scientific reports

OPEN

Integration of smart insoles for gait assessment in exoskeleton assisted rehabilitation

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A robotic exoskeleton enables individuals with limited or no mobility to engage in moderate exercises, thereby promoting physical fitness and overall well-being. However, exoskeletons alone do not provide comprehensive insights into gait pattern monitoring and analysis over time. This study proposes the integration of smart insoles as a cost-effective and non-invasive tool for gait assessment in exoskeleton-assisted rehabilitation. Ten participants, including three unimpaired subjects used only as a reference, one stroke, one spinal cord injury, one traumatic brain injury, and four multiple sclerosis subjects were involved in a 12-week program where weekly rehabilitation exercises were conducted and gait patterns were monitored in three assessment sessions. Gait phases were identified using a Finite State Machine, with transitions guided by predictions from a fuzzy c-means clustering algorithm. Kinematic and kinetic analyses revealed significant disparities in stride time, stance time, and the trajectories of the centre of pressure. The findings demonstrated that while the exoskeleton enabled participants with limited or no mobility to walk similarly to unimpaired individuals, the use of smart insoles identified notable differences in their gait patterns. These differences could be traced back to choices in the rehabilitation plan, underscoring the importance of such devices for understanding rehabilitation progress. An acceptability analysis showed that participants found the smart insoles comfortable and expressed a willingness to use them for future rehabilitation. In conclusion, this study demonstrates the potential of smart insoles for the assessment of individuals' rehabilitation progress while using an exoskeleton, laying the groundwork for a system that can support clinicians in developing tailored rehabilitation plans.

Keywords Gait analysis, Exoskeleton, Smart insoles, Rehabilitation, Gait kinematic parameters, Gait kinetic parameters

Gait is an important aspect of human life. An individual's gait involves the actuation of several lower-limb muscles, which are coordinated by the brain and neurons that allow the individual to maintain their balance and displace in the space[1]. Over time, an individual's ability to walk may face a gradual decline, which can be attributed to various factors such as ageing, weight gain, or the loss of muscle mass. Furthermore, other unexpected factors can affect an individual's gait, including but not limited to neurological diseases, musculoskeletal disorders, traumatic injuries, chronic pain, or the use of specific medications[2]. Multiple Sclerosis (MS), Parkinson's Disease (PD), Spinal Cord Injury (SCI), Stroke (ST), and Traumatic Brain Injury (TBI) stand as exemplars of neurological and musculoskeletal conditions capable of exerting a profound impact on an individual's gait. These conditions often develop into muscle weakness, coordination deficits, and balance disorders, forcing individuals to have a more sedentary lifestyle[3], leading to the emergence of secondary health problems such as diabetes, obesity, and a marked decline in cardiorespiratory capacity[4]. In light of the far-reaching consequences of gait impairment on an individual's health and well-being, it becomes imperative to address these issues as soon as they are identified. Rehabilitation and therapy, among other interventions, play a pivotal role in the management of gait disorders. However, in recent years, a promising technological advancement has emerged to offer new hope and possibilities to those grappling with gait limitations: the robotic exoskeleton.

A robotic exoskeleton is a wearable device meticulously designed to augment and enhance an individual's physical capabilities[5]. Typically, it includes a durable frame equipped with motors or other types of actuators, which generate the necessary force to facilitate coordinated and controlled movements. Robotic exoskeletons can be divided into three main categories[6]: human performance augmentation exoskeletons[7], which focus on enhancing an able-bodied person's strength, endurance, and other physical capacities to accomplish tasks like

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lifting, carrying, or working with heavy loads; assistive robotic exoskeletons[8], which are adopted by individuals with limited movement capabilities, such as individuals with musculoskeletal or neurological diseases, to allow them to complete movements that they could not complete on their own; and therapeutic exoskeletons for rehabilitation[9], which are used to train and stimulate an individual's muscles when he/she has completely or partially lost the ability to move. In subjects with limited or no mobility, prolonged use of a robotic exoskeleton carries the potential to improve the individual's quality of life[10], by enabling them to engage in a moderate level of exercise, fostering physical fitness and overall well-being[11], while reducing the impact of prolonged immobilisation and physical pain. Such benefits have been demonstrated for SCI patients, where reduced physical pain was identified[12], and in MS patients, where an improved gait speed and metabolic expenditure were observed[13].

When employing an exoskeleton for rehabilitation, it becomes imperative to implement an assessment system to analyse changes in an individual's gait over time, facilitating a comprehensive understanding of rehabilitation progress, particularly in discerning any developments in a disease. While the joint angles of the exoskeleton can be used to construct an inverse pendulum for acquiring gait parameters and evaluation[14], this approach has limitations in extracting information, rendering the exoskeleton unnecessarily complex and expensive. Existing commercially available exoskeleton solutions, such as the EksoNR by Ekso Bionics Holdings Inc.[15], the ReWalk by ReWalk Robotics Ltd.[16], the Hybrid Assistive Limb (HAL) by Cyberdyne Inc.[17], provide only information about steps completed, distance walked, walking speed, level of assistance, and joint angles. Consequently, recent studies have fostered the integration of the exoskeleton with additional systems, which are exclusively focused on gait assessment, such as pressure and inertial sensors[18]. The essential purpose of monitoring systems lies in their capacity not only to assess potential declines in the individual's functional abilities but also to pinpoint inaccuracies in exoskeleton settings that may result in improper posture and behaviour. Furthermore, they can be used to discern differences over multiple sessions and throughout the rehabilitation process.

This research aims to assess the feasibility of using smart insoles to monitor the gait characteristics of subjects with neurological and musculoskeletal diseases who use exoskeletons for rehabilitation purposes. Smart insoles are footwear accessories equipped with different sensors that collect and transmit data related to the user's foot movements and pressure distribution[19]. Smart insoles are designed to provide real-time information about gait, posture, and other biomechanical metrics, and usually include but are not limited to pressure and inertial sensors. Including smart insoles for assessing gait characteristics provides a minimally invasive system for the user, without increasing the complexity of the exoskeleton system. This study included seven volunteers affected by neurological and musculoskeletal disorders who participated in a 12-week rehabilitation program with weekly exoskeleton sessions. Three evaluation sessions in which participants were monitored using the smart insoles were conducted in the $1st$, $6th$, and $12th$ week, respectively. Besides these participants, three healthy participants who performed only one session were included as references for unimpaired subjects.

Due to the lack in the literature of data collected and annotated from users wearing smart insoles and exoskeletons, in this study, a novel smart insole-based unsupervised approach supported by rules dictated by knowledge of the gait cycle was proposed to identify the gait kinematic and kinetic parameters. The solution is based on an Finite State Machine (FSM) where the states are represented by gait phases and the transitions between them are handled by the predictions of a fuzzy c-means clustering model trained on real-world exoskeleton usage data. Furthermore, the possible transitions between the states have been limited based on the gait cycle oscillatory sequence to limit anomaly transitions. Unlike existing literature, this study focuses exclusively on developing a system based on data from real-world exoskeleton use, specifically with patients facing neurological and musculoskeletal diseases. Furthermore, using kinematic and kinetic gait parameters, an analysis to examine disparities for each participant between weeks and to evaluate common trends between different conditions was conducted as evidence of the insights that such a solution can provide to healthcare professionals to evaluate walking patterns in subjects undergoing rehabilitation using an exoskeleton. Additionally, the research investigates the feasibility and user acceptance of smart insoles, exploring their potential impact on the rehabilitation process.

The rest of the paper is structured as follows: Section 2 analyses current state-of-the-art solutions and the existing challenges. Section 3 presents how this study has been conducted and the principal techniques used, followed by a comprehensive discussion of the findings in Sect. 4. The paper concludes with Sect. 5 with a summary of the study and the future perspectives.

Related work

Monitoring the usage of an exoskeleton plays a crucial role in identifying specific patterns that significantly impact the quality of an individual's locomotion. Over time, diverse approaches have been employed, ranging from devices attached to the wearer's skin, posing potential hindrances and vulnerability to sweat, to devices integrated into the exoskeleton's structure[20], introducing heightened complexity and increased costs. To address these challenges, several examples can be found in the literature in which pressure sensors or Inertial Measurement Unit (IMU) sensors are employed to monitor the characteristics and steps involved in the gait of individuals wearing an exoskeleton.

Ding et al.[21] introduced an algorithm for online gait event detection utilising an IMU system in individuals wearing a lower-limb exoskeleton. They designed an IMU device consisting of an accelerometer and a gyroscope that can be attached to the anterior surface of a shoe. Employing a sampling frequency of 100 Hz, they applied a low-pass filter with a cut-off frequency of 40 Hz to the collected data. To identify six events, including Initial Output (no gait detected), Heel-Strike, Foot Flat, Heel Off, and Toe Off, a fixed window size of 10 ms, and a fixed threshold were implemented. To validate the algorithm, initial tests were conducted on 10 healthy subjects without exoskeletons during five walking trials, comparing the results to a force plate, showing significant agreement and an overall error of $10ms$ and $19ms$ for the heel-strike and toe-off phases, respectively. The algorithm's performance was further assessed at various speeds on a treadmill, accurately identifying all gait cycles. Subsequently, the solution underwent evaluation with a subject wearing a lower extremity exoskeleton, revealing challenges such as strenuous ripples near Heel-Strike and Toe-off, as well as alterations in acceleration that complicated the determination of precise peak or valley points corresponding to Heel-Strike.

