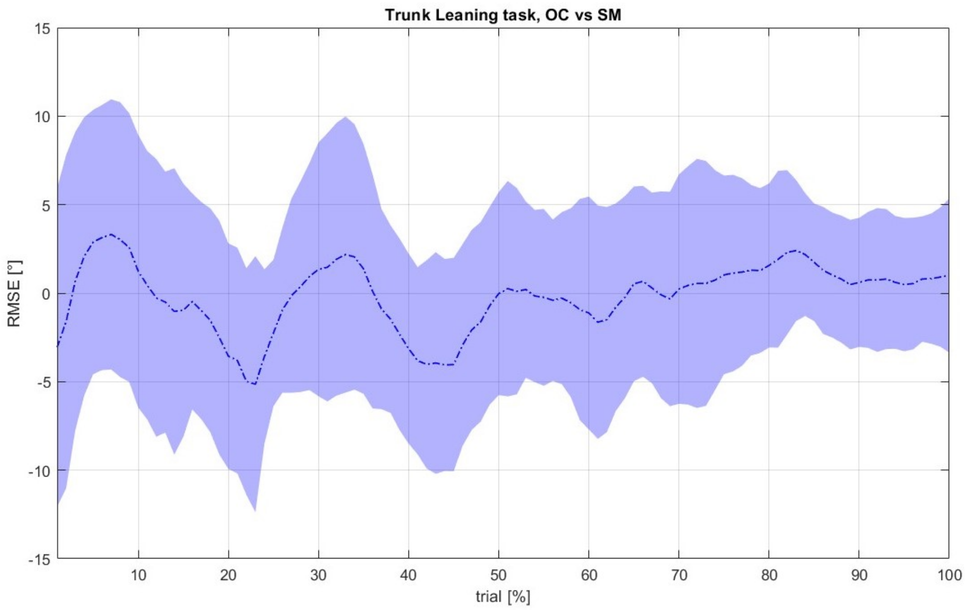

Figure 4.2: Mean Root Mean Square Error calculated for each frame, among all the trials, represented over the trial percentage

With regard to the coefficient of multiple correlation computing, it resulted in a CMC = 0,889 ± 0,078 (standard deviation), revealing a high correlation between the systems in terms of the trunk side angle measurement.

As for the results regarding the computing of the one-dimensional Statistical Parametric Mapping (SPM), there was no evidence of statistical difference between SageMotion and OpenCap in any instant of the trunk side angle curve, representing the mean TSA value on each time frame for all the subjects' trials.
This positive outcome is graphically displayed in the figure below [fig. 4.3], which exhibits the descriptive statistics for each system's dataset (mean ± standard deviation error cloud), represented over the percentage of the trials; the plot shows how the two curves are almost overlapping.

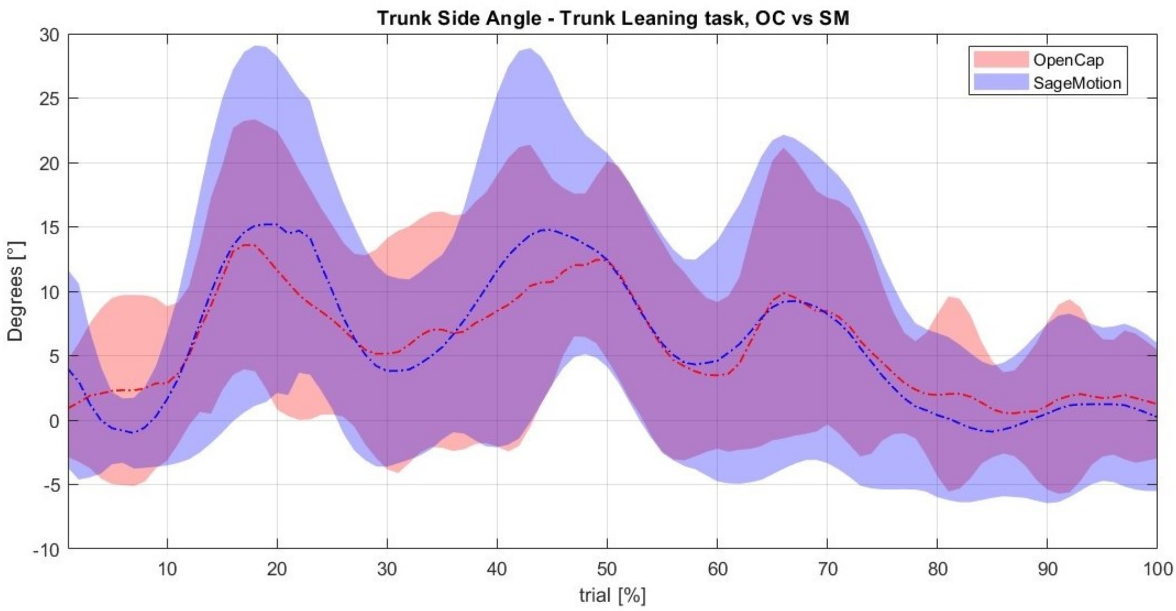

Figure 4.3: SPM1D results: mean FPA ± standard deviation error cloud, OpenCap vs Sagemotion

Moreover, as already illustrated in the previous chapter, it was decided to evaluate the intersubject variability by the extraction of the peak values of the trunk side angle (TSA) for each step of each acquisition, and the computing of other four *t tests*, each comparing all the peak values for one subject; this choice was made due to the assumption that for rehabilitation purposes the most relevant aspect is the maximum trunk leaning angle value reached by the patient on each step, while the intermediate values can be considered less significant.

The results of these tests led to the conclusion that, considering the peak TSA values, SageMotion's measures are significantly different from OpenCap's for subjects H03 and H04 (*p-values* < 0.05), while their difference is non significant for subjects H01 and H02, meaning that the measures of the two systems result to be comparable for these two subjects.

