DEVELOPMENT OF A NOVEL STANDARDIZED FRAMEWORK FOR AUTOMATED GAIT PARTITIONING

MASTERS THESIS

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MEDICAL DEVICE DESIGN

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Abstract

Conventional means of characterization, analysis, and diagnosis of gait pathology rely on large and expensive motion capture technology, which demands an elaborate laboratory set-up. Although the said means has established itself as the gold standard for gait analysis, the concomitant resources, accessibility to the patient, and the required expertise has deemed this solution non-scalable. New market solutions such as wearable sensor technology with machine learning-driven algorithmic diagnostics have paved the way for cost-effective alternatives. These novel market solutions see an advantage over the gold standard in terms of the scalability of deployment and accessibility to the end user, without the pre-requisite technical expertise at the users' end to engender an objective basis for gait analyses. This research project was aimed at providing a framework for the development of a novel machine learning-based algorithm for automated gait analyses by exploring and investigating trends in muscle activation and the resultant gait kinematics. Through this framework, a standardized method for partitioning the gait phases under investigation, and the subsequent analyses through feature extraction has been implemented. This standardized method was used to assess the scalability and flexibility of the novel ML-powered wearable sensor technology for unified gait analysis. Furthermore, this project forms a gold standard for the validation of the tool by comparing the data acquired from the conventional motion capture system and the ML-powered wearable-sensor technology.

Introduction

Human gait, which refers to the human locomotive act of walking is an important form of mobility that allows us to participate in and is paramount for labour, societal, and sports-related activities. Deviations in regular walking can have a significant impact on an individual's life. Without clinical intervention, the said deviations can develop into pronounced consequences. This could lead to the exacerbation of the underlying condition causing the deviation and may debilitate the individual. This would impair their ability to perform and contribute to work and society. In turn, this would burden the individual with financial constraints by driving up indirect costs incurred. Furthermore, this would result in the reclusion of the individual from society and would potentially progress to depression, anger, and other mental illnesses. Regaining full mobility through effective treatment has been the primary goal of rehabilitation. The choice of rehabilitation and its efficacy is heavily reliant on an accurate diagnosis of the atypical gait (Langhorne et al., 2009). The current established gold standard in gait analysis is the laboratory-based three-dimensional gait analysis (3D CGA) which includes motion capture analysis, measurement of external forces and muscle activation (Wren et al., 2020). Using 3D CGA analysis, clinicians can objectively identify limb motions, joint angles, muscle activation, and foot and joint loading. Although this gold standard means of analysis has proven to greatly improve the efficacy of treatment, it is accompanied by practical limitations. It relies on expensive equipment, requires an elaborate laboratory set-up, and needs highly trained personnel to ensure data integrity, to name a few. Accessibility to the patients, as these labs are present in highly specialized clinical institutes, and the high concomitant cost adds to 3D CGA's limitations. For example, in the northern Netherlands, only two such specialized facilities are available to patients. Patients in the said region must encumber a waiting period of up to 6 months of which the ones exhibiting the most severe gait pathologies gain precedence of consideration.

Wearable sensor-based systems were introduced as a potentially cost-effective, mobile, off-the-shelf alternative to the laboratory-based method. These sensor systems, which are designed to acquire both muscle activation (electromyography) and movement data (accelerometer, gyroscope, etc.), are driven by predictive machine learning analytics to detect specific gait events. These specific gait events such as heel strike, toe off, etc. are then used to segment the data into the gait phases (swing and stance) for subsequent analysis. In the case of 3D CGA analysis, these gait events are detected using a force plate to discern the start and end of plantar contact. Segmentation of the gait data into the gait phases is essential for further analysis as certain gait pathologies, such as gastrocnemius spasticity, are identified by abnormal ankle extension in the swing phase. Hence, apart from an effective and efficient means of acquiring gait data, segmentation of the same is paramount to robust analysis.

Laboratory-based force plate-based partitioning has shown high accuracy but shows a great deviation in the case of patients with severely impaired gait who exhibit very low foot clearance and very small step lengths (Caderby et al., 2013). It requires expensive equipment, i.e., force plates, and partitions applied to the entire data captured is extrapolated from the gait events captured within the area of the force plate: 2 to 3 steps. Furthermore, trained clinical technicians are required to assess the quality and integrity of the data by manually controlling the partitioning accuracy and correcting irregularities if any. Machine learning (ML) based partitioning overcomes the above limitations and has been widely used in wearable sensor technology as they can include a greater number of steps for accurate partitioning of the data recorded in the patient's home environment.

Although ML power wearable sensors see an advantage in accessibility to the patient, they still have some limitations. The main limitation seen is the lack of flexibility of these systems (i.e., highly dependent on the sensor systems that can be employed, and lack of expansion to partition data acquired through other means) and clinical flexibility. Most of the sensors which incorporate ML partitioning are highly reliant on specific patient groups with specific pathologies which reduces its purview to expand its application to other gait pathologies and applications and is mostly validated on healthy adults. Furthermore, as shown by Kidzinski et al. (Kidziński et al., 2019), a large set of data (>9000 annotated CGA recordings) was required to train the ML model incorporated to accurately partition the data. Concurrently, a dataset size of similar order would be required to re-train the system for a different patient demographic.

Through this master's project, a standardized framework for gait partitioning was implemented. This framework was aimed to be used in the design, development and validation of a novel AI tool conceptualized by Oro Muscles B.V., Groningen, Netherlands. The flexibility and accuracy of the tool were first established on data acquired from laboratory-based 3D CGA patient recordings and in a wearable sensor system designed by Oro Muscles.

Background information

Electromyography

Electromyography (EMG) is a process of recording the electrical activity of the muscles that arise from their activation by the nervous system. The bioelectric signal acquired through this process, called the Electromyogram can be employed in a wide range of applications such as sports analysis, and human-machine interfaces, to name a few. The primary use case of EMG has been to assess muscle health and muscle activity in the clinical sphere and was first introduced in 1966 to diagnose specific muscle disorders by Hardyck et. al. (Cram et al., 1998). The electromyogram can be recorded in two ways:

invasively and non-invasively. Invasive measurement, as shown in Figure 1 Is done by inserting percutaneous needles to specific sites in the muscle and is used where information on highly localized muscle activity is required. The non-invasive means, termed surface EMG (sEMG), uses gel electrode patches placed on the skin at specific sites and records more general activity. SEMG is preferred in applications that involve the dynamic acquisition of muscle activity, and the invasive needles may hinder movement and present discomfort to the subject. Improper functioning of the muscles can be caused by various defects to the neuromuscular or the skeletal system such as stroke, or spinal cord lesions. It can also result in complications such as skeletal deformity, issues with locomotion and development of pain to name a few. EMG of the muscle activity during any specific phase of motion or locomotion can yield an idea of muscle health and motor control. This information can be indicative of various abnormalities such as neural injury or compression, denervated muscles or primary pathological processes.

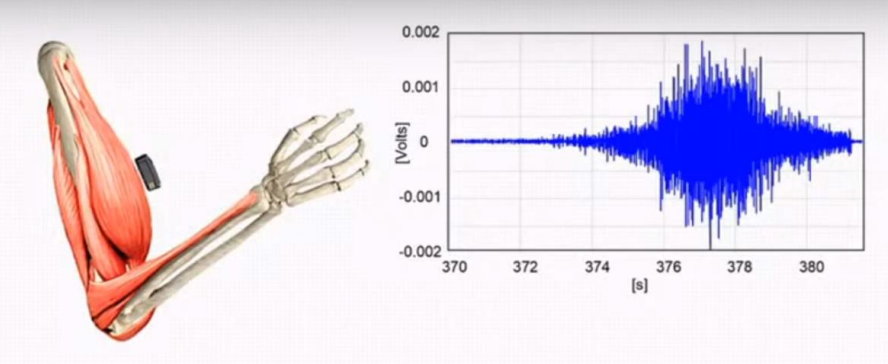

Figure 1: Image highlighting the electromyogram acquired from the biceps brachii.

Source: (Ebbecke, 2020)

Inertial measurement unit

An inertial measurement unit (IMU) is an electronic device that through accelerometers and gyroscopes measure the specific linear acceleration and angular velocity. IMUs are commonly employed in smartphones, and unmanned aerial vehicles, and have now seen an entry into the clinical sphere with human movement and locomotion analysis. The gyroscope measures the 3D orientation with respect to the inertial frame of the earth's gravity and the accelerometer measures the 3D rate of change of the velocity as shown in Figure 2. The data engendered by such an IMU would have 6 degrees of freedom. Newer IMUs also have a magneto meter included which measures the local magnetic field.

Before the introduction of IMUs in the clinical sphere, EMGs were considered a standalone parameter to assess muscle strength and output. The drawback of this approach is that the EMG data acquired cannot indicate the type of muscle contraction, i.e., isometric, eccentric or concentric. The incorporation of IMUs with EMGs can help discern between muscular force output and the actual extent of neuromuscular effort.

