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Neuroprosthetic device for functional training, compensation or rehabilitation of lower limbs during gait

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Abstract— **One of the most promising alternatives to train, compensate or rehabilitate patients after cerebrovascular accidents, spinal cord injuries, head trauma and physiological pathological tremors causing gait disorders are the motor neuroprosthestic devices (NP). However, there are not portable and flexible NP devices capable of fulfilling the requirements of different rehabilitation scenarios. In this work, the novel and flexible H-GAIT NP for lower limbs training and compensation is presented. This NP is able to detect four subphases of gait cycle and provide configurable surface stimulation patterns at each subphase. The H-GAIT NP can stimulate 4 independent channels for each subphase, allowing to reproduce diverse muscle activation patterns that can be needed in different rehabilitation scenarios. In order to validate the concept, several tests were carried on with 5 neuromuscularly intact participants and three different gait speeds in order to validate detection of the subphases. The algorithm showed an acceptable performance (over 95 % of gait subphases successfully detected in all cases at three different gait speeds (0.7, 0.85, and 0.97 m/s). The results were consistent among participants. To show the potential use of the NP in different rehabilitation scenarios, one stimulation profile was configured for hemiplegic gait compensation.**

I. INTRODUCTION

Neuroprosthestic (NP) devices interact with the body through electrical signals. The artificial application of electricity to the body can be used with many objectives, such as functional electrical stimulation (FES) or electrostimulation. The FES consists in the application of a low level electrical excitation to compensate a lost or reduced motor function due to trauma, illness or developmental complications. The basis of the FES for limb control is to activate the branches of the motor neurons by means of electric pulses through electrodes located on the skin (surface FES) on the affected muscle, or also by means of electrodes implanted on the muscle, to produce its contraction [1]. Continued use of FES has been shown to improve mobility [2], reduce spasticity, improve cardiac status [3] and promote motor functional rehabilitation [4].

Over the last years, with the irruption of wearables robots, exoskeletons, and advanced microelectronics, hybrids solutions including exoskeletons and advanced portable FES systems have drawn the attention of the scientific community[5], [6]. In applications related to compensartion por rehabilitation of human gait, the detection of gait phases and event is a key aspect. Modern biomechanics described muscle activation and limbs and joint dynamics and kinematics as a function of the gait cycle. Based on this knowledge, most of the technological lower limb rehabilitation devices propose compensation actions considering a precise timing.

A modern NP for motor training or compensation uses sensors to detect gait events and functional electrical stimulation to evoke muscle contraction. These NPs are usually configured for each participant considering gait parameters and conditions. This work presents the development of a flexible NP for lower limb functional training, compensation or rehabilitation. It provides a very flexible way to configure different applications based on the detection of gait events and adjustable stimulation parameters of 4 independent channels for functional electrical stimulation. The NP described in this paper was developed as part of the H-GAIT project, which proposes the development of the hybrid unilateral lower limb knee-ankle foot orthoses for gait compensation.

The paper presents the developed NP and shows first results in gait events detection. The work presented in this paper is focused on the demonstration of this new tool and not on specific applications.

II. H-GAIT NEUROPROSTHESIS ARCHITECTURE

Motor NPs are composed of different blocks, including electrostimulation components, sensors, control unit and power supply. The electrical stimulation is configured using parameters controlled by the user or the clinical professional.

The architecture of the proposed NOP is depicted in fig. 1. It is composed of the *Battery Management System* (BMS) that contains the batteries (*BATTERY*) and different converters that manage the voltage levels that are used by the other blocks in the diagram. The BMS also includes the battery charging module, which allows the system to be rechargeable. The SENSORS block is responsible for measuring the signals that help us detect the gait events of interest. The COMM module allows configuration of the device from a PC or mobile device. The MICRO block, which receives the information from the SENSORS block and the COMM block, processes the received data and generates the FES control signals that are sent to the ISO block, that isolates the analog and digital circuits of the system. These signals are named generically, to keep the simplicity in the diagram.