The *p-values* resulting from this set of tests are displayed in the table below [tab. 4.3], as well as the *q-values* obtained through the computing of the FDR correction, and a graphical representation of the differences between the systems are displayed through the use of boxplots [fig. 4.4, 4.5, 4.6, 4.7].

subject	**p-value**	**q-value**
H01	0.4749	0.5877
H02	0.5877	0.6331
H03	0.0010	0.0041
H04	0.0031	0.0061

Table 4.3: Statistical analysis: p-values and q-values resulting from the t-tests considering the TSA peak values; non significant p-values ($>$ 0.05) are highlighted in yellow

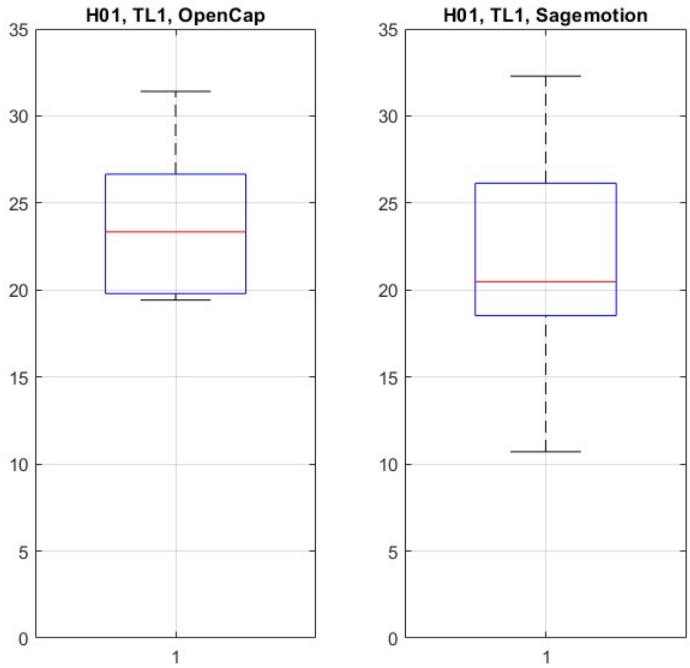

Figure 4.4: Statistical analysis: subject H01, statistically non-significant difference between OC (left) and SM (right), trunk leaning technique (q-value=0.5877)

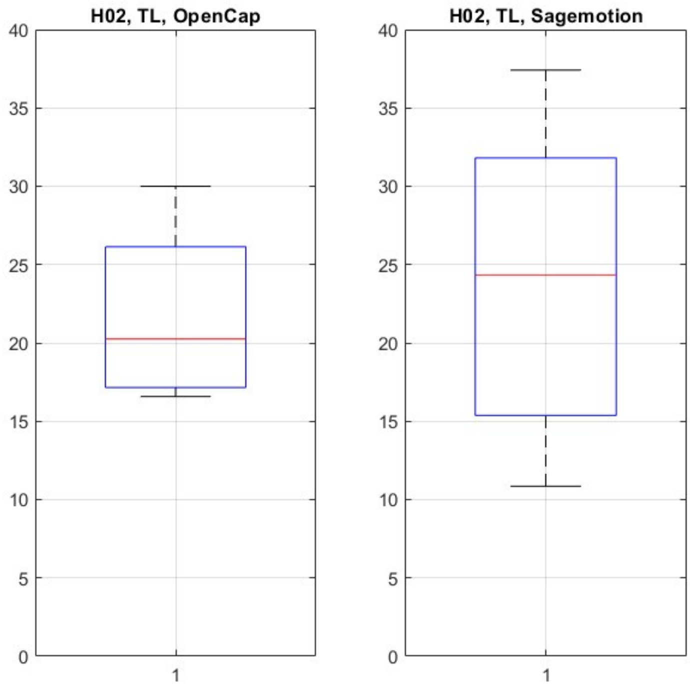

Figure 4.5: Statistical analysis: subject H02, statistically non-significant difference between OC (left) and SM (right), trunk leaning technique (q-value=0.6331)

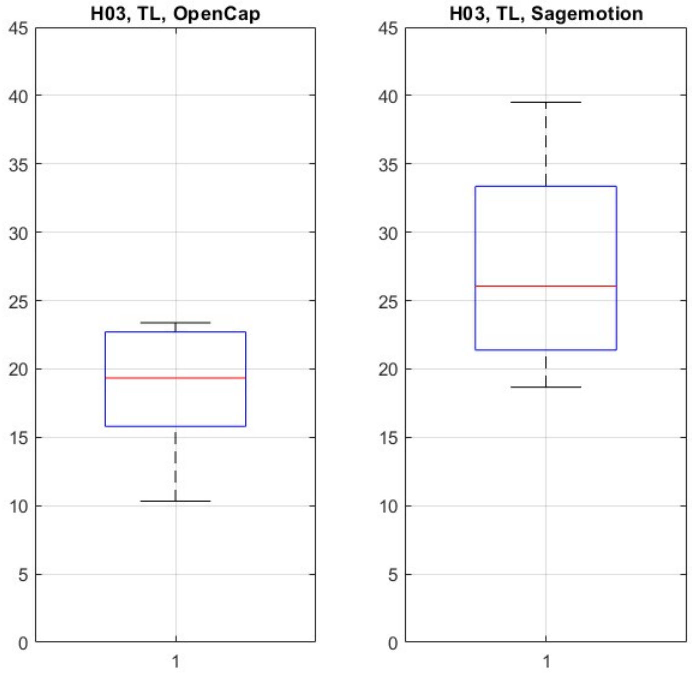

Figure 4.6: Statistical analysis: subject H03, statistically significant difference between OC (left) and SM (right), trunk leaning technique (q-value=0.0041)

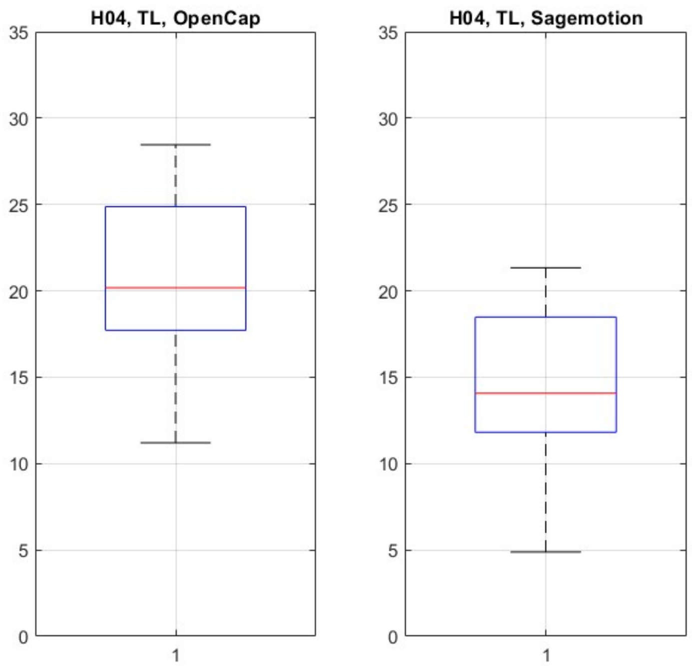

Figure 4.7: Statistical analysis: subject H04, statistically significant difference between OC (left) and SM (right), trunk leaning technique (q-value=0.0061)

The last step of the trunk leaning technique's statistical analysis consisted in the computing of another *t test*, where the groups under comparison were the two vectors containing all the peak TSA values measured for all the subjects, respectively by OpenCap and SageMotion.

