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FIELD MEDICINE

STUDY ON THE BIOMECHANICS OF GAIT, ASSISTED BY A NEW MECHATRONIC SYSTEM FOR PATIENTS WITH WALKING DISABILITIES, DEVELOPED WITHIN THE FRAMEWORK OF THE RESEARCH PROJECT PN II – PARTNERSHIPS IN PRIORITY AREAS – CONTRACT 190/2012: „3D REALITY MECHATRONIC SYSTEM FOR ENVIRONMENTAL RECOVERY OF PATIENTS WITH CENTRAL NEUROLOGICAL DISEASES – RELIVE"

PHD THESIS SUMMARY

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List of abbreviations and symbols

AMO=amplitude of the obliquity movement/motion

AVC=stroke

BWS=body weight support

CoM=center of mass

DGC=degree of unloading body weight

DoF=degree of freedom

EEG= electroencephalograph

EMG= electromyography

FAC=Functional Ambulation Categories

FES=Functional Electric Stimulation

IS=symmetry index

MAO=mean of the values of amplitude of obliquity movement

$MAO_{45,r}$= mean of the values of amplitude of obliquity movement for the right pelvis

$MAO_{45,l}$= mean of the values of amplitude of obliquity movement for the left pelvis

MAO_{90}= mean of the values of amplitude of obliquity movement for the right and left pelvis

MI=lower member

MISO=mean of the values of the symmetry index for obliquity

MPMV=mean of the values of the mean peak pressure

$MPMV_{24,r}$= mean of the values of the mean peak pressure for the right foot

$MPMV_{24,l}$= mean of the values of the mean peak pressure for the left foot

$MPMV_{48}$= mean of the values of the mean peak pressure for the both feet

MTS= metatarsal

PMV= mean peak pressure

Introduction

The importance of the chosen theme. The first World Report on Disability stated more than a decade ago, that there were more than one billion people living with some form of disability, of which 200 million had some form of functional disability, including ambulation disability. The causes of the change in the physiological walking pattern are varied: central nervous system disorders, degenerative osteo-articular disorders of traumatic nature, infectious or inflammatory nature, muscle deficiency, length difference between the lower limbs (MI), post-amputation MI prosthesis, cognitive disorders, obesity or sudden weight loss, vascular disorders, neoplastic disorders [1,2,3]. Of these causes, stroke is the third leading cause of death and long-term combined disability. Therefore, recently, the development of devices and systems for training gait in post-stroke patients has become a research topic of great interest [4,5,6].

The novelty and actuality of the theme. Considering the particularities of the changes brought to gait, in the case of post-stroke patients, the current trend is to try to develop some systems or robots for rehabilitation, which will improve the outcome of their recovery. The studies presented in the thesis are based on the RELIVE system. This is an assistive system for training gait on the ground, for the rehabilitation of patients with conditions that cause ambulation disabilities, which was designed and realized within the research project PN II - Partnerships in priority areas - contract 190/2012: "Mechatronic 3D reality system for the ambient recovery of patients with central neurological conditions - RELIVE" (CNDI–UEFISCDI PN-II-PT-PCCA-2011-3.2-0053). The development of such a complex system required interdisciplinary collaboration between rehabilitation medicine specialists, mechatronics specialists, engineers and psychologists. Due to the interdisciplinary nature of the studies, the coordination of the research activity was carried out in joint supervision (joint supervision agreement of 22.11.2017) between the University of Medicine and Pharmacy "Carol Davila" Bucharest, under the supervising of Prof. Dr. Mihai Berteanu and the University Politehnica of Bucharest, under the supervising of Prof. Dr. Eng. Petre Lucian Seiciu.

The motivation for choosing the theme. The system can have a significant impact in the rehabilitation of gait in post-stroke patients and the improvement of their quality of life, with an effect on the medical system, by reducing the expenses involved in the care of people with major ambulation disabilities.

Research hypothesis and the purpose of the scientific work. The study started from the hypothesis that the RELIVE system produces changes in the biomechanics of gait for the users who do not have walking pathologies. The purpose of this study is to evaluate the biomechanics of walking during the use of the RELIVE mechatronic system, and in the event that unwanted changes of the biomechanics occur, to identify the improvements that need to be made to the system to bring these changes back within normal limits.

I. Current state of the art (General part)

1. Introduction

During walking, the pelvis performs six movements in all three planes [7]: 3 translations: mediolateral (left/right); anteroposterior (forward/backward); superior-inferior (up/down) and 3 angular rotations or displacements: a) transverse rotation (or internal-external rotation), around the vertical axis, in the transverse (horizontal) plane; b) tilt (or antero-posterior rotation), around the transverse (mediolateral) axis, in the sagittal (longitudinal) plane; c) obliquity (supero-inferior rotation), around the sagittal axis, in the coronal (frontal) plane. Walking must be energetically efficient, and these pelvic movements are crucial for achieving normal gait patterns by optimizing energy consumption [8,9].

Stroke survivors tend to exaggerate pelvic movements to compensate for the abnormal gait pattern and to avoid falling during the swing phase. Previous studies have shown that survivors show increased amplitude of anterior pelvic tilt, contralateral pelvic drop in the coronal plane, and retraction of the hemipelvis in the transverse plane [9].

Conventional rehabilitation procedures require excessive effort on the part of therapists to assist severely walking impaired patients, positioning the paretic limb and controlling trunk movements. [9]. Currently, robotic systems for gait rehabilitation are being studied a lot and are developing rapidly. The most common are systems for assisted gait training on a fixed surface (overground) and exoskeletons [6].

The most important modules that a gait rehabilitation system should have are: the body weight support subsystem (BWS) or the body weight transfer module (in the case of exoskeletons), the reciprocal stepping mechanism (or the cyclic movement mechanism of the MI – in the case of exoskeletons), the pelvic mechanism (or the pelvis motor unit) and the environment module [7].

An insufficiently developed component to date is the pelvic mechanism, which would allow natural movement of the pelvis during gait training [10]. If the system does not provide movement according to the six DoFs of the pelvis, then mobility constraints and human-robot joint misalignment occur during walking [11]. The disadvantage of the systems that have a pelvic mechanism and assist the movements of the pelvis, is that they present many actuators and are complex, heavy structures [12].

2. Systems that allow the movement of the pelvis

2.1. Systems that allow active movement of the pelvis

In order to find out what is the current stage of development of systems for assisted gait training with pelvic mechanisms, it was necessary to carry out a bibliographic study [13]. PubMed, IEEE Xplore, ResearchGate, and Web of Science databases were searched. All systems having at least one pelvic DoF actuated by a pelvic mechanism actuator were searched.

The 19 identified systems are: Lopes II ([14,155–160]), PAM ([15]), NaTUre-Gaits II ([16]), Stand Trainer ([17]), mTPAD ([18]), WalkTrainer ([19]), Lokomat Pro ([20]), ALEX III ([21]), RGR Trainer ([22]), JARoW-II ([23]), IBWS ([24]), AssistOn-Gait ([25]), Gait Rehabilitation Robot ([26]), Lower Limb Rehabilitation Robot ([27]), String-man ([28]), TPMAD ([29]), Pelvic Support Walking Robot ([30]), Healbot T ([31]), Overground Pelvic Obliquity Support Robot + Walking Assist Exoskeleton ([6]).

For each of these systems, I presented the general characteristics: a) type of system; b) what type of surface the user can walk on; c) if the system is or consists of an exoskeleton or a robotic orthosis; d) the mechanical components of the system and whether or not it has a BWS subsystem; e) the type of human-robot interface that the system has at the pelvic level; f) if the system has a biofeedback subsystem or an intent recognition subsystem; g) the years of the first and last research papers found on the identified systems. To find out the date of the research papers, the name of each system and the authors were searched again in the same databases. I have also provided information on: a) the movements that the human pelvis can make while using each system; b) if the movement of the pelvis is actuated, passive or blocked; c) about the DoFs of the system, provided with actuators that allow movements of the human pelvis; d) about the operating modes of the systems; e) whether or not the systems influence the CoM trajectory.

2.2. Systems that allow only passive movement of the pelvis

In addition to systems with an active pelvic mechanism, there are also systems that ensure the movement of the pelvis only passively. Among them I mention: iReGo [32], System Corbys [33], KineAssist [34], RART [35], GaitEnable [36], Robotic Walker [37], System Walker [38] and BAR [39].

2.3. Conclusions

1. Although research has made great strides in the field of gait recovery, much more needs to be studied in this area to improve the effectiveness of this rehabilitation process.

2. The main objective of gait rehabilitation systems is to help patients with locomotion disabilities to achieve the highest possible level of functional independence.

3. Most systems are based on Saunders' theory of the six determinants of gait, which has subsequently been shown not to be useful in reducing the metabolic cost of gait by reducing CoM oscillations. Implementing other movements in an attempt to reduce metabolic energy cost could be a useful strategy.

4. Future research directions for system improvement should consider movement intention recognition systems based on human-robot interface, EMG, EEG, or other technologies that can be applied in a closed biofeedback loop (FES), to anticipate and assist patients' movements, adjusting their movement trajectory and amplitude only if necessary. An important advance would be achieved if this technology could be implemented to assist both the affected MI and the pelvis.

5. Gait assistance should be consistent with the sub-phases of the gait cycle, but few systems take this into account.

6. Other challenges concern the control system and the ability of the system to be operated in both directions, to be able to compensate for inertial effects and therefore automatically synchronize the movement of the system with the movement of the user, so that he does not encounter movement resistance from the system.

7. Harnesses and belts are essential to prevent falls. Although there is no perfect harness, it can be equipped with pressure sensors to determine the degree of pressure and help the patient release it by making adjustments.

8. Future research is needed to conclude whether and to what extent treadmill gait kinematics differ from floor walking kinematics.

