

# Design and Test of a Novel Closed-Loop System That Exploits the Nociceptive Withdrawal Reflex for Swing-Phase Support of the Hemiparetic Gait

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**Abstract**—A novel closed-loop system for improving gait in hemiparetic patients by supporting the production of the swing phase using electrical stimulations evoking the nociceptive withdrawal reflex was designed. The system exploits the modular organization of the nociceptive withdrawal reflex and its stimulation site- and gait-phase modulation in order to evoke movements of the hip, knee, and ankle joints during the swing phase. A modified model-reference adaptive controller (MRAC) was designed to select the best stimulation parameters from a set of 12 combinations of four electrode locations on the sole of the foot and three different stimulation onset times between heel-off and toe-off. It was hypothesized that the MRAC system would result in a better walking pattern compared with an open-loop preprogrammed fixed pattern of stimulation (FPS) controller. Thirteen chronic or subacute hemiparetic subjects participated in a study to compare the performance of the two control schemes. Both control schemes resulted in a more functional gait compared to no stimulation ( $P < 0.05$ ) with a weighted joint angle peak change of  $4.0 \pm 1.6$  (mean  $\pm$  Standard deviation) degrees and  $3.1 \pm 1.4$  degrees for the MRAC and FPS schemes, respectively. This indicates that the MRAC scheme performed better than the FPS scheme ( $P < 0.001$ ) in terms of reaching the control target.

**Index Terms**—Functional electrical therapy, hemiparetic gait, model-reference adaptive control (MARAC), nociceptive withdrawal reflex, rehabilitation.

## I. INTRODUCTION

PATIENTS who have suffered a cerebral stroke have often problems controlling their lower limbs, leading to a compromised gait pattern. The most affected limb presents gait kinematics deviating from normal, exhibiting typically decreased hip flexion, knee flexion, and ankle dorsiflexion in the swing phase, as well as decreased knee extension at heel strike [1].

To facilitate the initiation and to support the development of the swing phase of hemiparetic patients, the withdrawal reflex can be evoked, as it produces a synergistic contraction of several muscles in the limb resulting in adequate withdrawal from a potentially harmful stimulus [see Fig. 1(a)] [2]–[4]. This approach was used by Quintern *et al.* [5] to initiate the swing phase by using electrical stimulation of flexor reflex afferents during gait retraining. Quintern *et al.* concluded that it enhances the recovery of gait function in patients with hemiparesis after acute stroke. A similar approach was used by Braun *et al.* [6] and by Fuhr *et al.* [7], who evoked the withdrawal reflex using a closed-loop system for swing-phase support. Activating the withdrawal reflex is especially beneficial to initiate hip movement because the deep location of the main hip flexor (iliopsoas) makes it unsuitable for direct surface electrical stimulation.

Since the pioneering findings of Sherrington [8], withdrawal reflex responses have been conceived as stereotyped flexion responses; however, a more refined organization of the withdrawal reflexes has been proposed by Grimby [9], and Schouenborg [10], and studied in detail in anaesthetized rats [10], cats [11], and humans [2], [12]. The human lower limb nociceptive withdrawal reflex elicited by painful electrical stimulation of the foot depends on several stimulation parameters. Hence, the withdrawal strategy depends on the stimulation site [2], [13], intensity [14], frequency [14], posture [15], and phase of the gait cycle [16]–[18].

For stimulations near toe-off, withdrawal is primarily accomplished by ankle dorsiflexion, while the strategy for stimulations at heel-off is flexion of the knee and hip joints. Stimulation delivered to the distal stimulation sites evokes a distinct ankle dorsiflexion, whereas stimulation delivered to proximal sites evokes plantarflexion [4], [19].

Therefore, by selecting different combinations of stimulation site and timing, the resulting movement can be controlled to some extent due to the differences in withdrawal strategy.

A therapeutic modality for the rehabilitation of poststroke hemiparetic individuals called functional electrical therapy

Manuscript received August 16, 2010; revised November 22, 2010; accepted November 22, 2010. Date of publication December 3, 2010; date of current version March 18, 2011. This work was supported by the Danish Research Council for Technology and Production (FTP) and the Svend Andersen Foundation. Asterisk indicates corresponding author.

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Digital Object Identifier 10.1109/TBME.2010.2096507

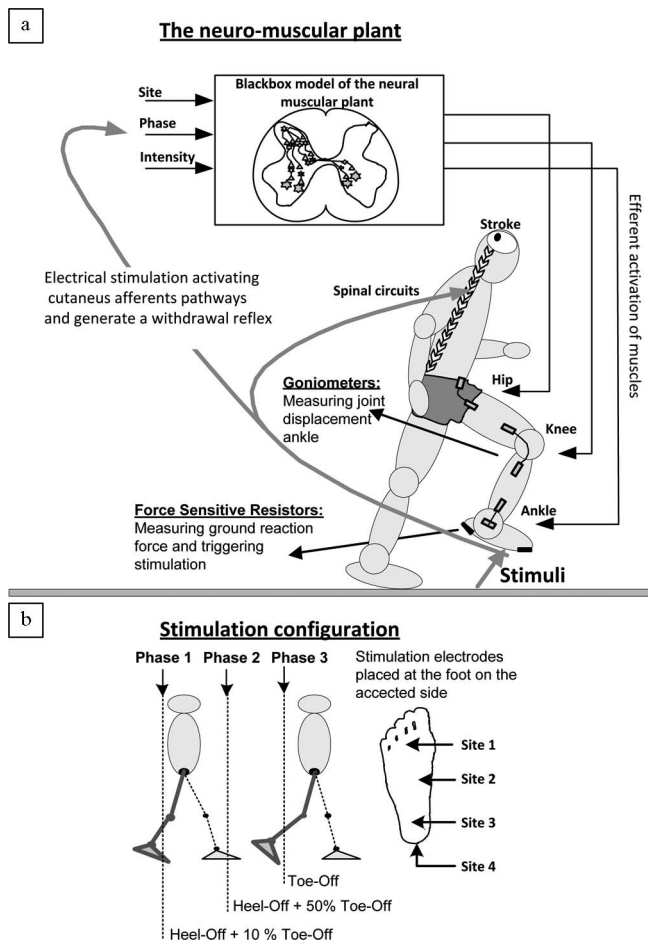


Fig. 1. (a) Neuromuscular plant (combination of process and actuator) from afferent input to kinematic response. Moderately painful electrical stimulations evoked afferent input to spinal circuits, which respond with activation of the muscle groups controlling the stimulated limb (and interacting with the entire locomotion pattern). This withdraws the affected site from the stimulus by activation of muscles controlling the hip, knee, and ankle joints depending on the stimulation parameters. The subject was instrumented with goniometers and force-sensitive resistors. (b) Stimulations were delivered to four locations at the foot at three different time points between heel-off and toe-off.