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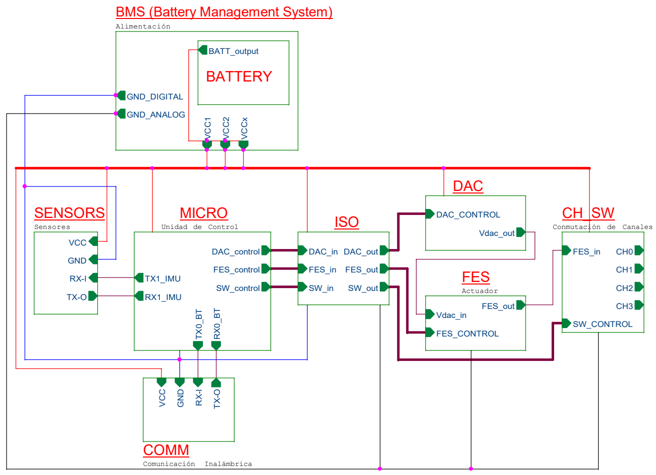

Fig. 1: Hardware scheme of the H-GAIT NP. The FES actuator receives analog signals (Digital to Analog Converter -DAC-) as input to control the amplitude of stimulation current pulses.

II-A. Sensors

The NP is mounted on the back of user's leg. For the detection of gait events, the variables of the angular position of the leg and the vertical acceleration of the NP are used, both in the sagittal plane. With these data, provided by 9-DoF IMU, gait events can be detected, basically consisting in the vertical acceleration change that is obtained at each impact of the heel and each time the foot is raised. At the same time, leg inclination is also obtained by the absolute angular position of the sensor. Unlike Force Sensitive Resistors, which are usually placed in foot insole in commercial NPs, in this case it is enough to place the module on the leg near the knee. Table I summarizes the technical details of the developed motor NP.

H-GAIT NP	
Functional Electrical Stimulation (Controlled Current Source)	
Current:	0-100 mA (@1kΩ load). 10 mA default Current step: 0.5 mA
Maximum output voltage:	100 V
Pulse width:	Up to 1000 μs, 2.5 μs step, 300 μs default
Frequency:	Up to 2 kHz
Stimulation waveform:	Rectangular monophasic and bipahsic pulses, with configurable ramps
Channels:	4 anode-cathode independents pairs
Stimulation:	Surface, transcutaneous
Electrical Characteristics	
Power Source:	2 Ion-Lithium Batteries,
Autonomy:	2.5 h aprox.
User Interface	
Communication Port:	Bluetooth 3.0 (Serial Port Profile)
Configuration:	Terminal (serial Port), command line
Dimensions:	11.3 x 6.5 x 5.9 cm

TABLE I: Technical details of the developed neuroprosthesis in the framework of the H-GAIT project and the REASISTE Network.

III. Neuroprosthesis Firmware

The detection of the specific moment the electrical stimulation must be applied is fundamental for the proper function of the NP. To accomplish this task, the Control Unit uses the data provided by the IMU. In this case, the *firmware* gets the values from the IMU sensors serially sent through the UART 2 in the microprocessor. In this instance, the detection of the gait sub-phases is executed by the finite state machine. There is the option to compensate the drop foot through FES or study the gait exclusively, measured with the IMU sensors. The subphases of interest in this application are: Heel Strike (HS), Medium Stance (MS), Terminal Stance (TS) and Terminal Swing (TW).

The gait cycle starts with the heel contact, *S0 state, "Heel Strike"*. In this state, the ankle is in neutral position and the leg is expected to pass through the zero angle (vertical position) and decreasing (backward) to the next state. In *S1 state, "Medium Stop"*, the Medium Stance starts. For the transition to the next state, the foot must be lifted "loosening" the ground, producing a peak in the vertical acceleration upwards. In *S2 state, "Final Stop"*, shortly before taking off the foot, there is a strong plantar flexion, which the patient has the ability to produce, to then start the swing phase. The transition to the last state is produced when the angle of the leg passes through zero (vertical position in the sagittal plane) and increasing (forward). Finally, in the state *S3, "Terminal Swing"*, the dorsal flexion must be kept. A vertical acceleration peak (with a range of defined thresholds) is expected in the direction of the ground at the heel strike to restart the cycle.

III-A. Stimulation parameters

The separation between positive and negative pulses is 100 μs as a safety measure to avoid the abrupt change of polarization in the skin. If positive or negative amplitude is null ('ap', 'an'), a single-phase pulse is configured. The number of repetitions (re) indicates how many more times the same channel should be stimulated and the order of pulses ('in') determines which pulse will be excited first between the positive and the negative.

The start and end of stimulation ('ip', 'fp') determine the percentage of the duration of the gait state that needs to be stimulated. The ascending ramp ('ra') parameter determines the percentage of duration of the state where the stimulation rises from the value of null amplitude, taking into account the start of stimulation ('in') until that established by the parameters 'ap' and 'an'. The parameter of descending ramp ('rd') determines the percentage by which the amplitude (ap, an) must descend to a null value determined by the end of stimulation ('fp').