9. Future goals should include increasing the addressability of these gait rehabilitation systems to cover more complex gait disabilities generated by various pathologies. This can be achieved by abandoning the mobile base of ground walking systems and coming up with a better mechanical solution that can allow the patient to train in more complex environments such as different ground textures or stairs.

II. Personal Contributions (Original Part)

3. RELIVE system, working hypothesis and general objectives

3.1. RELIVE system

The RELIVE system is at the TRL5 level, going through preclinical evaluation to reach the TRL6 level, according to the TRL classification adapted to medical devices [40,41]. The RELIVE system (Fig. 3.1.) consists of a set of support pillars and a subsystem consisting of 4 fixed beams (transverses), which delimit the therapeutic space, and a mobile beam on which the BWS subsystems and the mechatronic subsystem of alternating vertical oscillation of the pelvic belt (hereinafter referred to as "alternator") are placed. The alternator was described in a previous paper [42], being the innovative feature of the RELIVE system, responsible for producing the superior-inferior rotation (obliquity) movement of the pelvis. For this system, was obtained the invention patent with the title "Mechatronic system of alternating vertical oscillation of the pelvic belt", no. RO 131260 A2.

The user wears an approved harness (h/p/cosmos) which is attached to a cable in two-points, at shoulder level, through two rings (Fig. 3.1.), being suspended by mean of the rotating carriage mounted on the mobile beam, which allows 360° turns. The alternator moves vertically, alternately, the two points of the harness, at shoulder level [43]. A force transducer is placed between the cable and the harness rings, which converts the weight into an electrical signal. The cable passes through a perforated disk, which is mounted above the rotary carriage and connected to it, a roller being mounted in one of the holes. The vertical movement of the pelvis is achieved by rotating the perforated disc, one complete rotation being the equivalent of a double step. When the rotary carriage is in the reference position and the roller pushes the left cable, the cable lifts the left hemipelvis, and when the roller pushes the right cable, the cable lifts the right hemipelvis [42]. There are 4 holes on the radius of the perforated disc and the roller can be mounted in 4 distinct positions relative to the center of the disc. Depending on this position, the vertical translation of the hips changes. For this study, the roller was positioned in the third position from the center of the disc, in this position an optimal vertical translation of the CoM of 55÷60 mm and a vertical translation of the hips of 10 cm were recorded [42]. The RELIVE system also features a vertically adjustable pelvic frame with handrails attached to the vertical axis of the rotating cart to improve the user's posture and stability. Before the start of the training session, the harness attached to the ends of the suspension cable is fixed on the user, who is weighed using the force transducers located between the cable and the harness, at the two ends of the cable. Then some of the user's weight is unloaded as needed. In this phase, the roller must be placed on the vertical axis of the perforated disc (0° corresponding to 12 o'clock or 180° corresponding to 6 o'clock) so that the weight is unloaded symmetrically [42]. The drum is actuated, and by twisting, it lifts both ends of the cable at the same time.

The use of the alternator assembly – BWS has several advantages: a) it simulates the natural alternative vertical movement of the hemipelvis, being the first system of this type; b) it is versatile, adapting to the physical (weight, height) and physiological characteristics of the users (in the current stage, the walking speed, the degree of DGC of the user can be changed); c) allows the controlled transverse rotation (around the vertical axis) of the user's entire body; d) it can be easily adapted for any recovery system (on the ground, on a moving carpet, robotic, etc.); e) the construction is simple but robust [42]. In conclusion, the RELIVE system addresses patients in the subacute and chronic stage, with partial voluntary motor control of MI, with FAC (Functional Ambulation Categories) index values between 0 and 3.

3.2. Working hypothesis

The study started from the hypothesis that the RELIVE system produce changes in the biomechanics of gait in users who do not have walking pathologies. Given that the RELIVE system is at TRL5, it should be investigated/tested in relevant preclinical studies on healthy subjects. The purpose of this study is to evaluate the biomechanics of walking while using the RELIVE mechatronic system, and in the event that unwanted biomechanics changes occur, to identify the improvements that must be made to the system to bring these changes back within normal limits.

3.3. General objectives of the study

To achieve the above-mentioned goal, the following general objectives were taken into account:

a) recording the distribution of plantar pressure using the F-Scan device from Tekscan;

b) recording some walking parameters using the G-Walk device from BTS;

c) analysis of the obtained data and formulation of conclusions.

4. General research methodology

The study is further divided into two studies. The first investigates the plantar pressures, using the F-Scan device, and the second study investigates gait parameters, using the G-Walk device. Fifteen healthy, non-disabled subjects, both men and women, with no history of pathologies affecting MI participated in these studies. Among the *Inclusion criteria are*: Age >18 years; Weight < 130 Kg and height < 1.90 m; Length difference between MI <2 cm; Signing informed consent. *Exclusion criteria include*: Age <18 years; Weight >130 Kg and height >1.90 m; Pregnancy; Known chemical allergies to materials with which the participant comes into contact; Various medical conditions; Contraindications to physical exercise and suspension; Psychiatric conditions; Surgery in the last 6 months.

The initial and final recordings were made by walking, on a linear trajectory, a distance of 4 m, with freely chosen speed, i.e. with a speed of 0.1 m/s (walking in parallel with the RELIVE system that advances with a maximum speed of 0.1 m/s). In order to study the biomechanics of walking, 16 walking sessions were described (Table IV.1.). Each participant had to walk three times during each walking session, totaling 48 recordings with the F-Scan device and 48 recordings with the G-Walk device. During the walking sessions, participants were encouraged to note their observations related to the operation of the RELIVE system.

Tabel IV.1. Walking sessions.

A	Without RELIVE system		Self selected waking speed	
B	Without RELIVE system		RELIVE system speed	
C	With RELIVE system	0% DGC	With hands beside the body	Without alternator
D	With RELIVE system	0% DGC	With hands on handrail	Without alternator
E	With RELIVE system	0% DGC	With hands beside the body	With alternator
F	With RELIVE system	0% DGC	With hands on handrail	With alternator
G	With RELIVE system	10% DGC	With hands beside the body	Without alternator
H	With RELIVE system	10% DGC	With hands on handrail	Without alternator
I	With RELIVE system	10% DGC	With hands beside the body	With alternator
J	With RELIVE system	10% DGC	With hands on handrail	With alternator
K	With RELIVE system	20% DGC	With hands beside the body	Without alternator
L	With RELIVE system	20% DGC	With hands on handrail	Without alternator
M	With RELIVE system	20% DGC	With hands beside the body	With alternator
N	With RELIVE system	20% DGC	With hands on handrail	With alternator
O	Without RELIVE system		RELIVE system speed	
P	Without RELIVE system		Self selected waking speed	

The study was conducted without obstacles or impediments. Also, the study participants did not develop any of the complications described in the protocol.

5. Study 1: Contributions concerning the changes in plantar pressure during assisted walking

5.1. Introduction

5.1.1. Gait cycle phases and plantar pressure considerations

Analysis of foot function is essential, given that the foot is the main point of support during walking and must adapt to varied environments and exposure to high forces [44]. The measurement of plantar pressure distribution has brought essential information for the evaluation of certain pathologies (rheumatoid arthritis, Parkinson's disease, diabetes, etc.) [44], but the quantification and interpretation of the results are difficult, which limits analysis and diagnosis [45].

5.1.2. Working hypothesis

I started from the hypothesis that the RELIVE system produces changes in plantar pressure during walking.

5.1.3. Specific objectives

The objectives of this study are the following: a) Comparison of several sessions to see if and how the plantar pressure changes according to certain particularities of the sessions; b) Left-right comparison within the same sessions in terms of plantar pressure; c) Integration of all results and highlighting some conclusions.

5.2. Material/participants and method

The first step was to fit the sensor insoles to the size of each participant's foot by cutting them. Next, the F-Scan device was mounted on the belt, and after turning on the device, I calibrated it using the "Step Calibration" method provided by the F-Scan device software. Next, the participant was given time for accommodation.

Then I started recording for each walk of the 16 walking sessions, with the F-Scan device software the plantar pressure values. To analyze only complete stance phases, I deleted the first and last recorded steps. Next, I applied the peak/stance average formula defined as the average of the peak pressure values of all steps, corresponding to each square/analysis box, and obtained the distribution of peak mean pressure values (PMV) and their map for each leg. I divided the plantar surface into six areas of interest (hallux; metatarsal (MTS) I; MTS II and III; MTS IV and V, medial calcaneus; lateral calcaneus), and I divided the stance phase of the gait cycle into four subphases (initial contact and loading response, middle stance, terminal stance, pre-swing). The PMV values of each zone and each phase were averaged, thus obtaining a single value for each phase of each region. For each participant, 24 values were obtained for each leg, in case of a walk from a walking session. Then, the values of the three walks for each session were averaged, obtaining the mean PMV values (MPMV) for each leg, for each walking session: 24 MPMV values for the left leg and 24 MPMV values for the right leg.

To obtain a single MPMV value for each leg, for each walking session, I averaged the 24 MPMV values for the left leg ($MPMV_{24,l}$) and I averaged the 24 MPMV values for the right leg ($MPMV_{24,r}$). To obtain a single MPMV value for each walking session, I averaged the 48 MPMV values (24 MPMV values for the right leg and 24 MPMV values for the left leg), resulting the $MPMV_{48}$ value.

F-Scan is known for the errors it can introduce in the sensor's perception of pressure, its decoding and repeatability of values under the same conditions. To test whether the recorded values are repeatable, we repeated at the end of the walking sessions with the RELIVE system, the first two walking sessions without the RELIVE system and compared them, with the aim of seeing if there were any statistical differences. Another safety measure was to record three walks for each session and average them. In this study, we made several sets of comparisons, selecting specific walking sessions from the 16 possible.