(FET) combines functional electrical stimulation (FES) with task-dependent voluntary exercise. The background for this method is that many patients, who use FES on a regular basis, experience a significant carry-over effect in the function when the device is no longer in use [20], [21]. The basic idea is thus to use a neuroprosthesis in the recovery phase to facilitate functional exercises and achieve a lasting increase in function. Studies focusing on rehabilitation of reaching and grasping have [22] show that recovery is greatly promoted for acute stroke patients when using FET.

It can be speculated that reflex-based FET, i.e., electrical stimulation of the nociceptive withdrawal reflex combined with task-dependent voluntary exercise, applied in subacute hemiparetic subjects will result in faster and better recovery compared to conventional therapy. To be able to test reflex-based FET a control system for swing-phase support should thus be designed and tested.

The purpose of this study was therefore to examine if an adaptive closed-loop control system that exploits the modular organization of the nociceptive withdrawal reflex, and the site and phase modulation of the reflex during gait, would prove superior to a system with an open-loop fixed preprogrammed stimulation pattern for swing phase support of the hemiparetic gait, tested in a single-session study.

A sensor-driven control system for swing-phase support has been designed, and the gait pattern was controlled and evaluated based on measures of joint angles.

## II. METHODS AND MATERIALS

### A. Subjects

Thirteen chronic or subacute hemiparetic patients participated in the study (see Table I). The following inclusion criteria were used: 1) at least three months after the cerebrovascular accident; 2) functional ambulation category (FAC [23]) score 4–5; 3) have visible gait problems; 4) being able to walk continuously for at least 10 min and to resume walking after a period of rest; 5) endure walking for approximately 1–1.5 h with rest; and 6) ability to tolerate electrical stimulations. Informed consent was obtained from all the subjects and the Helsinki Declaration was respected. The study was approved by the local ethical committee (N-20070026). All subjects walked over ground with their preferred walking speed and were instructed to request as many pauses as needed during the experiment to minimize the risk of fatigue.

### B. Electrical Stimulation

The method for evoking the nociceptive withdrawal reflex has been described in earlier publications [3], [14], [18]. In short, the reflex was elicited by transcutaneous electrical stimulation delivered to one of four sites on the sole of the foot on the most affected side [see Fig. 1(b): S1—the third metatarsophalangeal (MP) joint; S2—the medial arch of the foot; S3—the plantar side of calcaneus; and S4—the posterior side of calcaneus]. Each stimulus consisted of a constant current pulse burst of five individual 1-ms pulses delivered at 200 Hz. This stimulus was repeated four times at a frequency of 15 Hz [4]. To evoke a reflex response in early swing, both the reflex response delay and the biomechanical delay must be taken into consideration, since they result in a mechanical response occurring no earlier than 140 ms after the onset of stimulation [18], [24]. Therefore, stimulations were enabled in the late stance, starting at *heel-off* and could be delivered at three phases of the gait cycle between *heel-off* and *toe-off* of the most affected side: Phase-1: 10% of *heel-off*/*toe-off* period; Phase-2: 50% of *heel-off*/*toe-off* period; and Phase-3: *toe-off* [see Fig. 1(b)]. Based on the obtained gait cycles, the delays from *heel-off* were ( $T_{P1} = 21 \pm 1$  ms (mean  $\pm$  standard deviation),  $T_{P2} = 109 \pm 13$  ms, and  $T_{P3} = 217 \pm 27$  ms).

### C. Outcome Measures

Three goniometers (type SG150 and SG110/A, Biometrics Ltd., Gwent, U.K., accuracy  $\pm 2^\circ$ ) were mounted on the most affected limb across the ankle, knee, and hip joints to monitor

TABLE I  
DATA FOR THE HEMIPARETIC SUBJECTS AND EVALUATION OF OPTIMAL WALKING REGIME FOR THE INDIVIDUAL SUBJECTS. TWO SUBJECTS (SUB#4 AND SUB#8) WERE EXCLUDED FROM THE DATA ANALYSIS DUE TO INCORRECT GAIT DETECTION AND INFERIOR REFLEX RESPONSES

Sub No.	Sex	Age	Years from stroke	Weight matrix			Qualitative aims for the MRAC- system	Best Regime
				Hip	Knee	Ankle		
1	M	46	5.3		-1.00		Additional knee extension in late swing	MRAC
2	F	33	12.6			1.00	Additional ankle dorsiflexion in mid swing	Equal
3	M	57	0.3	0.33	0.33	0.33	Additional flexion for all joints in mid swing	Equal
5	F	42	11.5	0.31	0.31	0.38	Additional flexion for all joints in mid swing. Ankle dorsiflexion highest priority	FPS
6	M	49	10.5		-0.56	0.44	Additional knee extension in late swing. Additional and prolonged ankle dorsiflexion in late swing	MRAC
7	M	50	2.0		0.60	0.40	Additional knee flexion in mid swing. Additional ankle plantar flexion in transition to swing to increase push off. Additional dorsiflexion during late swing	MRAC
9	F	48	3.3		0.80	0.20	Additional knee flexion in mid swing. Additional ankle dorsiflexion in mid swing	Equal
10	M	37	1.5		0.40	0.60	Additional dorsiflexion throughout swing (mid). Additional knee flexion in mid swing.	MRAC
11	M	48	0.2			1.00	Additional ankle dorsiflexion in late swing	MRAC
12	F	73	3.1		0.30	0.70	Additional ankle dorsiflexion in late swing. Additional knee flexion in mid swing	Equal
13	M	66	1.0		0.40	0.60	Additional dorsiflexion throughout swing (mid). Additional knee flexion in mid swing.	Equal

The shaded cell indicates the joint with the highest priority.

the kinematic response [see Fig. 1(a)]. For the data analysis, the difference between subsequent steps was used; hence, the absolute precision depending on the precise mounting on the joint plays an inferior role.