Ren et al.[22] presented a novel method for the recognition of the gait phases in walking and running locomotion with possible applications for exoskeleton users. Their method involved the utilisation of an 8-force sensing resistor plantar pressure measurement system and a feature-free approach based on an Mulit-Layer Perceptron (MLP) algorithm. The primary objective of their study was to detect the gait period and subsequently identify the gait sub-phases. Four male individuals were recruited for the study and asked to walk on a treadmill at different speeds while wearing the developed system for 1 min with a sampling frequency set to 100 Hz. The detected gait sub-phases included the heel contact, toe contact, and double stance phases. A leave-one-subject-out strategy was implemented to test the model, resulting in an average recognition rate for the gait phases of 93.4% during walking and 93.9% during running, with some delays when compared to the labelled data. Additionally, it was observed that the model exhibited misrecognition and oscillation when the subjects were running. However, it should be noted that the presented solution has not been evaluated with exoskeleton users, which was left for future investigation.

Lv et al.[23] proposed a novel radius-margin-based Support Vector Machine (SVM) model with Particle Swarm Optimization (PSO) algorithm for gait phase detection. The measurement system utilised in this study consisted of a smart insole equipped with nine pressure sensors. By leveraging the PSO algorithm, the authors were able to identify the optimal parameters for the SVM model using the feature space of the training set. Subsequently, the model was trained and tested to assess its performance in classifying the gait phases. The data collection process involved two subjects who were instructed to walk for 5 min at four different speeds while wearing the smart insoles with a sampling frequency of 50 Hz. The primary objective of this study was to classify five distinct gait phases, namely loading response, mid-stance, terminal stance, pre-swing, and swing. The proposed solution was compared against baseline models and demonstrated superior performance, achieving an overall accuracy exceeding 98% across varying speeds.

The above studies present several limitations that deserve careful consideration. The exclusive use of IMU sensors limits the ability to obtain detailed information about balance and stability, underlining the importance of using pressure sensors for a comprehensive evaluation. Additionally, IMU sensors can be affected by the drift problem when used for long-term measurements, and the placement of such sensors on the front of the show can generate discomfort for the user since the exoskeletons could present straps in that area. Furthermore, it should be noted that the studies available in the literature are often designed on data collected from healthy individuals and without the aid of exoskeletons, neglecting the intrinsic challenges linked to wearing such devices and how these can influence the biomechanics of walking and consequently the proposed solution. Finally, the lack of subjects with gait-related pathologies in the existing studies represents a further limitation, since these conditions can significantly alter people's way of walking, potentially impacting the performance of the solutions developed, especially in rehabilitation practices.

Methodology

To assess the feasibility of employing smart insoles for gait analysis in individuals using an exoskeleton for rehabilitation, data from participants, recruited from the No Barriers Foundation Ireland (https://nobarriers.ie), who suffer from neurodegenerative and musculoskeletal conditions were collected. This section delineates the methodology employed in conducting the study and presents the proposed solution for translating data from the smart insoles into gait parameters for comprehensive assessment.

This study has been reviewed and approved by the Ulster University Faculty of Computing, Engineering and The Built Environment Research Ethics Committee (reference number: 20.11) following the University's policies on Research Governance(https://www.ulster.ac.uk/__data/assets/pdf_file/0003/331878/Policy-Human-Research-V5.pdf), and in accordance with the Declaration of Helsinki (https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/). All participants provided informed written consent before the beginning of this research. All participants' information has been anonymised to ensure confidentiality.

Devices

In this research, the ActiSense Kit from IEE Luxembourg S.A.[24] has been employed for collecting data from participant ambulation. This kit consists of two IEE Smart Foot sensors and two ActiSense Electronic Control Unit (ECU), with the former positioned on the footbed and the latter attached to the side of the participant's shoes. The IEE Smart Foot Sensors are equipped with eight individual high dynamic pressure cells, positioned at the hallux, toes, first, third and fifth metatarsal, arch, and left and right side of the heel, whereas, the ECUs incorporate different IMU sensors, including a three-axial accelerometer (with a range of $\pm 8G$), a three-axial gyroscope (with a range of ± 1000 DPS), and a three-axial magnetometer (with a range of $\pm 4912\mu T$). The insoles were provided by the manufacturer in different sizes (from 3.5 to 11.5 UK sizes) to ensure a proper fit for each participant. The sampling frequency of the smart insoles for the entire duration of the study has been set to 200 Hz.

The exoskeleton used in this study is the EksoNR provided by Ekso Bionics Holdings Inc.[15], which is specifically designed to be employed in rehabilitation settings for supporting neurological and musculoskeletal patients in their exercises. It amplifies ambulation ability and allows for extended therapy sessions, increasing energy expenditure to a similar level as non-exoskeleton walking, which may improve cardiovascular function in limited mobility subjects[12]. The exoskeleton responds to changes in the user's centre of mass, shifting from one limb to the other, and when the exoskeleton senses these changes, it initiates the gait cycle[25]. Furthermore, the exoskeleton provided multiple assistive modalities, changing the extent of assistance or resistance during walking. In this study, the assistive modality was set to full assistance, which provided maximal mechanical support to activate and support participants' muscles. However, while this mode is designed to assist movement, emerging research indicates that similar muscle activation patterns may occur across different assistive levels, despite differences in support magnitude[26], hence, future investigations will focus on characterising specific muscle engagement in each assistive mode to better understand the neuromuscular effects of robotic gait training, which has not been investigated in this study. Finally, to adapt the exoskeleton to the different participants, the lower leg segments were adjusted by the physiotherapist to align with the participant's distance between the lateral joint of the knee and the bottom of the foot, and the ankle stiffness was adjusted according to the participant's mobility.

The exoskeleton provided only information about the number of steps, walking time, and time of verticalization[27], thus posing the need for an additional device, such as smart insoles, for assessing gait characteristics.

The devices involved in this study have been presented in Fig. 1 along with an example of a user wearing the exoskeleton suit and the smart insoles during data collection.

Participants

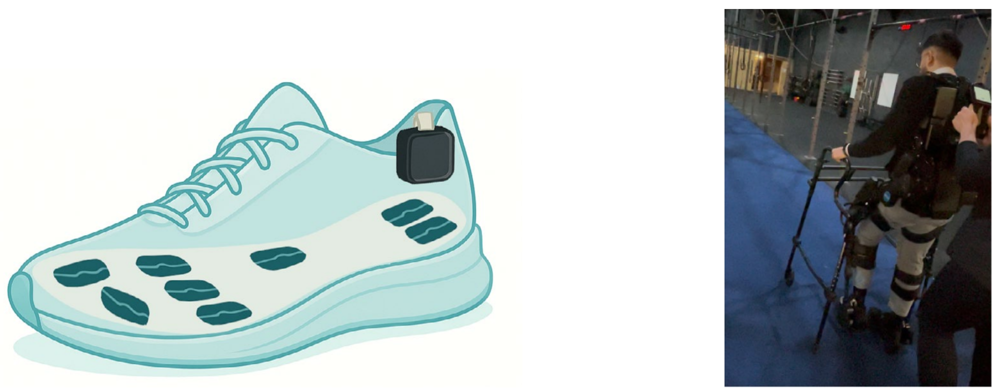
A comprehensive recruitment strategy was formulated to enlist volunteers from private clinics. The targeted participants were individuals aged between 18 and 70, possessing a well-established diagnosis of their respective conditions, and provided consent to participate in prolonged rehabilitation training with the exoskeleton.

A total of seven participants were successfully recruited, representing diverse conditions: four subjects with MS, one with SCI, one with ST, and one with TBI, however, the participant with ST was withdrawn before the beginning of the study due to an identified mistake in age on the screening form, rendering the participant ineligible based on the inclusion criteria. Additionally, three healthy (unimpaired) subjects were included to serve as reference data during the study. Such subjects reported no previous history of neurological or musculoskeletal conditions and were able to walk without any assistance. Healthy subjects completed only one session utilising the exoskeleton and smart insoles. The characteristics of each participant are presented in Table 1.

All participants with neurological or musculoskeletal diseases were in stable condition as confirmed by their healthcare providers, with no recent acute episodes or change in their diagnosis or treatment plan. Notably, only four participants had prior experience using an exoskeleton before the study commenced. Furthermore, the participants of the study presented different walking capabilities. The subject with TBI had power in the legs which allowed him to walk assisted, the subject with SCI had strength only in the left leg and therefore required a walking frame for walking, and finally, subjects with MS, although in different stages of the disease, had no or limited strength in their legs, which did not allow them to walk.

Data collection

The research spanned a 12-week duration. Each participant conducted one exoskeleton-assisted rehabilitation session and two home-based resistance training sessions per week. The rehabilitation sessions were tailored to the participants' needs and abilities, with the aim of improving their strength, balance, and mobility. The home-based resistance training sessions were designed to complement the exoskeleton-assisted rehabilitation sessions and to help the participants maintain their progress between sessions. Over the 12 weeks, 3 assessment sessions were defined, namely at the 1st, 6th, and 12th week. Before each session, physiotherapists assisted the subjects in wearing the smart insoles and the exoskeleton, and they were instructed about the protocol to follow.