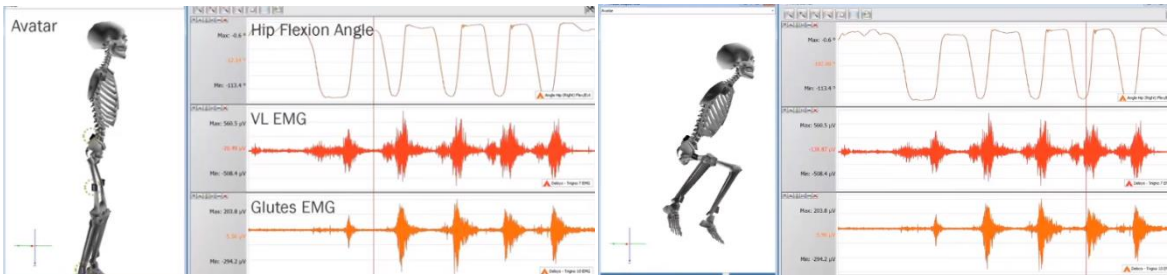

Figure 2: Illustration of EMG data acquired from the vastus lateralis (VL) and gluteus muscle mapped onto hip flexion angle. Source: (Noraxon USA, 2020)

Normal human gait

Normal human gait, as defined by Whittle (Whittle et al., 2007) is "a method of locomotion involving the use of the two legs, alternately, to provide both support and propulsion." It involves the combined activity of the musculoskeletal system, the peripheral nervous system, and the central nervous system's (CNS) centre for locomotion (Sadeghi et al., 2000), (Vaughan et al., 1992). Normal human gait encompasses a series of cascading events: 1) Activation of the CNS centre for locomotion; 2) transmission of the gait signal to the peripheral nervous system; 3) contraction of the respective muscle as a result of neuromuscular activation; 4) initiation of locomotion due to the joint movements, as regulated by the skeletal components, and; 5) the generation of a ground reaction force. One complete gait cycle comprises the duration of walking between two consecutive heel strikes or initial ground contact of the same foot. A complete gait cycle consists of two phases: the *stance phase* and the *swing phase*. These two phases can be further classified into eight sub-phases the start of the end of which can be determined by specific points in the gait cycle as illustrated in Figure 3.

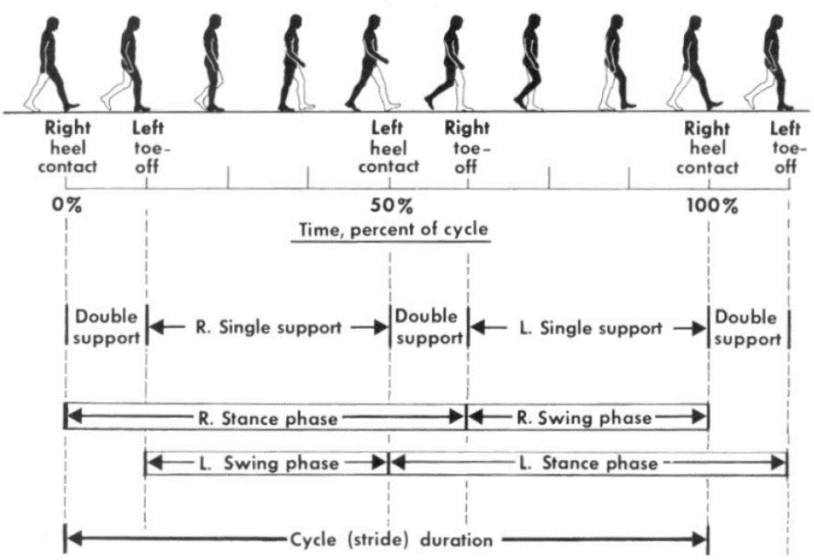

Figure 3: Phases and events of regular human gait. Source: (Perry & Burnfield, n.d.)

The stance phase refers to the part of the gait cycle where either or both feet maintain contact with the ground and amounts to about 60% of the entire gait cycle. This phase is further divided into the five following subphases:

1) *Initial contact* which is characterized by the first moment of contact between the foot and the ground termed *heel strike*. This marks the start of the gait cycle and the stance phase. The knee joint extends rapidly right before initial contact and is almost straight (with little to no flexion of the knee joint) at the point of contact. The ankle maintains a neutral position between *plantarflexion* (ankle extension) and *dorsiflexion* (ankle flexion) Figure 4 (b).

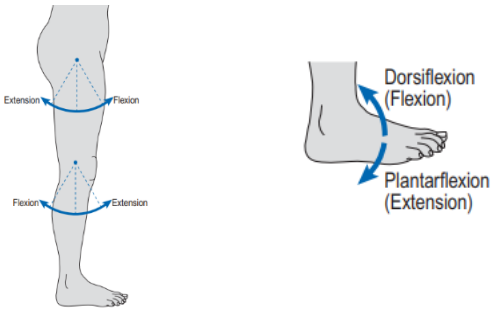

Figure 4: figure highlighting (a) flexion and extension of the hip and knee joint and, (b) plantarflexion and dorsiflexion of the ankle joint. Source: (Whittle et al., 2007)

2) *Loading response* is the stage where the body weight is transferred to the limb and progressively shared between the two limbs in contact. In addition to this, the foot is lowered through plantarflexion over the heel and is hence termed '*heel rocker'* till a stage of complete foot plantation called the *foot flat* period is reached. From a nearly straight knee joint, as seen in the heel strike stage, the knee joint reaches a '*stance phase flexion*' which is controlled by the contraction of the quadriceps Figure 5. This phase amounts to roughly 12% of the gait cycle from the point of initial contact.
3) The *mid-stance* phase is where the entire body weight is transferred to the single limb, and subsequently, the body progresses over the single limb. This is also the period of the gait cycle where the contralateral limb (opposite limb) swings by the ipsilateral limb (limb used as primary reference) and corresponds to a brief period termed as *feet adjacent*. This phase follows the foot flat and extends from 12% to 31% of the gait cycle.
4) *Terminal stance,* which occupies the 31% to 50% interval of the gait cycle following the midstance, begins with the period of the gait cycle where the lift of the heel from the planted surface or *heel off* is initiated. It is characterized by the body, or rather its centre of mass, and the contralateral limb moving ahead of the ipsilateral foot at which point the transfer of weight is initiated to the forefoot. The knee joint shows the most extension right before heel off, proceeding with which flexion of the knee begins. Furthermore, the ankle joint reaches peak dorsiflexion right before the toe-off, proceeding which plantarflexion or extension of the ankle joint begins. The end of the terminal stance is marked by the heel strike of the contralateral foot.
5) *Pre-swing,* which forms the last subphase of the stance phase, covers the 50% to approximately 60% interval of the gait cycle wherein the body weight is unloaded from the ipsilateral foot and transferred to the contralateral foot. The end of pre-swing is often termed as *toe-off,* and at this stage, the knee joint achieves about half of the maximum flexion it would achieve in the swing phase that follows. Additionally, the ankle achieves maximum plantarflexion right after toe-off.

During the entire stance phase, specifically during the initial and final 15%, both the limbs are in contact with the ground and hence these periods are termed *double-support* phases. The remaining duration of the stance phase, particularly in mid-stance, is spent in *single-support*.

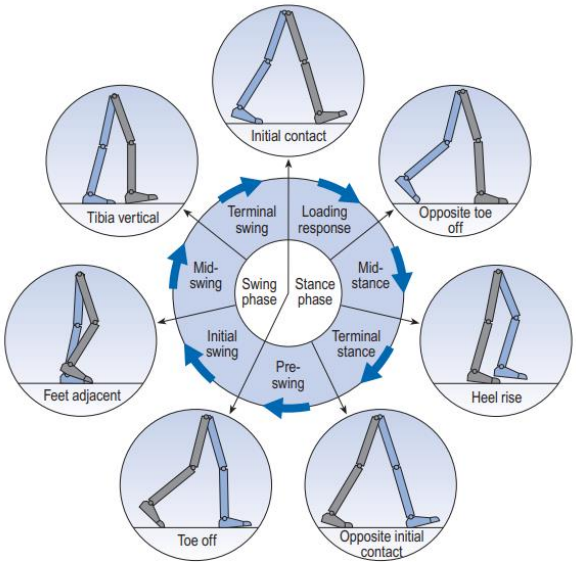

Figure 5: Events of the gait cycle. Source: (Whittle et al., 2007)

The swing phase amounts to the remaining 40% of the total gait cycle. During this period, the foot is not in contact, and the entire weight is borne by the other foot. In essence, while one foot is in its swing phase, the other foot is always in the stance phase. The opposite, however, does not hold true due to the periods of double support. The swing is can be further classified into the following three subphases

1) *Initial swing* covers 60% to 75% interval of the gait cycle following the toe-off where the thigh begins to advance. This stage begins with a rapid decrease in the body weight on the foot. The end of the initial swing is marked by the feet adjacent phase. The initial swing begins with about half of the maximum knee flexion (60° to 70°) achieved throughout the swing phase and with peak knee flexion at the knee adjacent. The ankle shows maximum plantarflexion at the beginning of the initial swing and remains plantarflexed throughout the stage.
2) *Mid-swinging* covers 75% to 87% interval of the gait cycle following the initial swing and its start coincides with the knee adjacent after which the rapid extension of the knee is initiated. The end of this stage is marked by a point in the gait cycle called *tibia vertical* wherein the tibia of the leg in the swing stage is perpendicular to the ground. Through the course of mid-swing, the angle goes from a plantarflexed state to an almost neutral state. A few degrees of plantarflexion or dorsiflexion may be observed at the end of the mid-swing phase.
3) *Terminal swing* or *late swing* covers the 87% to 100% duration of the gait cycle and features complete knee extension. The terminal swing begins with the tibia vertical and ends with the heel strike of the swing phase foot. Changes in ankle and knee flexion are considerably minimal during the terminal swing stage.