Timing of heel and toe contact with the ground was measured by force-sensitive resistors (FSR, LuSense, PS3, Standard 174). All data were sampled at 4 kHz, and stored for later analysis.

#### D. Experimental Protocol

The experiment was split in two parts.

*Part-I:* The initial assessment of baseline gait and measurement of nociceptive reflex responses to stimulation were performed in order to build a first model of the gait pattern of the subject. A sequence of ten unperturbed control steps was acquired and used for calculating the stimulation onsets. Afterward, stimulation was delivered in random sequence, repeating each combination of stimulation site and phase five times, resulting in a total of 60 combinations (four sites  $\times$  three phases  $\times$  five repetitions). The interstimulus interval was randomized to be between four and six steps.

*Part-II:* Three different walking regimes were tested. The subject walked 10 min with each of them:

- 1) walking with the closed-loop system (model reference adaptive controller, MRAC, see detailed description below);
- 2) walking with the open-loop system using a predefined fixed pattern of stimulation (FPS);
- 3) walking with no stimulation (baseline).

The order of the sessions was not randomized. The MRAC session was prioritized in case the patients could not finalize the entire experiment due to fatigue. Moreover, technical reasons related to manning during the experiment also rendered randomization impossible. Despite the concern, none of the subjects included in the presented study experienced fatigue during the recordings and were all able to complete the full protocol.

#### E. Data Analysis

For the offline analysis, steps with incorrectly identified step cycles due to fore foot landings or steps with intermittent ground clearance were excluded from the analysis. Steps were accepted

based on the following criteria: the present step lasted maximum 1.6 s, at least 40% of the subjects average step duration. The individual swing phase lasted minimum 50% of the average swing-phase duration, and the stance phase lasted minimum 100 ms. The accepted steps were inspected manually and eventually discharged. For the accepted steps (37% of the collected steps), the goniograms were low-pass filtered (Butterworth, 25 Hz, sixth order, no phase lag) and the kinematic response was calculated as the difference between the poststimulation goniogram and the average goniogram recorded during unperturbed gait (Baseline). *Peak change* (PC) in a time window defined according to the individual aims (see Table I) was reported. This could be either early, mid, or late swing by assessing either the first, mid, or last 50% of the *heel-off* period (see Fig. 5). The overall fulfilling of the targets for all joints was assessed by a performance index  $PC_w$  calculated as a weighted sum of PCs for each joint. The weights ( $W_j$ ) were individually set for each subject depending on their need for support, as described in the following section:

$$PC_w = [W_{HIP} \ W_{KNEE} \ W_{ANKLE}] \begin{bmatrix} PC_{HIP} \\ PC_{KNEE} \\ PC_{ANKLE} \end{bmatrix}. \quad (1)$$

To examine the performance across the entire swing phase, the area between the poststimulation goniogram and baseline goniogram was calculated via integration of the kinematic response. The overall weighed sum of the area was reported.

#### F. Patient-Specific Controller Targets

An experienced physiotherapist evaluated the walking pattern of each participant individually and suggested the primary and secondary needs based on the following forced-choice options: increased ankle dorsiflexion, increased knee flexion, increased knee extension, and increased hip flexion.

The need for support was identified for each joint and expressed as need for additional flexion/extension in either early, mid, or late swing. Moreover, a weight factor ( $W_j|J = [Hip, Knee, Ankle]$ ) was determined for each joint indicating how much the closed-loop controller should prioritize reaching the stated target for the three joints. Weights and aims for all subjects are shown in Table I.

#### G. Statistics

A repeated-measures analysis of variance (RM ANOVA) was used to analyze the between subject effect of using the two control schemes on the  $PC_w$ . To analyze the within subject effect on the  $PC_w$  (MRAC versus FPS for each subject), a paired *t*-test was used.

#### H. Modeling and Control

Modeling and control of the neuromuscular plant [see Fig. 1(a)] is complicated because knowledge about the neural pathways involved from the afferent activation to the kinematic response are not complete, so a precise parametric model cannot be established. Furthermore, after a cerebral stroke, major structural changes may occur in the nervous system, and during the

recovery phase, the reflex pathways may also change substantially. Therefore, an adaptive model is required to characterize this highly individual and plastic system.

The neuromuscular plant can be characterized as a multiple-input multiple-output (MIMO) dynamic system [see Fig. 1(a)]. The inputs *site* and *phase* are categorical variables without any intrinsic ordering but evoking different withdrawal strategies, while *intensity* is a continuous variable mainly affecting the amplitude of the reflex response [see Fig. 1(a) and (c)]. The output is coupled, highly time variant, stochastic, and nonlinear. Furthermore, there are significant latencies in the system, since the mechanical response occurs no earlier than 140 ms after the stimulation onset [18], [24]. Considering this, and that a normal swing phase lasts approximately 400 ms, it is clear that only one reflex response can be elicited and evaluated in each swing phase.

Stimulations delivered in the stance phase could lead to inappropriate perturbations and instability; hence, the stimulation was only enabled when the body weight was mainly supported by the contralateral leg. The control system was, therefore, only allowed to stimulate in a semiperiodic manner from the late stance to the early swing phases. Furthermore, the controller adapted between each step in order to handle fatigue, reflex habituation (gradually lower reflex responses), and gradual improvement in walking performance during therapy (later application of the system). To make the performance of the two systems comparable, it was vital to keep identical intensities. Therefore, it was chosen to fix the intensity at one level and develop a method for controlling the categorical variables. In future studies, it may be considered to incorporate a variable stimulation intensity to make the system more adaptive.