(a) (b)

Fig. 1. Experimental setup and equipment configuration. (**a**) Configuration of the smart insole system used in the experiments, showing its placement inside the user's shoe. Each insole was equipped with 8 pressure sensors and an Electronic Control Unit (ECU) containing Inertial Measurement Unit (IMU) sensors. The illustration was created by the authors using Photopea version 5.6. (**b**) Image of co-author Luigi D'Arco, who provided consent for the use of this photograph, wearing the smart insoles and an exoskeleton during data collection. The setup also includes a walking aid and support from a physiotherapist.

ID	Age	Weight (Kg)	Height (cm)	Gender	Condition	First diagnosis of the condition	Familiarity with the exoskeleton
1	29	70	174	F	H	–	Yes
2	58	40	162	F	H	–	No
3	27	72	170	M	H	–	No
4	69	40	162	F	MS	1999	Yes
5	58	67	177	M	SCI	2019	Yes
6	25	69	180	M	TBI	2018	No
7	63	64	178	M	MS	2002	No
8	52	85	183	M	MS	2011	Yes
9	72	66	160	F	ST	2001	No
10	60	62	160	F	MS	2007	No

Table 1. Characteristics of participants included in the study. *H* Healthy, *MS* Multiple Sclerosis, *SCI* Spinal Cord Injury, *ST* Stroke, *TBI* Traumatic Brain Injury.

ID	Description
Q1	Have you previously used wearable technology e.g. fitness trackers, to assist with your health and well-being?
Q2	Before taking part in this study, were you aware of the use of wearable technologies for assessing physical rehabilitation?
Q3	The purpose of wearing the insoles was clearly explained prior to starting the rehabilitation session
Q4	The insoles were comfortable to wear during the rehabilitation session
Q5	Wearing the insoles made a difference to my rehabilitation session when compared to not wearing them
Q6	Knowing that the insoles were measuring my movements affected my walking motion during the rehabilitation session
Q7	Wearing the insoles could have a positive impact on my rehabilitation by providing objective data on my walking motion to the physiotherapist
Q8	Receiving feedback on my progress is an important part of the rehabilitation process
Q9	Wearing the insoles could have a positive impact on my rehabilitation by providing clear feedback on my progress
Q10	I would be willing to continue using the insoles in future rehabilitation sessions
Q11	Were there any interruptions to your rehabilitation session due to wearing the insoles?

Table 2. Items of the questionnaire submitted to participants to evaluate their acceptance of the smart insoles.

The protocol used encompasses different activities including sitting in a steady position for 2 min, standing in a steady position for 2 min and 6-min walking in a hallway of approximately 10 meters, with a 180° turning left at the beginning and end. The walking activities were supervised by a physiotherapist, who timed the steps, to ensure the safety of the participants. Furthermore, all participants were provided with a walking frame to lean on during the activities.

At the end of the 12 weeks, the participants were given a questionnaire to evaluate their experience using the smart insoles. The questionnaire included 11 questions ranging from the subjects' acceptance of smart insoles to their opinion on how much this technology could impact their rehabilitation. The items of the questionnaire are presented in Table 2. Participants responded to questions 1, 2, and 11 with a binary choice of either yes or no. For the remaining questions, participants used a scale from 1 to 5, where 1 indicated "Strongly disagree" and 5 indicated "Strongly agree".

Extraction of gait phases

Gait is characterised by a cyclical nature, which is composed of a series of distinct phases and events, collectively forming what we refer to as gait cycles. Each gait phase represents specific functional segments of the walking process, such as the Stance (St) and Swing (Sw) phases[28]. The stance phase begins as one foot establishes its initial contact with the ground, and it persists until the same foot is lifted off the ground again, providing stability and support during the walking process. On the other hand, the swing phase encompasses the time when the foot leaves the ground after toe-off and extends until it once more makes contact with the ground. During the swing phase, the leg is in a free-swinging motion, transitioning to the next step. Under a more in-depth analysis, each stride contains eight functional patterns or sub-phases[29], which can be directly interpreted for impairment identification. The Initial Contact (IC) marks the beginning of a new gait cycle with the touching of the foot with the ground, and it is followed by the Loading Response (LR) in which the body's weight shifts onto the stance leg, reaching a complete foot flat on the ground in the Mid Stance (MSt) in which the entire body's weight is support be the stance leg providing stability and balance. The Terminal Stance (TSt) phase marks the progression of the body beyond the supporting foot, raising the heel and continuing the forward motion until the other foot touches the floor. The Pre-Swing (PSw) phase follows, involving the unloading of the stance leg in preparation for lifting off, thus marking the transition to the swing phase, which in turn is composed of Initial Swing (ISw), when the foot leaves the ground and starts the forward motion, the Mid Swing (MSw), when the swinging limb is opposite to the stance limb, and the Terminal Swing (TSw), in which the tibia is in a vertical position and move forward until the foot touches the ground. However, the walking phases presented are altered when using an exoskeleton due to its rigid structure around the foot[30]. Therefore, this study presents a novel solution to detect gait phases from smart insole data in subjects wearing an exoskeleton, taking into account that some phases may be missing or altered. In addressing the limitations posed by the exoskeleton, a preliminary analysis of the data collected revealed a lack of pressure in the forefoot, mainly due to the rigidity of the shoe's exoskeleton structure, which limited pressure in this area. For this reason, the TSt and PSw phases have been grouped and considered as a single sub-phase, which from here on will be referred to as TSt. Similarly, due to the limitations provided by the pressure sensors, which do not provide information when the foot is in the air, the swing phase was considered in its entirety and not in sub-phases.

The proposed approach leverages the use of the pressure sensors of the smart insoles by using an FSM for the identification of the different states of the gait cycles. This approach has been proven efficient and powerful in previous studies for the identification of gait phases in both healthy and PD individuals[31], and in amputee users[32]. In[32], the solution was compared with a gold standard solution, demonstrating a high level of agreement between the extracted gait parameters. The FSM has been defined as the quintuple $(\Sigma, S, s_0, \delta, F)$, where Σ is the set of input symbols and comprises the reading from the pressure sensors of the smart insoles, *S* is the set of states and has been extended from previous studies to include the above-mentioned gait phases (IC, LR, MSt, TSt, Sw) plus an additional state which represents that no gait cycle has been detected yet, named *Init*. The initial state of the FSM, s_0 has been set as the state *Init*, and the set of final states have been set to $\emptyset$ as the FSM will progress as long as there will be new data coming in. The transition between the states, δ, has been managed using a fuzzy c-mean algorithm[33], which is a soft clustering algorithm that assigns degrees of membership to each data point for every cluster. This allows for a more flexible representation of data points that may exhibit characteristics of multiple clusters simultaneously, allowing the handling of smart insole data without the need for labelling and providing a solution that can be easily updated when new data are considered. The number of clusters in the fuzzy c-means algorithm has been set to 5, representing the possible gait sub-phases. The fuzzifier parameter that controls the degree of fuzziness in the clustering process was set to 2, ensuring a balance between fuzziness in the data partitioning and computational complexity[34]. The distance between data points has been represented as the Euclidean distance. The transition function of the FSM can be defined as follows:

$$\delta : S \times \hat{y}(\Sigma) \longrightarrow S \tag{1}$$

where $\hat{y}(\Sigma)$ is the cluster prediction with the highest membership function of the timestep sample from the pressure sensors. The fuzzy c-means algorithm has been trained on the real-world exoskeleton usage data to ensure the reliability of the predictions. To further enhance the reliability of the transition function, the next FSM state has been predicted as the argument of maxima of a sample window that included 10 preceding and 10 subsequent samples for each data point. Hence the transition function presented in Eq. 1 can be rewritten as:

$$\delta_t : s_{t-1} \times argmax(\hat{y}(W_{[x_{t-10}, x_{t+10}]}) \longrightarrow s_t \tag{2}$$

where δ_t is the transition function for the time *t*, $s_{t-1} \in S$ is the state of the FSM at time $t-1$, $W_{[x_{t-10}, x_{t+10}]}$ is the sample window for the data point x_t, and $s_t \in S$ is the state at time *t*. To address the issue of missing or overlapping gait phases due to the structure of the exoskeleton, knowledge-driven rules were introduced into the FSM based on the walking cycle reference sequence. These rules allow for missing phases during gait cycle identification while preserving the system's functionality to accurately identify the gait cycles. The detailed states and transitions of the FSM are illustrated in Fig. 2.