This test resulted in a non-significant *p-value* = 0.9456, suggesting that, for the trunk leaning technique, if considering only the angle's peak values (which is more clinically relevant), there's no statistical evidence that proves a significant difference between the TSA peak values measured by SageMotion and the ones measured by OpenCap.

A visual representation of this result is displayed through the boxplots in [fig. 4.8].

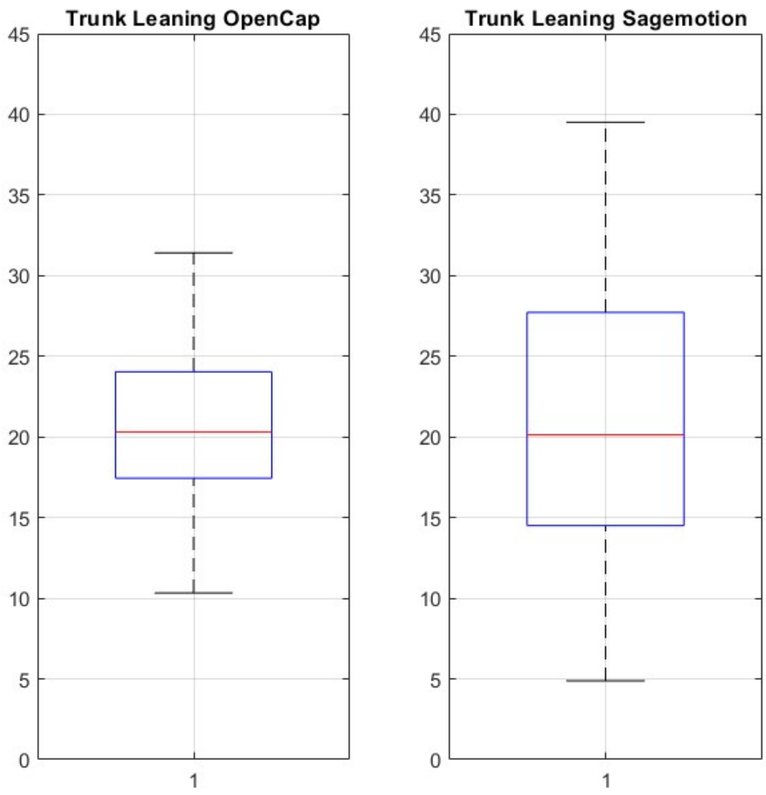

Figure 4.8: Statistical analysis: statistically non-significant difference between OC (left) and SM (right), all subjects, trunk leaning technique (p-value = 0.9456)

4.2 Toe-in

In the toe-in section of the study, the data were collected from 4 participants, each of whom performed the toe-in technique 4 times, for a total number of 16 tasks' repetitions.

As previously illustrated in Chapter 3, SageMotion's output values for the toe-out were the mean values of the foot progression angle (FPA) during the 15%-50% of each left foot's stance phase. For this reason, since the system didn't provide the FPA instant-by-instant, during the data processing it was necessary to calculate the mean values for the left foot's stance phases also from the OpenCap's data.

In order to have a first overview of the results, the mean FPA value was calculated for both the systems.
As expected, the mean values were positive for the toe-in gait, resulting in a mean FPA of 11.2° (with a standard deviation of 12.5°) for OpenCap, and a mean FPA of 10.8° (with a standard deviation of 12.5°) for SageMotion.

Subsequently, after the computation of the *Shapiro-Wilk test* for testing the normality of data distribution, which resulted in a non-normal distribution of the SageMotion data, it was decided to perform a non-parametrical statistical test, the *Wilcoxon-Mann-Whitney test*, in order to compare, for each subject, the mean values on each step.

The results of the *Wilcoxon-Mann-Whitney test* highlighted a non-significant difference between the groups for all the subjects (*p-values* > 0.05).
Subsequently, the FDR correction was performed and the *q-values* were extracted, even though this didn't constitute a shift in terms of the results' significance.

The *p-values* and the matching *q-values* computed through the FDR correction are displayed in the following table [tab. 4.4], and the visual representations of the tests results are provided through the use of boxplots [fig. 4.9, 4.10, 4.11, 4.12].

subject	p-value	q-value
H01	0.2251	0.3001
H02	0.5293	0.5293
H03	0.1903	0.3805
H04	0.0596	0.2384

Table 4.4: Statistical analysis: p-values and q-values resulting from the Mann-Whitney test considering the FPA peak values for toe-in technique; non significant p-values (> 0.05) are highlighted in yellow

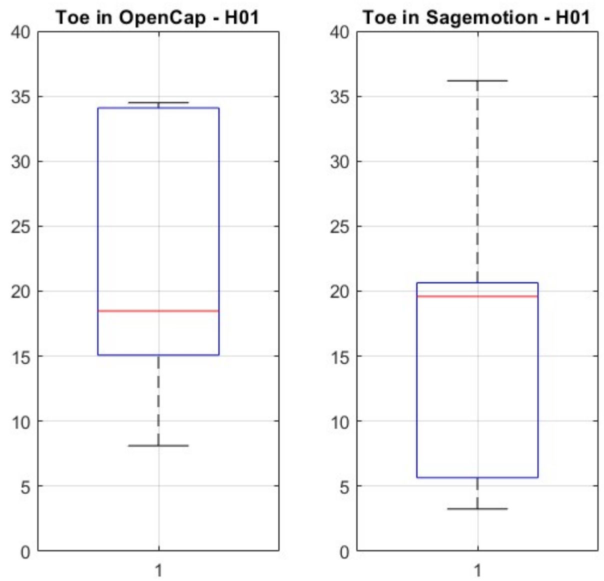

Figure 4.9: Statistical analysis: subject H01, statistically non-significant difference between OC (left) and SM (right), toe-in technique (q-value = 0.3001)