Multiple muscles and bones of the body, and specifically the lower limb, are involved in the gait cycle. Many researchers have tried to explain the activity of the various muscles in the gait cycle with an “on-off diagram” as shown in Figure 6 (Gillies & Lieber, 2011). Other researchers have attempted to draw information through the normalization of the RMS envelope and the temporal characteristics of

muscles with peak activity, generally to the reference point of maximal isometric contraction (Stulen & DeLuca, 1981).

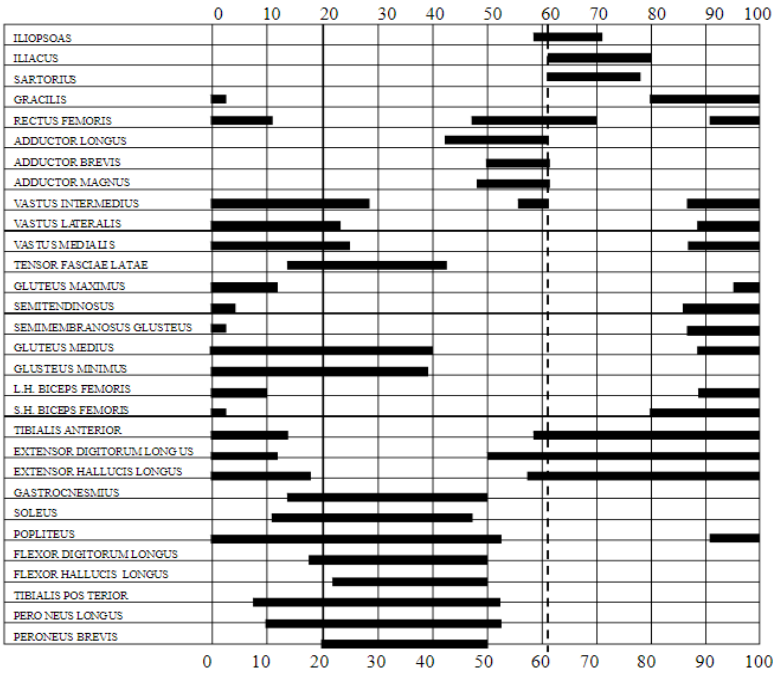

Figure 6: The "on-off" diagram highlighting the activation of the muscles of the trunk and the lower limb in the various phases of the gait cycle. Source: (Tao et al., 2012)

Gait pathologies and abnormalities

The sequence of the gait stages mentioned above may vary between individuals, and even with the individual themselves and still qualify as normal gait. Significant aberration in the gait sequence can be indicative of gait pathologies or abnormalities, some of which can be visually identified, while others need elaborate clinical analysis. For gait efforts to amount to locomotion of the body certain requirements must be met. Each limb should be capable of supporting the load generated by the body mass, balancing the body during single support stages must be possible, and the leg in the swing phase should advance the planted limb at the end of the swing with sufficient force and energy. These requirements are met in the case of both normal gait and some forms of pathological gait, in the case of the latter deviations in the form of abnormal and/or asymmetrical movement, a significant increase in the expenditure of energy, compensatory mechanisms or the need for gait assist devices is seen. For example, a patient with pain in the left knee may display asymmetrical walking wherein a greater portion of the gait cycle is spent on the right limb. This may either be a compensatory means to reduce pain, or a relative improvement in the efficiency of energy expenditure when compared to their walking pattern conforming to normal gait. The gait process is a collaborative task of the central nervous system, the peripheral nervous system, and the musculoskeletal system, clinical dysfunction of any of these parts may result in atypical gait patterns.

In a general sense, the following aspects can be analyzed to identify irregular gait:

Table 1: Observed gait irregularities.

IRREGULARITY OBSERVED	DESCRIPTION
Abnormal initial contact	Visible irregularity in ankle flexion during the transition from terminal swing to initial contact which can lead to subsequent variation in the loading response. May range from excessive plantarflexion which results in a '*foot slap*' to excessive dorsiflexion resembling a '*foot drop*.'
Impaired flexion control	Inadequate control of the flexion of the ankle to promote toe-off at the end of pre-swing
Contralateral vaulting	Defined as "plantar flexion of the contralateral ankle during the single-limb support phase" (Drevelle et al., 2014).
Excessive knee flexion/extension	Significantly high-grade knee extension or flexion which would result in a gait pattern that resembles 'crouched walking.'
Irregular rate of knee extension	An abrupt or accelerated rate of knee extension in the pre-swing segment of the swing phase
Asymmetrical hip movement	Gait patterns that resemble *hip thrusting, pelvic retraction,* or asymmetrical sway of the hip.
Gait circumduction	Gait pattern where the foot follows a semi-circular path parallel to the ground during efforts of advancement of the swinging limb
Increased lumbar lordosis	Characteristic increase in the curvature of the lower lumbar segment of the spinal cord during selective phases of gait.
Unusual lean of the trunk	Unusual lean of the upper body in either the posterior or anterior direction during the gait cycle. Asymmetrical or excessive lean of the trunk sideways during the gait cycle may also be observed

According to Jacquelin Perry (Perry & Burnfield, n.d.), the causes of atypical gait can be classified into five broad categories which encompass both pathological gait and abnormal gait. These five categories are elucidated below.

1. *Structural deformity*

This form of atypical gait is generally caused due to the impairment in the range of motion of the joint brought about by tissue contracture i.e., "permanent shortening of the musculotendinous complex limiting the mobility of the joint" as defined by Stephane Armand (Armand & Attias, 2019). The structural deviation exhibited in the cases of tissue contracture is primarily due to the development of fibrous tissue either due to prolonged periods of local or general musculoskeletal inactivity or scar tissue formation from an injury. Apart from tissue contracture, congenital deformities such as atypical joint curvatures and conditions like *club foot* contribute to atypical gait pertaining to structural deformities.

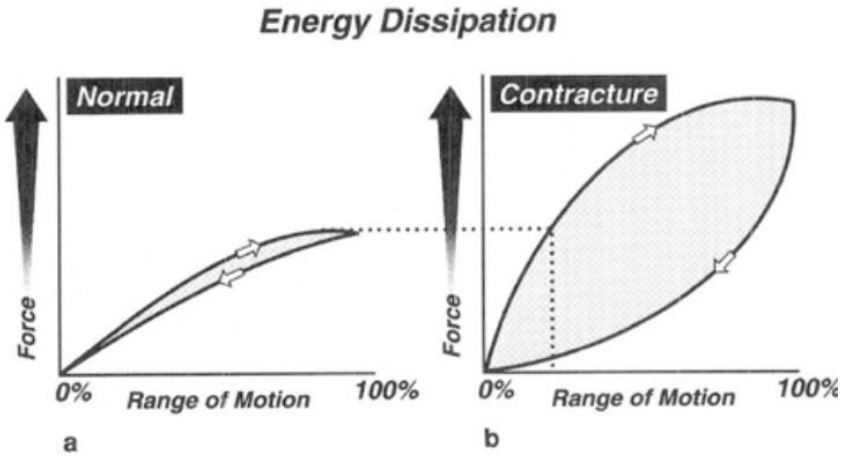

Figure 7: Joint force as a function of Range of Motion (ROM) in the case of (a) healthy adult joint and, (b) joint contracture. Source: (Perry & Burnfield, n.d.)

Knee flexion contracture, to elucidate the effects of tissue contracture with an example, results in impaired advancement of the thigh of the swinging limb as a result of excessive flexion of the knee Figure 7. This results in improper distribution of weight in the tibia vertical phase, which is then compensated by the subject by conscious additional extension of the knee, as determined from the muscle activation trends, to prevent asymmetrical terminal knee extension. In other cases, pathological conditions can catalyse structural deformity, and subsequently affect the range of motion or induce joint contracture. Deformity or disorder with an upper neuron process, as is in the case of a stroke with concomitant hypertonicity, can bring about the same effect (Webster & Darter, 2019).

2. *Muscle Weakness*

Gait aberrations that are a result of muscle weakness generally arise due to the lack of recruitment of the necessary number of motor units required to generate sufficient force to either generate the required wing or withstand the load on the limb during the stance phase. This muscle weakness can either be attributed to an upper neuron condition pertaining to the CNS and the spinal cord, a lower neuronal disorder relating to the peripheral nervous system or the aspects of the neuromuscular junction or muscle atrophy. Upper neuronal conditions are generally indicated by hindered control of the muscle with hypertonicity and, hyperreflexia with concomitant impairment in the impression of tactile sensation. Pathology with the lower neuron segment usually results in hypotonicity of the muscles, and sedate reflexes. On the contrary, upper neuronal pathologies manifest as hypotonicity of the muscles and impaired or delayed lower limb reflexes. The orthotic rehabilitation intervention for both differs vastly. Clinical analysis of the type of muscle weakness should also take into consideration the localization of the pathology. Localized muscle weakness, as observed by premature foot flat or foot slap on the onset of loading for patients with impaired dorsiflexion.