5.3. Results

Some of the results obtained are the following:

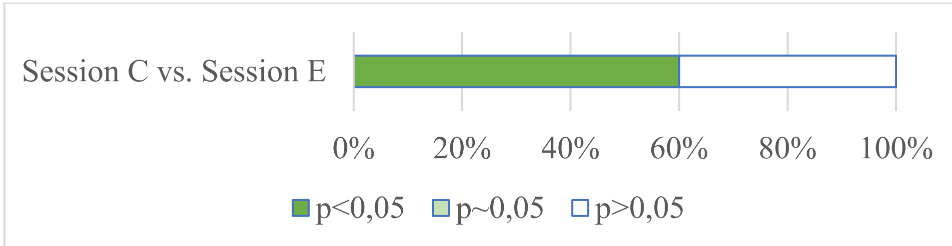

Fig. 5.1. Session C versus Session E.

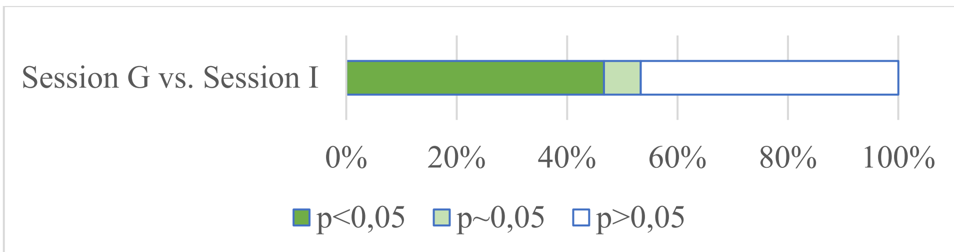

Fig. 5.2. Session G versus Session I.

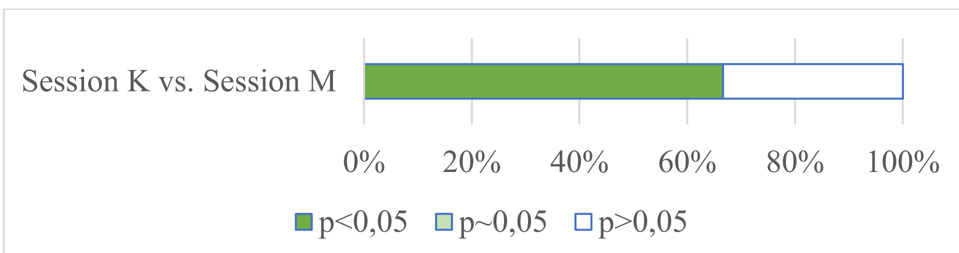

Fig. 5.3. Session K versus Session M.

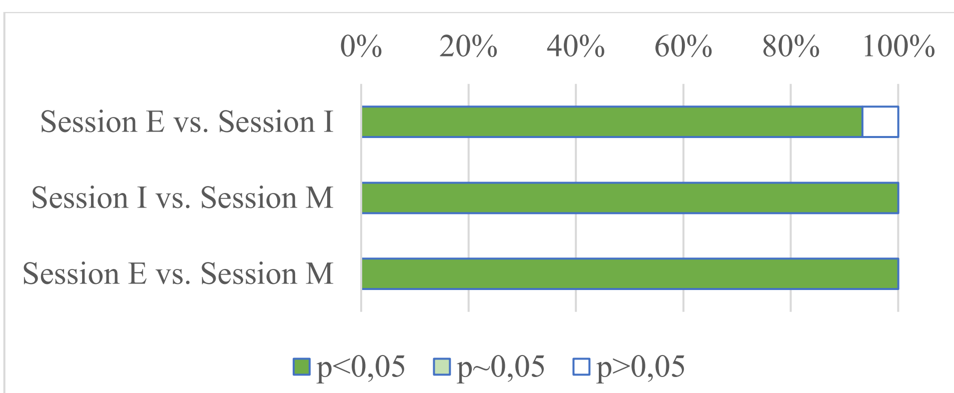

Fig. 5.4. Session E versus Session I versus Session M.

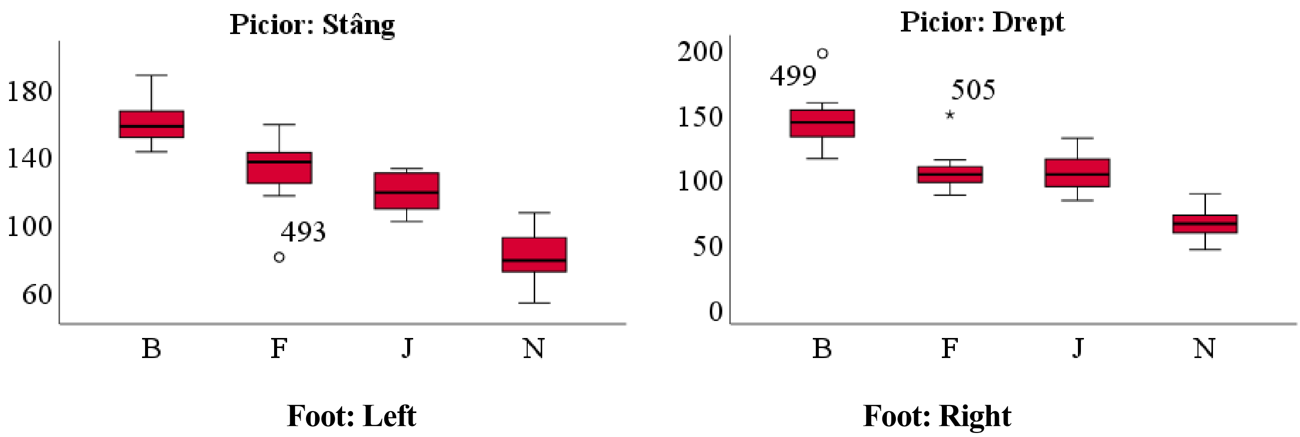

Fig. 5.5. Zone 5, phase 1.

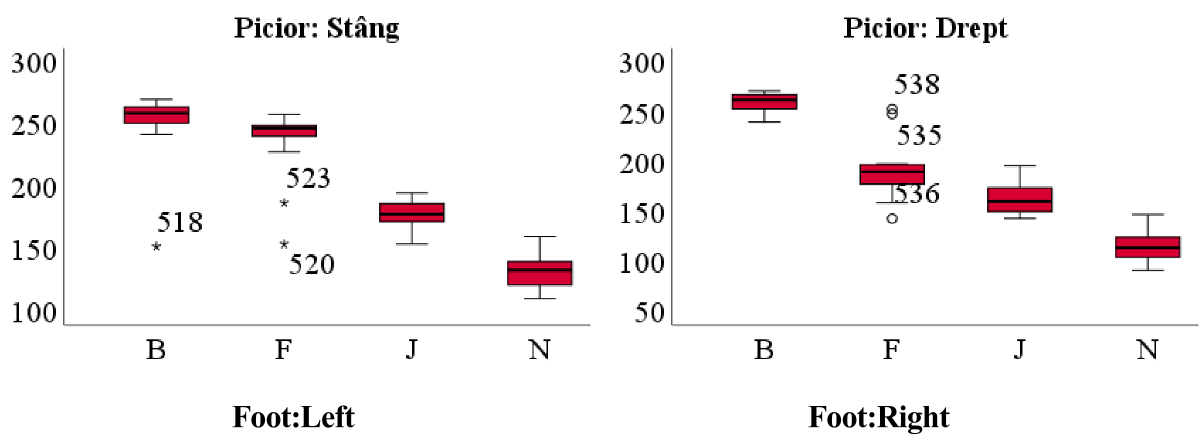

Fig. 5.6. Zone 5, phase 2.

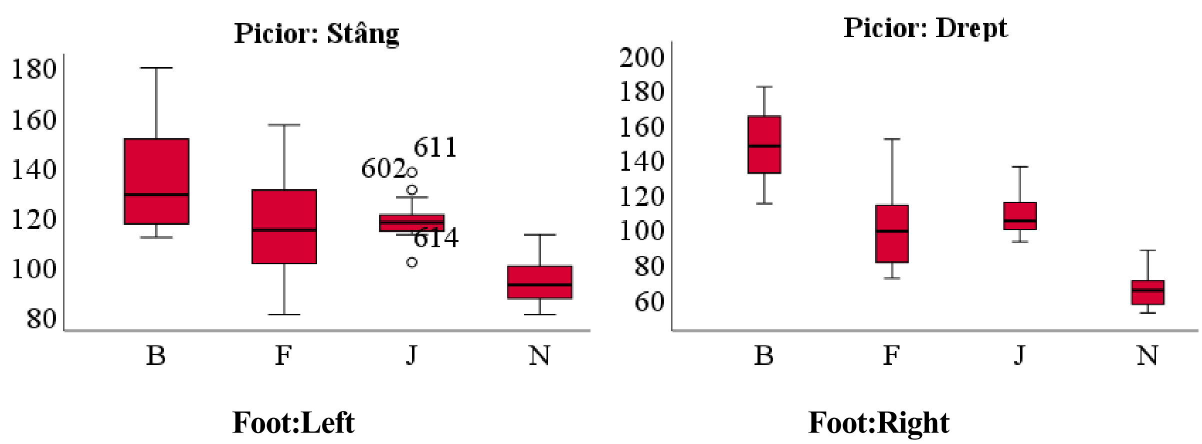

Fig. 5.7. Zone 6, phase 1.

