The adaptive drop foot stimulator – Multivariable learning control of foot pitch and roll motion in paretic gait

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\textbf{A B S T R A C T}

Many stroke patients suffer from the drop foot syndrome, which is characterized by a limited ability to lift (the lateral and/or medial edge of) the foot and leads to a pathological gait. In this contribution, we consider the treatment of this syndrome via functional electrical stimulation (FES) of the peroneal nerve during the swing phase of the paretic foot. A novel three-electrodes setup allows us to manipulate the recruitment of m. tibialis anterior and m. fibularis longus via two independent FES channels without violating the zero-net-current requirement of FES. We characterize the domain of admissible stimulation intensities that results from the nonlinearities in patients’ stimulation intensity tolerance. To compensate most of the cross-couplings between the FES intensities and the foot motion, we apply a nonlinear controller output mapping. Gait phase transitions as well as foot pitch and roll angles are assessed in real-time by means of an Inertial Measurement Unit (IMU). A decentralized Iterative Learning Control (ILC) scheme is used to adjust the stimulation to the current needs of the individual patient. We evaluate the effectiveness of this approach in experimental trials with drop foot patients walking on a treadmill and on level ground. Starting from conventional stimulation parameters, the controller automatically determines individual stimulation parameters and thus achieves physiological foot pitch and roll angle trajectories within at most two strides.

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\textbf{1. Introduction}

In many cases, stroke leads to impaired motor function. Even after weeks of rehabilitation, many patients suffer from a limited ability to lift the inner (medial) or the outer (lateral) edge, or both, of the foot by voluntary muscle activation. This syndrome is known as drop foot (or foot drop), and it also appears in patients with other neurological disorders. As Fig. 1 indicates, foot drop leads to a pathological gait with an increased risk of fall. A common treatment is to fix the foot in the lifted (dorsiflexed) position by an orthosis. While this approach may improve safety and stability in the patient’s gait, it promotes muscle atrophy and joint stiffness.

Drop foot neuroprostheses, also known as peroneal stimulators, represent an alternative treatment that aims at generating a natural foot lift via activation of the patient’s shank muscles, cf. [1]. The technology known as Functional Electrical Stimulation (FES) facilitates the artificial generation of action potentials in subcutaneous efferent nerves by applying tiny\textsuperscript{1} electrical pulses via skin electrodes or implanted electrodes. By modulating the frequency or dimensions of these pulses, one can control the contraction of paretic muscles and induce movements in the affected limbs. Unfortunately, FES may also trigger action potentials in afferent nerves, causing discomfort at medium and pain at high stimulation intensities. In most subjects, however, the sensation is weak enough to allow the generation of functional movements without discomfort. Abundant research demonstrates the potential of FES in neuroprosthesis design, beyond the application of drop foot treatment, see for example [2] and references therein.

\textbf{1.1. Challenges and state of the art in research and industry}

For drop foot treatment, a few commercially available solutions make use of FES, some via skin electrodes, others via

\begin{footnote}{1} When using skin electrodes, e.g., 20–50 rectangular current pulses are applied per second, each having an amplitude of less than a tenth of an ampere and a pulse width of less than half a millisecond.
\end{footnote}
implanted electrodes. The review articles by Lyons et al. [3] and Melo et al. [4] provide an excellent overview of drop foot stimulators in research and industry and classify them in several ways. Until now, all commercially available devices have been solely based on open-loop architectures, they only use sensors to time the stimulation [4]. Most of them employ heel switches to detect two gait phases: one when the heel of the paretic foot is on the ground and the other when it is not. In each stride, as soon as the heel is lifted, FES is applied with a fixed stimulation intensity profile over time, typically a trapezoidal shape tuned by an experienced clinician. The ankle joint, however, exhibits two degrees of freedom that are actuated by the shank muscles in a nontrivial, coupled way. Thus, finding stimulation parameters that yield a physiological foot motion can be cumbersome, as illustrated in Fig. 1.

Moreover, FES dynamics are typically very time-variant. When activated by FES, muscles may fatigue rapidly [5]. Moreover, residual voluntary muscle activity as well as, for example, the muscle tone (spasticity) in antagonistic muscles often change within a few strides. In all of these cases, repeated manual adaptations of the intensity profile are required to maintain a physiological foot motion for more than a few strides. An obvious escape strategy that is often pursued is to choose larger stimulation intensities and accept exaggerated foot lift. While this strategy provides a certain amount of safety and functionality, increasing the stimulation intensity may accelerate muscular fatigue and lead to a salient peculiarity in the patient’s gait, cf. Fig. 1.