3. *Impaired sensory perception*

According to Dan Brennan (Brennan, 2021), “proprioception, otherwise known as kinesthesia, is your body’s ability to sense movement, action, and location.” Impairment of the same can lead to obstruction in walking by resulting in excessive motion of the swinging limb to achieve the required clearance. This is more common in patients with peripheral neuropathies as compared to those with single peripheral nerve lesions which have been (Webster & Darter, 2019). Sensory impairment can also affect ambulation due to hindered perception of gait events such as heel strike and toe-off, which can significantly alter the loading response. This hindered sensory impairment may also result in

exaggerated and hard contact with the ground or premature unloading. Rehabilitation and treatment for sensory impairment are complex because it tends to be ignored as it is not categorically visible (Perry & Burnfield, n.d.). Special care must be taken in the case of orthotic rehabilitation to ensure complications from impaired sensory perception such as damage to the skin and progression of peripheral neuropathy. Furthermore, rehabilitation in the case of proprioceptive loss remains burdensome most tests to assess the impairment are subjective, and objective assessment encompasses just three grades: absent, impaired, and normal, and hence not quantifiable.

4. *Pain*

A wide range of conditions involving either the neuronal system or the skeletal system (muscles, tendons, etc.) can subject a patient to significant amounts of pain, which can subsequently affect their gait. Increased tension of the tissues of the limb and the joint, which is the case in conditions such as tissue damage due to trauma or arthritis, remains the primary cause of pain. Furthermore, prolonged atypical gait because of pain has been shown to result in eventual skeletal deformity and muscle weakness due to atrophy. This increase in tissue tension is most commonly indicated by a change in the intraarticular pressure which can lead to a change in posture i.e., degree of flexion or extension of the joint.

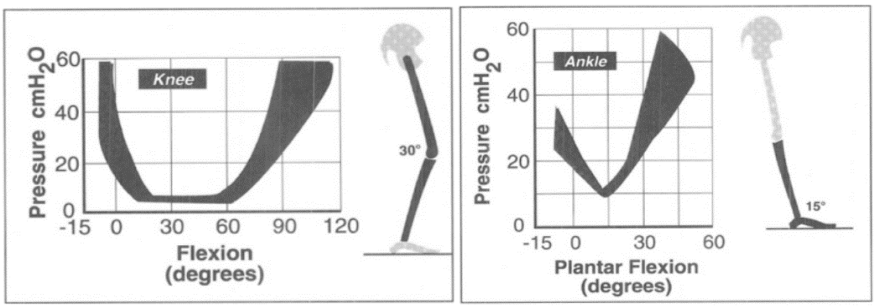

Figure 8: Degrees of flexion of (a) the knee joint and, (b) the ankle joint as a function of intra-articular pressure. Source: (Perry & Burnfield, n.d.)

In Figure 8 shown above, which corresponds to a swollen knee joint and a swollen ankle joint, it is noticeable that the intraarticular pressure is the least in a range of 15° to 60° in the former case and around 15° in the latter. This reduced range of motion would result in the patient relying on these angles of flexion/extension while walking as a means of relieving discomfort. Since the extent of pain is hard to quantify and purely relies on the subject/patient's interpretation and understanding of the same, is it hard to account for in gait analysis and rehabilitation. Proper understanding of the underlying cause of pain is paramount for effective rehabilitation.

5. *Impaired motor control*

Patients with lesions in the central neurological system see the development of spastic paralysis. This paralysis generally manifests as four primary functional deficits which can either present themselves alone or emerge in combination with each other to varying extents. Impaired motor control can result from trauma and injury to the brain or the cervical and the thoracic segments of the spinal cord as seen in stroke, tetraplegia, multiple sclerosis, cerebral palsy, certain infections, and tumours. The four primary functional deficits are impaired selective control of muscle groups, muscle weakness, spasticity, and the emanation of primary patterns of locomotion (Perry et al., 1978), (Perry et al., 1974).

Selective control of muscle groups allows the independent movement of a specific joint, muscle, or muscle groups. Regular human gait relies on simultaneous selective control of multiple muscle groups during the various phases of the gait cycle. Impairment of the same leads to the loss of the patient's ability to recruit specific muscle groups. Muscle and joint reflexes however remain intact. Muscle weakness due to impaired motor control manifests itself in the display of atypical gait in a similar way. In the swing phase of the gait cycle, a characteristic net flexion pattern is observed and subsequently a net extension pattern for the stance. In the case of muscle weakness, the patient exhibits an inability to activate the distinct muscle groups which pertain to the different phases of gait. This leads to an inability to transition smoothly from swing to stance (and vice versa).

Impaired motor control due to muscle spasticity hinders the quality of the activity of the eccentric muscles involved in the gait cycle. Spasticity can be categorically identified by observing the muscle's response to stretch. In the case of a quick stretch, an onset of clonus, i.e., a neurological condition that results in rapidly occurring involuntary rhythmic contraction of the muscle is observed. On the contrary, continuous muscle activation is observed in response to slow stretch, which is often clinically misinterpreted as muscle contracture as shown in Figure 9 . Furthermore, muscle spasticity can further

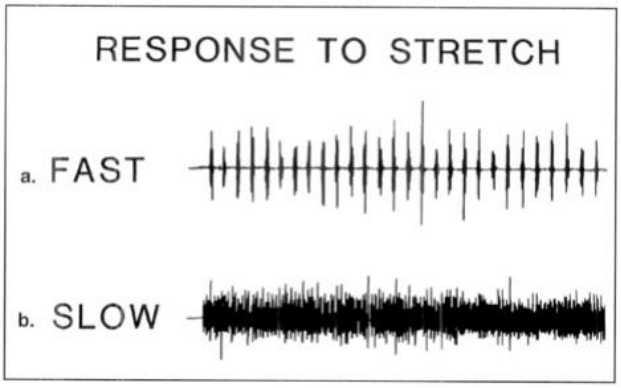

Figure 9: Muscle response to fast and slow stretch in the case of spasticity. Source: (Perry & Burnfield, n.d.)

complicate gait findings during physical examinations as the hypertonicity can mask the extent of the weakness of the opposing muscle groups if present in conjunction. For example, in the case of spasticity of the soleus and the gastrocnemius muscle, exaggerated plantar flexion is observed during the swing phase. This phenomenon, termed *foot drop*, can lead to the patient's impaired ability to shift from the sing phase to the stance phase due to the absence of an effective ankle rocker, which subsequently engenders an improper loading response during the gait phase transition. The visible emergence of primary locomotor patterns is another embodiment of impaired motor control. This pattern can be visually identified, as shown in Figure 10 through a pattern of mass flexion during the swing phase i.e., flexion of the hip and the knee joint in conjunction with ankle flexion accompanied by inversion. On the contrary, a pattern of mass extension is observed during the stance phase. The inability to attain a mixed response of flexion and extension during the individual phases of gait results in a non-fluidic gait motion, especially during the transition of the two gait phases.

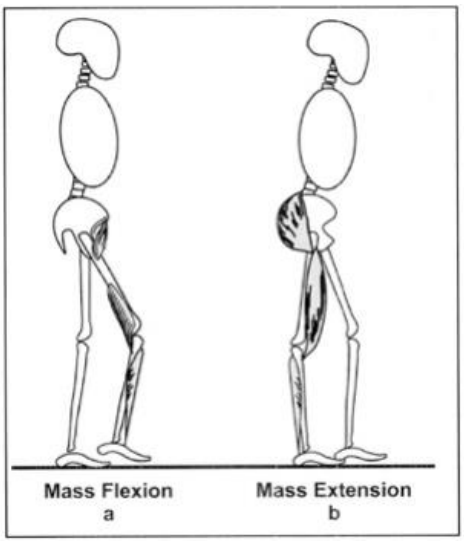

Figure 10: Primary locomotor patterns due to impaired motor control resulting in (a) mass flexion and (b) mass extension. Source: (Perry & Burnfield, n.d.)