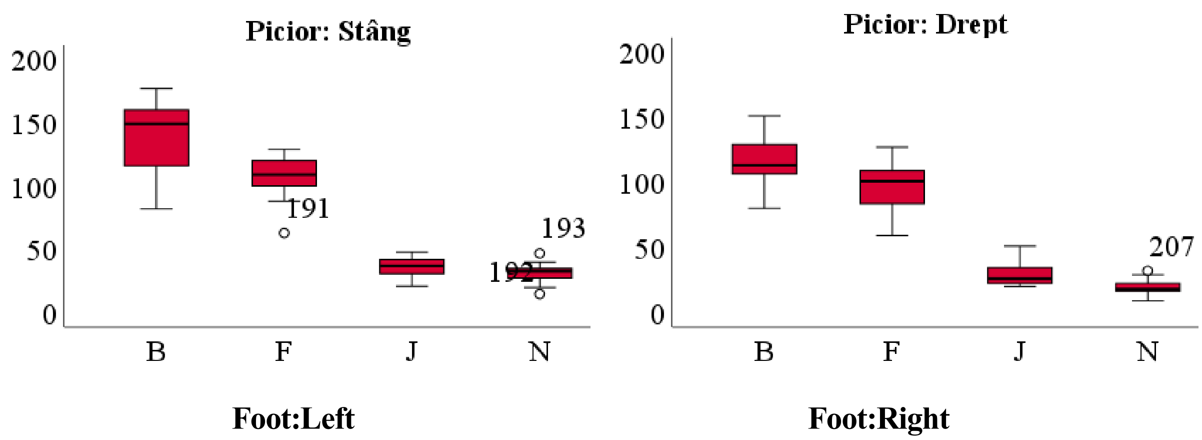

Fig. 5.8. Zone 2, phase 3.

5.4. Discussions

a) For each participant, when walking with the hands by the body and the alternator on, the BWS subsystem determines the gradual DGC, according to the degree of DGC commanded, the $MPMV_{48}$ values decreasing with each percentage of weight unloaded (Fig.5.4.). Also, the alternator subsystem interferes with the BWS subsystem by increasing the degree of operator-commanded DGC when it is turned on, during sessions with the same percentage of DGC when the participant walks with their hands beside the body in the RELIVE system (Fig. 5.1., Fig. 5.2., Fig. 5.3.). This was proven by the drop in all PMV_{48} values during sessions with the alternator on. This finding could be due to the fact that the alternator is not a mechanically separate subsystem from the BWS. Another possible explanation is that the double stance phase is shortened, with many participants saying they did not have enough time to move their CoM from one MI to the other.

b) For each participant, when walking with hands on the handrail and with the alternator on, the BWS subsystem determines gradual DGC according to the degree of DGC commanded by the operator, the $MPMV_{48}$ values decreasing with each percent of weight unloaded. The alternator subsystem also interferes with the BWS subsystem by increasing the degree of DGC, when it is turned on, during 20% DGC sessions, the participant walking with their hands on the handrail. This was evidenced by the decrease in $MPMV_{48}$ values during these sessions.

c) The alternator subsystem does not change the maximum pressure zones during the gait cycle, when waking with 0% DGC and hands on the handrail, from the maximum pressure zones during the gait outside the RELIVE system, at its speed. The right leg MPMV values appear to be lower than the left leg when waking at 0% DGC with the alternator on. The alternator subsystem interferes with the BWS subsystem, resulting in lower MPMV values and therefore increased DGC when it is switched on, in the case of walking with 0% DGC with hands on the handrail, compared to walking outside the RELIVE system, regardless of the plantar area studied or the subphases of the stance phase. The alternator does not change the maximum pressure areas during the gait cycle at 10% DGC, compared to the maximum pressure areas during the gait at 0% DGC. The alternator subsystem, when waking with the hands on the handrail, does not change the maximum pressure zones during the gait cycle at 10% DGC, compared to the maximum pressure zones during the gait at 0% DGC. The right leg MPMV values appear to be lower than the left leg when waking at 10% DGC with the alternator on. The alternator subsystem interferes with the BWS subsystem, resulting in lower MPMV values and therefore increased DGC when turned on, in the case of walking with 10% DGC with hands on the handrail, compared to walking with 0% DGC, regardless of the plantar area studied or the subphases of the stance phase. The alternator subsystem, in the case of walking with the hands on the handrail, can change the maximum pressure zones during the pre-swing subphase of the gait cycle, at 20% DGC compared to 0% DGC, at the level of the left leg there are two maximum pressure zones with values lower than those at the level of the left leg, during walking at 20% DGC. The alternator subsystem interferes with the BWS subsystem, leading to lower MPMV values and therefore to an increased degree of DGC when it is switched on, in the case of walking with 20% DGC with hands on the handrail, compared to walking with 0% DGC, regardless of the plantar area studied or the subphases of the stance phase. The right leg MPMV values may be lower than the left leg when the alternator is on. For this reason, we compared the MPMV values of the right leg with those of the left leg for all sessions with the alternator on and the average of MPMV values for the same leg ($MPMV_{24,l}$, respectively $MPMV_{24,r}$), in the sessions of walking with hands on the handrail with the alternator on versus those with the alternator off (Fig. 5.5., Fig. 5.6., Fig. 5.7., Fig. 5.8.).

d) Waking with the RELIVE system, with the alternator on, leads to lower MPMV values at the level of the right leg compared to the left leg, regardless of the degree of DGC and regardless of whether the participant walks with the hands beside the body or with the hands on the handrail of the RELIVE system. This can happen if the force with which the system pulls the end of the cable belonging to the right hemibody is greater than that with which it pulls the end of the cable belonging to the left hemibody, and if the end of the cable belonging to the right hemibody is shorter than the other. Considering how the alternator is built, it is unlikely that the pull force will be different for the two ends of the cable. Therefore, the end of the cable related to the right hemibody could be shorter.

e) The alternator, when switched on, does not produce changes in the $MPMV_{24,l}$ values, in the case of waking with the RELIVE system, at 0% DGC, with the hands on the handrail, compared to the sessions when the alternator is switched off. The alternator, when switched on, results in lower $MPMV_{24,r}$ values when waking with the RELIVE system at 0% DGC with hands on the handrail compared to sessions when the alternator is switched off. The alternator, when switched on, does not produce changes in the $MPMV_{24,l}$ values, in the case of waking with the RELIVE system, at 10% DGC, with the hands on the handrail, compared to the sessions when the alternator is switched off. The alternator, when switched on, leads to lower $MPMV_{24,r}$ values when waking with the RELIVE system at 10% DGC with hands on the handrail compared to sessions when the alternator is switched off. The alternator, when switched on, does not produce changes in the $MPMV_{24,l}$ values, in the case of waking with the RELIVE system, at 20% DGC, with hands on the handrail, compared to the sessions when the alternator is switched off. The alternator, when switched on, leads to lower $MPMV_{24,d}$ values when waking with the RELIVE system at 20% DGC with hands on the handrail compared to sessions when the alternator is switched off. It cannot be stated whether waking with the RELIVE system, at 0% DGC, hands on the handrail and with the alternator on, changes the $MPMV_{24,l}$ values compared to the $MPMV_{24,l}$ values when waking without the RELIVE system, at its speed. Waking with the RELIVE system at 0% DGC, with hands on the handrail and with the alternator on, results in lower $MPMV_{24,d}$ values compared to the $MPMV_{24,d}$ values when waking without the RELIVE system at its speed. Waking with the RELIVE system, at 10% DGC, with hands on the handrail and with the alternator on, changes the $MPMV_{24,l}$ values, which are lower than the $MPMV_{24,l}$ values in the case of waking without the RELIVE system, at its speed. Walking with the RELIVE system, at 10% DGC, with hands on the handrail and with the alternator on, changes the $MPMV_{24,d}$ values, which are lower than the $MPMV_{24,d}$ values obtained, for the same leg, in the case of walking without the RELIVE system, at its speed. Waking with the RELIVE system, at 20% DGC, with hands on the handrail and with the alternator on, changes the $MPMV_{24,l}$ values, which are lower than the $MPMV_{24,l}$ values in the case of waking without the RELIVE system, at its speed. Walking with the RELIVE system, at 20% DGC, with hands on the handrail and with the alternator on, changes the $MPMV_{24,d}$ values, which are lower than the $MPMV_{24,d}$ values in the case of walking without the RELIVE system, with its speed.

Limitations of the study

The study has some limitations, in terms of the number and age of the participants, the inclusion criteria, the type of footwear worn, the known problem of repeatability of measurements obtained using the F-Scan device, the sensitivity of the sensor for detecting pressure, and the positioning of the pelvic frame of which the hand handrail is a part.

5.5. Conclusions

The study revealed changes in the mean peak mean pressure values (MPMV) during sessions with the alternator on versus those with the alternator off under the same conditions.

Starting from the results obtained in this study, several conclusions can be drawn:

1) The body weight support subsystem (BWS) unloads the weight of the participants.

When the alternator subsystem is turned on, the $MPMV_{48}$ values (obtained as the average of the right leg and left leg MPMV values) gradually decrease with increasing body weight unloading (DGC)) for each individual participant, regardless of hand position, on the handrail, or next to the body. The BWS subsystem represents an advantage for the recovery of gait of people with ambulation disabilities. DGC improves the walking pattern by decreasing the effort exerted and reducing the energy cost with which the steps are performed, which leads, in the case of neurological patients, to a decrease in tonic reflexes and spasticity. When the alternator subsystem is turned on, $MPMV_{48}$ values also improve the somatosensory and proprioceptive deficits required for physiological walking. In addition to the effect on the gait pattern, the BWS subsystem is also necessary for training the transfer from sitting to standing position and vice versa, for training walking with obstacles or in the case of applying perturbations. It also has a role in the prevention of falls and last but not least, it ensures comfort from a psychological point of view, the patient feeling safe and willing to practice more. A disadvantage could be inhibition of trunk postural reflexes and more difficult balance training. In the case of patients without neurological impairment, the BWS subsystem provides DGC in order to avoid pain or additional damage to the affected area, allowing patients to focus on the dynamic aspects and symmetry of the walking pattern.