Preceding its input into the FSM, the data from smart insoles were comprehensively preprocessed involving sensor aggregation, noise reduction, and data normalisation. Analysing the pressure sensors data, utilising Pearson's correlation coefficient (*r*), revealed a strong correlation ($r > 0.5$) among pressure sensors situated within the same foot zone, aligning with findings from prior research[35]. Consequently, a magnitude calculation was employed to combine pressure sensors within the back, middle, and front zones. To reduce the noise in the sensor readings a Butterworth low-pass filter has been implemented[36], to attenuate the high frequencies and allow the low frequencies to be preserved. The cutoff frequency was set to 10 Hz with a second-order filter since the walking frequency is lower than 5 Hz[37]. Finally, the data has been normalised transforming the data

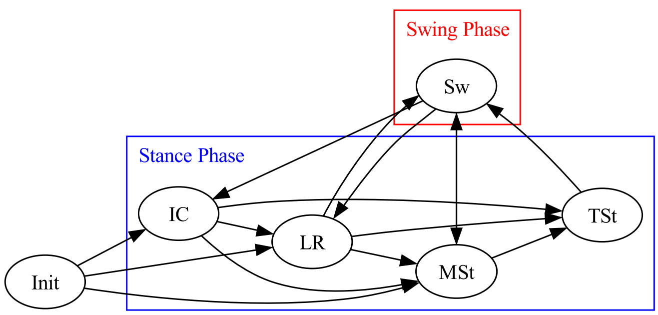


Fig. 2. Finite State Machine for gait phase identification. The states represent the gait phases, and the transitions between them are handled by the predictions of a fuzzy c-means clustering model with allowed transitions based on gait cycle knowledge.

range into a range between 0 and 1. The data was grouped by foot, and each group was fed into a different FSM to independently extract gait sub-phases for each foot. By aligning the extracted gait phases for each foot, information on the single or double support task was extracted, and the gait cycles were identified by considering the consecutive occurrence of stance and swing phases as a distinctive feature of a complete gait cycle.

Furthermore, considering that the data collected concerned continuous 6-min walks, turning activities were present. Thus, to prevent turning activities from affecting the statistical analysis of the gait parameters, since they have a longer duration and sparse patterns, an approach based on the interquartile range[38] was used to eliminate the outliers among gait cycles using the stride duration.

Extraction of gait parameters

For each participant, the key gait kinematic and kinetic parameters were extracted to comprehensively assess and quantify the gait aspect, as summarised in Table 3. The kinematics parameters offer insights into the spatial and temporal movement patterns exhibited by an individual, while kinetic parameters gauge aspects of stability and balance for effective ambulation. Notably, the analysis of kinetic parameters has focused on the evaluation of the Centre Of Pressure (COP), a virtual point delineating the base of the ground reaction force vector within the foot[46]. This parameter serves as a robust indicator of postural competency and sway, offering valuable insights into gait dynamics.

The gait parameters were utilised to compare differences across various weeks among participants and to evaluate distinctions between different condition groups. A preliminary analysis revealed that the data did not satisfy the requirements for parametric tests such as ANOVA. Therefore, the Friedman test[47], a non-parametric alternative, was employed to assess the differences among the weeks for each participant. Afterwards, for the groups that showed statistical difference ($p < 0.05$), the Conover post-hoc test was employed to understand which group differed from the other, offering a comprehensive analysis of the fluctuations in the gait metrics.

Results and discussion

This section presents the findings of the analysis of kinematic and kinetic gait parameters extracted from smart insoles for individuals wearing an exoskeleton during rehabilitation, demonstrating the additional information such smart insoles can provide and their feasibility of integration into rehabilitation practices.

Evaluation of gait phases detection

The proposed solution for identifying the gait phases leveraged a FSM, wherein transitions were determined by the predictions of a fuzzy c-means clustering algorithm applied to windows of samples. This novel approach demonstrated adaptability across diverse samples despite significant variations, as shown in Figure 3. The data collected varied according to the wearing of the smart insoles, the condition of the participants, and the amount of force and weight applied to their feet. While the objective encompassed recognising five distinct walking phases (IC, LR, MSt, TSt, Sw), the presence of an exoskeleton introduced alterations, constraining the typical oscillatory movements inherent in gait. Consequently, not all phases manifested consistently across every gait cycle.

Figure 3a portrays an ideal scenario characterised by a healthy subject's gait cycle. The pressure patterns are distinct and well-distributed across the front, mid, and back regions of the feet, as well as the transitions between different gait phases, are clear and consistent, reflecting a typical gait cycle[48]. In contrast, the participant with MS exhibited notable irregularities (Fig. 3), particularly in the front and back foot sensors, leading to incomplete and less pronounced gait phases, reflecting difficulties in maintaining balance and weight distribution. The SCI participant's data (Fig. 3c) are characterised by severe fluctuations and missing data in foot regions, pointing to pronounced gait abnormalities and highly variable phase transitions. The TBI participant (Fig. 3d) shows considerable overlap in pressure signals between the back and mid-foot zones, especially on the right foot, which complicates the accurate identification of gait phases and results in incomplete phase transitions. These inconsistencies suggest potential issues with insole placement or the participants' gait mechanics due to their conditions, which will need further investigation when increasing the number of participants under analysis. Despite these challenges, the proposed solution demonstrates robustness and adaptability, managing to reconstruct gait cycles across various conditions. Specifically, the proposed solution can handle the absence of pressure sensor data and the difference in pressure patterns resulting from insole misplacement or the subject's condition.

Analysis of gait parameters

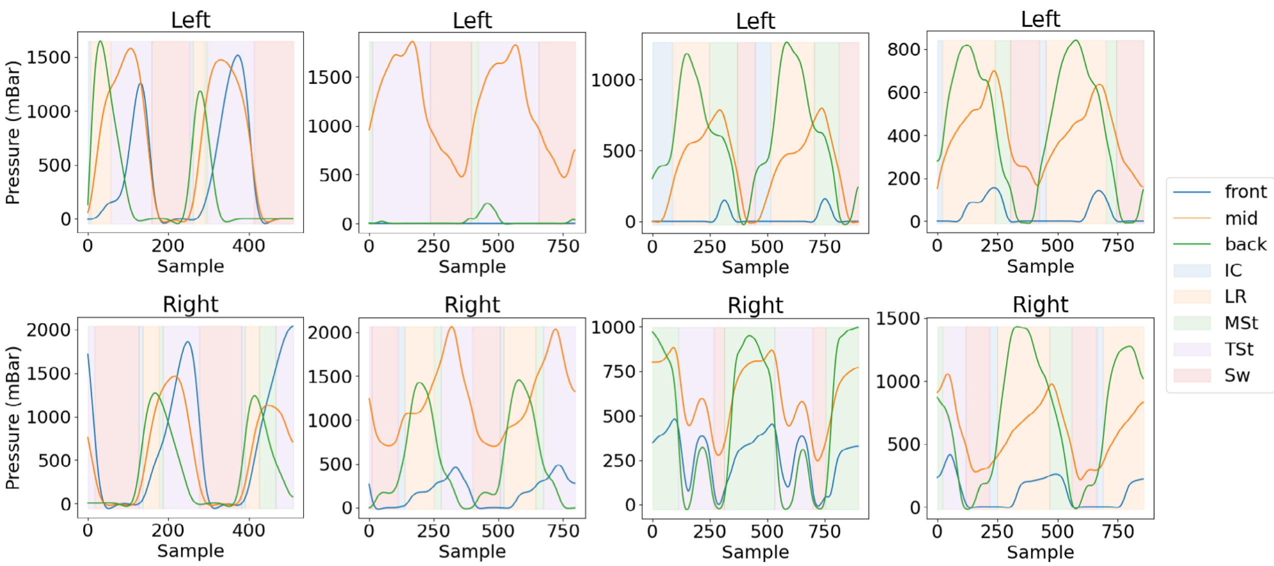
Participants were involved in a 12-week rehabilitation program with three assessment sessions. By evaluating the gait kinematic and kinetic parameters across the weeks, insights can be gained from each participant for the evaluation of walking patterns and postural control. Such analysis allowed us to evaluate whether smart insoles had consistent results over time, as well as evaluate the support that such information can provide to physiotherapists to monitor participants' gait changes over time.

Kinematic analysis

Table 4 presents the kinematic parameters extracted from the smart insoles for each participant across the three assessment sessions. The results provide a comprehensive overview of the participants' gait patterns, highlighting the differences between healthy individuals and those with neurological impairments.

