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Dejan Popović and Lana Popović-Maneski

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The Instrumented Shoe Insole for Rule-Based Control of Gait in Persons with Hemiplegia

Popović DB^{1,2}, Popović Maneski L³

¹Serbian Academy of Sciences and Arts, Belgrade, Serbia

²Aalborg University, Aalborg, Denmark

³Institute of Technical Sciences of the Serbian Academy of Sciences and Arts, Belgrade, Serbia

Abstract: We describe the use of an insole with five pressure sensors having small hysteresis, an inertial measurement unit, and the circuitry for wireless synchronized communication for the rule-based control of gait. The system was tested with the multichannel electronic stimulator MOTIMOVE that can receive signals from analog and digital sensors to activate up to eight muscle groups. The rule-based control implements the heuristically determined mapping of the four joint states (blocked -B, flexion - F, extension - E, loose - L) and Gait Teacher based representation of the events and phases of the gait cycle. The four joint states can be achieved by the activation of flexors (F), extensors (E), coactivation of flexors and extensors (B), and no action (L). The feasibility of the operation was tested only in a small number of persons with hemiplegia since the stimulator certification procedure required for the full clinical study is in progress.

Keywords: Control of gait, hemiplegia, intelligent sensors, multichannel electrical stimulation

Introduction

Hemiplegia in persons after stroke limits their standing and gait. The lack of the ankle dorsiflexion is the most prominent impairment, but the ankle plantarflexion, hip and knee muscles activations are also compromised. Multichannel electrical stimulation can assist several of the motor outputs; thereby, control movements of the leg segments [1 - 3].

More than three decades ago, we proposed the use of rule-based control for gait restoration [4 - 6]. An example of effective use of rule-based control, which used data from the force-sensing resistors built into the insole and an implantable stimulation system was described by Kostov et al. [7]. We also tested the rule-based control for assisting the gait in hemiplegics with the UNA SISTEMI stimulators that were sensory driven (force sensing resistors built into the insoles and wearable accelerometers) [8]. A recent study described the FES assistance in healthy persons with the computer-generated input-output mapping with force sensing resistors built into the insole and inertial measurement units mounted at the leg segments [9]. The force sensing resistors have large hysteresis; their output depends on the deformation of the sensor, they are sensitive to the variation of the temperature and humidity and the response time is too long for the real-time applications. Also, the system uses distributed sensors system over the legs, which is less attractive for normal life activities.

The missing elements in the puzzle for the effective use of the FES are sensors that provide reliable, reproducible information about the events during the stance phase integrated with the motion sensor that is required for the determination of phases and events during the swing phase. The performance of the sensors system presented by Papas et al. [10] for the correction of drop-foot influenced the development of a self-contained

instrumented insole (Gait Teacher). The Gait Teacher uses robust pressure transducer sensors with no hysteresis, and the 6D inertial measurement unit, circuitry for wireless communication and the rechargeable battery [11]. The positioning of the insole is trivial and identical to the procedures used for standard shoe insoles.

We validated the insoles in the gait laboratory with force plates and camera systems (Fig. 1).

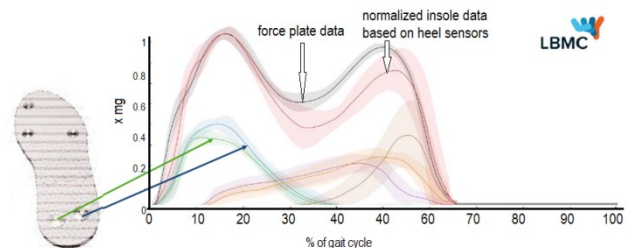


Fig.1: Signals from the five force sensors, a total force estimated from the five force sensors and the force plate data. Unpublished results from the recordings in Laboratoire de Biomécanique et Mécanique des Chocs (LBMCM), IFSTTAR, Lyon, France, courtesy of Prof. Raphael Dumas).

The total force estimated from the measurements which use discrete pressure sensors does not carry information about the full ground reaction force since the loading is measured in only distinct areas. This drawback is not relevant for the rule-based control, which requires only the temporal synergy.

The second important puzzle element for the effective use of FES is the new multichannel MOTIMOVE system [12] which allows distributed and asynchronous stimulation enabling the selective activation of prime hip, knee and ankle flexors and extensors and postpones the FES induced fatigue [13].