The control scheme must be able to adjust to variation of the reflex excitability within a session. This was achieved by adjusting the parameters of the controller by a model-follower technique, where the closed-loop output (combined output of controller and plant  $Y$ ) was designated to follow the output of a reference model with a specified dynamic [see Fig. 2(a)]. The latter approach was chosen, since estimating model parameters was unrealistic due to the inherent difficulty in establishing a satisfactory dynamic plant model that considers the gradual improvement during therapy, and the habituation of the reflex response within sessions. The control system was, therefore, designed as a modified model reference adaptive system (MRAC) [25], [26]. Conventional MRAC concepts are associated with parametric models [25], but in this application, neither model structure nor parameter values were known. Instead, a novel modified MRAC method was introduced in which models of entire kinematic trajectories ( $\hat{Y}$ ) in the *heel-off* phase were recursively derived from input–output data for the three joint angles (hip, knee, and ankle). Based on this model, the controller continuously compared the deviation of the present step to a target trajectory [see Fig. 2(b)]. The controller minimized the error  $e_2$  between the predicted output and the target trajectory. Changes in the baseline gait pattern or in the reflex response induced changes in a plant model implicitly embedded in the MRAC controller. The controller then predicted all outcome possibilities and chose the combination of *site* and *phase* that

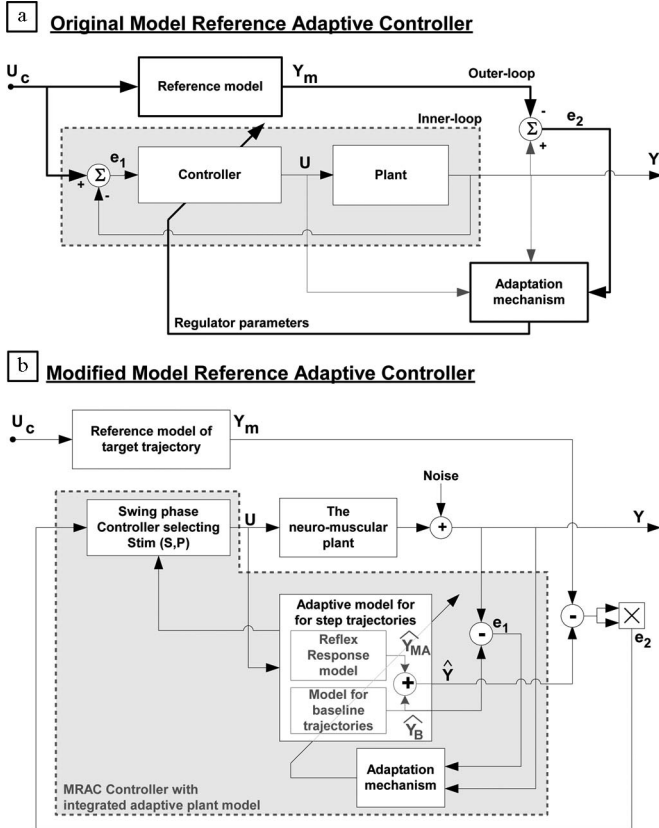


Fig. 2. Original [25] and modified block diagrams for the model reference adaptive control system. The combined output of controller and plant were designed to follow the output of a reference model (technique called a model follower). The parameters in the system are adjusted in order to get  $Y$  as close as possible to  $Y_m$  for all given input signals.

resulted in the lowest error; the embedded plant model forced, thereby, the adaptive controller to change the stimulation parameters, if needed.

The MRAC strategy included: specification of a reference model with the desired dynamics and on-line parameter estimation. The system consisted of an ordinary feedback loop composed of the process and the controller (see Fig. 2). The error ( $e_2$ ) was the squared difference between the predicted outputs of the system ( $Y$ ) and the reference model ( $Y_m$ )

$$e_2 = \frac{1}{T_H - T_0} \int_{T_0}^{T_H} (\hat{Y} - Y_m)^2 dt \quad (2)$$

where  $t$  denotes time ( $t \geq 0$ ),  $T_0$  describes the start of the *heel-off phase* and  $T_H$  describes the end of the *heel-off phase* (*heel-on*). There were two loops in the system: an inner loop, which provided the ordinary control feedback and an outer loop that adjusted the parameters in the inner loop. Thus, the aim for the closed-loop system was to follow the reference model trajectory  $Y_m$

$$Y_m(t) = \begin{bmatrix} \tau_{HIP}(t) \\ \tau_{KNEE}(t) \\ \tau_{ANKLE}(t) \end{bmatrix}, \quad \text{for } T_0 \leq t \leq T_H \quad (3)$$

while the neuromuscular plant model was described by  $\hat{Y}$  as follows:

$$\hat{Y}(S, P, t) = \begin{bmatrix} \hat{\tau}_{HIP}(S, P, t) \\ \hat{\tau}_{KNEE}(S, P, t) \\ \hat{\tau}_{ANKLE}(S, P, t) \end{bmatrix}, \quad \text{for } T_0 \leq t \leq T_H. \quad (4)$$

In (3) and (4),  $S \in \bar{S} = \{1, 2, 3, 4\}$  denotes the *site*,  $P \in \bar{P} = \{1, 2, 3\}$  the *phase* (see Fig. 1). The use of *trajectories*, rather than parameterized dynamical input–output models, was stressed by the use of the symbol  $\tau$  for the individual coordinates.

The dynamics of the outer loop, which adjusted the controller parameters, is normally assumed to be slower than the inner loop, and the adjustments are often based on a gradient approach [25]. However, since a parametric model was not available for the present system, the gradient approach was deemed infeasible. In this study, it was crucial to reflect gait improvement, habituation, and fatigue as well as to reduce noise from normal step-to-step variability. This was achieved by introducing a simple moving average (MA) approach for modeling the kinematic reflex responses trajectory, where the length of the MA-filter reflected the adaptation rate.

### I. Adaptive Neuromuscular Plant Model

The predicted trajectory  $\hat{Y}$  is considered to be a sum of two parts: a contribution from the kinematic reflex responses  $\hat{Y}_{MA}$  and a contribution from the unperturbed gait (baseline trajectory  $\hat{Y}_B$ ) [see Fig. 2(b)]

$$\hat{Y}(S, P, t) = \hat{Y}_{MA}(S, P, t) + \hat{Y}_B(t). \quad (5)$$

In part I of the experiment,  $\hat{Y}_{MA}$  was calculated as the difference between the poststimulation goniogram and the corresponding goniogram recorded in the step cycle immediately prior to stimulation [see unperturbed gait, Fig. 3(a)]. This was averaged in groups with similar input parameters; the baseline model ( $\hat{Y}_B$ ) was extracted as an average of all unperturbed control steps.