Type	Name	Description	Equation		References
Kinematic	Stride time	Duration in seconds between the initial contact of one foot to the next contact of the same foot. It is expressed in seconds	$\frac{\sum_{e}^{E} e_{END} - e_{START}}{fs}$, $E = \{IC, LR, MSt, TSt, Sw\}$	where *E* is the set of events composing the stride, *END* and *START* are the last and first index for the event *e*, and *fs* is the sampling frequency	39
	Stance time	Duration during which a foot is in contact with the ground during a single gait cycle. It is expressed in seconds	$\frac{\sum_{e}^{E} e_{END} - e_{START}}{fs}$, $E = \{IC, LR, MSt, TSt\}$	where *E* is the set of events composing the stance phase, *END* and *START* are the last and first index for the event *e*, and *fs* is the sampling frequency	39
	Swing time	Duration during which the foot is off the ground and swinging forward in the air during a single gait cycle. It is expressed in seconds	$\frac{Sw_{END} - Sw_{START}}{fs}$	where Sw_{END} and Sw_{START} are the last and first index of the swing phase, and *fs* is the sampling frequency	39
	Stance percentage	Proportion of the gait cycle spent in the stance phase, expressed as a percentage	$\frac{\text{Stance time}}{\text{Stride time}} \times 100$		40
	Swing percentage	Proportion of the gait cycle spent in the swing phase, expressed as a percentage	$\frac{\text{Swing time}}{\text{Stride time}} \times 100$		40
	Single support time	Duration when only one foot is in contact with the ground during a gait cycle. It is expressed in seconds	$\sum_{\forall x \in GC} \frac{1}{fs}$ if $x_l \in \text{St} \wedge x_r \in \text{Sw}$,	where *fs* is the sampling frequency, e_l and e_r are the left and right foot event respectively, and *St* and *Sw* are the stance and swing phases	39
	Double support time	Duration during which both feet are in contact with the ground during a gait cycle. It is expressed in seconds	$\sum \frac{1}{fs}$ if $e_l \in \text{St} \wedge e_r \in \text{St}$, $\forall e \in GC$	where *fs* is the sampling frequency, e_l and e_r are the left and right foot event respectively, and *St* is the stance phase	39
	Single support percentage	Proportion of the gait cycle spent in single support, expressed as a percentage	$\frac{\text{Single support time}}{\text{Stride time}} \times 100$		40
	Double support percentage	Proportion of the gait cycle spent in double support, expressed as a percentage	$\frac{\text{Double support time}}{\text{Stride time}} \times 100$		40
Kinetic	COP ML	It is the Centre of Pressure on the Mediolateral sagittal plane.	$\frac{\sum F_i X_i}{\sum F_i}$	where F_i is the force applied to the i-th pressure sensor and X_i is the sensor's position on the mediolateral plane	41
	COP AP	It is the Centre of Pressure on the Anterior-posterior sagittal plane.	$\frac{\sum F_i Y_i}{\sum F_i}$	where F_i is the force applied to the i-th pressure sensor and Y_i is the sensor's position on the anterior-posterior plane	41
	Range COP ML	Amplitude of mediolateral COP displacement. It is expressed in cm	$max_{n,m}\lvert ML_n - ML_m \rvert$	where ML represents the COP ML	42
	Range COP AP	Amplitude of anterior-posterior COP displacement. It is expressed in cm	$max_{n,m}\lvert AP_n - AP_m \rvert$	where AP represents the COP AP	42
	Planar deviation	Average distance of each COP point from the mean COP position in the transverse plane. It is expressed in cm	$\sqrt{\text{RMS(ML)}^2 + \text{RMS(AP}^2)}$	where RMS is the root mean square, ML is the COP ML, and AP is the COP AP	43
	Confidence ellipse area	Area of the ellipse that contains 95% of the COP points in the transverse plane. It is expressed in cm^2	$\pi \sqrt{\lambda_1 \lambda_2} \chi^2_{2,0.95}$	where λ_1 and λ_2 are the eigenvalues of the covariance matrix, and $\chi^2_{2,0.95}$ is the chi-squared value for 2 degrees of freedom at the 95% confidence level	44
	Principal sway direction	Angle between 0° and 90°, between the anterior-posterior axis and the direction of the main eigenvector produced by the Principal Component Analysis (PCA). It is expressed in degrees	$arccos(\frac{\lvert v_2 \rvert}{\sqrt{v_1^2 + v_2^2}}) \times \frac{180}{\pi}$	where $v = (v_1, v_2)$ denotes the eigenvector associated with the highest variance produced by the PCA of the COP	45

Table 3. Gait parameters extracted from the gait cycles of the subjects included in the study. *IC* Initial Contact, *LR* Loading Response, *MSt* Mid-stance, *TSt* Terminal Stance, *Sw* Swing *COP* Centre of Pressure, *ML* Mediolateral, *AP* Anterior-posterior.



(a) Participant 1 (H) **(b)** Participant 10 (MS) **(c)** Participant 5 (SCI) **(d)** Participant 6 (TBI)

Fig. 3. Gait phases extraction examples for each condition group. The samples are referred to the week 6th, except for the healthy participant, which was a test session. The terms "front", "middle", and "back", stand for the pressure data collected from the foot's front, foot's middle, and foot's back zones respectively, whereas "IC", "LR", "MSt", "TSt", and "Sw" stand for the gait phases, initial contact, loading response, mid-stance, terminal stance, and swing, respectively.

Healthy participants showed the longest stride times compared to the other groups, averaging 2.51*s* for the left and 2.29*s* for the right leg. Variability in stride time among the groups highlights the differences in their walking abilities, however, in all the participants, a decrease in stride time can be observed over the weeks. Participant 5 on the left limb, Participant 6 on both limbs and Participant 7 on the right limb showed no statistical differences between week 6 and week 12 ($p > 0.05$). Similarly, a decrease in stance time and an increase in swing time can be identified across the weeks, showing that participants became more confident with the exoskeleton.

Stance and swing percentages from healthy participants reflected the natural walking pattern without an exoskeleton, aligning with previous research. For example, Iosa et al.[49] identified a golden ratio between stance and swing of 1.6. In line with this, the stance and swing percentages in healthy participants in this study were approximately 67.69% stance and 32.31% swing. In contrast to healthy participants, all other participants showed a higher stance percentage, indicating a more cautious walking pattern. Participants 4, 5, 6, and 7 showed asymmetry between the limbs in the assessment weeks, with Participant 5 moving towards a more balanced distribution over the weeks. Among the participants, only Participant 6 showed almost no statistical differences among the weeks for almost all the gait kinematic parameters ($p > 0.05$).

Single support time and percentage were similar among all the participants, except for Participant 5 in week 12, who showed a significant decrease in single support time (0.01*s*), which is the result of misclassification due to wrong placement of smart insole in the user's shoe. Double support time and percentage were significantly lower in healthy participants compared to the other groups, indicating more confidence during walking. Participant 6 showed a decrease in double support time over the weeks, however, no statistical differences were identified for the right limb ($p = 0.36$). All MS participants showed stable double support percentage over the weeks, except for Participant 10, who showed a significant decrease in double support time in week 6.

Overall, the results suggest that healthy participants exhibited more stable walking patterns compared to those with neurological impairments, who showed more cautious and variable walking patterns.

Kinetic analysis

Table 5 presents the kinetic parameters extracted from the smart insoles for each participant across the three assessment sessions. The results provide insights into the participants' postural control and balance, highlighting the differences between healthy individuals and those with neurological impairments.

Evaluating the average COP position among participants revealed differences in postural control and balance. The results showed that all participants tended to lean more towards the right foot with the mean COP in the mediolateral plane greater than the left counterpart. Such a trend, invisible to the eye of the physiotherapist, requires further investigation to understand its underlying causes, which may be the result of the exoskeleton settings, the participants' conditions or the definition of the test protocol, in which walking tasks were performed with a left rotation at the beginning and end of the hallway. In terms of mean COP in the anterior-posterior plane, differences can be observed between participants. Participant 5 and Participant 10 showed a marked lean