To estimate the duration of a given state, the moving average method is used. To forecast next state duration, the average of the n most recent measured state duration values is used.

III-B. General parameters

In addition to the parameters previously mentioned, the stimulation period (tg) also requires to be configured. This parameter defines the stimulation frequency and the inter-group period (ti).These two parameters affect all channels, regardless of the state.

IV. Validation of gait events detection algorithm

Gait subphases detection, or state detection, is the basis of the H-GAIT function. In this section the validation process of this algorithm is presented.

IV-A. Participants

The test was carried on with 5 participants and three different gait speeds in order to validate the finite state machine algorithm. These were executed in the Digital Electronics Laboratory (LED) of the Universidad Católica "Nuestra Señora de la Asunción". All participants were informed about the objective and procedure to be performed and expressed their consent. User description and results are summarized in table II. The algorithm showed an acceptable performance (over 95 % in all cases at three different gait speed (0.85, 0.7 and 0.97 m/s). During these tests, the importance of the NP placement could be seen. However, once is placed, the algorithm parameters can be set to get the best accuracy and performance.

TABLE II: Data on participants in the study

Subject	Age (years)	Gender	Height (cm)
Subject 1	22	F	172
Subject 2	25	M	170
Subject 3	24	M	186
Subject 4	24	M	180
Subject 5	18	M	175

IV-A.1. Methods: The participants received functional electrical stimulation (FES), in order to simulate the drop foot compensation, achieving dorsiflexion by stimulating the anterior tibial muscle. A single channel was used with two outputs (anode - cathode), of the 4 available channels in the device, each output with a superficial electrode. Before performing the tests, the correct location of the electrodes was determined through constant stimulation. The participants were standing or sitting without supporting the leg to stimulate, keeping the tibial muscle relaxed. The position of the electrodes was changed until getting an optimal response to the stimulus. For safety reasons, the amplitude of the stimulation pulses was gradually increased.

Each participant made a total of 100 steps on a treadmill at three constant speeds (0.7 m/s, 0.83 m/s and 3.97 m/s), receiving stimulations during the swing phase, corresponding to the S2 state and S3 in the state machine explained before. The device was placed on the back of the leg, on the region of the calf, connected to the electrodes. Participants walked on a treadmill as can be seen in Fig. 2.

Fig. 2: Gait subphases detection tests. The picture depict a participant walking on a treadmill with the H-GAIT NP.

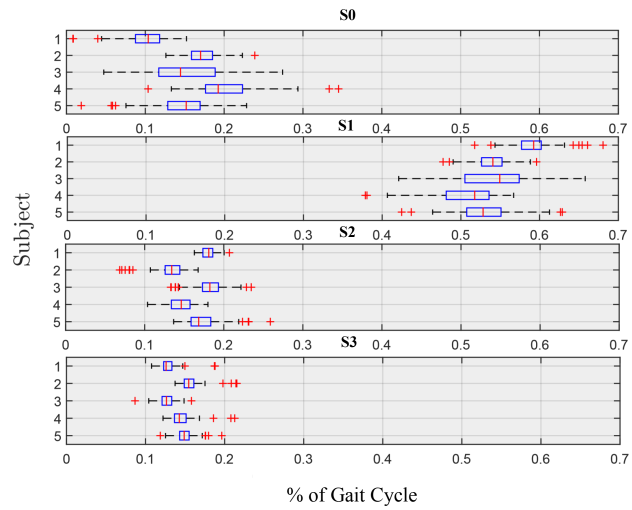

Fig. 3: Detected states during gait of each state (S0-S3) for each participant at a gait speed of 0.85 m/s. Consistent duration of states (S0, S1, S2 and S3) among participants can be seen. Similar results were obtained at different gait speeds.

IV-A.2. Results: The duration of the states in each of the participants and for each speed was studied. In Fig. 3, corresponding to the measurements for a speed of 0.83 m/s, it is possible to observe how the results obtained were consistent among all the participants. At this particular speed, the state S0 corresponds to an average of 15.48 % of the gait cycle for all participants, in the same way the state S1 corresponds to 54.01 %, the state S2 to 16.30 % and state S3 to 14.09 % respectively.

The results obtained for other speeds were consistent among all participants, where the variance obtained on each measurement does not exceed 5 %.