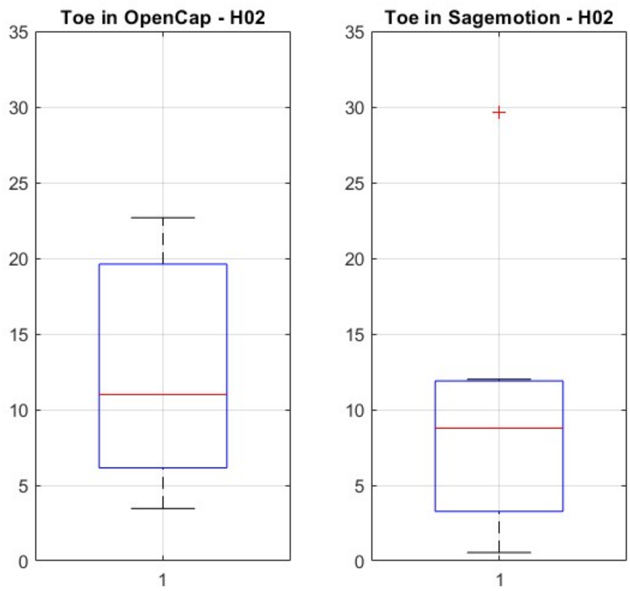

Figure 4.10: Statistical analysis: subject H02, statistically non-significant difference between OC (left) and SM (right), toe-in technique (q-value = 0.5293)

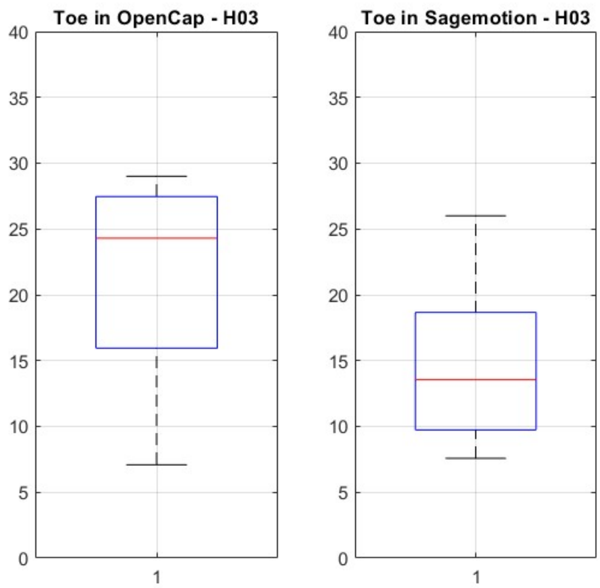

Figure 4.11: Statistical analysis: subject H03, statistically non-significant difference between OC (left) and SM (right), toe-in technique (q-value = 0.3805)

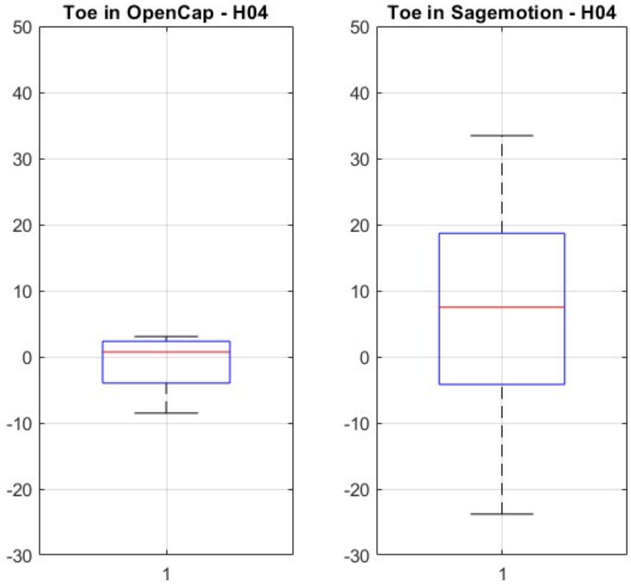

Figure 4.12: Statistical analysis: subject H04, statistically non-significant difference between OC (left) and SM (right), toe-in technique (q-value = 0.2384)

The last step of the toe-in technique's statistical analysis consisted in the computing of another *Wilcoxon-Mann-Whitney test*, where the groups under comparison were the two vectors containing all the mean FPA values measured for all the subjects, respectively by OpenCap and SageMotion.

This test resulted in a non-significant *p-value* = 0.7103, suggesting that, for the toe-in technique, if considering only the angle's mean values, the analysis doesn't show a significant difference between the FPA mean values measured by SageMotion and the ones measured by OpenCap, meaning that SageMotion can perform accurate measurements, therefore it's suitable for the employment regarding this gait retraining technique.

A visual representation of this result is presented through the boxplots in [fig. 4.13].

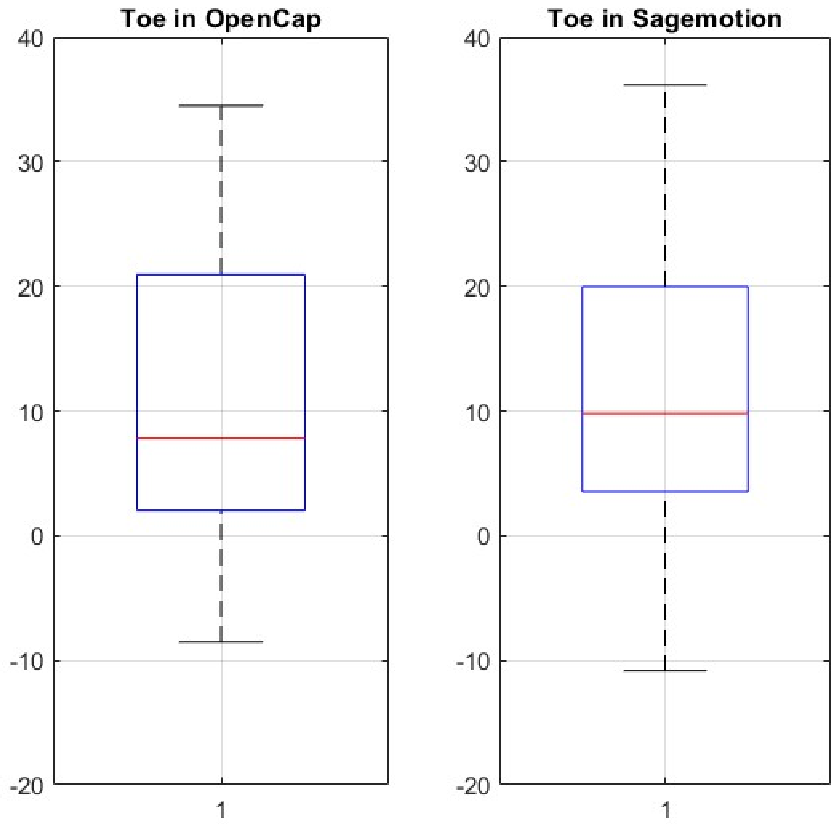

Figure 4.13: Statistical analysis: statistically significant difference between OC (left) and SM (right), all subjects, toe-in technique (p-value = 0.7103)

4.3 Toe-out

In the toe-out section of the study, the data were collected from 4 participants, each of whom performed the toe-out technique 4 times, for a total number of 16 tasks' repetitions.