			Stride time (s)		Stance time (s)		Swing time (s)		Single support time (s)		Double support time (s)		Stance percentage (%)		Swing percentage (%)		Single support percentage (%)		Double support percentage (%)	
Participant	Condition	Week	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R
1	H	TEST	2.55 (0.16)	1.77 (0.55)	1.60 (0.13)	1.07 (0.50)	0.95 (0.17)	0.70 (0.22)	0.65 (0.14)	0.77 (0.42)	0.95 (0.17)	0.40 (0.36)	62.89 (6.26)	59.06 (10.37)	37.11 (6.26)	40.94 (10.37)	25.69 (5.54)	43.84 (18.98)	37.21 (6.97)	21.54 (13.48)
2	H	TEST	2.43 (0.13)	2.48 (0.21)	1.81 (0.19)	1.52 (0.27)	0.62 (0.20)	0.95 (0.20)	0.49 (0.42)	0.77 (0.21)	1.32 (0.57)	0.76 (0.23)	74.58 (7.96)	61.38 (10.34)	25.42 (7.96)	38.62 (10.34)	20.20 (17.14)	30.57 (8.20)	54.51 (23.43)	30.81 (10.82)
3	H	TEST	2.55 (0.13)	2.62 (0.15)	1.66 (0.12)	1.93 (0.25)	0.89 (0.12)	0.68 (0.21)	0.81 (0.17)	0.92 (0.24)	0.84 (0.17)	1.01 (0.29)	64.95 (4.25)	73.89 (8.62)	35.05 (4.25)	26.11 (8.62)	31.99 (6.98)	35.25 (9.58)	32.96 (6.09)	38.64 (9.90)
4	MS	1	2.15 (0.27)*†	2.28 (0.23)*†	1.94 (0.24)*†	1.40 (0.20)*†	0.21 (0.13)*†	0.87 (0.13)*†	0.78 (0.19)*†	0.20 (0.07)*†	1.15 (0.24)*	1.21 (0.19)*†	90.44 (5.83)*†	61.57 (5.38)	9.56 (5.83)*†	38.43 (5.38)	37.04 (10.16)*†	8.61 (2.88)*†	53.40 (6.99)*†	52.96 (4.85)*†
		6	1.78 (0.35)*‡	1.90 (0.21)*	1.48 (0.32)*‡	1.24 (0.20)*	0.31 (0.13)*‡	0.66 (0.22)*‡	0.45 (0.21)*‡	0.38 (0.19)*‡	1.03 (0.44)*†	0.95 (0.29)*‡	82.84 (6.43)*‡	65.80 (10.51)	17.16 (6.43)*‡	34.20 (10.51)	26.20 (13.13)*‡	19.71 (9.82)*‡	56.44 (19.33)*‡	50.71 (16.29)*
		12	1.86 (0.38)†‡	1.83 (0.31)†	1.61 (0.32)†‡	1.23 (0.26)†	0.26 (0.10)†‡	0.60 (0.28)†‡	0.25 (0.29)†‡	0.23 (0.16)†‡	1.30 (0.60)†	0.89 (0.31)†‡	86.51 (3.95)†‡	68.20 (12.92)	13.49 (3.95)†‡	31.80 (12.92)	16.16 (19.53)†‡	12.11 (8.23)†‡	66.53 (21.73)†‡	48.40 (13.14)†
		p	0	0	0	0	0	0	0	0	0.0019	0	0	0.8152	0	0.8152	0	0	0	0
5	SCI	1	2.29 (0.16)*†	2.28 (0.15)*†	1.68 (0.32)	2.08 (0.13)*†	0.61 (0.27)*†	0.20 (0.06)*†	0.27 (0.13)*	0.66 (0.24)*†	1.42 (0.24)	1.43 (0.30)*†	73.41 (11.78)*†	91.36 (2.42)*†	26.59 (11.78)*†	8.64 (2.42)*†	11.67 (5.26)*†	29.03 (10.57)*†	61.79 (8.96)*†	62.34 (11.38)*†
		6	2.09 (0.06)*	2.20 (0.20)*‡	1.85 (0.10)	1.93 (0.19)*‡	0.24 (0.13)*	0.27 (0.11)*	0.29 (0.03)†	0.16 (0.20)*‡	1.56 (0.12)	1.77 (0.26)*‡	88.53 (6.19)*	87.86 (5.42)*	11.47 (6.19)*	12.14 (5.42)*	13.70 (1.30)*‡	7.19 (8.91)*‡	74.83 (7.27)*	80.67 (10.53)*
		12	2.01 (0.20)†	2.07 (0.38)†‡	1.66 (0.19)	1.81 (0.33)†‡	0.35 (0.20)†	0.26 (0.13)†	0.01 (0.08)*†	0.08 (0.12)†‡	1.65 (0.21)	1.73 (0.37)†‡	83.11 (8.95)†	87.66 (4.97)†	16.89 (8.95)†	12.34 (4.97)†	0.68 (3.44)†‡	3.91 (6.36)†‡	82.43 (10.27)†	83.75 (8.41)†
		p	0.0076	0	0.2231	0	0.0111	0	0.0015	0	0.093	0	0.0111	0	0.0111	0	0.0015	0	0.0208	0
6	TBI	1	2.24 (0.17)*†	2.22 (0.33)	1.71 (0.17)*†	2.04 (0.33)	0.53 (0.23)	0.18 (0.06)	0.09 (0.08)*†	0.41 (0.21)	1.62 (0.16)*†	1.57 (0.39)	76.98 (9.69)	91.56 (3.28)	23.02 (9.69)	8.44 (3.28)	4.18 (3.35)*†	18.56 (9.65)	72.81 (9.37)*†	69.99 (12.06)
		6	2.03 (0.16)*	1.98 (0.20)	1.53 (0.19)*	1.57 (0.16)	0.49 (0.18)	0.40 (0.18)	0.45 (0.14)*‡	0.49 (0.19)	1.08 (0.28)*	1.09 (0.27)	75.76 (8.49)	80.07 (8.34)	24.24 (8.49)	19.93 (8.34)	22.49 (7.01)*‡	24.71 (9.67)	53.26 (12.57)*	55.37 (13.89)
		12	1.98 (0.15)†	2.58 (0.01)	1.45 (0.20)†	2.10 (0.01)	0.52 (0.23)	0.48 (0.01)	0.31 (0.30)†‡	0.81 (0.01)	1.14 (0.46)†	1.29 (0.01)	73.88 (11.04)	81.20 (0.01)	26.12 (11.04)	18.80 (0.01)	15.46 (14.63)†‡	31.20 (0.01)	58.42 (24.65)†	50.00 (0.01)
		p	0.0001	0.3679	0.0009	0.3679	0.4169	0.3679	0.0013	0.3679	0.0001	0.3679	0.3114	0.3679	0.3114	0.3679	0.0019	0.3679	0.0019	0.3679
7	MS	1	2.55 (0.28)*†	2.37 (0.14)*†	2.38 (0.27)*†	1.89 (0.17)*	0.17 (0.06)*†	0.48 (0.05)*†	0.46 (0.13)*	0.12 (0.10)*†	1.94 (0.26)*†	1.84 (0.26)*†	93.26 (2.13)*†	79.74 (2.73)*†	6.74 (2.13)*†	20.26 (2.73)*†	18.01 (5.27)*†	5.08 (4.34)*†	76.21 (7.06)*	77.60 (8.62)*
		6	2.35 (0.28)*‡	2.11 (0.10)*	2.08 (0.29)*‡	1.56 (0.10)*†	0.26 (0.06)*‡	0.54 (0.02)*‡	0.33 (0.17)*†	0.24 (0.15)*	1.78 (0.37)*‡	1.45 (0.28)*‡	88.71 (2.85)*‡	74.14 (1.62)*‡	11.29 (2.85)*‡	25.86 (1.62)*‡	14.73 (8.46)*‡	11.52 (7.11)*	75.27 (10.11)†	68.80 (12.88)*†
		12	1.91 (0.53)†‡	2.06 (0.06)†	1.29 (0.49)†‡	1.90 (0.06)†	0.62 (0.33)†‡	0.16 (0.04)†‡	0.45 (0.35)†	0.32 (0.10)†	0.85 (0.65)†‡	1.59 (0.11)†‡	66.69 (14.67)†‡	92.31 (1.70)†‡	33.31 (14.67)†‡	7.69 (1.70)†‡	24.78 (18.82)†‡	15.29 (4.88)†	42.42 (30.18)*†	77.02 (4.53)†
		p	0	0.0011	0	0.0009	0	0.0001	0.0007	0.0131	0	0.0131	0	0.0001	0	0.0001	0.0003	0.0018	0	0.0164
8	MS	1	2.65 (0.29)*†	2.86 (0.16)*†	2.21 (0.45)*	2.36 (0.15)*†	0.44 (0.18)	0.50 (0.05)*†	0.55 (0.08)*†	0.24 (0.08)*†	1.66 (0.52)*	2.11 (0.19)*†	82.53 (8.74)	82.47 (1.87)*	17.47 (8.74)	17.53 (1.87)*	21.33 (4.96)*†	8.52 (3.04)*	61.20 (13.47)	73.95 (3.65)*†
		6	2.48 (0.13)*‡	2.54 (0.19)*‡	2.07 (0.12)†	2.23 (0.17)*‡	0.42 (0.08)	0.30 (0.10)*‡	0.41 (0.08)*	0.19 (0.12)*‡	1.66 (0.15)†	2.04 (0.21)*‡	83.29 (3.21)	88.19 (3.57)*†	16.71 (3.21)	11.81 (3.57)*†	16.50 (3.18)*	7.69 (4.67)†	66.79 (5.66)	80.49 (4.51)*‡
		12	2.29 (0.17)†‡	2.47 (0.13)†‡	1.93 (0.09)*†	2.04 (0.12)†‡	0.36 (0.15)	0.43 (0.05)†‡	0.40 (0.06)†	0.46 (0.04)†‡	1.53 (0.10)*†	1.58 (0.13)†‡	84.62 (5.94)	82.53 (2.04)†	15.38 (5.94)	17.47 (2.04)†	17.47 (2.36)†	18.72 (1.94)*†	67.15 (6.70)	63.81 (2.94)†‡
		p	0	0	0	0	0.2625	0	0	0	0.0025	0	0.9131	0	0.9131	0	0.0001	0	0.8124	0

Continued

Participant	Condition	Week	Stride time (s)		Stance time (s)		Swing time (s)		Single support time (s)		Double support time (s)		Stance percentage (%)		Swing percentage (%)		Single support percentage (%)		Double support percentage (%)	
			L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R
10	MS	1	2.27 (0.11)*†	2.33 (0.15)*†	1.70 (0.14)*	1.70 (0.16)*†	0.57 (0.15)*†	0.63 (0.03)*†	0.53 (0.16)*	0.62 (0.14)*†	1.17 (0.27)*†	1.09 (0.24)*†	74.95 (6.17)*†	72.73 (2.25)*†	25.05 (6.17)*†	27.27 (2.25)*†	23.42 (7.12)*	26.55 (6.01)*†	51.53 (12.19)*	46.18 (6.96)*†
		6	2.09 (0.09)*‡	2.10 (0.15)*‡	1.36 (0.09)*†	1.54 (0.17)*‡	0.73 (0.05)*‡	0.55 (0.04)*‡	0.55 (0.04)*†	0.70 (0.15)*‡	0.80 (0.08)*‡	0.85 (0.24)*‡	64.97 (2.54)*‡	73.45 (3.06)*‡	35.03 (2.54)*‡	26.55 (3.06)*‡	26.55 (1.88)†	33.30 (7.39)*	38.44 (2.95)*†	40.17 (8.12)*‡
		12	1.99 (0.17)†‡	2.04 (0.11)†‡	1.66 (0.26)†	1.44 (0.11)†‡	0.32 (0.22)†‡	0.60 (0.03)†‡	0.62 (0.18)†	0.69 (0.12)†‡	1.03 (0.31)†‡	0.75 (0.17)†‡	83.72 (10.97)†‡	70.50 (2.03)†‡	16.28 (10.97)†‡	29.50 (2.03)†‡	31.46 (8.90)*†	33.74 (5.97)†	51.57 (13.55)†	36.76 (5.97)†‡
		p	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 4. Gait kinematic parameters analysis results for each participant. All values are presented as: mean (standard deviation); p stands for the p_value between the weeks for the same participant; *, †, ‡ represent that two groups have statistical difference ($p < 0.05$) resulted from post-hoc test.

towards the front of the foot, particularly in the right limb in the first and both in the second. For Participant 5 this behaviour can be attributed to the difference in strength in the legs, having only strength in the left leg. Participant 10 instead did not show strength in both legs, so the difference compared to other participants with the same condition, could be attributed either to his aptitude to lean forward or to the type of support given by the physiotherapist during the tests. Participant 6 showed in the first assessment week an unbalanced distribution between the limbs, with the left COP tending towards the back of the foot.