2) The alternator subsystem interferes with the BWS subsystem in all driving sessions studied.

The alternator, when switched on, has the effect of decreasing the $MPMV_{48}$ values (obtained as the average of the MPMV values for the right leg and those for the left leg) and therefore further increasing the degree of DGC, compared to the previously set percentage: a) regardless of the position of the hands, on the handrail or next to the body; b) for all the plant areas studied; c) during all subphases of the studied stance phase. The explanation for the occurrence of this change in $MPMV_{48}$ can be given by the fact that the two subsystems (alternator and BWS) are not completely mechanically separated from each other, which can lead to the influence of one by the other or their mutual influence. Given that this leads to a further increase in the degree of DGC, a degree too high of DGC may be reached, which could lead to the modification of the gait pattern by decreasing the amount of energy required for propulsion, generated in the posterior muscles of the lower limb at the end of the stance phase. As the DGC increases, the ground reaction forces also decrease causing the walking speed to decrease. However, increasing walking speed is essential in the rehabilitation of post-stroke patients.

3) The alternator subsystem does not exert a symmetrical action on the two hemi-bodies.

For all participants, the alternator subsystem produced no changes in the $MPMV_{24,l}$ values (obtained as average of the MPMV values of the left leg), regardless of the degree of DGC and regardless of the position of the hands. Instead, it produces changes in the $MPMV_{24,r}$ values (obtained as average of the MPMV values of the right leg), which are lower than the $MPMV_{24,l}$ values. Therefore, the additional DGC is only done on the right side, the left side being unaffected. This influences the walking pattern, generating a limping asymmetrical gait. It is most likely generated by the different length of the two distal segments of the cable, the right one being shorter. The force with which the distal segments of the cable are pulled is unlikely to be the cause because it cannot differ, given the construction of the alternator subsystem. Another possible cause is the existence of a slight asymmetry in the construction of the rotary carriage at the level of the grooves through which the two distal segments of the cable pass. The right groove, through which the right segment of the cable passes, may have a lower slope compared to the slope of the left groove, through which the left segment of the cable passes, and thus the end of the right segment of the cable may be higher than the end of the left segment. If the right segment of the cable is shorter or if the end of this segment is located higher, then the right hemibody (and therefore the hemipelvis and lower limb) will be positioned higher compared to the left, which would explain the lower MPMV values on the right side. Although the fact that the alternator generates this asymmetry seems like a negative thing, it may be to the advantage of patients with right hemiparesis. If on the side with hemiparesis, the system unloads more of the weight, it assists the patients at the end of the stance phase and the beginning of the swing phase, so that the detachment of the leg from the ground is achieved much easier, with less energy consumption. This can result in reduction of compensatory movements (compensated Trendelenburg gait and circumflex gait) and relearning of the normal gait pattern. To reverse left to right, the position of the rotary carriage should be changed without changing the position of the cable ends. Thus, at the level of the right leg, there would be no changes in the $MPMV_{24,d}$ values, and at the level of the left leg, the MPMV24,s values would decrease. In this case, it would be possible to train patients with left hemiparesis as well.

4) The assembly alternator–BWS subsystems, changes the foot maximum pressure zones during DGC by a percentage lower than the threshold (30%) estimated in literature for the occurrence of changes.

In hands on handrail walking sessions with the alternator on, there is no change in the foot maximum pressure zones (zones with the highest MPMV values) at 0% and 10% DGC compared to the maximum pressure zones recorded during walking without the RELIVE system with its speed (0.1 m/s). The maximum pressure zones for both feet are located at the medial and lateral calcaneus during the mid-stance subphase and at metatarsals IV and V during the pre-swing subphase. With the alternator on and 20% DGC, the maximum pressure zones change only for the right leg, with two maximum pressure zones appearing during the pre-swing subphase: the zone at the level of metatarsals IV and V and the zone at the level of metatarsal I. During the mid-stance subphase, the zones of maximum pressure for both feet remain the same (medial and lateral calcaneus). For overground systems, a DGC percentage of 20% should not alter walking kinetics according to the literature. In the present case, the behavior can be explained by two arguments: a) the alternator subsystem interferes with the BWS subsystem, leading to the additional increase in the degree of DGC, resulting in a percentage of DGC >20%; b) an error in the DGC, the BWS subsystem offloading more than the operator command. Thus, a future study should verify whether the RELIVE system correctly offloads the set weight. With an increased DGC, pressure is concentrated under the metatarsal heads during the terminal stance subphase, which may increase the risk of ulceration in patients with diabetic neuropathy. Also, an increased pressure is correlated with the appearance of pain, which can cause an antalgic gait. For post-stroke patients, the strike is done with the toes due to plantar flexion. Plantar inversion results in the redistribution of maximum pressures on the lateral side of the plant. Taking into account that in the study the participants did not have pathologies of the lower limbs and at 20% DGC an additional area of maximum pressure appeared on the medial side of the right foot (metatarsal I), could be at the disadvantage of patients with right hemiparesis, an increased pressure and force in the medial area may accentuate the inversion.

These conclusions confirm the hypothesis from which the study started, namely that the RELIVE system produces changes in plantar pressure during walking.

6. Study 2: Contributions concerning the kinematic changes in pelvic motion during assisted walking

6.1. Introductions

6.1.1. Considerations about the amplitude and symmetry of motion for healthy individuals and post-stroke patients

The physiological amplitude of obliquity is 8° (4° superiorly and 4° inferiorly) [271]. In post-stroke patients the mobility of the pelvis is impaired. On static examination, the pelvis can be seen rotated in the sagittal plane and in the frontal plane. On dynamic examination, the compensated Trendelenburg gait leads to an increased amplitude of superior obliquity during the swing phase of the affected MI [27]. In terms of symmetry, physiological gait is described as symmetrical. In post-stroke patients with hemiparesis, gait symmetry is reduced. During walking, in these patients, both MI, affected and the unaffected one, make a greater effort, the asymmetry between the steps persisting. Asymmetry, both learned and acquired, is a major challenge for gait rehabilitation, aiming to restore/restore symmetry [66].

6.1.2. Working hypothesis

To further study the effect of the alternator subsystem on walking kinematics, I resorted to recording the data provided by G-Walk (BTS). The role of the alternator is to actively assist, during walking, the obliquity of the pelvis. Therefore, in this study I aimed to estimate the amplitude of pelvic motion and highlight whether and how it changes during alternator action. I started from the hypothesis that the RELIVE system produces changes in the amplitude of obliquity during gait.

6.1.3. Specific objectives

The objectives of this study are the following: a) Comparison of several sessions to see if and how the amplitude of obliquity (AMO) changes according to certain particularities of the sessions; b) left-right comparison within the same sessions in terms of AMO and symmetry index (IS) of obliquity; c) Synthesis of the observations made by the participants; d) Integration of all results and highlighting some conclusions.

6.2. Material/Participants and method

All participants were attached to the G-Walk device using its belt, so that the device was positioned on the dorsal side of the participant, next to the L5-S1 vertebrae. The participant was asked to remain in place until the device self-calibrates. After the time provided for accommodation, the movements within each session described in Table IV.1 were carried out. A new analysis is recorded for each move. In this study the parameters of interest were: AMO of the pelvis and IS for obliquity. I note that the AMO of the left pelvis represents the AMO of the pelvis when the participant steps with the left foot, and the AMO of the right pelvis represents the AMO of the pelvis when the participant steps with the right foot. Thus, in the case of AMO for each session, 45 values were obtained for the left pelvis and 45 values for the right pelvis. These 45 values were averaged, obtaining the mean value of the amplitude for obliquity (MAO) for the left pelvis ($MAO_{45,l}$) and for the right pelvis ($MAO_{45,r}$). The 90 values were also averaged, resulting the MAO_{90} value for each session separately, for the left and right pelvis together. In the case of IS, 45 values were obtained, their average determining the mean IS value for obliquity (MISO) for each individual session. In this study, we made several sets of comparisons, selecting specific walking sessions from the 16 sessions.

6.3. Results

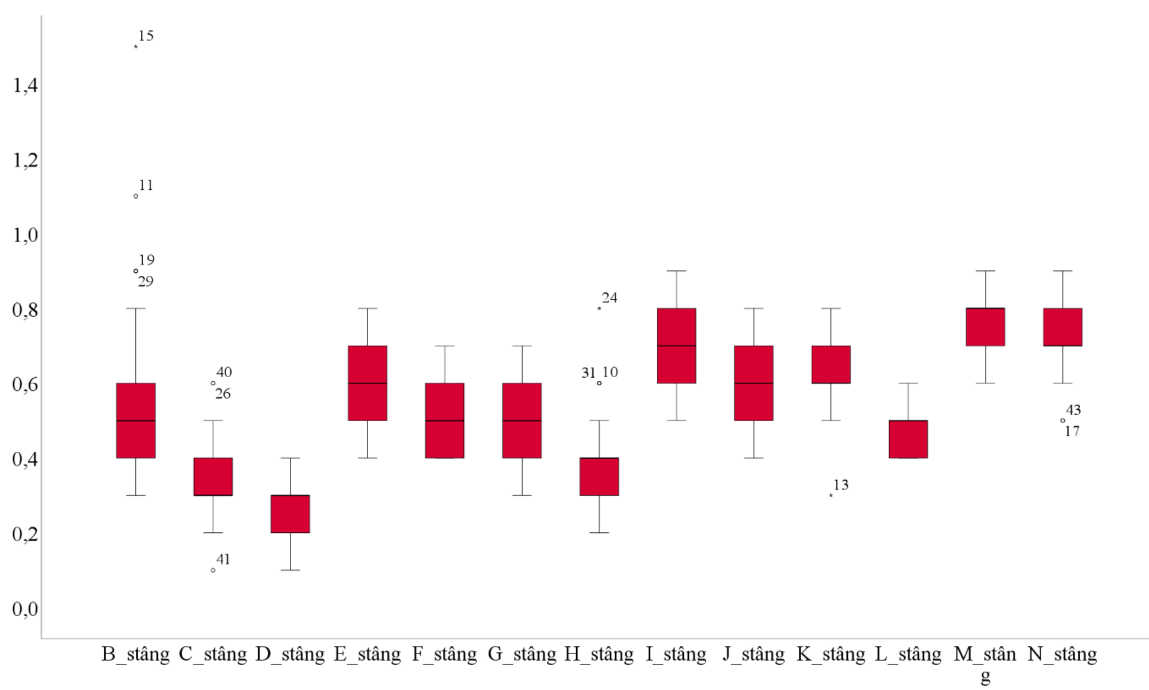

Fig. 6.1. AMO for left pelvis.