The described challenges can be faced in a much more effective and elegant way by the use of feedback control. The stimulation parameters can be adjusted automatically to delay the onset of fatigue and to induce the optimal level of foot lift. This requires measurement of the foot motion via, for example, an inertial sensor or a goniometer. It was recently demonstrated that a foot-mounted inertial sensor can be used to detect four gait phases [6] and to measure the foot orientation with respect to the horizontal plane [7]. See Figs. 2–4 for illustration.

1.2. Previous contributions on feedback control of drop foot stimulation

Despite increasing efforts in the last decades to make closed-loop gait neuroprostheses a reality, it is still a challenging task to control paralyzed limbs with FES [4]. Several control techniques have been proposed, and some respectable results have been obtained at least for the much simpler case of a sitting or lying subject, i.e. without the tight time constraints and the strong disturbances imposed by gait. For example, Kobravi and Erfanian [8] and Valtin [9] proposed a fuzzy controller and an iterative learning controller, respectively, and performed experimental trials with sitting subjects. Hayashibe et al. [10] and Benedict and Ruiz [11] suggested the use of predictive control and PID control, respectively, but tested their controllers in simulation studies only. Artificial neural networks were employed by Chang et al. [12] and Chen et al. [13], who validated the controller in trials with subjects lying on a bed.

Besides those experimentally simplified studies, intense efforts have also been made to close the loop on FES during walking. Veltink et al. [14] used an inertial sensor on the foot to tune an implantable drop foot stimulator such that a desired foot orientation just prior to initial contact was achieved. Negård [15] proposed run-to-run control of the maximum foot pitch angle occurring during swing phase and tested the controller in trials with a walking drop foot patient. Previously, Mourselas and Granat [16] had briefly reported similar results obtained with a bend sensor and a fuzzy logic algorithm.

While these latter results represent important technical improvements with respect to all commercially available stimulators, one major shortcoming remains: The entire foot motion is reduced to a single scalar measure, for example a minimum foot clearance [17] with respect to ground or a desired foot pitch angle at initial contact. Obviously, this is a strong simplification of the control problem. As we will demonstrate, conventional stimulation intensity profiles may yield (for example) a desired maximum foot pitch angle, while causing too weak or too strong foot lift during the
In a recent conference article, we demonstrated that ILC can be employed for the two-dimensional problem of controlling both the foot pitch and the foot roll motion simultaneously [19]. To the best of our knowledge, this is the first time that automatic feedback control of the entire foot pitch and roll angle trajectory is achieved in walking drop foot patients. In the present contribution, we explain the methods that enabled this result, and we extend the approach by taking the cross-couplings between the FES parameters and both foot orientation angles into account. To this end, we first describe the motions that are caused by applying two-channel FES via a three-electrodes setup. Since both the pitch and roll angle of the foot are influenced by both FES channels, we adopt a nonlinear decoupling strategy that facilitates the implementation of a decentralized ILC scheme. In contrast to the vast majority of previous contributions, we demonstrate the effectiveness of this approach in drop foot patients walking on a treadmill and on level ground. The remainder of this contribution is organized as follows. In Section 2, we discuss the basic principles of FES-induced foot motion and propose a three-electrode setup that enables the manipulation of two independent stimulation intensities (pulse charges) via only three surface electrodes and, nevertheless, ensures a zero net current. Subsequently, in Section 3 we use a pair of nonlinear FES intensity parameters to solve the problem of interdependent saturation limits in multi-channel FES and compensate most of the multivariable cross-couplings between the stimulation intensities of both channels and the foot motion they trigger during gait. With

Fig. 2. Illustration of the transitions (arrows) between the four gait phases (ellipses) that are detected in realtime using the measured angular rate and acceleration of a foot-mounted inertial sensor.

Fig. 3. Definition of the foot pitch angle (corresponding to dorsiflexion) and the foot roll angle (corresponding to eversion/inversion) of the foot. Note that both angles are defined with respect to level ground and that their signs are defined such that both the pitch and the roll angle of the patients are smaller than those of healthy subjects at the same moment of swing phase.

first half of the swing phase, or while using larger intensities than necessary.

With respect to overcoming these limitations, it was demonstrated in [18] that iterative learning control (ILC) can be used to control the entire foot pitch angle trajectory of drop foot patients during the swing phase, cf. Fig. 4. This approach yields a stimulation intensity profile over time that induces a foot motion close to those of healthy walkers, while using only as much FES as needed. However, the roll motion of the foot is neglected completely, which represents a strong simplification.