We hypothesize that the combination of the MOTIMOVE and Gait Teacher with the rule-base controller for

synergistic activation of leg muscles in a manner that fits into the preserved motor control of persons with hemiplegia is a useful tool for neurorehabilitation. The sketch of the system components for the gait assistance is shown in Fig. 2.



Fig. 2: "Gait teacher" insoles with five robust pressure sensors and one inertial measurement unit (IMU) each, "MOTIMOVE" stimulator for surface activation of up to eight muscle groups and the sketch of the person with hemiplegia when assisted with the system and using the rolling walker.

Material and Methods

The complete data analysis was based on the recordings from the nonparetic leg of 6 persons who recovered after stroke and can walk up to 1m/s with no assistance. The data acquisition software was custom designed in the LabVIEW environment to allow the on-line inspection and storing in time-stamped files comprising accelerations (a_x , a_y , a_z), angular velocities (ω_x , ω_y , and ω_z) and pressures (P1, P2, P3, P4, P5) from both insoles. The sampling rate was 100 samples per second. We show one representative set of data from force sensors and gyroscopes used for the analysis (Fig. 3).

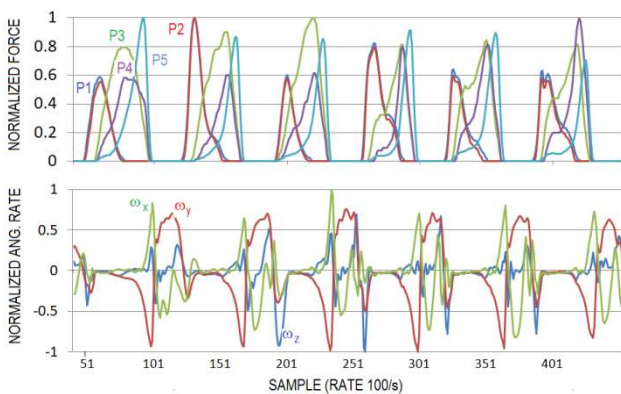


Fig. 3: Six consecutive steps from the recordings during the ground level walking. Top panel shows normalized ground reaction forces (P1, P2, P3, P4, P5) to their maximum values. Bottom panel shows gyroscope data for the three axes normalized to their maximum absolute values. The y-axis is perpendicular to the sagittal plane.

For the better inspection of the quality of data coming from the Gait Teacher, we show one gait cycle (Fig. 4) from the recordings presented in Fig. 2.

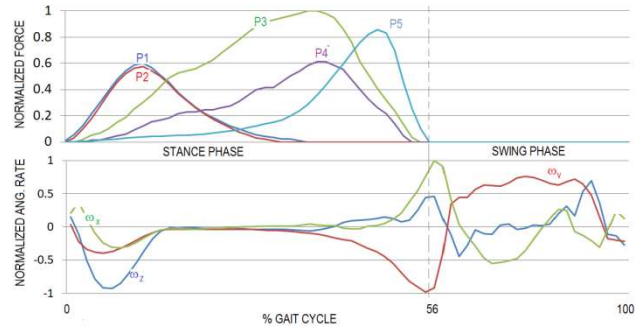


Fig. 4: P1, P2, P3, P4, and P5 are the unprocessed signals from force sensors. ω_x , ω_y , and ω_z are signals from the gyroscopes of the IMU recorded during the one gait cycle. All signals are normalized to their absolute maximum values.

We model the gait with a sequence of states at joints [11]. The heuristic analysis and minimum entropy analysis can be used for generating rules for various gait modalities [14, 15]. In this presentation, the minimum entropy approach was used [14].

The output from the rule-based control was reduced to four states (Fig. 5). These four states can be realized as the combination of activated agonist and antagonist's muscles: 1) B - both muscles stimulated generating net torque zero (co-contraction) resulting in high joint stiffness, 2) X - both muscles sluggish (no stimulation) resulting with a zero joint stiffness 3) F - strong flexor activation with no or low-level extensor activation and 4) E - no or low-level flexor activation and strong extensor activation. The low level of activation of antagonistic muscles was introduced to minimize the state to state transitions. The other characteristic for a smooth transition is the ramping-up and ramping-down of stimulation bursts.