As previously illustrated in Chapter 3, and further investigated in the Toe-in section of the results, SageMotion's output values for the toe-out were the mean values of the foot progression angle (FPA) during the 15%-50% of each left foot's stance phase. For this reason, since the system didn't provide the FPA instant-by-instant, during the data processing it was necessary to calculate the mean values for the left foot's stance phases also from the OpenCap's data.

With regard to the toe-out gait, as well as for the toe-in technique, in order to have a first overview of the results, the mean FPA value was calculated for both the systems.
As expected, the mean values were negative for the toe-out gait, resulting in a mean FPA of -7.7° (with a standard deviation of 8.0°) for OpenCap, and a mean FPA of -20.5° (with a standard deviation of 10.7°) for SageMotion.

Subsequently, after the computation of the *Shapiro-Wilk test* for testing the normality of data distribution, which resulted in a non-normal distribution of the SageMotion data, it was decided to perform a non-parametrical statistical test, the *Wilcoxon-Mann-Whitney test*, in order to compare, for each subject, the mean values on each step.

The results of the *Wilcoxon-Mann-Whitney test* highlighted a significant difference between the groups for 3 subjects out of 4 (*p-values* < 0.05).
Subsequently, the FDR correction was performed and the *q-values* were calculated; however, although the *q-values* relative to the subjects that presented a non-significant difference were higher than the corresponding *p-values*, they didn't represent a change in terms of statistical significance.

The *p-values* and the matching *q-values* computed through the FDR correction are displayed in the following table [tab. 4.5], and the visual representations of the tests results are provided through the use of boxplots [fig. 4.14, 4.15, 4.16, 4.17].

subject	p-value	q-value
H01	0.00399	0.00532
H02	0.79844	0.79845
H03	0.00031	0.00616
H04	0.00002	0.00009

Table 4.5: Statistical analysis: p-values and q-values resulting from the Mann-Whitney test considering the FPA peak values for toe-out technique; non significant p-values (> 0.05) are highlighted in yellow

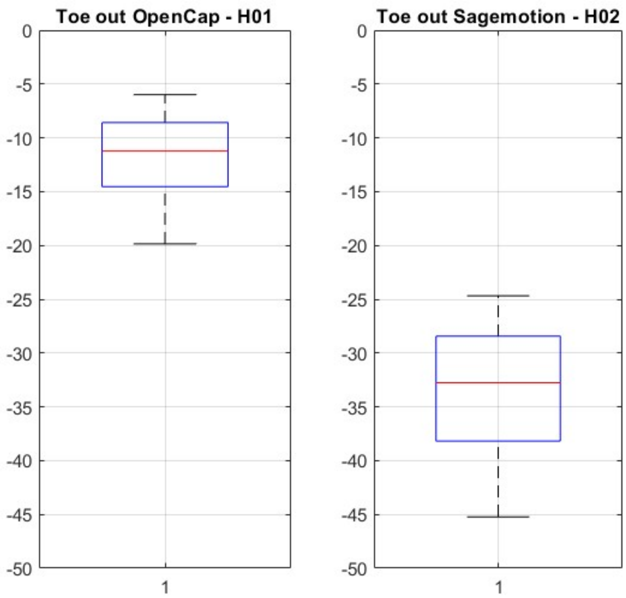

Figure 4.14: Statistical analysis: subject H01, statistically significant difference between OC (left) and SM (right), toe-out technique (q-value = 0.00532)

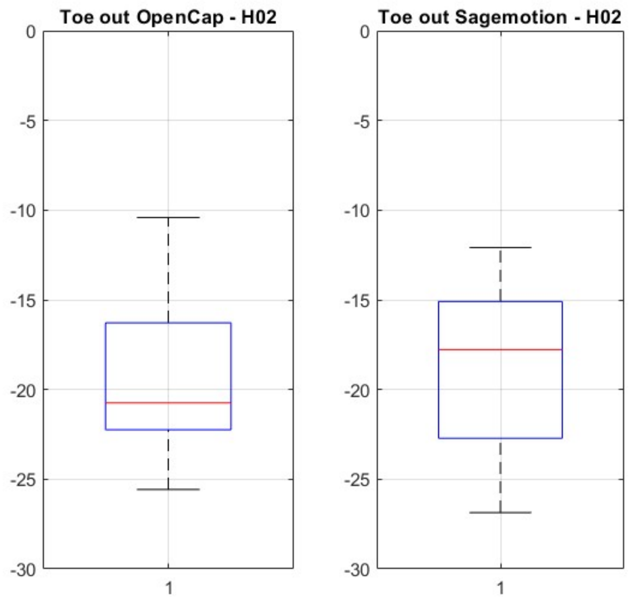

Figure 4.15: Statistical analysis: subject H02, statistically non-significant difference between OC (left) and SM (right), toe-out technique (q-value = 0.79845)

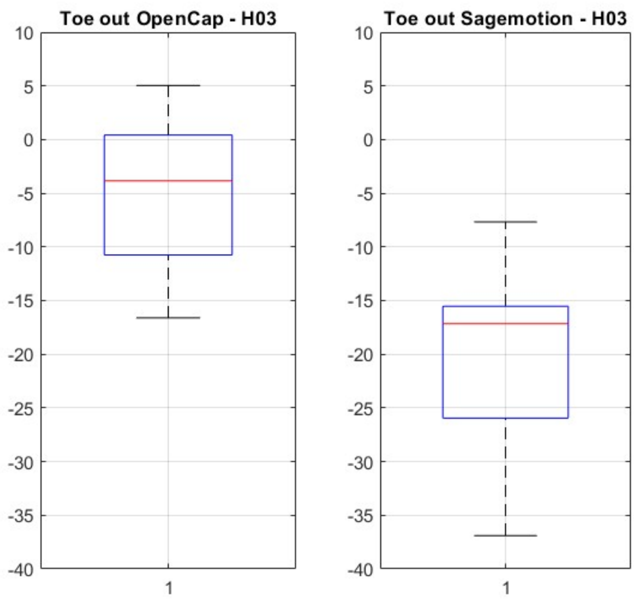

Figure 4.16: Statistical analysis: subject H03, statistically significant difference between OC (left) and SM (right), toe-out technique (q-value = 0.00616)