Gait analysis

Gait analysis is a multi-faceted and systematic approach that requires the integration of multiple dimensions of information to study human locomotion (Tao et al., 2012). This information can pertain to joint and limb motion, the forces generated by the said motions, the moments and power generated by the joint due to the resultant joint flexion and extension, and data pertaining to muscle activation. Through the integration of this information, various phases of gait can be identified, the kinetic and kinematic parameters for the identified gait stages and events can be obtained, and the musculoskeletal functions can be subjectively assessed by quantifying them. Gait kinetics refers to the moments and forces resulting in the motion of the lower limbs during the gait cycle such as the distribution of plantar pressure, and ground reaction force (GRF) (Tahir et al., 2020). Gait kinematics uses the range and angles of motion of all the joints that produce that motion. Gait analysis has also been used in sports sciences, rehabilitation, and biomedical engineering for effective means of characterization of human locomotion. Two main techniques have been employed in human gait analysis. These two methods are elucidated below:

1. 3-Dimensional Clinical Gait Analysis (3D CGA)

This form of clinical gait analysis has established itself as the gold standard over the years. It features a large room, or a 'laboratory,' in which a subject is asked to walk through, and their gait kinetics and kinematics parameters are measured and analyzed. The gait kinematics measurement system includes a camera system, several markers, and a computer software. The camera system comprises multiple cameras placed at various positions in the room to simultaneously capture the movement of the subject from different angles. The markers are camera identifiable fixtures placed on specific locations on the skin, limb, joint and even the trunk. The markers can either be rigidly placed on the specific segments using rigid arrays or can be placed directly on the skin as shown in Figure 11. These markers

can be active, i.e., infrared emitting and equipped with a power source or passive, which rely on the reflection of light from a stationarily placed light source

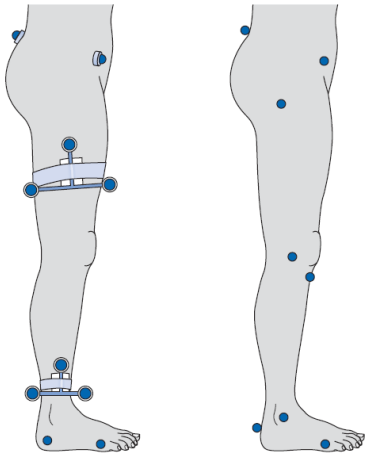

Figure 11: Rigid and skin placement of optical markers. Source: (Whittle et al., 2007)

The camera system captures the position of these specific markers as the subject is asked to perform a task like walking, running, etc. without altering the position of the camera system and the integration of these images from all the different angles gives the 3-dimensional coordinates of each of these markers thereby indicating the position of the joints and libs in free space. Special plug-in software integrates the images of the marker positions to determine the joint positions, and calculate the angular and linear joint velocities and acceleration by subsequent mathematical differentiation (Delisa & Kerrigan, 1998). The rate of error in the position, velocity and acceleration with a similar system will boil down to the choice of marker positioning. The gait kinematics are computed using the muscle activation recordings and measurements of ground reaction forces (GRF). EMG electrodes are placed at specific locations on the muscles of interest primarily on the lower limb, and sometimes the hip to measure muscle activation at specific cycles of gait. The ground reaction force is measured using a force platform, commonly known as a 'force plate' as shown in Figure 12 which is typically a rectangular plate measuring 60 cm x 40 cm x 1 cm (Zhang et al., 2017a). The plate houses tiny transducers which measure 3-dimensional forces applied to them. The forces measured when a subject steps on them are used to discern the initial contact, the maximum load, and the toe-off. The

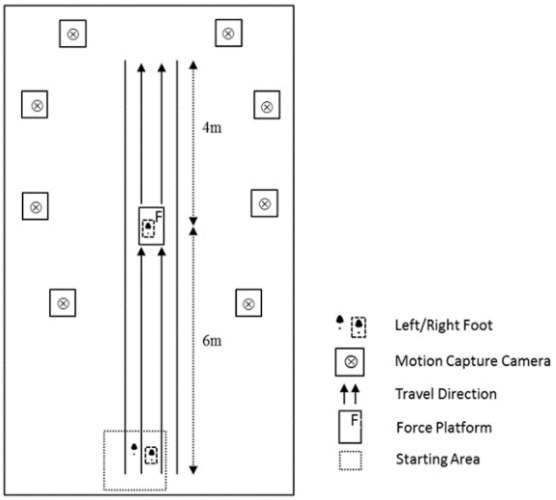

Figure 12: Typical layout of the 3D CGA architecture. Source: (Zhang et al., 2017b)

timing of these events is used over the entire gait recording to partition the various gait phases and gait events.

Apart from the above systems described for the measurement of gait kinetics and gait kinematics, this means of gait analysis also requires an experienced clinician to ensure the integrity of the set-up, the protocol followed during gait recording, any aberrations encountered during the data acquisition, and identification and rectification of corrupted data.

2. *Wearable sensor-based methods*

Analysis of gait can also be carried out with wearable sensor systems instead of a laboratory setup, as first proposed and conceptualized by Morris in 1973 (Morris, 1973). These primarily incorporate the use of IMUs and EMG sensors that can be placed at various locations of interest on the limbs and the trunk. Synchronization and processing of the acquired data can be done externally on a computer after wired or wireless transmission of the same or can be done online. Online wearable sensors generally are equipped with machine learning analysis capabilities that was been trained with multiple sets of data before carrying out specific analyses. Other wearable sensor solutions include the use of flexible goniometers which measure the joint angle, and force sensors embedded into the soles of shoes to measure the centre of pressure and the ground reaction force. These wearable sensor-based methods have provided a low-cost alternative to laboratory setups and have shown the potential for wide-scale deployment.

Materials and methods

The following section describes the equipment used and the procedure involved during the process of data collection, pre-processing, and subsequent analysis. The demographic of the patients included in the study for the different setups are highlighted as well.

Experimental setup

1. *3D CGA lab setup*

The 3D CGA data recordings of patients were carried out in the human movement laboratory, roughly the size of two hospital rooms, equipped with a complete motion capture system and force plates embedded in the ground at the University Medical Centre Groningen. The set-up included 3D markers, visible as the iridescent spheres in Figure 13, placed on the lower limb as prescribed by the plug-in gait model (2010) by Vicon. Limb kinematics were recorded using 10 Vicon Vero optical cameras sampled at 100Hz and the subsequent visual data processing was carried out with the proprietary Vicon motion capture software Nexus 2.12. Two AMTI force plates were employed to record the ground reaction force at a sampling rate of 1000 Hz to identify gait events, i.e., heel strike and toe off in conjunction with the Vicon Nexus algorithm. A vertical ground reaction force of 10N was set as the threshold to discern between *heel strike* and *toe-off* events. In cases where the force plate data engendered corrupted data due to significant deviation in gait, experienced lab personnel manually annotated the gait events under the supervision of the principal investigator. The activity of the major muscles of the lower limb (rectus femoris, vastus medialis, semitendinosus, and the medial head of the gastrocnemius, soleus, and the tibialis anterior muscle) were acquired using Cometa EMG sensors at a sampling rate of 1000 Hz. The EMG sensors, the black sensors seen in Figure 13, were placed next

to the 3D marker set in accordance with SENIAM (Surface ElectroMyoGraphy for the Non-Invasive Assessment of Muscles) guidelines for electrode placement. The absolute distance between the 3D markers placed on the lateral malleolus of the left and the right limb was used to compute the step lengths using the Vicon plus-in gait model. The anterior spine marker was used for the identification of gait speed. Additionally, custom Python scripts were employed to extract these spatiotemporal parameters, which were then checked by the principal investigator for data integrity.

2. ORO Muscles set up

The wearable sensor technology by Oro Muscles B.V. used in this study is an integrated system which records muscle activation and the resultant joint movement simultaneously. The EMG data was acquired at a sampling frequency of 500 Hz and the joint kinematic data was acquired with the inertial measurement unit (IMU) recorded accelerometer and gyroscope readings at 100 Hz each. Two IMU and EMG sensors, seen as the sensor taped to the foot with one set of white electrodes in Figure 13, were placed proximal to the Cometa EMG sensors on the shank and the foot of the gastrocnemius and tibialis anterior muscles respectively. All the Oro sensor system channels were linked via raspberry pi for data recording.

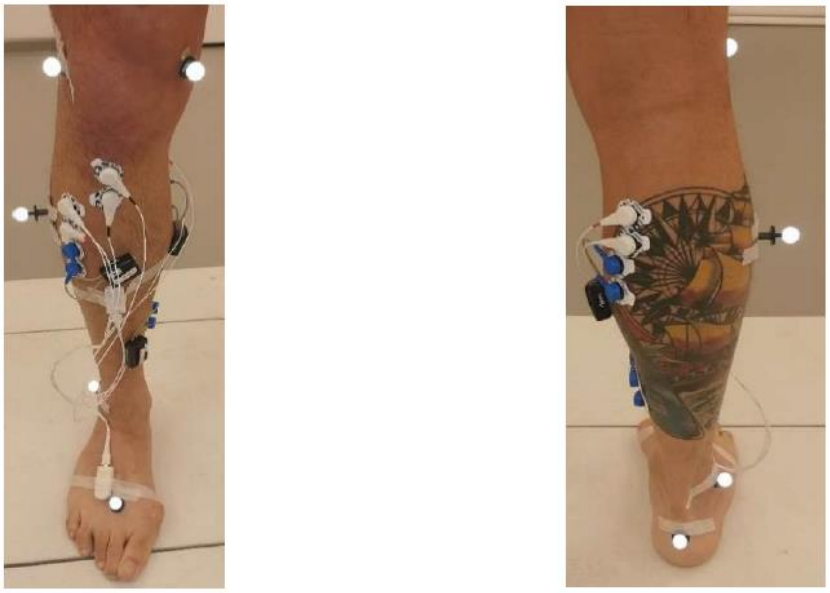

Figure 13: Image indicating the placement of the 3D CGA sensors with the optical markers and the Oro sensor system. Source: (Christian Greve et al., 2022)

Data pre-processing

The data acquired from the Oro system was time synchronized with the data obtained from the 3D CGA data through custom MATLAB scripts. Furthermore, the EMG data from both, the Cometa system and the Oro system were bandpass filtered at 20 Hz (upper cut-off) and 450 Hz (lower cut-off) with a fourth-order Butterworth filter. The envelope of the EMG signal was obtained by rectifying and low-pass filtering the EMG data at 10 Hz with a fourth-order Butterworth filter.