In part II, it was ensured that the system was insensitive to the fluctuations in gait velocity, by normalizing all the measured goniograms from hip, knee, and ankle to the length of the initially acquired *baseline step* from part I. To compensate for eventual drift in the goniograms during the session (up to 4 h long), each joint trajectory was corrected to start at the same initial value as the initially acquired *baseline step*, assuming thereby that the initial position of the joints at *heel-off* was constant and that the main change occurs poststimulation. This results in the present step trajectory:

$$Y(t) = \begin{bmatrix} \tau_{HIP}(S, P, t) \\ \tau_{KNEE}(S, P, t) \\ \tau_{ANKLE}(S, P, t) \end{bmatrix}, \quad \text{for } T_0 \leq t \leq T_H. \quad (6)$$

In part II of the experiment, both models ( $\hat{Y}_{MA}$ ,  $\hat{Y}_B$ ) were continuously updated (see Fig. 2). By disabling the stimulation with a five-step interval, a *baseline step* was acquired and used as an updated  $\hat{Y}_B$ , by letting  $\hat{Y}_B = Y$ . In the other four

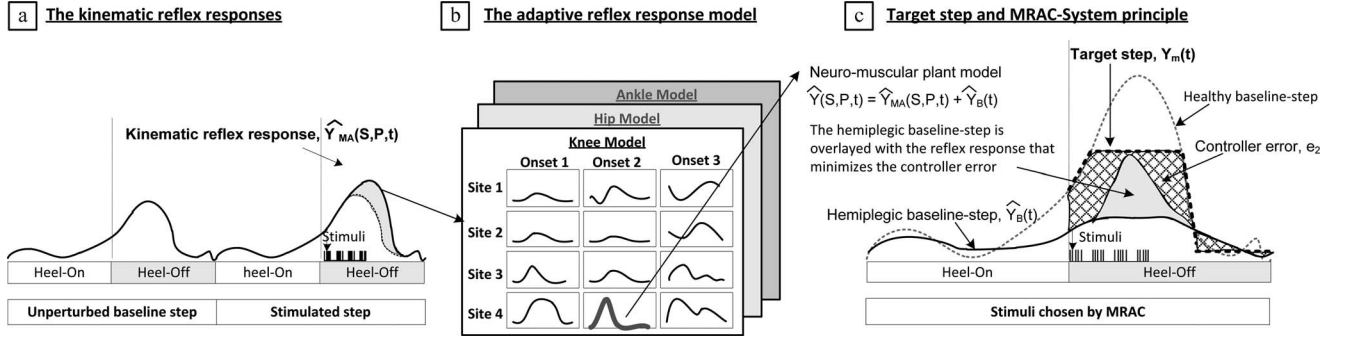


Fig. 3. (a) Reflex response curve is the difference between an the unperturbed control step and the step immediately after stimulation. (b) Adaptive model of the kinematic reflex responses for each of the 36 trajectories. (c) Sketch of the MRAC controller principle. The ultimate aim would be to approach the hemiparetic baseline step to the level of a reference step from a healthy subject; this was, however, often too ambitious and would require too painful stimulation intensities. Therefore, the target trajectory was “negotiated” based on an assessment of what was realistic for the individual subject. The MRAC system chose the stimulation most likely to minimize the squared error  $e^2$  from formula (8).

*controller-corrected steps*, the reflex response model ( $\hat{Y}_{MA}$ ) was updated by first calculating the reflex response as the error between the present step and the latest *baseline step* ( $e_1 = Y - \hat{Y}_B$ ), and then use a simple MA approach for estimating  $\hat{Y}_{MA}$  at time  $t$ . The MA of the last five steps corresponding to the same input parameters was calculated as follows:

$$\hat{Y}_{MA}(S_v, P_v, T_{0,v} + \Delta t) = \frac{1}{n} \sum_k \begin{bmatrix} \hat{\tau}_{HIP}(S_k, P_k, T_{0,k} + \Delta t) \\ \hat{\tau}_{KNEE}(S_k, P_k, T_{0,t} + \Delta t) \\ \hat{\tau}_{ANKLE}(S_k, P_k, T_{0,k} + \Delta t) \end{bmatrix} \quad (7)$$

$\Delta t \in [0; T_H - T_0]$

where  $v$  denotes the *step number*, the model adaptation rate was adjusted by the length of the MA filter,  $n = 5$ , and  $k$  denotes the last  $n$  steps, where  $S_k = S_v$  and  $P_k = P_v$ .

#### J. MRAC Swing-Phase Controller

At the end of each swing phase, immediately after the update of the adaptive neuromuscular plant model, the controller algorithm calculated the predicted step ( $\hat{Y}$ ) for all combinations of stimulation site and phase based on the adaptive neuromuscular plant model [see Fig. 2(b)]. Based on the weight matrix with a value for each joint ( $W_j$ ) that allowed the control system to prioritize between joints, a weighted sum of squared errors (see Fig. 2(b),  $e_2$ ) was calculated as follows, for all combinations of  $\bar{S}$  and  $\bar{P}$ :

$$e_2(S, P) = \frac{1}{T_H - T_0} \int_{T_0}^{T_H} [Y_m(t) - \hat{Y}(t)]^T \cdot \begin{bmatrix} W_{HIP} & 0 & 0 \\ 0 & W_{KNEE} & 0 \\ 0 & 0 & W_{ANKLE} \end{bmatrix} [Y_m(t) - \hat{Y}(t)] dt. \quad (8)$$

The inputs (i.e., stimulation site and phase) that minimized the weighted squared error were chosen for the subsequent stimulus

$$[S, P]_{v+1} = \arg \min_{S \in \bar{S}, P \in \bar{P}} \{e_2(S_v, P_v)\} \quad (9)$$

where  $v$  denotes the *step number*.

#### K. Reference Model of Target Step

By considering the unperturbed gait of the subject, normal healthy gait, and the stimulation-induced pain, an individual controller target for each joint was derived [see Fig. 3(c)]. Moreover, a weight factor was determined for each joint that indicated how much the controller should prioritize reaching the aim for the different joints. Weights and aims for all subjects are shown in Table I.

#### L. Fixed Pattern of Stimulation

The stimulations of the FPS system were delivered to the arc of the foot at *heel-off* ( $S = 2, P = 1$ ). This electrode site and stimulation timing were chosen based on earlier studies [4], [18], where stimulations at the arc of the foot provoked large and robust reflexes, while stimulation at *heel-off* resulted mainly in increased hip and knee flexion.

### III. RESULTS

#### A. Excluded Subjects

For one of the subjects (Sub#4), the step cycle was incorrectly identified due to forefoot landings and minimal ground clearance, resulting in numerous false-positive heel contacts, and therefore, the subject was excluded from the offline analysis. Another subject (Sub#8) had problems tolerating the electrical stimulations, which resulted in stimulations with insufficient strength to evoke noticeable kinematic reflex responses; the subject was, therefore, also excluded. Data from 11 subjects are thus presented.