Fig. 4. Pitch and roll angle trajectories (average lines ± standard deviation bands) of healthy subjects (left) and of a drop foot patient who received zero, optimal and overdosed FES support (right). In conventional drop foot stimulators, a physiological foot motion can be achieved by iteratively repositioning the stimulation electrodes and adjusting the stimulation intensity (optimal FES). In the trial labeled standard FES, we omitted this commonly suggested, but tedious procedure. The result is an outwards foot roll (eversion) that is much stronger than the physiological variability in the gait of healthy subjects. Vertical lines indicate average gait phase transition times.

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Generation of a secondary stimulation effect (i.e., between toe-off and initial contact) is enabled by the use of the peroneal nerve. The electrode is placed directly into the peroneal nerve, which is sensitive to stimulation from the percutaneous stimulator. During swing phase, the stimulation is applied to the tibialis anterior muscle. In contrast, during the support phase, the stimulation is applied to the flexor hallucis longus muscle, which is sensitive to stimulation from the percutaneous stimulator. The stimulation is applied for 200 ms, and the stimulation intensity is varied between 0 and 100 mA. The stimulation is applied in a rectangular waveform, with a frequency of 50 Hz. The stimulation is applied to the subject while they are standing on a treadmill.

2. Inducing foot pitch and roll motion by FES

The human ankle includes the talocrural joint and the subtalar joint. The former admits dorsiflexion and plantarflexion, while the latter allows inversion and eversion. In contrast, the subtalar joint allows for supination and pronation, which corresponds to rotation of the foot about a combined pitch, roll, and yaw axis that is oriented 16° from the sagittal plane and 42° from the horizontal plane. Since this implies that every yaw motion of the foot is directly affiliated with a roll motion, we can disregard the yaw motion and characterize the rotational state of the foot entirely by the pitch and roll angle, cf. Figs. 3 and 4.

The peroneal nerve divides into a superficial and a deep branch, which innervate the m. fibularis longus and m. tibialis anterior, respectively, as depicted in Fig. 5. In a standard drop foot stimulator, both muscles are activated by positioning a pair of skin electrodes on the skin above the nerve branches and applying symmetric biphasic pulses between the electrodes. Since the peroneal nerve is a fundamental requirement, since a non-zero net current through the body is known to cause electrolysis and tissue damage in the long term.

To assure a straight foot lift at least for a few minutes, both electrodes must be carefully placed on the frontal and the lateral side of the upper region of the shank (just below the knee) and the stimulation intensity must be well chosen. Some recent contributions suggest the use of electrode arrays in combination with a search algorithm that finds the best position of a virtual electrode consisting of one of multiple array elements, see for example [9,22,23]. At the current state of the art, however, this identification takes several minutes, and the virtual electrode is not adjusted when muscle tones or FES dynamics (and thus the induced foot motion) change during walking.

As an alternative to such precise-placement-and-parameterization approaches, two-channel stimulators have been proposed by several authors, for example [14,24–26]. When transcutaneous FES is applied via skin electrodes, two channels typically require the use of four electrodes. In contrast, we propose a setup with three electrodes, as illustrated by Fig. 6. FES pulses with the third electrode acting as cathode are found to cause almost no muscle contraction in drop foot patients and only weak recruitment of m. fibularis longus in healthy subjects. Therefore, we use it as common counter electrode, i.e., as cathode for the balancing pulse of both the frontal and the lateral electrode pulse. Both bi-phasic pulses are applied subsequently within the 20 ms time window of each stimulation period. The product of pulse width and current amplitude of the first channel (the lateral FES channel) shall be denoted by \( q_{\text{lat}}(t) \), while the product of pulse width and current amplitude of the second channel (the frontal FES channel) shall be denoted by \( q_{\text{fro}}(t) \). Even if these two intensities are chosen independently, the net current is zero for each stimulation period and for each electrode.

As discussed above, the motion that is induced by FES depends on the subject, varies with time, and is sensitive to small changes in the electrode positions. In most subjects, however, the proposed setup leads to the following observations: the frontal FES channel mainly recruits m. tibialis anterior, which raises the inner edge of the foot and thereby causes a combined foot pitch and roll motion. On the contrary, the lateral FES channel recruits mainly m. fibularis longus and causes foot roll in the opposite direction (by lifting the outer edge of the foot) along with foot pitch (especially at larger intensities \( q_{\text{lat}} \)). By balancing the intensities of both channels, a straight foot lift is easily achieved in almost every subject with almost every reasonable electrode placement.