Patient recordings

The following section elaborates on the patient demographic that fit the inclusion criteria for the laboratory-based and wearable sensor-based data recordings. Patients with gait pathologies as mentioned in the section were selected and were required to carry out walking trials either barefoot, with shoes with specifically designed orthosis on, or a combination of these.

1. *Patient recordings for lab-based 3D CGA set up*

   Patient data recordings between April 2021 and June 2021 carried out at the human movement laboratory at the University Medical Centre Groningen (UMCG), Netherlands were selected for analysis. A total of 14 datasets from 13 patients, who had provided informed consent (refer to Appendix), participated in 60 walking trials in a total of an average distance of 8 metres each. Recording of the left and the right limb was acquired separately resulting in a total of 120 datasets. Of the 13 patients, 8 children (12.8 ± 3 years) and 5 adults (43.8 ± 14.6 years), nine of the patients included were diagnosed with spastic cerebral palsy, one patient with an incomplete lesion of the spinal cord, one with an undetermined lesion of the CNS, and one with primary lateral sclerosis. One of the patients with spastic cerebral palsy participated in the study before and after rehabilitation for the same.

2. *Patient recording for the Oro wearable set-up*

   The first 5 patients included in the lab-based set-up had participated in the data recording with featured the wearable sensor set-up. The average age for this set of patients was (59.2 ± 14.6) years old. Of the five, two patients were diagnosed with a stroke, one patient with cerebral palsy, one with partial injury to the spinal cord, and the last with multiple sclerosis. The spatiotemporal gait parameters of the patients involved in the Oro sensor system as shown in Table 2.

Table 2: Spatiotemporal gait parameters of the patients recorded with the Oro sensor system. Source: (Christian Greve et al., 2022)

Condition	Step Length Left (Mean (m))	Step Length Right (Mean (m))	Step Length Left std (Mean (m))	Step Length Right std (m)	Gait Speed (Mean (m/s))	Number of Steps Left	Number of Steps Right
Barefoot	0.149	0.24	0.06	0.056	0.134	7	7
Barefoot	0.467	0.501	0.046	0.045	1.133	29	30
Shoes/Orthotic	0.439	0.485	0.053	0.053	0.979	43	41
Barefoot	0.254	0.032	0.014	0.01	0.184	27	21
Shoes/Orthotics	0.278	0.058	0.017	0.025	0.228	11	12
Barefoot	0.222	0.25	0.023	0.011	0.287	10	11
Shoes/Orthotic	0.284	0.362	0.024	0.022	0.449	8	8
Barefoot	0.475	0.14	0.024	0.022	0.237	24	22
Shoes/Orthotics	0.478	0.186	0.02	0.042	0.273	29	28
Mean	0.338	0.250	0.031	0.031	0.433	20.9	20
std	0.119	0.160	0.016	0.016	0.344	11.8	10.9

Results

Approximately 300 features, including Time domain (TD) and Frequency domain (FD), were extracted from the muscle activation data (EMG) and the movement data (accelerometer and gyroscope), and mapped with each other to identify trends indicative of pathological gait. To establish and demonstrate a clinical use case, the data collected was restricted to the muscle activation and resultant motion of the lower limb, specifically the gastrocnemius muscle. The partitioning of the data to discern between the swing and the stance phases of the recorded gait was done with the proprietary Oro Muscles Graphical User Interface (GUI) (Figure 14) based on the accelerometer and gyroscope data fed in. The user manually annotated the swing phases of a few steps (3 to 5) which acted as "hints" for the Oro Muscles AI tool to partition the rest of the dataset. This tool subsequently outputs the partitioned accelerometer and EMG data annotated.

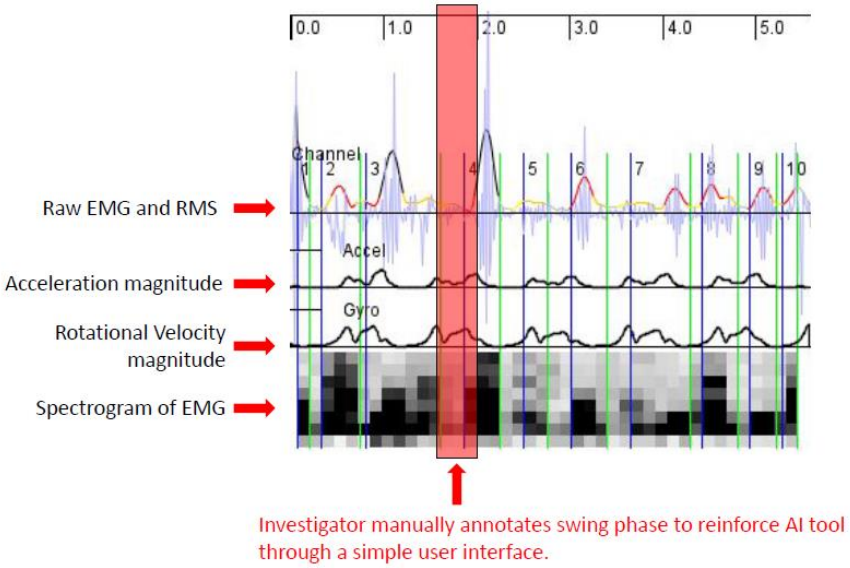

Figure 14: Snapshot of the Oro muscles GUI for gait phase partitioning. Courtesy of Oro Muscles B.V, Groningen, Netherlands.

Part 1: partitioning of the 3D CGA data

The 3D CGA data recorded was fed into the Oro muscles software for segmentation. The force plate events in the data input were checked by a qualified technician prior to segmentation to ensure data integrity. The data output by the software was visualized using custom MATLAB scripts to assess the accuracy of the partitioning. The partitions of the accelerometer data were mapped onto the EMG data for subsequent feature extraction. The partitioned EMG and accelerometer data for the left and right gastrocnemius muscle recorded from a healthy individual is shown in Figure 15. It is noteworthy to observe that the technician-validated partitions accurately match the AI partitioning.

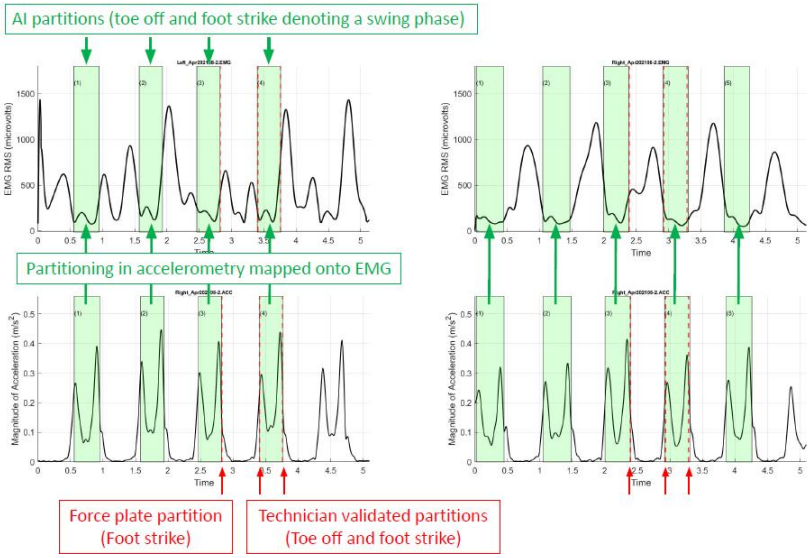

Figure 15: Visualization of partitioned data of the left the right limb. Source: (Christian Greve et al., 2022)

Atypical gait was identified by the visually noticeable asymmetry in the activation of the gastrocnemius muscle of the two limbs which did not correlate with the observed motion of the two limbs. Furthermore, noticeable *foot drop* during the swing phase and/or a *foot slap* during the start of the loading response, which have been the established tell-tale signs in visual identification of gait pathology was observed. The data recorded from a patient with gastrocnemius spasticity was partitioned and visualized to observe relevant objective trends to extract (Figure 16).

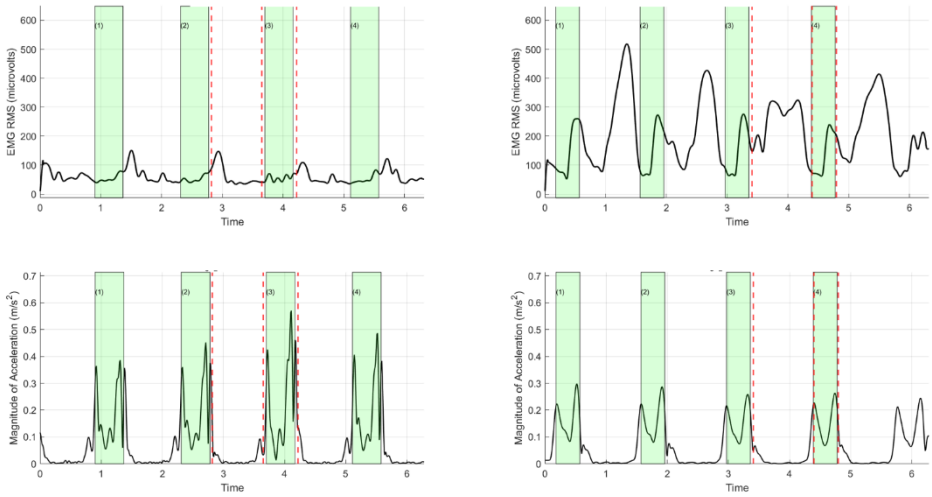

Figure 16: EMG and accelerometery data visualized for patient with left gastrocnemius spasticity.