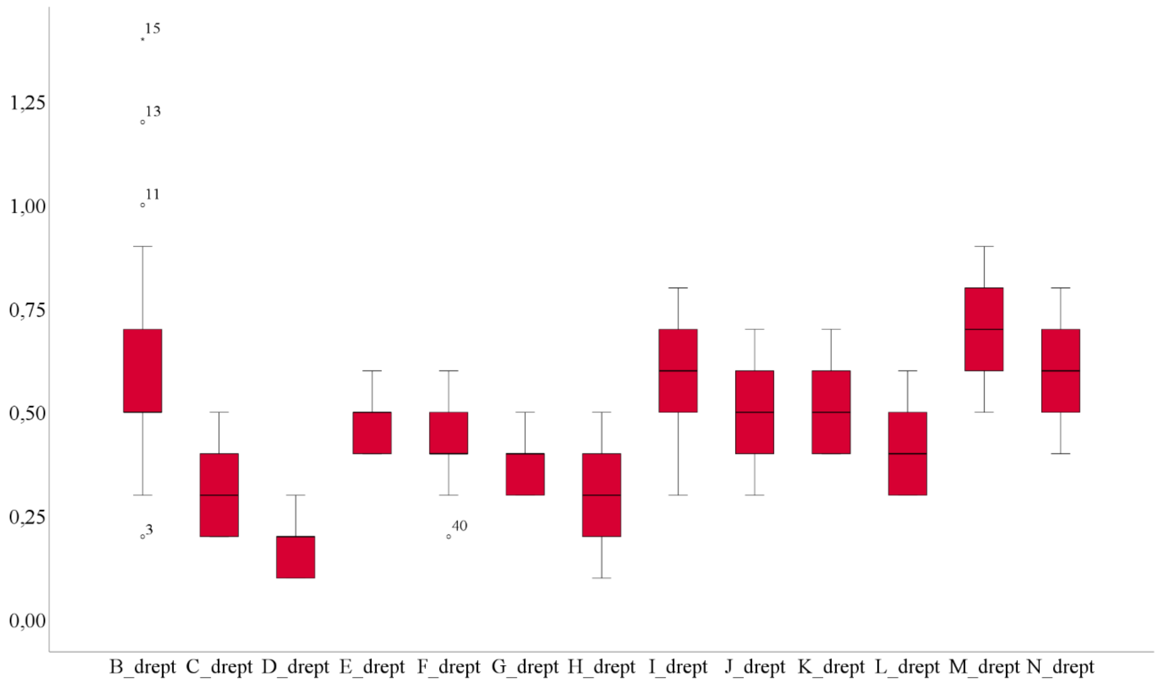

Fig. 6.2. AMO for right pelvis.

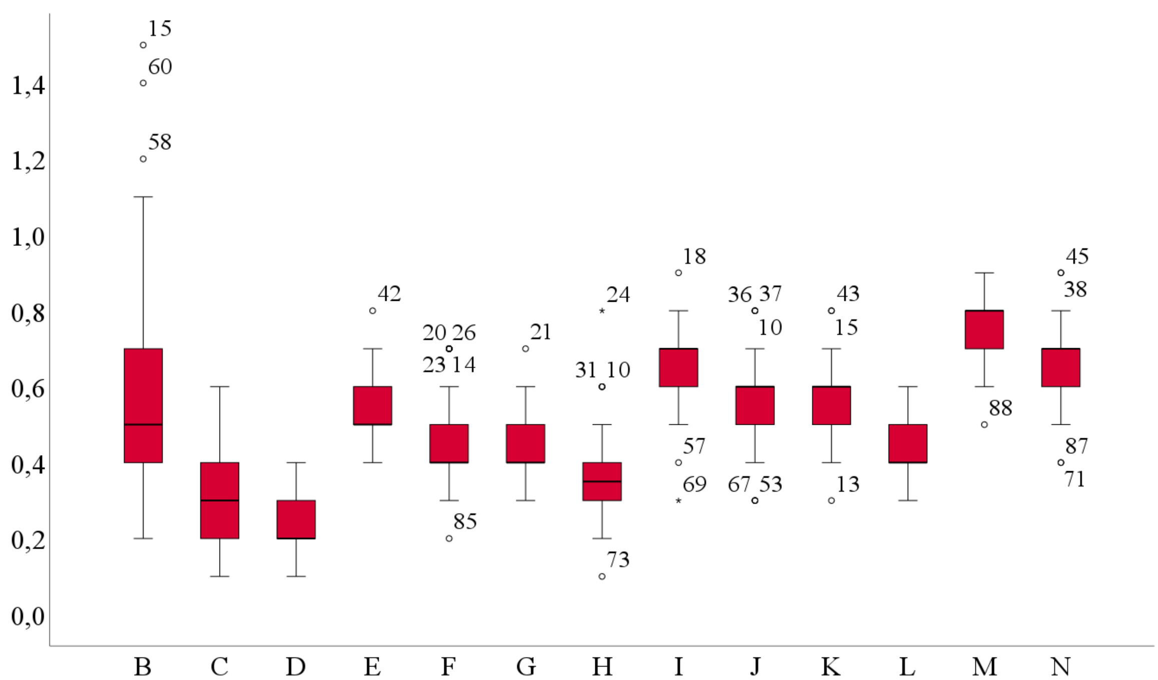

Fig. 6.3. AMO for pelvis (left and right pelvis).

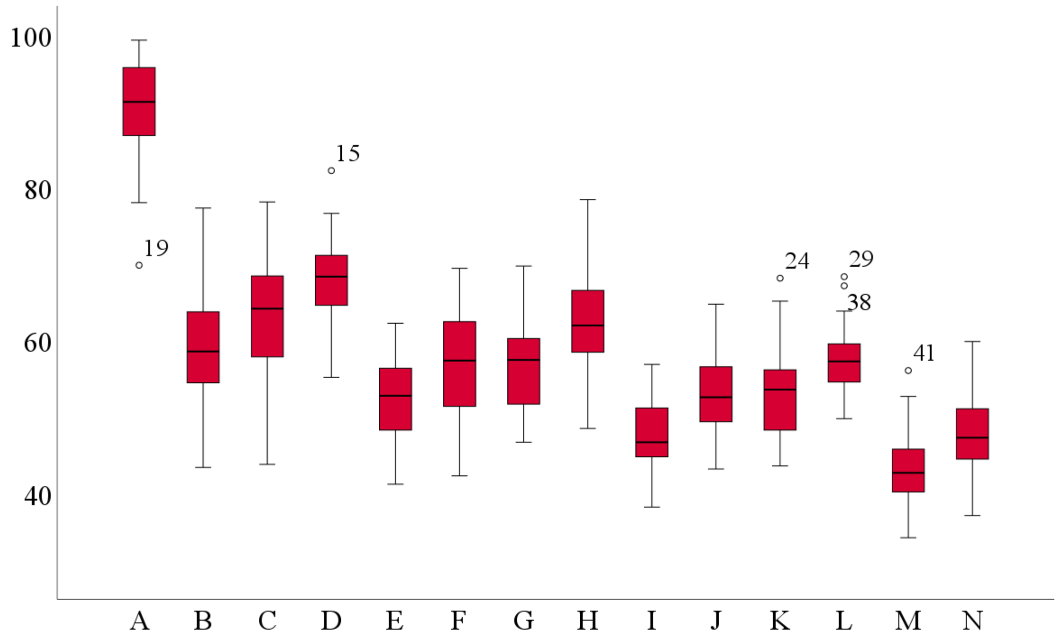

Fig. 6.4. Symmetry index for obliquity movement.

6.4. Discussions

The results obtained indicate the following:

a) AMO is reduced when the participant walks with his hands on the handrail, both with the alternator off and with the alternator on, regardless of the degree of DGC; b) AMO increases when the participant walks with both hands beside the body and hands on the handrail, with the alternator on, compared to sessions with the alternator off, regardless of the used degree of DGC; c) AMO increases when the participant walks with both hands beside the body and hands on the handrail, with the alternator on, with the increase in the degree of DGC; d) AMO is increased for the left pelvis, compared to the right one, for sessions with the alternator on, regardless of the used degree of DGC (Fig. 6.1., Fig. 6.2., Fig. 6.3.); e) The IS for obliquity increases when the participant walks with hands on the handrail compared to walking with hands beside the body, regardless of the degree of DGC used, both with the alternator off and with the alternator on; f) The IS for obliquity decreases when the participant walks with both hands beside the body and hands on the handrail, with the alternator on, compared to sessions with the alternator off, regardless of the used degree of DGC; g) The IS for obliquity decreases by approximately one-third when the participant's walking speed is reduced from a free, comfortable walking speed to a walking speed of 0.1 m/s (RELIVE system walking speed); h) The IS for obliquity increases when the participant walks in the RELIVE system, at 0% DGC, with the alternator off. IS increases the most when the participant walks with their hands on the handrail; i) The IS for obliquity decreases when the participant walks in the RELIVE system, both hands beside the body and hands on the handrail, with the alternator on, as the degree of DGC increases (Fig. 6.4.); j) AMO of the pelvis decreases in the case of walking sessions with the RELIVE system, with the alternator off, with the hands beside the body, at 0% and 10% DGC; k) AMO of the pelvis decreases in the case of walking sessions with the RELIVE system, with the alternator off, with the hands on the handrail, regardless of the degree of DGC; l) The RELIVE system, when the alternator subsystem is on, reduces the pelvic AMO at 0% and at 10% DGC, when stepping with the right leg and hands on the handrail.