3. Choosing suitable stimulation intensity parameters

The force generated by FES increases monotonously with the frequency and the charge (i.e., the product of pulse width and amplitude) of the applied current pulses. Therefore, adjusting the stimulation intensity typically relates to adjusting either (or both) of these quantities. For the sake of brevity, we assume a fixed pulse frequency of 50 Hz and manipulate only the pulse charge. In order to avoid high and narrow pulses as well as low and wide pulses, we implement all stimulation intensity changes in such a manner that pulse width and amplitude are always increased or decreased by the same factor, i.e., their ratio remains constant.

Before FES can be applied in a control system that automatically adjusts stimulation intensities, it is advisable to identify the maximum tolerated intensity of the subject and make sure that this value is never exceeded. In the current application, these values are easily identified for both stimulation channels individually. However, when stimulation is applied to both electrodes, the subject feels the combined sensation and typically tolerates only 70–80% of the single-channel maximum intensities. More precisely, let \( q_{\text{lat}} \), \( q_{\text{fro}} \), and \( q_{\text{lat}} \) be the maximum tolerated stimulation intensities for the lateral electrode, for the frontal electrode, and for equal stimulation via both electrodes, respectively. Then, with\footnote{\textsuperscript{5} i.e., in the order of 1 cm.} \footnote{\textsuperscript{6} i.e., the maximum pulse charge that causes neither discomfort nor pain.} \footnote{\textsuperscript{7} Note that this is an arbitrary choice and that the proposed methods work equally well with other stimulation frequencies.} \footnote{\textsuperscript{8} Note that the same phenomenon is observed if a larger common counter electrode is used and if separate counter electrodes are used for each channel.} \footnote{\textsuperscript{9} Scaled to the stimulator maximum pulse charge of about 20 \( \mu \text{C} \).} \footnote{\textsuperscript{10} i.e., \( q_{\text{lat}} \) and \( q_{\text{fro}} \) are increased simultaneously until the patient reports discomfort.}
We propose a two-channel solution, in which the third electrode serves as common counter electrode for both stimulation channels. Foot pitch and roll can now be influenced by balancing the channel intensities \( q_{lat}(t), q_{fro}(t) \). Furthermore, a foot-mounted inertial sensor enables realtime control of the foot motion by adjustments of these intensities.

![Diagram](image)

**Fig. 6.** (a) Classic drop foot stimulators apply current-balanced FES pulses between a lateral electrode and a frontal electrode, which yields a balanced foot lift (at least shortly) if the electrode positions and the intensities are carefully chosen. (b) We propose a two-channel solution, in which the third electrode serves as common counter electrode for both stimulation channels. Foot pitch and roll can now be influenced by balancing the channel intensities \( q_{lat}(t), q_{fro}(t) \). Furthermore, a foot-mounted inertial sensor enables realtime control of the foot motion by adjustments of these intensities.

\[
\begin{align*}
q_{lat}(t) & = i_{lat}(t) \Delta t_{lat}(t) \\
q_{fro}(t) & = i_{fro}(t) \Delta t_{fro}(t)
\end{align*}
\]

**Fig. 7.** (a) The domain of stimulation intensity combinations that are tolerated by the subject is defined by the initially determined maximum tolerated values \( q_{lat}, q_{fro}, u \). It can be parameterized by the polar-type coordinates \( u_\Sigma, \rho \). (b) These new coordinates can be chosen independently of each other within their defined ranges. Every point in this rectangle corresponds to one specific point in the quadrangular set of admissible stimulation intensities.

\[
\begin{align*}
q_{lat} & \text{ [20 μC]} \\
q_{fro} & \text{ [20 μC]} \\
\rho & \text{ [-1, 1]} \\
\rho & \text{ [-1, 1]}
\end{align*}
\]

![Diagram](image)

**4. Improving FES parameters by realtime learning control**

We will now design a controller network that manipulates the FES intensity parameters in order to influence the orientation angles of the paretic foot during walking. Recall that the gait events heel-off \( t_{h,j} \), toe-off \( t_{t,j} \), initial contact \( t_{ic,j} \) and full contact \( t_{fc,j} \) of the paretic foot are detected in realtime for every stride. Recall furthermore that the control objective is to manipulate the stimulation intensity parameters \( u_\Sigma(t) \in [0, 1] \) and \( \rho(t) \in [-1, 1] \) such that the pitch and roll angle trajectories \( \alpha(t), \beta(t) \) during swing phase resemble those of healthy subjects.