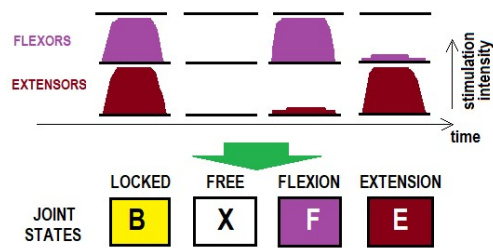


Fig. 5: The sketch of the outputs of the rule-based controller.

The design of rules includes the expected delay (time between the time of pulse sent to the targeted nerve and the motor response) of about 100ms. The delay is essential since in many phases during the gait cycle if the action is coming late, the consequences could be catastrophic (e.g., fall of the person using the system). The basis of the heuristics implemented for the generation of the training data for minimum entropy can be found in Džepina et al. [16].

Results

The gait events and phases were detected automatically based on the rules shown in Fig. 6.

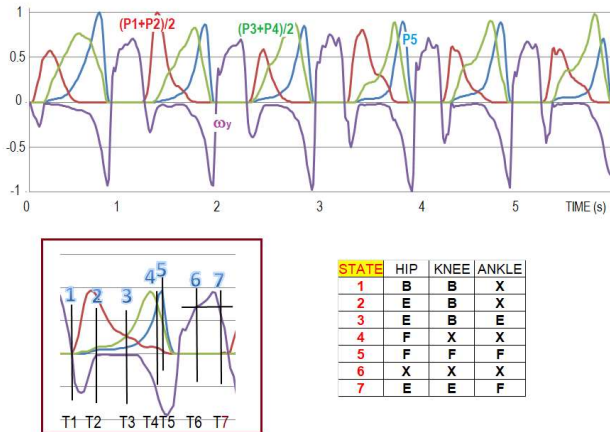


Fig. 6: The schematic presentation of the If-Then rules used for the control. One gait cycle was divided into seven phases based on the machine classification, which uses minimum entropy method. T_i ($i=1-7$) are the notations showing the transition points determined between the rules shown in Table 1. The acronyms: B – co-contraction of flexors and extensors, X – no stimulation, F – stimulation of flexors, and E stimulation of extensors.

Table 1: The estimated signals from sensors by the inductive learning, which predict 100 ms in advance the joint states.

T1	The change of the sign of ω_y from positive to negative.
T2	Three samples of gyroscope signal $\omega_y < 5\%$ of the maximum negative angular rate.
T3	The intersection of signals $P1+P2$ and $P3+P4$ when $P1+P2$ are decreasing, and $P3+P4$ is rising.
T4	The intersection of signals $P3+P4$ and $P5$ when $P3+P4$ is decreasing, and $P5$ is rising.
T5	The toe force reaches maximum
T6	The output from the gyroscope $\omega_y > 70\%$ of the maximum positive angular rate in the sagittal plane.
T7	The output from the gyroscope $\omega_y < 70\%$ of the maximum positive angular rate in the sagittal plane.

The MOTIMOVE supports the rule-based control and communicates wirelessly with the Gait Teacher. The MOTIMOVE supports frequencies of stimulation on each channel separately from 1 to 100 pulses per second, the amplitude of stimulation on all eight channels up to 170 mA, and the pulse duration from 10 to 1000 μ s. The MOTIMOVE allows trapezoidal stimulation profiles (Fig. 6, bottom panel).

The MOTIMOVE supports the antifatigue unit (AFU) that allows distributed low-frequency activation of large muscles *via* an array electrode. Each AFU connects to one stimulation channel and can drive up to four sets of motor units, and the fused contraction can be generated at the pulse rate as low as 10 to 12 pulses per second.

Fig. 6 is the sketch showing the stimulation paradigm: 1) sensors read the interaction with the ground and the kinematics of the foot, 2) the preset thresholds define state transitions, 3) stimulator selects the channels to be turned on and off with trapezoidal burst shapes, 3) biphasic current-controlled, charge-balanced pulses are sent to electrodes that are positioned at the appropriate positions over the innervations of targeted muscles. The interface (GUI operating on the tablet/computer) for the user works in Win10 environment.

Discussion

This presentation is intentionally limited to technical aspects of the new system for FES assisted gait.