#### B. Overall Performance

Overall, both controllers resulted in a more functional gait compared to no stimulation ( $P < 0.05$ ), as judged by the generated joint trajectories approaching the targets and with a  $PC_w$  of  $4.0 \pm 1.6$  (mean  $\pm$  standard deviation) and  $3.1 \pm 1.4$  for the MRAC and FPS system, respectively (RM ANOVA,  $P < 0.001$ , see Fig. 4). In 45% of the subjects (5/11, see Table I), both controllers supported the hemiparetic gait equally well; the MRAC system was better for 45% (5/11) of the subjects, while

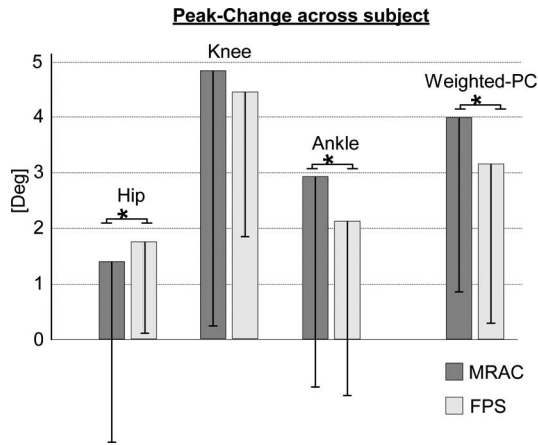


Fig. 4. Overall across-subject performance for the two controllers. The bars indicate PC for all joints and weighted PC combined for all joints, weighted according to WT. The error bars indicate  $\pm$ two standard deviations (95% confidence interval) and the \* indicates a significant difference.

the FPS system was better for one subject. Both controllers were equally good at providing knee support. For hip support, the FPS system was superior (RM ANOVA,  $P < 0.001$ , see Fig. 4), while for ankle support, the MRAC system was the best (RM ANOVA,  $P < 0.001$ ). An inspection of the stimulations applied by the MRAC system (see Fig. 5) revealed that the controller applied changing stimulation parameters during the MRAC-regime for all subjects. Timewise, across-subject development of the within-session *weighted* PC is depicted in Fig. 6 and illustrate large variations in the  $PC_w$ , and also the within-session habituation (RM ANOVA, Bin and Controller interaction,  $P < 0.001$ ). During the first 5 min, both controllers had a slow decreasing  $PC_w$ , where the FPS system was performing better in two bins (paired  $t$ -test,  $P < 0.05$ ); however, after 5 min, the curves separated and the FPS system continued with increasing habituation while the MRAC system maintained a significant larger  $PC_w$  (paired  $t$ -test,  $P < 0.05$ ) and resulted in overall 52% larger  $PC_w$ .

This observation may have explanation in the parameter selection for the FPS system that used stimulations in the arc of the foot at *heel-off*. Stimulations with this parameter configuration can be expected to evoke the large responses while the MRAC chose different parameters with overall lower reflex amplitude.

#### IV. DISCUSSION

##### A. Main Findings

Both controllers resulted in a more functional gait compared to no stimulation as judged by generated joint trajectories approaching the targets. In 5/11 of the subjects, both controllers supported the hemiparetic gait equally well; MRAC was better for 5/11 of the subjects, while FPS was better for one subject. This suggests that if applied during several daily sessions, most hemiparetic subjects may benefit from withdrawal-reflex-based support during gait training, which likely will facilitate the rehabilitation of gait. Furthermore, the results indicate that

the MRAC system performed better in reaching the control target and that it alternated the stimulation parameters (see Fig. 5), suggesting that the control strategy in the MRAC system might adapt better to the varying needs during rehabilitation therapy.

##### B. Reflex-Based Gait Support

To support the rehabilitation of gait, electrical stimulation that activates efferent motor nerves has been used for several decades in the review by Lyons *et al.* [27]). This technique has both pros and cons; a clear advantage is the possibility to control the movement of the legs to great detail, while one of the drawbacks is the inverse recruitment order of motor units as compared to the physiological recruitment order. Inverse recruitment leads to faster muscle fatigue and poor force gradation [28]. Another drawback of muscle-nerve stimulation is the limited number of muscles that can be activated using surface stimulation and the high amount of stimulation channels needed to activate multiple muscles controlling the entire leg. As an alternative to muscle-nerve stimulation, the withdrawal reflex can be used to activate afferent nerves that through spinal circuits activates specific muscles with a normal physiological recruitment order and at the same time activates multiple muscles of the leg. This is in particular relevant for muscles flexing the hip joint, as these muscles are difficult to access via surface electrodes. The exact muscle activation profile for each muscle may differ between normal walking and walking with withdrawal-reflex-based support, even though both movements result in the production of a step. There is increasing evidence in the literature that the spinal neural network transmitting long latency flexion reflexes is closely connected to the spinal networks generating rhythmic activity for locomotion [29], [30]. Therefore, it is very likely that electrical stimulation of reflex pathways gives access to these spinal networks for locomotion and it is hypothesized that despite differences in the exact muscle activation profiles, the prospect for a therapeutic effect of reflex-based FET will be comparable to that of the conventional FET approach.

##### C. MRAC Versus FPS

The results of this study indicated that both controllers were equally good at supporting the knee joint movement, while the MRAC system was optimal for the ankle, and the FPS system was optimal for hip support (see Fig. 4). Earlier studies investigating the modular organization of the withdrawal reflex have produced interpolated maps of the kinematic reflex response to the reflexes evoked from up to 16 stimulation sites covering the sole of the foot [13], [16]. Andersen *et al.* observed that for the ankle joint, the reflex response is typically dorsiflexion for mid-distal stimulation sites, plantarflexion for proximal sites, inversion for medial sites, and eversion for lateral sites. The knee and hip joint both responded with flexion for all sites; however, with largest responses for stimulation sites near the arc of the foot. Functionally, this implies that the variety of evoked movements is largest at the most distal joint (ankle), while it is reduced to flexion for the proximal joints (knee and hip). This