In order to formulate drop foot stimulation as a repetitive control task, we follow the arguments and mathematical notations...
of [18] – the reader is kindly advised to refer to this reference for detailed arguments on the controller design and to Seel et al. [27] for further mathematical insight. We apply the methods presented therein to the current pitch and roll angle control task. Precisely, let the trajectories of the stimulation intensity parameters \( u_{ij}(t) \) and \( \rho(t) \) of stride \( j \) be denoted by
\[
\begin{align*}
\mathbf{u}_{x,j} &:= [u_{\Sigma}(t_0,j), u_{\Sigma}(t_0,j + t_s), \ldots, u_{\Sigma}(t_0,j + (\pi - 1)t_s)]^T, \\
\mathbf{u}_{\rho,j} &:= [\rho(t_0,j), \rho(t_0,j + t_s), \ldots, \rho(t_0,j + (\pi - 1)t_s)]^T,
\end{align*}
\]
and let the resulting pitch and roll angle trajectories be denoted by
\[
\begin{align*}
\alpha_j &:= [\alpha(t_0,j + \delta t_s), \alpha(t_0,j + \delta t_s + t_s), \ldots, \alpha(t_n,j)]^T, \\
\beta_j &:= [\beta(t_0,j + \delta t_s), \beta(t_0,j + \delta t_s + t_s), \ldots, \beta(t_n,j)]^T,
\end{align*}
\]
where \( t_s \) is the sampling interval, \( \delta t_s = 0.2 \) s compensates most of the delay of FES dynamics, \( \pi \) is an upper bound on the pass length \( n_j := \lfloor \frac{t_n,j - t_0,j}{t_s} \rfloor + 1 \) and the start time \( t_0,j \) of each stride \( j \) is determined in real-time based on the detected gait phase transitions [cf. [18]].

In the first stride, when no measurement information from previous strides is available, a conservative strategy is advisable: for example, we may set \( \mathbf{u}_{x,0} \) to constant zero (corresponding to \( q_{x0} = q_{\alpha0} \)) and \( \mathbf{u}_{\rho,0} \) to a trapezoidal profile with an amplitude of 0.9 (corresponding to 90% of the maximum tolerated intensities) and a considerably short rise time. In most patients, this assures a safe swing phase with sufficient but most likely exaggerated foot pitch and roll.

At the beginning of each following stride, we use the deviation between the measured angle trajectories \( \alpha_j, \beta_j \) and the first \( n_j \) samples \( \bar{\mathbf{u}}_{x,j} \) of the respective reference trajectories \( r_{x,j}, r_{\beta,j} \) to adjust the controller output trajectories by using the following modified version of a standard ILC learning law [27]:
\[
\begin{align*}
\mathbf{u}_{x,j+1} &= \text{sat}^{+1}_{\alpha} \left( \mathbf{Q} \mathbf{u}_{x,j} + \lambda_{\alpha} I_{n \times n} \left[ \begin{array}{c} r_{x,j} - \alpha_j \\ 0 \end{array} \right] \right), \\
\mathbf{u}_{\rho,j+1} &= \text{sat}^{+1}_{\beta} \left( \mathbf{Q} \mathbf{u}_{\rho,j} + \lambda_{\beta} I_{n \times n} \left[ \begin{array}{c} r_{\beta,j} - \beta_j \\ 0 \end{array} \right] \right),
\end{align*}
\]
where \( \lambda_{\alpha, \beta} \in \mathbb{R}_{+} \) are adjustable learning gains, and \( \text{sat}^{\lambda}_{b}(\cdot) \) denotes element-wise saturation to the interval \( [a, b] \). Furthermore, \( \mathbf{Q} \in \mathbb{R}^{n \times n} \) is a symmetric matrix with Toeplitz structure containing the Markov parameters of a lowpass filter (2nd order, Butterworth) with cutoff frequency denoted by \( f_{Q} \).

The rationale behind this learning approach is as follows: when a certain section of an angle trajectory is lower than it should be, the update law (6) increases the corresponding section of the respective controller output trajectory. On the contrary, whenever the foot pitch or roll is stronger than necessary, the respective stimulation intensity parameter is reduced.