Although this visually observed trend in the acquired data was indicative of atypical gait as a result of the spasticity of the gastrocnemius muscle, it only formed a subjective basis of identification of the same. A quantifiable metric representing the trends indicated was required to establish an objective basis for analysing the gait pathology. The RMS envelope of the partitioned EMG data was primarily used to analyze trends pertaining to muscle activation. One primary feature that showed promise in

the identification of gastrocnemius pathology was the ratio of the area under the curve (AUC) of the RMS envelope in the swing phase as compared to the whole gait cycle.

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Left				Right				Ratios Left/Right				
2	Cycle	AUC Swing	AUC Stanc	AUC total	Cycle	AUC Swing	AUC Stance	AUC total	Swing	Stance	Total	Swing/Total	Stance/Total
3	1	55.99377	297.9663	353.9601	1	48.32831	324.49847	372.8268	1.158612	0.918236	0.949396	1.2203682	0.96718004
4	2	91.50758	367.5957	459.1033	2	47.37795	375.10393	422.4819	1.931438	0.979984	1.086682	1.7773726	0.90181303
5	3	69.25331	209.3431	278.5965	3	78.17878	306.43205	384.6108	0.885833	0.683163	0.724359	1.2229187	0.94312765
6	4	83.94555	728.431	812.3766	4	43.60613	346.97206	390.5782	1.925086	2.099394	2.079933	0.9255519	1.00935636
7					5	45.67864	319.03044	364.7091					

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Left				Right				Ratios left/right				
2	Cycle num	AUC Swing	AUC Stanc	AUC total	Cycle num	AUC Swing	AUC Stanc	AUC total	Swing	Stance	Total	Swing/Total	Stance/Total
3	1	21.6105	67.32559	88.93609	1	56.39221	245.8915	302.2837	0.383218	0.273802	0.294214	1.302514294	0.210210345
4	2	21.25216	60.72839	81.98054	2	59.91152	221.6175	281.529	0.354726	0.274023	0.291198	1.218161827	0.224948333
5	3	23.20124	56.99163	80.19287	3	59.3556	249.1637	308.5193	0.390885	0.228732	0.259928	1.503820908	0.152100324
6	4	21.03732	51.97674	73.01406	4	52.9148	319.8019	372.7167	0.39757	0.162528	0.195897	2.029483856	0.080083386

Figure 17: AUC ratios for a) normal gait and b) left gastrocnemius spasticity.

Figure 17 shows the AUC ratios for the graph of the normal gait shown in Figure 15 and for left gastrocnemius spasticity shown in Figure 16. This shows a clear deviation in the asymmetry of the muscle activity in the left and the right gastrocnemius muscle activity. Multiple datasets were analyzed to find a definitive trend to not rely on symmetrical data to draw analyses. In general, it was observed that in patients with normal gait, the AUC ratio of the gastrocnemius activity in the swing phase as compared to the total cycle was around 15%. Higher values of swing phase to total phase AUCs were associated with higher levels of gastrocnemius spasticity with the above subject's mean value at 27%.

Thus, an objective basis for identifying pathology was established. Clinicians could choose the metric of interest based on the muscle under investigation to identify trends and establish a quantifiable means of assessing gait pathologies.

Part 2: Evaluation of the flexibility of the tool

The tool was evaluated for flexibility of application by matching the partitioning accuracy for the 3D CGA data with the data fed in from the Oro Sensor system collected simultaneously. After the partitioning of the data, the two sets of data were time-synchronized by matching the peaks of the accelerometer data of the two datasets such that the net difference between the two datasets and the AI-identified partitions were minimal as shown in Figure 18.

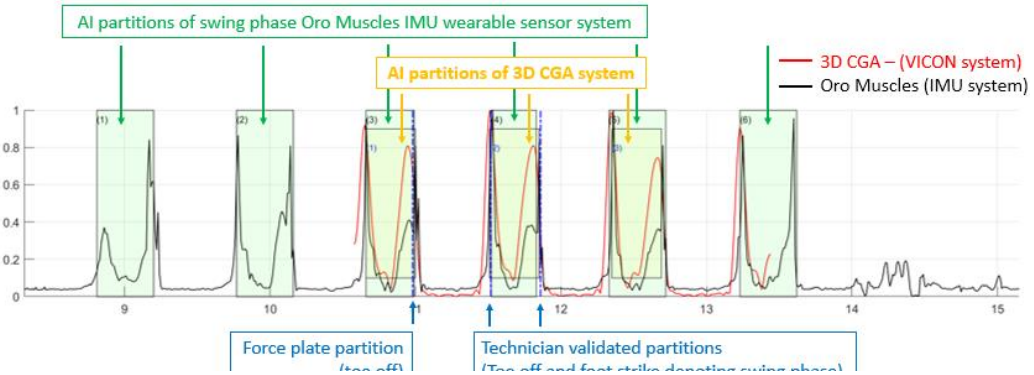

Figure 18: Partitioned Oro sensor data visualized with partitioned 3D CGA data.

As seen in the figure, the AI partitions for the 3D CGA data and the AI partitions for the Oro Systems data match to a great degree and agree with the technician-validated force plate readings. This establishes the flexibility of the AI tool with data acquired from different systems. Partition mapping from accelerometer data to EMG data as shown in Figure 19 can also be carried out with the tool and implementation of the same showed similar accuracy.

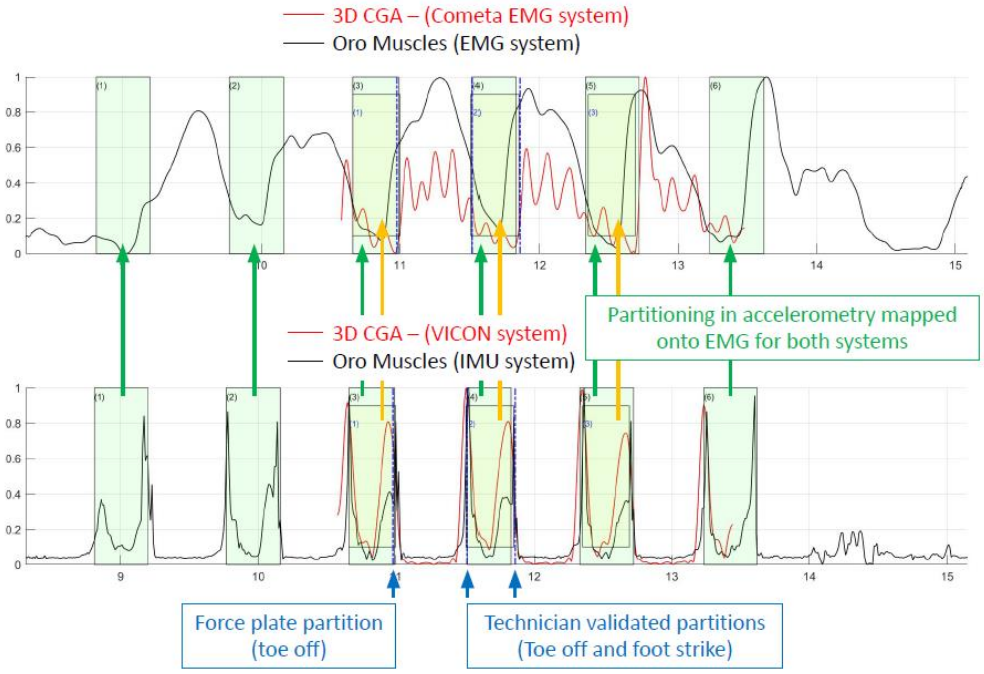

Figure 19: Mapping of partitioned accelerometery data onto EMG data.

Discussion

In a previous study carried out by Oro Muscles B.V., high-performance athletes equipped with the Oro sensor system were used to map the activity of specific muscles (Figure 20) to the visually perceivable phenomena (posture, technique, etc.) to assess the efficacy and efficiency of performance. Through the course of this study, analyses drawn through the data acquired from the Oro sensor system were

Figure 20: Objective trends of "technique" featuring the EMG signal, accelerometer, and gyroscope data and, spectrogram of muscle activation in the respective graphs. Courtesy of Oro muscles B.V, Groningen, Netherlands.

key in establishing the potential of developing a quantifiable basis for human motion analysis. Through its application in the sports use case, it was established that an objective basis of observation, visualization and analysis can be formulated. To translate the same to clinical applications encompassing the identification of atypical and aberrant gait, a standardized framework for the objective analysis of the same was conceptualized and conceived. Characterization of this observed gait disparity through categorical and quantifiable metrics would vastly improve the efficacy of the assessment and the subsequent choice and trajectory of rehabilitation.