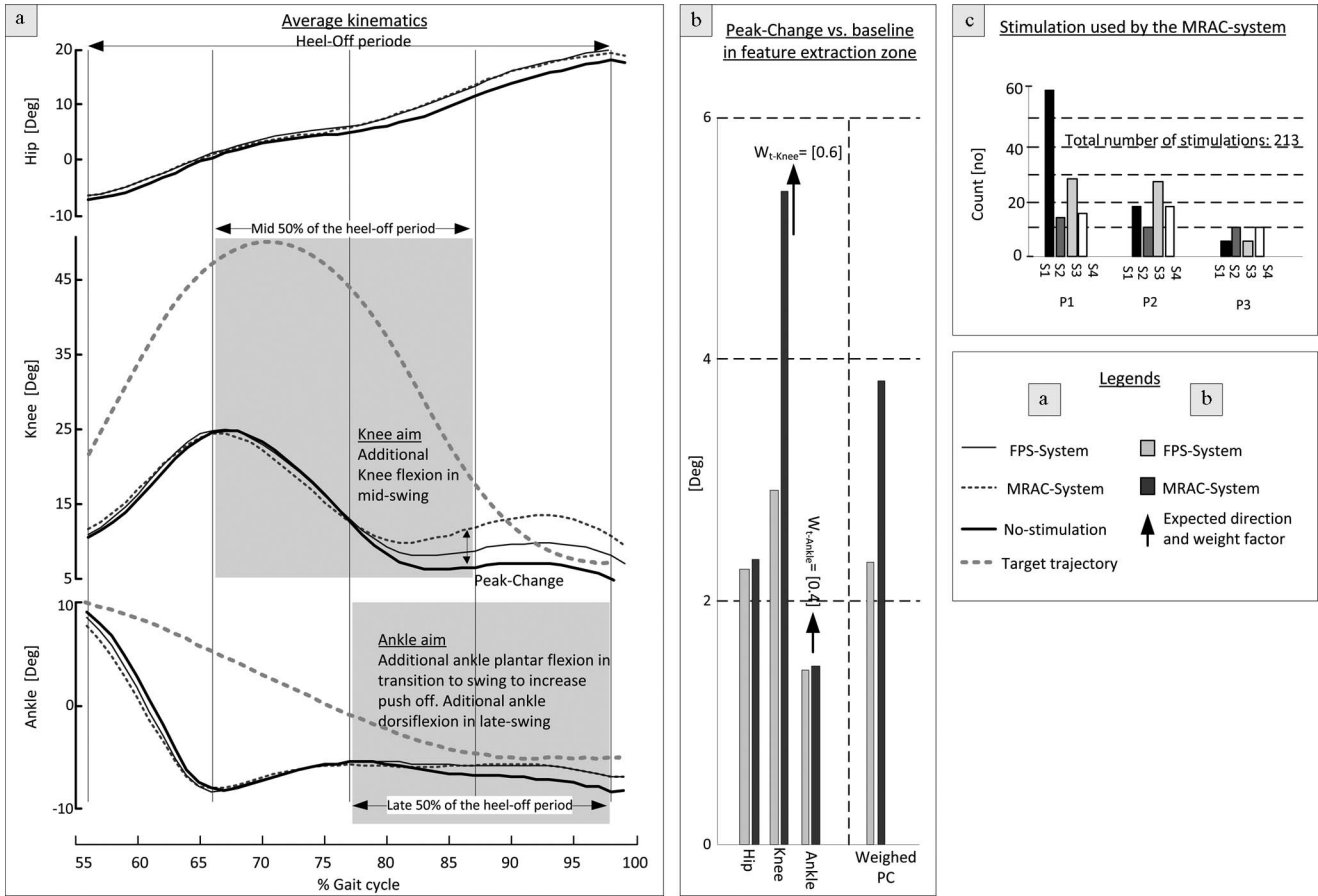


Fig. 5. (a) Average joint kinematics for Sub#7 depicting each of the three 10-min regimes; baseline, MRAC, and FPS. Features were extracted (in the gray-shaded area) according to the individual aim. (b) Extracted features for each joint. The arrows on the top of the first bar plot indicate the individual aim by direction and weight factor. (c) Distribution of the alternating stimulations used by the MRAC system.

pattern fits well with the findings from this study. For the ankle joint, the changing stimulation pattern provided by the MRAC system might have helped to provide the desired movement and the four available stimulation sites likely provided the necessary motion variability. This probably resulted in the better performance of the MRAC system as compared to the FPS system, when supporting the ankle joint.

In this study, a stimulation site on the posterior side of the heel was included to provide forward propulsion of the leg and knee extension. Therefore, it was expected that for subjects with need for knee flexion, both stimulation paradigms would perform equally, while for subjects with need for knee extension, the MRAC system would be superior.

Largest hip flexion was observed following stimulation of sites near the arc of the foot [16]. Therefore, the results from our study are in line with the expectation that the FPS system would result in a larger amount of hip flexion when compared to the MRAC system that might have selected other stimulation sites to fulfill the primary support needs, and that none of the subjects had hip flexion as their primary need.

*D. Closed-Loop Control of the Withdrawal Reflex Response*

A modified model reference adaptive control system was tested with an embedded adaptive plant model for estimation of the trajectories of the entire swing phase for combinations of two categorical variables: stimulation site and stimulation onset (phase of the gait cycle). Based on weight factors defined for each of the joints (hip, knee, and ankle), the weighted squared error to a preset target trajectory was used to select the optimal stimulation configuration. Such a system has, to the authors' knowledge, not been reported in the literature before. The controller chose different stimulation parameters during the MRAC regime (see Fig. 5) in order to improve the gait pattern by approaching the desired controller target. This utilized the differences in withdrawal strategy dependent on the stimulation site. For Sub#1 the aim was knee extension in late swing, the MRAC system applied the majority of the stimulations to the posterior side of calcaneus (S4) at the two last onsets.