1) Synthesis of the observations about gait cycle. All study participants mentioned not knowing which MI to start stepping with when the alternator is turned on. Five participants pointed out that the action of the alternator is not perfectly synchronized with the sub-phases of the gait cycle, the double stance phase being too short. Thus there is not enough time to move the CoM from one leg to the other. Three participants mentioned that the system prevents the user from taking longer steps (reduces stride length), pulling them back. Two participants mentioned that the step width is reduced. *2) Synthesis of observations related to stability during walking*. Out of a total of 15 participants, 13 stated that when the alternator is switched on, walking becomes difficult, especially when the hands are next to the body, causing an imbalance or destabilization. In this context, 4 of the participants mentioned that, to maintain balance and CoM, the energy cost is high, putting a lot of effort. Two participants found that balance was more easily maintained with the upper limbs away from the trunk rather than next to the body. *3) Synthesis of observations related to pelvic movements*. Another aspect related to the alternator subsystem, pointed out by one participant, is that it would only facilitate active pelvic obliquity, not the other pelvic movements. One participant suggested that it should be studied whether the alternator could provide obliquity for only one hemipelvis and not influence the other. Two participants stated that the pelvis is kept fixed in posterior tilt. *4) Synthesis of harness observations*. Other problems reported were related to the system harness. One participant mentioned that it interferes with postural reflexes because it prevents the natural movements of the trunk. Another participant mentioned that the harness restricts the advancement of the MI in the swing phase. Two participants reported that the pelvis was kept in posterior tilt, resulting in lumbar hyperlordosis, and two other participants complained of lumbar pain during or after RELIVE walking sessions, with the harness position being the most likely cause.

Limitations of the study. The study has some limitations in terms of participant batch, way of measuring obliquity motion, mutual interactions between harness and belt, height of pelvic frame, and roll position in the alternator subsystem.

6.5. Conclusions

The study revealed changes in the values of the mean amplitude of obliquity (MAO) and the mean of the symmetry index for obliquity (MISO) during the sessions with the alternator on, compared to those with the alternator off, under the same conditions.

Starting from the results obtained in this study, several conclusions can be drawn:

1) The RELIVE system, reduces the amplitude of the pelvic tilt movement when the alternator subsystem is off and increases the symmetry of pelvic tilt movement during walking without DGC

When walking with the RELIVE system and the alternator turned off, regardless of the position of the hands, the values of MAO_{90} (the mean of amplitude of the obliquity of the pelvis when stepping with both the left and the right leg) are lower than those when stepping without the RELIVE system, at its speed (0.1 m/s). MISO values increase when walking with the RELIVE system, with the alternator off, without DGC, regardless of the position of the hands, on the handrail or next to the body, compared to walking without the RELIVE system, at its speed (0.1m/s). Decreasing the amplitude of the pelvic tilt movement and increasing the symmetry of the pelvic tilt movement leads to balance maintenance, increase coronal plane gait stability, and increase gait symmetry.

Patients with hemiparesis present the lower rotation or the fall of the hemipelvis on the affected side, and in order to walk, they resort to compensatory movements, of which the Trendelenburg gait involves an increased amplitude of the obliquity. Following training, which involves improving voluntary motor control and increasing muscle strength, the exaggerated amplitude of obliquity must be brought back to normal limits. Thus, the system supports patients, having the ability to reduce the amplitude of obliquity.

2) The alternator subsystem generates a gait asymmetry.

The values of $MAO_{45,s}$ (the mean amplitude of the pelvic tilt movement when stepping with the left foot) are higher than the values of $MAO_{45,d}$ (the mean amplitude of the pelvic tilt movement when stepping with the right foot). Thus, an asymmetry of the gait appears by increasing the amplitude of the obliquity, when stepping with the left leg, similar to the one that occurs in hemiparetic patients.

This difference between $MAO_{45,s}$ and $MAO_{45,d}$ values may be the result of compensatory movement (compensated Trendelenburg gait). If the right hemipelvis and lower limb (MI) are located slightly higher than the left hemipelvis and MI (due to the shorter length of the right cable segment or the higher position of its end), the tendency of the participant is to tilt to the right side, so that the center of mass is above the right MI, during its stance phase. It results in an obliquity with greater amplitude when stepping with the opposite leg, i.e. the left. This amplitude is greater than that generated by the alternator, and thus the MAO values when stepping with the left foot can be higher than those when stepping with the right foot.

Therefore, the alternator subsystem does not have a direct influence on the amplitude of the pelvic tilt movement when stepping with the left foot, but an indirect one by placing the right hemipelvis and the MI higher.

The indirect influence of the alternator subsystem on the amplitude of the obliquity of the pelvis can also explain the decrease in the symmetry of the obliquity, with the increase in the degree of DGC, regardless of the position of the hands. With this higher position of the pelvis on the right side, the weight of the body falls predominantly on the left side, thus exerting a stronger stretching force on the elastic structures of the harness, on this side. With the increase in the percentage of DGC, the stretch of the elastic structures also increases, more on the left side than on the right. Thus, the left MI reaches lower position than the right one, increasing the amplitude of the movement that the pelvis must make during walking.

Furthermore, in addition to these left-right comparisons, this study also demonstrates that IS for obliquity decreases from one walking session to another. Thus, the alternator subsystem, when it is turned on, leads to a decrease in MISO values, compared to the sessions when it is turned off: a) regardless of the position of the hands, on the handrail or next to the body; b) within the sessions with the same degree of DGC; c) within the sessions characterized by the increase in the degree of DGC.

For patients with hemiparesis, results may differ. In case of right hemiparesis, we have shown in the previous study, that additional DGC on the right side can raise the fallen hemipelvis, bringing it closer to the level at which the left hemipelvis is located. By reducing the level difference between the two hemipelvises, compensatory movements are less likely to occur. Thus, the amplitude of obliquity on the left side is greater than that on the right side, but it no longer increases, and IS increases.

3) Turning on the alternator subsystem leads to an increase in the amplitude of the obliquity.

The alternator subsystem, when switched on, has the effect of increasing the MAO_{90} values, compared to the MAO_{90} values in the sessions when the alternator is switched off: a) regardless of the position of the hands, on the handrail or next to the body; b) within the sessions with the same degree of DGC; c) within the sessions characterized by the increase in the degree of DGC.

Increasing the amplitude of obliquity leads to an increased effort (energy cost) to maintain stability in walking. Most of the time imbalances occur, which can cause an unstable and asymmetrical gait.

Although the amplitude of obliquity decreases with right foot stepping, it increases with stepping with the left foot, causing an overall increase in the amplitude of obliquity in healthy users. In the case of patients with right hemiparesis, the result may be different, as we mentioned in the previous conclusion, so that the amplitude of obliquity on the left side does not increase.

4) The RELIVE system, when the alternator subsystem is turned on, reduces the amplitude of the pelvic tilt movement for 0 and 10% DGC, when stepping with the right foot and hands on the handrail.

When walking with the RELIVE system, at 0 and 10% DGC, with the alternator on and hands on the handrail, the MAO values obtained when stepping with the right foot decreased compared to the MAO values obtained when stepping with the left foot, during the walking session without the RELIVE system, at its speed. Thus, when walking with the right foot, the balance and stability in walking increases in the coronal plane, even during DGC with 0 and 10%. This behavior was not highlighted when walking with the left foot, due to the existence of gait asymmetry.

In the case of patients with right hemiparesis, we showed in the previous study that at 0% DGC provided by the BWS subsystem, an additional DGC generated by the alternator on the right side can raise the fallen hemipelvis, bringing it closer to the level at which the left hemipelvis is located. In addition, the use of the handrail at a DGC of 10% leads to increased stability in the coronal plane, the amplitude of obliquity being kept low when stepping with the paretic leg.

5) The maximum walking speed of the RELIVE system (0.1 m/s) produces a significant decrease in the symmetry of obliquity.

The MISO value decreases by approximately one-third when the participant's walking speed is reduced from a free, comfortable walking speed to a walking speed of 0.1 m/s (the maximum walking speed of the RELIVE system). This is explained by the fact that at low speeds the gait becomes unstable. The speed of 0.1m/s is a speed too low to maintain a stable gait, causing an increase in the effort (energy cost) applied, which leads to changes in the gait pattern, through the appearance of imbalance and the constant production of rebalancing reflexes. Therefore, the system should be modified to allow higher travel speeds.

A low initial speed is preferred for post-stroke patients so that they can get used to the system and improve their somatosensory, proprioceptive, vestibular, etc. deficits. But, in order to relearn a walking pattern as similar as possible to the one before the stroke, the walking speed must be increased. This helps increase gait stability, decrease imbalances, and increase gait symmetry.

In addition to those mentioned above, other conclusions were drawn:

1) The handrail contributes to the stabilization and increase of gait symmetry.