IV-B. Application scenario: Gait compensation in Hemiplegia

This application scenario is motivated by the work presented in [7]. It consists of a stimulation profile for training an d compensating of patients with Hemiplegia. Functional electrical stimulation is applied to tibialis anterior (channel 0), soleo and gastrocnemius (channel 1), hamstrings (channel 2) and quadriceps (channel 3), as shown in Fig. **??**. The size and arrangement of electrodes for each of the muscles

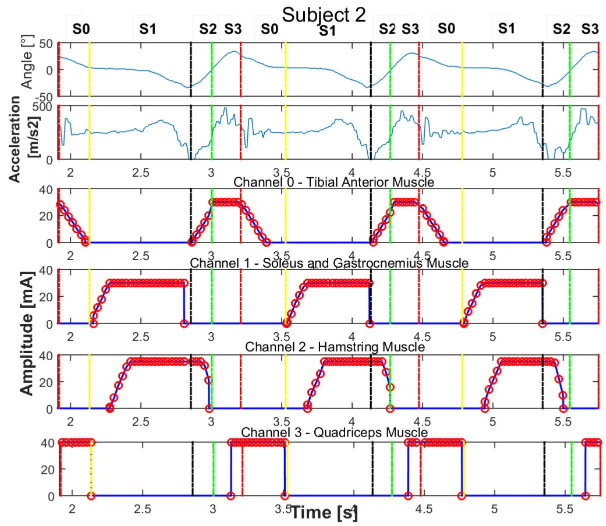

Fig. 4: Data from H-GAIT NP configured for Hemiplegia compensation application. Four stimulation channels are used with specific stimulation patterns for each state. Stimulation pulses are symmetric and biphasic. However, only absolute magnitude of the pulses are plotted.

was taken into account according to the manufacturer's recommendation.

Stimulation of the tibial muscle is produced in channel 0 from the Heel Strike, corresponding to the end of the S3 state, and up to 80 % of the duration of the S1 state (ip = 0, fp = 80), with a gradual decrease on its amplitude (ra = 0, rd = 80). The ending of the descending ramp produces a progressive descent of the foot once the heel rests on the surface. Stimulation on channel 1 begins with the end of the midstance, and continues throughout the terminal stance in the support phase. Channel 2, corresponding to hamstring muscle, is stimulated from 30 % of state S1, to the end of state S2 (ip = 30, fp = 100 for S1, ip = 0 fp = 100 for S2). A ramp is implemented ascending from the start of stimulation to 50 % of state S1 (ra = 50, rd = 100), and a descending ramp from 50 % of state S2 to the end of that state (ra =0, rd=50).

Channel 3, placed on the quadriceps, is stimulated constantly from the middle of the state S3 (ip = 50, fp = 100) and during the entire state S0 (ip = 0, fp = 100). This stimulation does not have a ramp. Fig. 4 shows the information obtained for three strides. The data obtained by the NP on the angle and acceleration in each sampling is observed, and the stimulation provided in the four channels, according to the given configuration.

V. Discussion and Future Work

The presented NP represents a powerful tool to explore and research on hybrid gait rehabilitation applications. This NP is mostly based on the detection of gait events. This detection is based on lineal accelerations (heel contact and toe off) and orientation (inclination) of the leg. The algorithm was only tested in non-pathological participants, and some changes are expected when dealing with users with gait disorders. However, as it was explained it is quite simple, and basic adjustments can be easily applied to improve the detection of gait events.

Regarding potential applications, the H-GAIT NP functions such as inner state timing offset parameters (ip, fp) and the capability of creating incremental stimulation amplitudes, make this device very flexible and able to fit to many applications.The estimation of each state duration can lead to small drifts in stimulation patterns as could be seen in channel 2 in the application of hemiplegic gait compensation (see Fig. 4). As the current cycle duration is shorter than those used to estimate it, there is an unexpected state transition, before the descending ramp reaches the final value of current. The dynamic behavior can be adjusted by changing the number of gait cycles used in the state duration estimator.

Further validation tests, regarding the algorithm and potential applications of the NP will be driven in near future in the framework of REASISTE network with participants with gait disorders.

VI. Conclusions

A novel and flexible NP for lower limb training and compensation was presented. The H-GAIT provides in a portable device several useful functions demanded by hybrid rehabilitation approaches. The NP is able to detect four subphases of gait cycle. The user can set stimulation patterns for 4 channels for each subphase, allowing to reproduce many muscle activation patterns described in the literature. The H-GAIT NP can boost the development of hybrid robotic solutions for lower limbs.

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