Sub#7 needed support for knee-flexion and ankle dorsiflexion; for this, the preferred stimulation pattern applied by the MRAC system was to the forefoot (S1) at *heel-off* (see Fig. 5), which is in line with the earlier findings [4], [19]. However, since



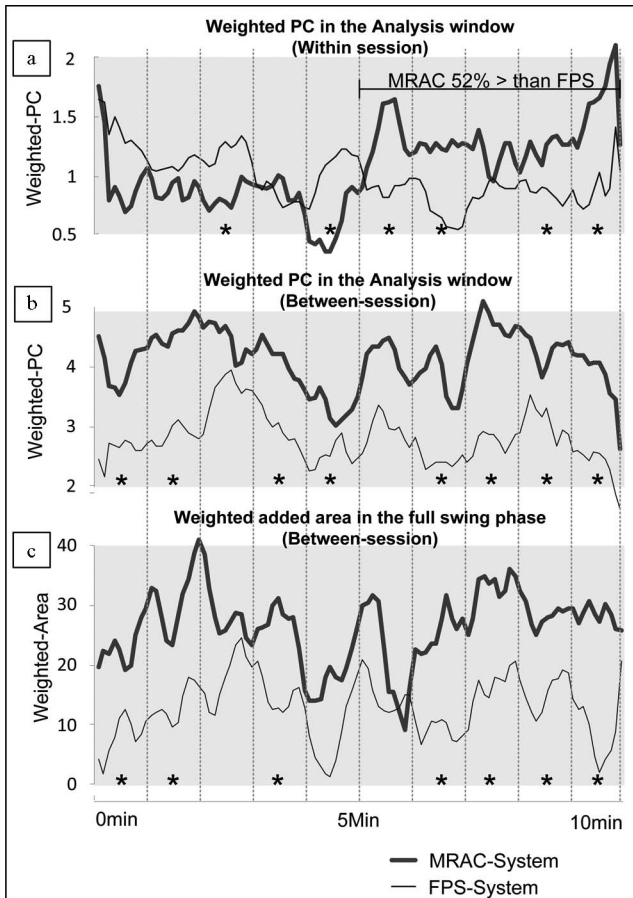


Fig. 6. (a) Overall across-subject development of the within-session weighted PC for the two controllers for the 10-min sessions. The session was divided in bins of 1 min and the \* indicates a significant difference between the controllers. After 5 min, the curves separated and MRAC system maintained a 52% larger weighted PC than the FPS system. (b) Between-session weighted PC. (c) Between-session weighted added area.

the aim for largest knee flexion and largest ankle dorsiflexion according to the earlier findings was incompatible, the MRAC system used the weight factors to reach a compromise. Furthermore, as a secondary effect, the MRAC system maintained a large response likely by minimizing the effect of habituation. Reduction of habituation by changing the stimulation site has been investigated by Dimitrijevic *et al.* [31] who observed that stimulation of sites 3–4 cm away from a habituated stimulation site still evoke a full response. Related findings were reported by Carstens *et al.* [32] who examined habituation in rats by testing tail flick by noxious radiant thermal stimulation. They observed that a habituated response at one site did not transfer to a site 0.75 cm from the habituated site. The MRAC system appeared to take advantage of this phenomenon.

### E. Gait-Phase Detection

In the offline analysis, steps with incorrect gait detection due to forefoot landings and minimal ground clearance were removed. However, this analysis is not possible to perform during online applications. When the adaptive plant model was updated, nonstereotyped steps had a larger impact on the baseline

model ( $\hat{Y}_B$ ) than on the reflex response model ( $\hat{Y}_{MA}$ ), since the acquired *baseline step* was used directly as baseline model without any preprocessing, and therefore, incorrect gait-cycle detection had a large impact on the neuromuscular plant model. In future experiments, this may be circumvented by applying a moving-average filter to the baseline model in order to reduce the impact of nonstereotyped steps. The gait-detection method used in this study was based on FSRs. This approach was primarily selected due to its low cost and ease of implementation, and despite its relatively poor accuracy [33], [34]. It is known that the ability of FSRs to accurately detect heel contact and toe contact in patients may be problematic. Therefore, offline analysis was needed in this study, so only accurately detected gait cycles were included in the analysis. However, for future applications, better gait-detection sensors are needed to detect gait events more reliably and accurately, e.g., a combination of accelerometers and tilt sensors.

### F. Use of the Habituation Level to Control the Stimulation Intensity

The overall within-session *weighted PC* (see Fig. 6) indicate that the reflex responses vary greatly for both systems. However, habituation was evident with the FPS system toward the end of the session, while the MRAC system maintained the response amplitude throughout the session. This is likely due to the varying stimulation parameters. In this first feasibility study, it was chosen to keep the stimulus intensity fixed. In future studies, the benefit of including variable stimulus intensity in the controller should be investigated. This could be beneficial in case the reflex starts to habituate, since varying the stimulus intensity might also help to dishabituate the reflex as demonstrated by Granat *et al.* [35], [36]. They investigated surface stimulation of the peroneal and saphenous nerves to obtain a synergistic flexor response of the hip and knee flexors, as well as the ankle dorsiflexors during the swing phase in spinal cord injured patients. They showed that habituation could be reduced by multiplexing between two stimulation sites and by applying single high-intensity pulses. Similar findings were obtained by Carstens *et al.* [32] who observed reflex dishabituation in rats following high-intensity tail pinching at another site.

The discomfort/painfulness caused by the stimulation argues against using a reflex-based gait support system as a take home device for long-term use. However, the promising results observed in studies applying FET suggest that if the reflex stimulations are applied only in a limited time span as a part of therapy, patients might accept a certain degree of discomfort caused by the stimulation intensities. In this study, none of the subjects expressed that they wanted to drop out of the study due to discomfort, and all reported that they would be willing to use the method as a therapeutic tool for a short period.

## V. CONCLUSION

Two online, real-time, swing phase controllers that exploit the nociceptive withdrawal reflex were designed, implemented, and tested in a single-session study on 11 chronic and subacute

hemiparetic subjects. The controller was an open-loop system using an FPS and a closed-loop system inspired by an MRAC.

Both controllers were equally good at providing knee support. For hip support, the FPS system was superior, while for ankle support, the MRAC system was the best. Further, both controllers resulted in a more functional gait compared to no stimulation as judged by generated joint trajectories approaching the targets. Moreover, the MRAC system performed better than the FPS system in terms of reaching the control target, which suggests that the MRAC system might be able to adapt better to the varying needs presented during lengthy rehabilitation therapy. Further clinical studies in acute and subacute hemiparetic patients are needed for investigating withdrawal-reflex-based gait support during daily therapy. This should reveal if it will facilitate gait rehabilitation by supporting the voluntary effort for establishing an appropriate, functional gait pattern.

#### ACKNOWLEDGMENT

The experimental studies were conducted at the University Rehabilitation Institute, Republic of Slovenia, Ljubljana, and at Aalborg University, Denmark.

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