This better stabilizes the pelvis while walking by decreasing the amplitude of the pelvic obliquity (reduces MAO values) and increases the symmetry of the obliquity (increases MISO values), regardless of whether the alternator is on or off and regardless of the degree of DGC. This also leads to stabilization of the trajectory of the center of mass in the frontal plane.

In post-stroke patients, the bar offers, in addition to stabilization and help in increasing gait symmetry, additional safety by being a support point.

2) The foot of the first step is unpredictable

All study participants did not know which hemibody/hemipelvis would be the first hemibody/hemipelvis lifted by the alternator and therefore did not know which leg to start stepping with. The leg of the first step is given by the position of the roller on the perforated disc of the alternator subsystem. This start parameter should be introduced into the software so that the operator can inform the participant with which foot to take the first step.

3) The gait cycle subphase at gait initiation is unpredictable

This aspect is also related to the position of the roller on the perforated disc. If the roller is in an intermediate position between the 12 o'clock and 6 o'clock positions on the perforated disc, then the start of the movement will not coincide with the beginning of the stance phase for one leg and the beginning of the swing phase for the other leg.

4) The observations of the participants open directions for further research: a) study of other walking parameters (step length and width and the phase of double stance); b) study of the influence of the alternator subsystem - BWS subsystem assembly on the other movements of the pelvis; c) study of the different types of existing harnesses and how they influence pelvic movements to identify alternative solutions.

These conclusions confirm the hypothesis from which the study started, namely that the RELIVE system produces changes in the amplitude of obliquity during walking.

7. Conclusions and personal contributions

Reaching goals.

The goals initially set to evaluate the biomechanics of gait while using the RELIVE mechatronic system were fully achieved. Plantar pressure distribution was recorded using Tekscan's F-Scan device and gait parameters were recorded using BTS's G-Walk device. The data obtained during the different walking sessions (with the alternator on or off, with the hands next to the body or on the handrail, with different degrees of body weight unloading (DGC) - 0%, 10%, 20%) were statistically processed, the results were analyzed and conclusions were drawn regarding the operation of the RELIVE system.

Economic advantages.

The RELIVE system is dedicated to the rehabilitation people with locomotor impairments to improve their quality of life. The economic implications of system development and improvements refer to the cost/benefit ratio that favors the latter by reducing health care costs for people with post-stroke disabilities. Its main technical advantage results from the fact that it is an assistive system that integrates the body weight support subsystem (BWS) with an original subsystem (the alternator), capable of producing the active obliquity movement of the pelvis. Its development and improvement are essential to increase the quality of rehabilitation. For this, both the strong and weak points of the system must be taken into account, which are correlated with its technical advantages and disadvantages.

Personal contributions.

The original contributions concern the identification of technical advantages and disadvantages that can be fixed so that the RELIVE system can enter tests on patients suffering from ambulation disabilities caused, in the first instance, by conditions of the central nervous system. For this, it was used the study of the kinetic (of the plantar pressure) and kinematic (of the amplitude of the pelvic obliquity) changes during assisted walking, to see how the RELIVE system influences the average values of plantar pressure and the amplitude and symmetry index of the pelvic obliquity. Thus, I identified the main strengths and weaknesses of the system.

The strengths of the RELIVE system: **1)** The BWS subsystem unloads the weight of the participants. DGC improves the walking pattern by decreasing the effort exerted and reducing the energy cost with which the steps are performed, which leads, in the case of neurological patients, to a decrease in tonic reflexes and spasticity. **2)** The RELIVE system, when the alternator subsystem is turned off, reduces the amplitude of the pelvic tilt motion and increases the symmetry of the tilt motion during walking without DGC. Thus, the system supports patients with hemiparesis, reducing the amplitude of obliquity, which in these patients is exaggerated and must be brought back to normal limits. **3)** The alternator subsystem does not exert a symmetrical action on the two hemibodies, generating an asymmetry of the gait. On the one hand, an additional DGC occurs on the right side, and on the other hand, the range of motion of the pelvic tilt in left foot stepping is greater than in right foot stepping, resulting in increased amplitude of the global obliquity motion of the pelvis. Also, the IS for the tilt motion decreases. This is determined by either the shorter length of the right cable segment or the higher position of its end, resulting in a higher positioning of the right hemipelvis and lower limb (MI). The alternator subsystem does not have a direct influence on the amplitude of the pelvic tilt movement when stepping with the left leg, but an indirect one by positioning the right hemipelvis and MI higher. Although the fact that the alternator generates this asymmetry seems like a negative thing, it may be to the advantage of patients with right hemiparesis. If on the side with hemiparesis, the system unloads more of the weight, it assists the patients at the end of the stance phase and the beginning of the swing phase, so that the detachment of the leg from the ground is achieved much easier, with less energy consumption. This can lead to a reduction in compensatory movements (compensated Trendelenburg gait and circumflex gait) and relearning of the normal gait pattern. Thus, the amplitude of obliquity on the left side is greater than that on the right side, but it does not increase anymore, and the IS increases. If the rotary carriage is rotated without changing the position of the cable ends, then all these things apply on the opposite side and the system can also assist patients with left hemiparesis. **4)** When the alternator subsystem is turned on, the RELIVE system reduces the amplitude of the pelvic obliquity to 0 and 10% DGC, when stepping with the right foot, hands on the handrail. For patients with right hemiparesis at 0% and 10% DGC, the additional DGC that the system generates on the right, paretic side can raise the dropped hemipelvis, bringing it closer to the level where the left hemipelvis is. By rotating the rotary carriage, the same result can be obtained in the case of paresis on the left side. **5)** The handrail helps to stabilize and increase the symmetry of the gait. The bar better stabilizes the pelvis in walking by decreasing the amplitude and increasing the symmetry of obliquity. In post-stroke patients, the bar offers, in addition to stabilization and help in increasing gait symmetry, additional safety by being a support point.

Weaknesses of the RELIVE system: **1)** The alternator subsystem interferes with the BWS subsystem in all the walking sessions studied, leading to the additional increase of the degree of DGC, compared to the preset percentage. As the DGC increases, the ground reaction forces also decrease. Decreased propulsive force and ground reaction forces, decrease walking speed, increasing walking speed being essential in the rehabilitation of post-stroke patients. **2)** The alternator subsystem – BWS subsystem assembly changes the maximum plantar pressure areas during DGC by 20%, only for the right leg. Because it interferes with the BWS subsystem, the alternator subsystem causes a supplementary degree of DGC, the percentage of 20% set by an operator resulting in an actual percentage of DGC >20%. There is also the possibility that the BWS subsystem may unload more than the operator commands. At 20% DGC, an additional area of maximum pressure appears on the medial side of the right foot (metatarsal I). This implies an increased force in the medial area that can accentuate the inversion of patients with right hemiparesis. **3)** The maximum walking speed of the RELIVE system (0.1 m/s) is a low speed and produces an important decrease in the symmetry of obliquity. Even if a low initial speed is beneficial for post-stroke patients, subsequently, in order to relearn a walking pattern as similar as possible to the one before the stroke, the walking speed must be increased. This helps increase gait stability, decrease imbalances, and increase gait symmetry. **4)** The leg of the first step and the subphase of the gait cycle with which walking begins are unpredictable.

The starting hypotheses for both the first study (the RELIVE system produces changes in plantar pressure during walking) and the second study (the RELIVE system produces changes in the amplitude of obliquity during walking) were confirmed. Waking with the RELIVE system produces changes in the plantar pressure, by influencing the values of the average of the mean peak pressure and the values of the mean of the amplitude and symmetry index for obliquity, by influencing the MAO and MISO values. *In conclusion*, the RELIVE system, influences the biomechanics of walking, both kinetically and kinematically. The system has great potential, being one of the few that assists obliquity, necessary for hemiplegic patients, while walking on the ground. Weaknesses must be corrected to improve the system and move to the next level, patient testing. The system thus modified will be able to be used in assisting the recovery of patients with neurological pathology, particularly hemiparetic ones, bringing additional benefits compared to conventional therapy. To achieve this goal, research must be continued in the direction of system optimization.

The directions in which the research should be continued, in order to optimize the RELIVE system.

1) Modification of the current system, based on the results obtained in the thesis: a) complete mechanical separation of the alternator subsystem from the BWS subsystem; b) increasing the speed of movement of the system in the horizontal plane; c) developing the software so that it can specify with which MI the user begins to step; d) equalizing the lengths of the distal segments of the cable that lifts, in turn, the hemipelvis; e) checking and correcting the inclination (slope) of the grooves through which the distal segments of the cable pass; f) turning the rotary carriage without changing the position of the ends of the cables.

2) Investigation of the effects of changes of some components of the system: a) the distance between the segments of the cable driven by the alternator that pull the harness; b) the angle at which the cable segments pull the harness; c) obliquity should be provided by the alternator only for one hemipelvis, the other not being influenced; d) study of the different types of existing harnesses and finding an alternative solution that does not restrict the movements of the pelvis and MI; e) adding of some restrictions to the movements of the harness, with the aim of achieving better symmetry and balance;

3) System upgrade: a) attachment of surface EMG or EEG for movement intention recognition and motor control training; b) attachment of a closed-circuit FES unit, which, through biofeedback, can adapt the stimulation intensity according to the amplitude of the movement produced and the subphases of the gait cycle, synchronizing the pelvic movements with them; c) implementation of the "system follows the patient" mode of operation, for which it is necessary that the system can be operated in both directions so that the user does not encounter resistance from the system during movement; d) assistance through virtual reality techniques for immersive or augmented reality experiences;

4) Completing the study with other biomechanics studies of walking, regarding: a) muscle activation during walking with the RELIVE system; b) the influence of the alternator subsystem - BWS subsystem assembly on the other movements of the pelvis; c) checking how correct the BWS subsystem unloads the preset weight; d) other gait parameters (step length, step width and double stance phase).

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List of published scientific papers

As main author:

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