As discussed in the previous sections, current methods of clinical analysis of gait pathologies rely on expensive equipment and an elaborate laboratory set-up. Experienced and highly trained personnel are required to carry out the clinical analysis in these gait laboratories. This results in an increased concomitant cost for the patients as well as the other stakeholders involved in clinical analysis. Although this means of clinical analysis has established itself as the gold standard for diagnosis and assessment of rehabilitation, it still has some limitations. It relies on very limited information which is collected over walking trials that span over a long duration of time, which impacts the quality of the data and limits the number of subjects studied in a specified time frame. During these walking trials, patients are required to walk relatively short distances (about 20 m), of which only a fraction (3 to 5 steps) is used to segment the phases of gait required for subsequent analysis. Analysis of atypical gait, the trajectory of rehabilitation to be followed and the assessment of the efficacy of rehabilitative efforts are concluded from this limited amount of data and is generally associated with a high turnover time. Furthermore, the accessibility of the patient to the relevant facilities adds to the list of the limiting factors, and the patient's inability to replicate everyday gait at the said facilities compromises the quality and integrity of the data collected.

The trends in muscle activation identified through the data acquired using the wearable sensor technology in the current study potentially be used to identify patients displaying pathological gait, who can then be channelled to relevant healthcare facilities with elaborate gait analysis laboratories for thorough clinical analysis. The tool created was not proposed to replace the laboratory-based 3D CGA but rather to equip non-specialized clinics to perform basic assessments and screen out patients who exhibit the requirement of specialized clinical intervention. This would reduce the load on the clinical infrastructure by reducing the influx of patients that would have to visit the hospitals for clinical analysis. Analysis of gait with the use of the wearable sensor system relies on low infrastructural needs as it does not require an expensive laboratory system or highly skilled medical personnel. It can be used by the patient remotely and the gait metrics can be shared with the clinician without the need for a direct visit to the healthcare facility. This improves the quality of the data collected as the patient can replicate everyday gait, which would result in an analysis of greater integrity for effective rehabilitation and increases the clinical accessibility to the patient. This would in turn significantly increase the number of patients analyzed in a given duration of time when compared to the laboratory set-up, thereby reducing the turnover time, and improving the efficacy of clinical intervention as rehabilitation efforts can be changed at a much quicker pace.

A notable advantage of the AI tool developed is the accuracy of gait partitioning achieved with a lot more data, as opposed to just a few steps in the case of 3D CGA, at a fraction of the time required by laboratory-based studies. The short duration of time required for partitioning in conjunction with the quick turnover time would significantly bring down the cost and overall engineering time. Moreover, since the partitioning is based on a significantly larger dataset as compared to that used in a laboratory setup, diagnostic validity in patients with aberrant gait is greatly improved. Furthermore, since the wearable sensor system is highly scalable and requires low technical expertise, it can be widely deployed in healthcare facilities lacking specialized clinical infrastructure. Perhaps the biggest

advantage of this means of gait analysis is that it would drive down the cost incurred by all the stakeholders: the patient, hospital, clinical analysis technicians, insurance companies, and rehabilitation doctors/physicians.

Pitfalls and Ethical Considerations (Ethics paragraph)

Although this study establishes a clinical use case for gait assessment with wearable sensor technology, it is accompanied by some pitfalls. The accuracy and efficacy of the tool were based on a small number of participants. This was further limited by the patient demographic chosen as it only included healthy patients and those with severe gait impairments, specifically pathologies that resulted in gastrocnemius spasticity, despite the proposal of its application on patients exhibiting a wide variety of gait pathologies. This study was aimed at establishing the remote use of the wearable sensor system without the assistance of personnel with technical expertise but the entirety of data used was acquired from a fully-fledged clinical gait laboratory. This study shines light on the potential of gait assessment that can be carried out in the patients' home environment but does not explicitly establish the same. The tool developed delivers an objective report with quantifiable metrics to equip non-specialized facilities to identify a wide range of gait pathologies instead of engendering a categorical diagnosis. This puts a patient at potential risk as the requirement to avail specialized rehabilitation would be based on a subjective decision made on objective metrics presented to the clinician involved.

Since the tool created aims to decentralise gait diagnostics from specialized gait assessment institutes, certain technical and ethical considerations should be factored in. Firstly, the level of expertise of the clinician, or rather the "interpreter" of the data cannot be guaranteed, and hence the resultant analysis would exhibit high variability and low repeatability. Unlike the case of an elaborate laboratory with a qualified clinician to check the quality of the data recorded, expecting the interpreter to assure the integrity of data acquired would not be pragmatic. Owing to the lack of expertise and experience, incorrect sensor placements, despite the prescribed guidelines on the same can be expected, further exacerbating the quality of data. Secondly, unlike the "one patient, same clinician" approach adopted in most specialized healthcare facilities, the same individual may be involved with multiple clinicians in a non-specialized facility due to a myriad of factors ranging from administrational redundancies to excessive patient load. This may result in a clash in the choice of the trajectory of rehabilitation due to varied interpretations. Thirdly, specialized facilities run routine and thorough check-ups of the equipment and apparatus used for analysis to ensure patient safety and the quality of the data acquired. This cannot be expected from a non-specialized facility. Apart from adding to the uncertainty of the data recorded, the patient is put at a physical risk in the case of device malfunction, the accountability for which can neither be assumed by the manufacturer of the sensor nor the assessing facility.

Although a cost-effective means of remote gait assessment has been presented and established, the level of risk associated with its application must be investigated for specific intended use cases. A cost-benefit analysis should be carried out considering the patient demographic, the range of pathologies considered, technical and clinical prowess of the interpreter, the ratio of patients assessed to the number of clinicians available, the healthcare climate of the country or region the tool and device are employed in and, the prevalence of gait pathologies in the said region to name a few.

Conclusion

Through this master's project, a standardized framework to aid the design of an automated gait partitioning and analysis tool was developed. This tool exhibits and establishes a clinical use case of a wearable sensor system then can be widely deployed, owing to its high scalability, and can be employed in clinical backgrounds which lack the specialization with respect to the architecture and the personnel involved. This novel solution proposed does not aim to replace the current gold standard of gait analysis but rather work in line with it as a form of triage to assess and evaluate individuals who need an elaborate clinical evaluation. This would thereby offer a means of reducing the logistic load on the highly specialized tertiary clinical institutes and improve patient accessibility while driving down the concomitant cost for all the stakeholders involved

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Appendix

This section includes the consent forms signed by the patients who participated in the study, in accordance with the declaration of Helsinki, and the approval received from the Medical Ethics Review Board of the University Medical Centre Groningen (UMCG), Netherlands.

Toestemmingsformulier gebruiksrecht Gangbeeldonderzoek

Ondergetekende,

Naam: .....
Geboortedatum: .....
UMCG nummer: .....

Geeft hierbij toestemming aan het UMCG om onderstaande van mijzelf of van mijn kind te gebruiken voor onderzoek en onderwijs met onderstaande gegevens*:

- Data verzameld tijdens gangbeeldonderzoek
- Foto/video materiaal
- Gegevens uit het medisch dossier
- Uitkomsten van vragenlijsten

De bovengenoemde gegevens mogen gebruikt worden voor*:

- Onderwijs aan (medische) studenten, co-assistenten, arts-assistenten en artsen in opleiding
- Wetenschappelijke lezingen in binnen en buitenland
- Wetenschappelijk onderzoek

*Doorhalen wat niet van toepassing is

Ik kan te allen tijde mijn toestemming intrekken door dit schriftelijk aan te geven bij UMCG, Centrum voor Revalidatie. Alle gegevens, inclusief foto/video materiaal, blijven wel onderdeel van mijn medisch dossier.

Datum: .....

Handtekening: .....

Handtekening (kind tussen 12-18 jaar): .....

Het formulier kan worden meegenomen bij het eerstvolgende bezoek.

Uw gegevens wordt conform de Algemene Verordening Gegevensbescherming (AVG) verwerkt.

umcg

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Medical Ethics Review Board

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Enclosure(s) -----
Ref. M21.273323

Date 7 April 2021
METc number METc 2021/226
Title **Smart algorithm for automatic detection of neuromuscular abnormalities during gait.**
UMCG RR number 202100177

The Medical Ethics Review Board of the University Medical Center Groningen (METc UMCG) has discussed the above mentioned protocol and considered whether or not the research falls within the scope of the Medical Research Involving Human Subjects Act (WMO).

Based on the submitted documents the METc UMCG concludes that the above mentioned protocol is not a clinical research with human subjects as meant in the Medical Research Involving Human Subjects Act (WMO).

Therefore the METc UMCG has no task in reviewing the protocol and you do not need a WMO approval before you can start the research.

Please note that other legal Acts and/or guidelines, such as the Medical Treatment Agreement (WGBO), General Data Protection Regulation (GDPR) and codes of conduct of the FEDERA (Federation of Medical Scientific Institutions) may apply to the scientific research.

Before you can start your study/study activities, you must await the favourable opinion of the CTc/LTc.

Kind regards,
on behalf of the Medical Ethics Review Board

Prof. W.A. Kamps, MD Ph.D.
chairman

J. Davids, MSc
official secretary

umcg