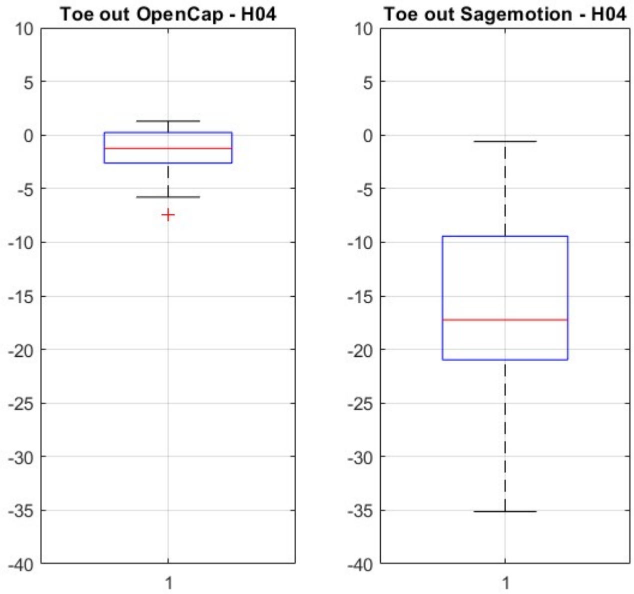

Figure 4.17: Statistical analysis: subject H04, statistically significant difference between OC (left) and SM (right), toe-out technique (q-value = 0.00009)

The last step of the toe-out technique's statistical analysis consisted in the computing of another *Wilcoxon-Mann-Whitney test*, where the groups under comparison were the two vectors containing all the mean FPA values measured for all the subjects, respectively by OpenCap and SageMotion.

This test resulted in a highly significant *p-value*, very close to 0 (3.997×10^{-8}), suggesting that, for the toe-out technique, if considering only the angle's mean values, the analysis shows a significant difference between the FPA mean values measured by SageMotion and the ones measured by OpenCap, meaning that SageMotion is not precise in its measurements, therefore not suitable for the employment regarding this gait retraining technique.

A visual representation of this result is presented through the boxplots in [fig. 4.18].

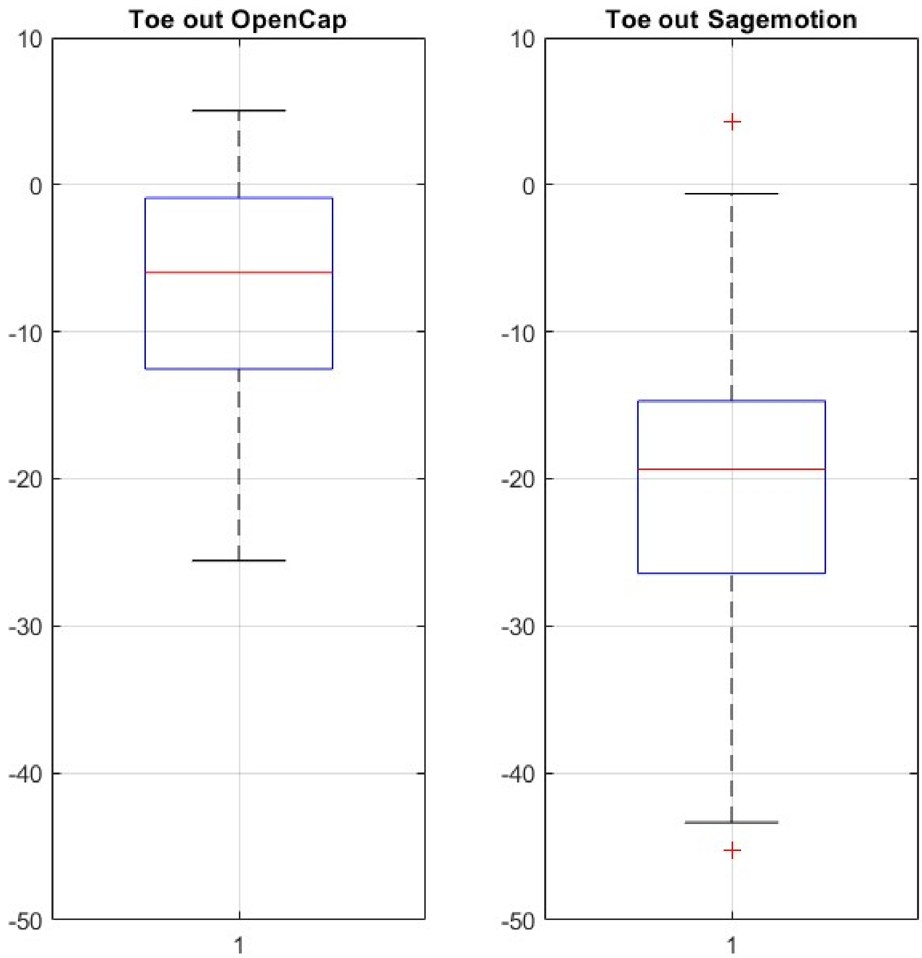

Figure 4.18: Statistical analysis: statistically significant difference between OC (left) and SM (right), all subjects, toe-out technique (p-value = 3.997×10^{-8})

5

Discussion and Limitations

The SageMotion's system validation protocol involved the participation of 4 healthy individuals who were tested in the execution of three different gait retraining strategies.
The primary goal of this thesis work was to evaluate SageMotion's data accuracy and the system's potential as a gait retraining and modification tool, through its comparison with OpenCap, whose suitability had already been tested and demonstrated.
The data processing, followed by the implementation of several statistical procedures, allowed to highlight the distinguishing factors between the two systems, and led to the results summarized in Chapter 4.
This chapter will go through some considerations about the obtained results, discussing and giving an interpretation of the main findings of this study, and trying to trace back to the factors that most effectively discriminated between the two systems' output results.

As for the *Results* part of the thesis, this chapter will discuss the results in separate sections, since each gait retraining technique analyzed led to different findings and associated considerations.
The last section will list some of the limitations of the study, which could have affected the obtained results, and for this reason deserve to be taken into consideration.

5.1 Trunk leaning

The Root Mean Square Errors' (RMSEs) calculation allowed a representation of the discrepancy between the tho systems' measurements.
Regarding the trunk leaning technique, the kinematic data collected by SageMotion compared moderately well on average with those collected by OpenCap, achieving an average overall RMSE of 4.80° with a standard deviation of 2.25°.
These findings suggest a favorable outcome in the evaluation of SageMotion's accuracy with respect to this gait retraining technique, since the results are consistent with several studies which aimed at evaluating and validating markerless or IMU-based acquisition systems comparing them with the gold standard marker-based system. These studies reported, for example, RMSE values ranging from 2° to 10.2° degrees for activities such as walking, running or squatting [11], or a RMSE lower than 5.5° for most segment angles [44], meaning that, overall, the RMSE's results of this study are aligning (and also refining) with those reported in existing literature.