Healthy participants demonstrated lower displacement of COP on the mediolateral plane (1.35cm left, 1.18cm right), indicating stable mediolateral control. Participants diagnosed with MS, who had no strength in their legs, showed values that resembled those of healthy participants, suggesting that the exoskeleton provided adequate support to maintain balance. In contrast, the participant with SCI and TBI, who had strength mainly in one of their legs, showed higher values, reflecting greater instability possibly due to the resistance to the exoskeleton. All participants showed disparities between the limbs in both the mediolateral and anterior-posterior planes, indicating the need for further investigation to understand the underlying causes.

The COP planar deviation resulted in a similar trend among all the participants, with the highest values for the right limb only for Participant 5. The confidence ellipse area highlighted the disparities between the limbs in all the participants. Finally, the principal sway direction showed how the exoskeleton influenced the participants' balance, with all the participants showing low values, indicating a forward sway.

Overall, the analysis of kinetic parameters provided valuable insights into the distinct postural control mechanisms among the participants, underscoring the importance of considering these parameters along with the kinematics parameters for the assessment of the gait in individuals undergoing rehabilitation with the exoskeleton, which can provide physiotherapist with additional information for evaluating the progress of the rehabilitation.

Acceptability analysis

At the end of the 12 weeks, participants were given a questionnaire to assess their experience with the smart insoles. The results, depicted in Fig. 4, revealed that although none of the participants had previous experience with wearable technology (Q1), 50% were familiar with wearable technologies used in physical rehabilitation, such as smart bands and watches (Q2). Everyone, except for one subject, was fully aware of the purpose and operation of smart insoles, demonstrating that the prior lack of use and awareness of wearable technology has had no impact on the current understanding (Q3). Feedback on comfort revealed that 66% of participants found the smart insoles very comfortable, one participant found them comfortable, and another remained neutral (Q4). Additionally, the majority of participants expressed neutrality regarding whether the insoles had influenced their rehabilitation (Q5). Notably, most participants believed that their walking motion remained unaffected by their awareness of the insoles tracking their movements (Q6), while 50% were optimistic about the potential benefits of providing insights to their physiotherapist (Q7), with the remaining respondents expressing neutrality. All participants acknowledged the importance of receiving feedback on their progress (Q8), and 50% recognised the potential impact of smart insoles in rehabilitation by offering precise feedback (Q9). Except for one neutral response, all participants indicated willingness to continue using the insoles for further rehabilitation (Q10). The absence of reported interruptions due to wearing the insoles (Q11) suggests that their use did not disrupt the continuity of rehabilitation sessions, which is crucial for integrating such technology practically into rehabilitation practices.

Limitations

This study should be considered as a preliminary investigation into the integration of smart insoles for gait assessment in exoskeleton-assisted rehabilitation.

The presented solution adeptly tackles numerous challenges arising from the lack of pressure data in certain areas due to participants' condition and the wearing of the exoskeleton, the absence of predefined patterns, and inaccuracies resulting from the misplacement of the smart insoles. However different limitations should be considered. The number of participants involved in the study was limited and didn't allow for generalisation of the results. Collecting the data from existing facilities and rehabilitation programs provided a unique opportunity to assess the impact that smart insoles can have on such practices. However, the absence of ground truth information limited the comparison with other approaches and technologies and the validation of the presented solution. Furthermore comparing the results with results from other state-of-the-art solutions was not possible as existing solutions are designed mainly to evaluate distance walked, steps taken and speed as highlighted in[12].

The potential issue with insole misplacement during data collection, leading to data alteration, suggests the need for further investigation into the integration of additional modalities to augment the analysis. Furthermore, the insoles currently consist of a film without any covering material which can cause slip in the shoe. The inclusion of an additional soft material layer such as a common insole could reduce such behaviour.

Future research will aim to enhance the number of participants involved in the study to provide a more comprehensive evaluation of the proposed solution. Furthermore, the analysis can be extended to include participants from different conditions, rehabilitation programs, and exoskeleton models and settings. Different additional modalities will be investigated, such as IMU sensor data, to enhance the analysis and overcome the limitations of the current solution.