The tests of the system in persons after stroke are for the illustration only since the certification of the system is in progress. The ethics board of the Clinic for rehabilitation "Dr. Miroslav Zotović," Belgrade approved the clinical tests in persons with MS and stroke. So far, only selected persons with chronic hemiplegia participated in the testing. Subjects claimed that the donning and doffing of sensors is simple if they use shoes that are one or two sizes bigger compared to their regular shoe size. Subjects tolerated without any complains the stimulation currents in the range from 20 to 50 mA, with the pulse duration of 350 μ s, and at frequencies of 40 pulses per second. The gait analysis suggests that the assisted gait after short adaptation is more symmetric and slightly faster ($\approx 15\%$) compared to no stimulation.

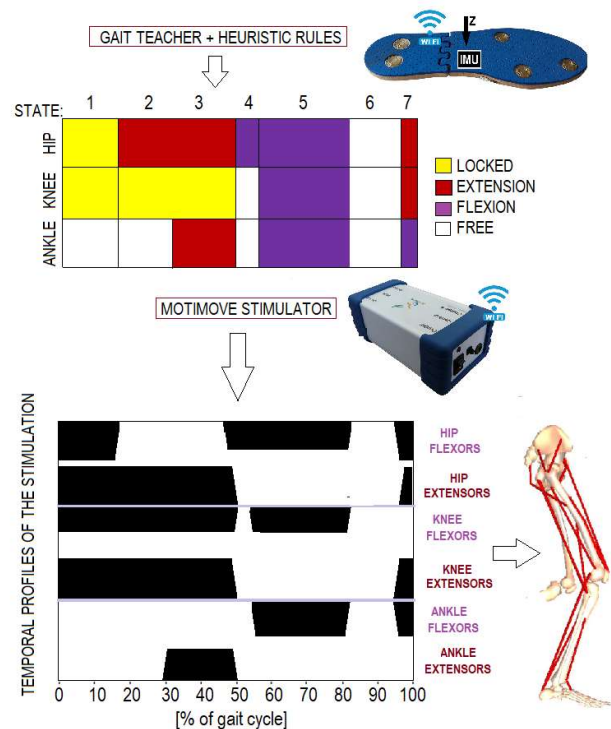


Fig. 6: The diagram showing the application of the rule-based control activating six muscle groups for supporting the gait in persons with hemiplegia.

When we tested the FES subjects claimed that the timing of stimulation for lower leg muscles assisted their ground clearance better and contributed to the better push-off by the paretic leg and hip extension during the late stance.

We presented only the example of signals and rules for the ground level walking. The same methodology applies to the generation of the sets of rules for walking at different speeds, climbing stairs, slope, and other gait modalities. A pending clinical study needs to confirm the previous statement. The critical consideration in the pending clinical study is the practicality of the control when used in real-life.

The contraction resulting from the voluntary effort and stimulation must generate appropriate joint torques for the targeted joint rotations. If this is not the case, then the muscle exercise needs to be initiated (for at least 20 sessions during the four weeks) to train the muscles before any attempt to assist gait. Once the muscle strength is achieved, the MOTIMOVE can be used to support gait training.

The initial step in applying the system is setting the stimulation parameters and deciding on the positions of the stimulation electrodes. The stimulation parameters (pulse duration, pulse amplitude, pulse rate) determine the intensity of stimulation. The selection of the appropriate settings is a compromise between the level of tolerance by the person using the system and the muscle achieved.

The setup is time consuming (20 minutes or similar) during the initial session, while in the later sessions, the installation is short (<5 minutes).

In the system for the gait restoration, the thigh muscles are at the highest risk for being fatigued. The trials of using the antifatigue device for the activation of thigh muscles that require prolong stimulation have been done in an exercise protocol on the exercise bicycle [unpublished data], and the periods where the fatigue does not compromise the application are several times longer compared with the conventional stimulation paradigm [13].

Fine adjustments of the intensity of the stimulation need to be performed during the use to compensate for the muscle fatigue.

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Author's Address

Dejan B. Popović
Serbian Academy of Sciences and Arts, Belgrade, Serbia
and Aalborg University, Aalborg, Denmark
11000 Belgrade, Knez Mihailova 35, Serbia
e-mail: dbp@etf.rs
URL: <https://vbn.aau.dk/en/persons/100233>