With regard to the inter-subject RMSE comparison, as it's visible from the bar plot displayed in the *Results* section [fig. 4.1], for three subjects out of four the RMSE's values appeared to be consistent with the mean value, which was demonstrated to be aligned with the acceptable values for systems' validations in literature; subject H03, on the other hand, exhibited a 50% higher RMSE value. This result is in accordance with the significant *p-value* extracted for this individual's data, and, since the data plots on the two systems exhibited a sort of offset value between each other, it could probably be attributed to a calibration error of the SageMotion system, that couldn't be verified due to the lack of an explained calibration procedure.

As for the coefficient of multiple correlation, it resulted in a CMC = 0,889 ± 0,078.
This result, which is aligning with the favorable mean RMSE calculated, indicates a strong positive correlation between the TSA waveforms measured by SageMotion and OpenCap, meaning that the values are coherent and similar to each other, and confirms SageMotion's reliability with regard to the trunk leaning technique.

The results obtained by the computing of the one-dimensional SPM allow to state that there was no evidence of statistical difference between SageMotion and OpenCap in any instant of the trunk side angle curve, which represents a positive and encouraging outcome in assessing SageMotion's accurateness in the TSA measurement, and consequently the system's suitability as a gait retraining tool for the trunk leaning strategy.

As already mentioned, under the assumption that for rehabilitation purposes the most relevant aspect is the maximum trunk leaning angle value reached by the patient on each step, it was decided to perform the t tests only taking into consideration the peak values [45].
This set of *t tests*, subsequently subjected to false discovery rate (FDR) correction, resulted in two non significant *q-values* for the first two subjects [tab. 4.3], which confirm the suitably low RMSE values associated to the TSA calculated for H01 and H02; on the other hand, H03 and H04 presented slightly significant *q-values*. This could be attributed to a wrong or imprecise positioning of the SageMotion's nodes, since also a minor rotation of the sensor could impact the measured outcomes, especially for sensitive biomechanical parameters such as the TSA; moreover, the reason for the significant discrepancy between the systems can depend on the calibration procedures of both the systems, as well as on the individual features of the subjects, such as body morphology or walking style, which could affect the measurements of the trunk leaning angle.

Finally, the test was repeated for all the peak values belonging to all the trials for all the subjects, resulting in a non significant *p-value* = 0.945 [fig. 4.8].
This promising outcome, which confirms the SPM results and the favorable RMSE and CMC calculations' outcomes, suggests the suitability of SageMotion as a gait modification tool for osteoarthritic patients within the trunk leaning technique; it is therefore to keep in mind that this result doesn't provide a comprehensive assessment regarding the whole movement; in fact, the repetition of the tests only focusing on the peak values can lead to the loss of information and may not fully represent the complexity of the movement.

5.2 Toe-in and Toe-out

For the toe-in and toe-out analysis it was decided not to compute the root mean square error values, differently from what happened for the trunk leaning technique.

This approach was chosen because the calculation of the RMSE on mean values of the foot progression angle during each stance phase wouldn't have been particularly meaningful; in fact, the mean output value, with respect to the value computed at each instant, could mask detailed variations in the movement pattern and may not accurately reflect discrepancies during specific phases of movement.

Toe-in With regard to the toe-in gait, in order to have a first overview of the results, the mean FPA value was calculated for both the systems.
As expected, the mean values were positive for the toe-in gait, resulting in a mean FPA of 11.2° (with a standard deviation of 12.5°) for OpenCap, and a mean FPA of 10.8° (with a standard deviation of 12.5°) for SageMotion. These mean values are well comparable to each other, and in accordance with the FPA obtained for healthy participants in previous research studies (mean value between 7° and 10°) [46] [47], while the standard deviations result almost doubled, indicating a higher data variability.

The non-parametric *Wilcoxon-Mann-Whitney tests* conducted for each subject, after the FDR correction, resulted in four non-significant *q-values* [tab. 4.4], suggesting SageMotion's reliability and validity in measuring and detecting the FPA changes during the execution of the toe-in strategy.
This finding was finally confirmed by the last non-parametric test, which considered all the mean FPA values for all the subjects, and resulted in a non-significant *p-value* = 0.710 [fig. 4.13].

Toe-out With regard to the toe-out gait, as well as for the toe-in technique, in order to have a first overview of the results, the mean FPA value was calculated for both the systems.
As expected, the mean values were negative for the toe-out gait, resulting in a mean FPA of -7.7° (with a standard deviation of 8.0°) for OpenCap, and a mean FPA of -20.5° (with a standard deviation of 10.7°) for SageMotion. The SM mean absolute value is more than two times higher than the OC's, which doesn't represent a promising result; anyway, it is to specify that in this case the SageMotion mean value is in accordance with the FPA obtained for healthy participants in previous validation studies (mean value between -19° and -17°) [46] [47], while the OpenCap's absolute value is lower than the ones found in the literature, indicating a milder toe-out

gesture. As for the standard deviations, they result almost doubled with respect to the research literature, indicating a higher data variability, aligning with the toe-in technique results.

The non-parametric *Wilcoxon-Mann-Whitney tests* conducted for each subject, after the FDR correction, resulted in three significant *q-values* out of four [tab. 4.5], with only one subject's (H02) measures being comparable between the two systems. This result excludes SageMotion's reliability and validity in measuring and detecting the FPA changes during the execution of the toe-out strategy.
This unpromising finding was confirmed by the last non-parametric test, which considered all the mean FPA values for all the subjects, and resulted in a highly significant *p-value* [fig. 4.18].

The different results obtained for SageMotion's reliability regarding toe-in and toe-out strategies could be attributed to different reasons.
First of all, SageMotion's *Walking Foot Progression Angle App* promised to be able to recognize all the gait phases during the individual's deambulation, and basing on the identified stance phases, to calculate the mean FPA value for each step. However, the number of steps detected by SM in most cases was not corresponding with the number of mean FPA values calculated from OC, whose correctness could be verified thanks to the recorded videos and the movement reconstruction on OpenSim. For this reason, due to the mismatched number of angles' values, it was necessary to cut some of the SM values, in order to be able to perform the tests. This could have affected the results, since it's not possible to assure that each angle value measured by SM was paired with the corresponding one measured by OC. In addition, the inability of SageMotion to properly detect the gait phases during walking represents an important concern for its suitability as a gait retraining and biofeedback tool for pathological patients.
Moreover, some error amplification could have been caused by the nodes' movement, as the foot sensors were placed above the subjects' socks; although they were secured as firmly as possible, some unwanted movement may have still occurred.
Finally, both the studies aiming at validating OpenCap's kinematics and kinetics highlighted the highest errors when analyzing the movement of the subtalar joint, due to the high complexity of the foot segment, which represents a more demanding goal also for marker-based systems. For this reason, the evaluation and interpretation of the results concerning this joint is always more difficult, and the achievement of a good performance of the acquisition system could be

challenging for OpenCap as well [11] [48].