Participant	Condition	Week	Mean COP ML (cm)		Mean COP AP (cm)		Range COP ML (cm)		Range COP AP (cm)		Planar deviation (cm)		Confidence ellipse area (cm^2)		Principal sway direction (deg)	
			L	R	L	R	L	R	L	R	L	R	L	R	L	R
1	H	TEST	4.14 (0.20)	7.25 (0.23)	8.69 (1.61)	12.91 (1.99)	1.33 (0.42)	1.52 (0.33)	4.87 (2.46)	16.39 (3.90)	9.80 (1.52)	15.59 (1.77)	8.00 (7.33)	29.68 (16.97)	6.09 (4.79)	1.89 (2.36)
3	H	TEST	4.04 (0.17)	7.38 (0.16)	7.97 (1.97)	7.54 (0.93)	0.96 (0.29)	1.28 (0.33)	5.58 (1.88)	7.18 (1.99)	9.15 (1.72)	10.87 (0.80)	4.74 (2.69)	10.35 (5.10)	5.19 (3.27)	5.76 (4.57)
2	H	TEST	4.63 (0.53)	6.18 (0.25)	8.92 (3.93)	5.84 (1.78)	1.95 (1.18)	0.81 (0.30)	8.15 (3.91)	3.69 (1.39)	10.44 (3.57)	8.63 (1.49)	11.44 (10.46)	1.58 (1.07)	7.34 (10.22)	9.70 (4.57)
4	MS	1	3.72 (0.63)*	6.22 (0.20)*†	8.46 (1.48)	8.23 (1.66)*†	1.36 (0.51)	1.13 (0.27)*†	8.03 (2.35)*†	8.69 (2.48)*†	9.59 (1.56)	10.66 (1.35)*†	8.61 (4.09)*†	12.06 (4.82)*†	2.35 (1.56)*†	5.35 (6.26)*
		6	3.93 (0.75)†	6.19 (0.15)*	8.99 (1.33)	7.54 (2.00)*‡	1.32 (0.91)	0.62 (0.28)*‡	6.08 (3.85)*	9.23 (3.32)*	10.05 (1.07)	10.14 (1.50)*‡	7.91 (6.98)*	5.50 (2.96)*	8.26 (5.73)*‡	2.82 (5.76)*†
		12	4.00 (0.52)*†	6.10 (0.29)†	8.77 (1.23)	9.39 (2.20)†‡	1.43 (0.71)	0.81 (0.47)†‡	6.15 (2.46)†	8.04 (4.58)†	9.86 (0.97)	11.53 (1.56)†‡	6.14 (3.96)†	5.49 (3.86)†	10.40 (5.25)†‡	5.40 (6.78)†
		p	0.0348	0.0039	0.1456	0	0.1371	0	0	0.0204	0.1292	0	0	0	0	0
5	SCI	1	5.79 (0.38)*†	7.83 (0.08)*†	5.02 (1.05)*†	9.58 (0.29)*†	2.10 (0.51)	2.25 (0.72)*	8.16 (4.85)*†	9.92 (2.47)*	8.06 (0.75)*†	12.51 (0.23)*†	9.10 (4.43)	8.42 (3.05)*†	7.75 (4.24)	2.21 (3.66)*†
		6	4.71 (0.13)*‡	7.97 (0.29)*	7.83 (1.14)*	14.60 (1.17)*	1.97 (0.26)	2.50 (0.69)*†	8.80 (2.16)*	10.00 (2.12)†	9.52 (1.07)*	16.93 (1.00)*	10.72 (6.92)	24.29 (10.16)*‡	9.39 (2.87)	4.24 (3.73)*
		12	5.03 (0.14)†‡	7.95 (0.25)†	9.22 (2.26)†	14.87 (1.49)†	1.78 (0.68)	2.28 (0.82)†	9.95 (4.19)†	8.82 (2.37)*†	10.95 (2.09)†	17.10 (1.32)†	10.28 (6.76)	21.60 (9.31)†‡	6.05 (5.37)	3.60 (2.49)†
		p	0	0	0	0	0.0874	0.0031	0.0468	0.0002	0.0001	0	0.9394	0	0.0681	0
6	TBI	1	6.35 (0.44)*†	7.46 (0.16)*†	3.54 (0.39)*†	7.22 (1.77)*†	1.51 (0.62)	1.82 (0.73)*	3.47 (1.53)*†	5.98 (2.89)*†	7.39 (0.27)*†	10.59 (1.16)*†	7.94 (3.75)*	6.74 (4.86)*†	12.66 (4.82)*†	9.69 (11.80)*
		6	5.20 (0.13)*‡	7.78 (0.40)*‡	10.33 (1.64)*	10.90 (1.55)*	1.66 (0.63)	1.75 (0.63)†	10.12 (2.01)*‡	8.11 (3.67)*‡	11.97 (1.45)*	13.63 (1.21)*	15.60 (5.57)*†	12.90 (7.85)*‡	2.95 (3.94)*‡	7.67 (7.51)†
		12	3.99 (1.18)†‡	7.02 (0.55)†‡	11.19 (2.88)†	10.55 (2.29)†	1.07 (0.77)	3.90 (1.40)*†	6.29 (5.12)†‡	14.12 (4.41)†‡	12.28 (2.19)†	13.22 (2.17)†	6.05 (6.69)†	29.38 (10.47)†‡	6.23 (7.61)†‡	1.36 (1.31)*†
		p	0	0	0	0.0004	0.096	0.0015	0.0001	0.0001	0	0.0004	0	0.0001	0	0.0004
7	MS	1	5.24 (0.05)*†	8.18 (0.11)*†	5.85 (0.49)*†	7.49 (0.34)*†	1.98 (0.86)*†	2.07 (0.42)*†	6.31 (0.98)*†	8.34 (2.13)*	8.03 (0.33)*†	11.23 (0.34)*†	5.84 (2.93)*†	11.72 (4.12)*†	11.85 (3.71)*†	11.69 (4.36)*†
		6	5.18 (0.11)*‡	7.61 (0.12)*‡	6.57 (0.70)*‡	8.47 (0.68)*	1.55 (0.64)*	3.84 (0.81)*‡	7.19 (0.85)*‡	9.03 (1.88)†	8.71 (0.51)*‡	11.61 (0.63)*	12.95 (3.62)*	18.13 (6.82)*‡	3.84 (1.85)*	8.90 (2.26)*‡
		12	4.54 (0.30)†‡	8.03 (0.01)†‡	11.58 (3.60)†‡	8.74 (0.20)†	1.80 (0.69)†	1.15 (0.35)†‡	13.26 (6.22)†‡	6.20 (0.37)*†	13.17 (3.61)†‡	11.97 (0.16)†	25.27 (21.61)†	6.06 (0.90)†‡	5.50 (6.15)†	1.06 (0.87)†‡
		p	0	0	0	0	0.0066	0	0	0	0	0	0	0	0	0
8	MS	1	4.40 (1.15)*†	7.44 (0.04)*†	7.97 (3.69)*†	6.25 (0.69)*†	0.81 (0.09)	0.50 (0.16)*†	4.52 (0.47)	4.83 (1.27)*†	9.61 (2.72)*†	9.89 (0.50)*†	1.98 (0.45)*†	2.81 (1.04)*†	7.61 (0.68)*†	2.88 (2.80)*
		6	5.36 (0.08)*	7.29 (0.04)*‡	4.79 (0.70)*	5.24 (0.31)*‡	0.82 (0.14)	0.35 (0.04)*‡	4.63 (1.40)	3.24 (0.70)*‡	7.38 (0.54)*	9.05 (0.23)*‡	3.75 (4.06)*	1.12 (0.31)*‡	8.36 (2.38)*‡	5.79 (5.45)*†
		12	5.04 (0.45)†	7.21 (0.03)†‡	5.92 (1.94)†	7.07 (0.48)†‡	1.68 (1.14)	0.90 (0.07)†‡	6.41 (3.56)	8.48 (1.28)†‡	8.08 (1.29)†	10.35 (0.39)†‡	4.04 (3.66)†	7.42 (1.83)†‡	11.70 (8.67)†‡	2.43 (0.90)†
		p	0	0	0	0	0.1177	0	0.282	0	0	0	0.013	0	0	0
10	MS	1	3.43 (0.85)*†	6.89 (0.07)*†	10.97 (2.18)*	11.88 (0.48)	1.41 (0.96)*†	1.08 (0.25)*	6.29 (2.70)*	6.23 (1.10)*†	11.79 (1.63)*	13.91 (0.40)	5.84 (6.12)*†	5.95 (1.45)*	7.54 (2.22)*	2.80 (1.58)*†
		6	2.93 (0.18)*‡	6.81 (0.10)*‡	13.49 (0.59)*†	11.78 (0.94)*	0.84 (0.20)*‡	0.94 (0.20)*†	2.76 (0.73)*†	7.71 (1.71)*‡	13.84 (0.57)*†	13.90 (0.81)	2.05 (1.10)*‡	5.75 (2.12)†	8.65 (6.93)†	5.47 (1.78)*‡
		12	3.28 (0.32)†‡	6.89 (0.18)†‡	11.10 (1.56)†	12.01 (0.78)*	0.79 (0.27)†‡	1.09 (0.27)†	6.71 (2.41)†	6.48 (1.56)†‡	11.81 (1.35)†	14.05 (0.65)	5.52 (2.92)†‡	7.99 (2.59)*†	2.97 (2.57)*†	4.14 (5.67)†‡
		p	0	0	0	0.0396	0	0	0	0	0	0.159	0	0	0	0

Table 5. Gait kinetic parameters analysis results for each participant. All values are presented as: mean (standard deviation); *p* stands for the p_value between the weeks for the same participant; *, †, ‡ represent that two groups have statistical difference ($p < 0.05$) resulted from post-hoc test.

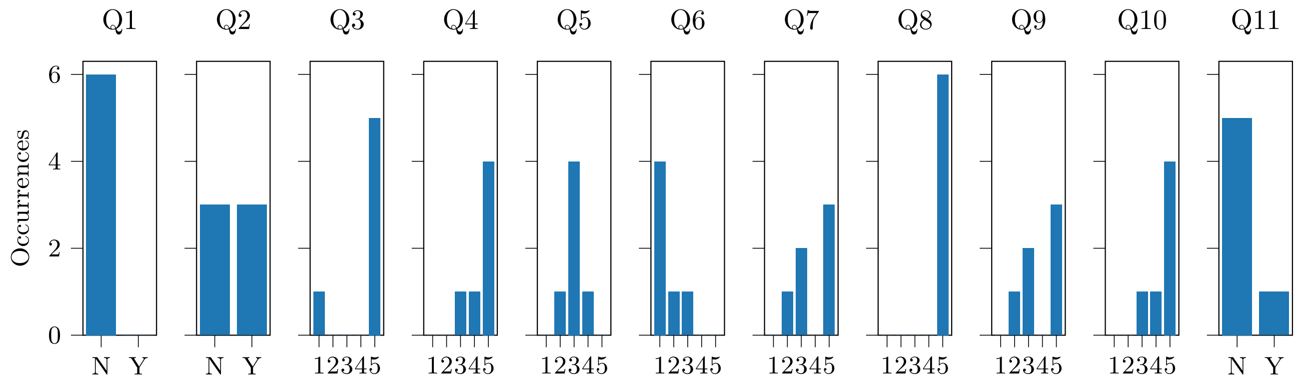


Fig. 4. Results of the questionnaire to evaluate participants' acceptance of smart insoles.

Conclusion

This study examined the integration and acceptance of smart insoles for assessing gait characteristics in individuals with neurological and musculoskeletal diseases undergoing exoskeleton-assisted rehabilitation. Smart insoles were found to be a feasible and minimally invasive method for assessing gait characteristics in individuals wearing an exoskeleton, providing insights into gait kinematic and kinetic parameters. Results showed that the exoskeleton positively impacted mobility, enabling individuals with limited leg strength to achieve gait patterns similar to healthy individuals, particularly notable in those with MS. Participants expressed positive acceptance of smart insoles, emphasising comfort and willingness to continue using them for future rehabilitation, underscoring the importance of continuous feedback for individuals undergoing rehabilitation. Future research will focus on enhancing smart insole integration into exoskeleton systems, optimising real-time monitoring, improving the number of gait parameters extracted, and employing IMU sensors for additional insights. Furthermore, long-term studies with larger cohorts will further validate the findings and explore the impact of smart insole in exoskeleton-assisted rehabilitation.

In summary, the combination of robotic exoskeletons and smart insoles presents a promising avenue for advancing rehabilitation practices. This study contributes to the growing body of knowledge in the field, providing a foundation for further exploration and innovation in personalised and effective rehabilitation strategies for individuals with neurological and musculoskeletal conditions.

Data availibility

The datasets generated and analysed during the current study are available from the corresponding author upon reasonable request.

Received: 31 March 2024; Accepted: 1 July 2025
Published online: 04 August 2025

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Acknowledgements

This study is funded by Ulster University UKRI prime-pump funding and the Ulster-Beitto Collaboration Programme. Authors would like to thank the No Barriers Foundation Ireland for the valuable support in participant recruitment, data collection and discussion.

Author contributions
L.D. was responsible for the conceptualisation, investigation, methodology and writing of the original draft. H.W. and H.Z. were responsible for research identification, conceptualisation, study design & discussion, acquiring funding, manuscript review and editing. All authors have read and accepted the manuscript.

Declarations

Competing interests
The authors declare, that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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