5.3 Limitations of the study

This study presents some limitations that could have affected the obtained results, and for this reason deserve to be taken into consideration.

First of all, the number of subjects that was involved in the study was limited; in fact, a validation study usually recruits at least 10 subjects, which can enhance the results' accuracy and reliability, allowing a wider and more valuable analysis.
The limited number of individuals participating in the study was due not to the lack of individuals available for the data acquisition, but to connection issues between the SageMotion's hub and the sensing nodes during the acquisition, which didn't allow to collect data from all the subjects available. This represents a big concern for SageMotion's accessibility, especially because the system promises to be suitable for acquisitions in any type of environment, for any type of motorial gesture, at any execution speed, but despite these guarantees, the issues occurred for a data collection that took place in a controlled environment with no obstacles or disturbances.
Moreover, three subjects out of four were males, while it would have been more significant if the study had involved an equal number of males and females. In fact, a more heterogeneous group would have allowed for the assessment of any potential influence of gender on the analysis' results.
Additionally, it's important to highlight that SageMotion's ability to estimate informative dynamic measures was tested by having healthy individuals simulate different movement patterns associated with pathology or treatment; the next step represents the validation of these measures in the populations of interest.
Furthermore, the lack of a detailed calibration procedure's explanation for the SageMotion's system didn't allow to delve into the reasons that caused some significant differences between subjects; for example, for one of the subjects (H03), the trunk leaning data for the two systems seemed to present an offset value, that could have been caused by a calibration error for one of the two systems, ascribable to a wrong positioning or a slight rotation of the sensors. While the

OpenCap's *neutral pose* was investigated, and it was established that there were no calibration inaccuracies, it wasn't possible to do the same for SageMotion due to the absence of a reference pose at the beginning of the data collection. The possibility to check and assess the calibration's validity could have influenced the statistical tests' results and consequently the final considerations about the system's suitability.

Another obstacle regarding the evaluation of the system's reliability concerns SageMotion's *Walking Foot Progression Angle App* structure. In fact, the measurement of the foot progression angle at each instant throughout the stance phase would provide a more detailed and accurate representation of gait dynamics compared to only relying on the average angle between 15% and 50% of the stance phase; indeed, it would allow to capture the full variability and subtleties of the foot's orientation during walking, enabling to identify specific points of discrepancy between the systems and leading to more informed decisions regarding the validation and comparison processes.Moreover, the lack of an instant-by-instant output angle value is particularly disadvantageous for the feedback capabilities of the system, since it doesn't allow for the rapid detection of alterations in the foot movement during the support phase, nor for immediate corrections of posture or balance.

Finally, despite OpenCap's promising features, comprising the capability to detect between-condition differences with similar statistical power as motion capture and force plate analysis, with kinematic errors similar to the ones reported for inertial measurement unit–based approaches and commercial and academic video-based systems with eight cameras [11], the system also presents some limitations. In fact, another study [48] highlighted higher RMSE values (with respect to the Ulrich et al. study) for the comparison between OpenCap's and a marker-based system's kinematics of the pelvis, hip, knee, and ankle joints, with the highest errors observed for the subtalar joint.

For this reason, in order to give more credit to the SageMotion's validation, it would have been more significant to compare the system with a gold standard marker-based acquisition system.

6

Conclusions

The primary objective of this thesis project was to test and validate SageMotion, a wearable IMU-based haptic feedback system for gait retraining and modification. SageMotion was presented as an innovative solution for training and rehabilitation, and its applications include walking training, balance training and running training, each of whom intended for a specific target of users (both pathological patients and recreational or professional athletes).
In order to achieve this goal, the system was compared to OpenCap, an already validated video-based system, which provides 3D kinematic and dynamic analysis of human movement.

The performed statistical analysis regarding the execution of three gait retraining techniques, aiming at evaluating SageMotion's suitability as a gait modification tool for patients affected by knee osteoarthritis, shed light on some strengths of the system, as well as some limitations.

The trunk leaning technique analysis brought to encouraging results concerning the Statistical Parametric Mapping outcomes, as well as the Root Mean Square Errors and Coefficient of Multiple Correlation calculation, and also when focusing on the peak trunk side angle values, suggesting that the use of the system can be considered adequately accurate and reliable within this gait retraining technique. This allows to declare SageMotion as a potential tool for biofeedback and gait modification for patients affected by OA regarding the trunk leaning strategy, even though the next step could be represented by a validation study against the gold standard (stereophotogrammetry), whose accurateness and precision have already been proved and assessed in several studies.

The toe-in and toe-out section presented the most controversial results, revealing highly significant discrepancies between the systems for the toe-out technique, while the system proved to be potentially more usable and precise regarding the toe-in technique.
However, the fact that SageMotion provides a mean output FPA, relying on its own gait phases detection, which has been proven to be often imprecise, represents a noteworthy obstacle in terms of the system's accuracy and suitability for rehabilitation purposes; other studies aiming to validate wearable systems for gait retraining [49] [46], perform their statistical analysis by considering an instant-by-instant angle, confirming the unsuitability of only possessing a mean value, which prevents from a precise detection of alterations in the foot movement during the support phase, and as a consequence doesn't allow for immediate corrections of posture or balance.

In conclusion, SageMotion system owns potential as a gait modification and biofeedback tool for patients with knee osteoarthritis, thanks to its features of portability, short acquisition time and limited cost.
However, despite these encouraging attributes, the system presents some concerns that, at time, don't make it a feasible solution for clinical rehabilitative usage for all the gait retraining strategies, such as the lack of a detailed calibration procedure and frequent connection issues, as well as some app's settings and features that hinder its ease of use.
Therefore, this study represented a first insight in assessing the system's accuracy and precision, revealing through its comprehensive statistical analysis some significant discrepancies between the systems (especially for the toe-in and toe-out techniques) that could be attributed to different factors, and for this reason need to be further investigated in the future, ideally by conducting an analysis against a marker-based system, whose accuracy is more extensively verified than OpenCap's.

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