The learning gains \( \lambda_{\alpha, \beta} \) as well as the cutoff frequency \( f_Q \) of the Q-filter are chosen according to the guidelines for ILC design in variable-pass-length systems given in [27] and based on experimental data from [18,28]. From both, we conclude the following for both the pitch and the roll control task: choosing a Q-filter cutoff frequency of \( f_Q = 5 \) Hz limits the learning to a reasonable frequency range; a phase-lead of \( \delta t_s = 0.2 \) s compensates most of the slow FES and muscle dynamics; and a learning gain of \( \lambda = 0.5 \) yields fast convergence without overshoot.

5. Experimental evaluation in stroke patients

In experimental trials with drop foot patients, we now evaluate the previously designed ILC scheme in combination with decoupling parameterization proposed in Section 3. The four patients that were recruited for these trials are ambulatory, aged 50–70, BMI 20–27, at least three months post-stroke and suffer from a drop foot syndrome in combination with at most moderately increased muscle tone (hypertonia) of the leg musculature. Some of them use a walking stick or an ankle-foot orthosis in everyday walking. All of them have used FES before (at least three sessions of at least 30 min). Informed consent of the patients was obtained and the trials have been approved by the ethics committee of Charité Universitätsmedizin Berlin.

Initially, we determine the maximum tolerated stimulation intensities \( q_{x0}, q_{\alpha0}, q_{\beta0} \) of each patient by increasing the intensities of both FES channels (each individually and then both together, respectively) until the patient reports discomfort. These values are then used to implement the previously defined controller output mapping, along with the decentralized ILC network, on a real-time computer system.

During the subsequent evaluation trials, the patients walk at constant, self-selected speed on a treadmill and on level ground. A wireless inertial sensor is attached to the paretic foot and three FES electrodes are placed on the shank as depicted in Fig. 6. The measured accelerations and angular rates are used to calculate the current gait phase as well as the foot pitch angle and roll angle trajectories for each stride in real-time, as described in [6,7].

Before evaluating the automatic adaption of the ILC, we briefly investigate the effect of both stimulation channels on the foot motion of each patient. We find that, for each patient, a desirable foot motion is only obtained by a combination of both FES channels. Fig. 8 presents the angle trajectories of a patient for four different manual FES intensity settings. Stimulating both channels individually leads either to excessive inversion or to excessive eversion, whereas a manually optimized (balanced) FES leads to sufficient foot lift at almost neutral eversion/inversion (cf. Fig. 4).

We then investigate whether such an optimized FES intensity setting can be automatically identified by the proposed iterative learning control algorithms. For the first stride \( j = 0 \), we choose \( \mathbf{u}_{x,0} \) and \( \mathbf{u}_{\rho,0} \) as trapezoidal input profiles with manually chosen heights and rise times. After each stride \( j \geq 0 \), during the short period of time for which the heel and toes of the paretic foot are on the ground, the controller uses the measured pitch and roll angle trajectories \( \alpha_j, \beta_j \) to adjust the stimulation intensities \( \mathbf{u}_{x,j+1}, \mathbf{u}_{\rho,j+1} \) automatically according to the update law (6).
(a)

During the subsequent stride $j+1$, stimulation intensity trajectories $q_{op}(t)$, $q_{ol}(t)$ are applied via the frontal and lateral electrode, according to the nonlinear controller output mapping (1) and (2).

Results from a representative trial are depicted in Fig. 9. The desired foot pitch and roll angle trajectories are indicated by large circle markers to improve readability and to emphasize that, in practice, perfect tracking is not required. Instead, any trajectory that is close to $r_{\alpha}$ (or $r_{\beta}$) is desirable. For each sample instant of a stride, the curves in the upper and lower subplot indicate the foot orientation measurements and FES parameter values, respectively. The solid segments of these curves indicate the actually applied sections $\mathbf{u}_{\alpha,j}$, $\mathbf{u}_{\beta,j}$ of the input trajectories (3) and the output trajectories (4).

To improve comprehensibility, we briefly explain the learning process that is evident in Fig. 9a. The manually chosen initial stimulation intensity trajectories $\mathbf{u}_{\alpha,0}$, $\mathbf{u}_{\beta,0}$ induce a foot motion with too weak foot pitch $\alpha_0$ and strong negative roll $\beta_0$, i.e. the foot drops and exhibits inversion similar to the foot depicted in Fig. 1a and d. Consequently, the controller prepares input profiles $\mathbf{u}_{\alpha,1}$, $\mathbf{u}_{\beta,1}$ with increased values of $u_{\alpha}(t)$ and $\rho(t)$ for the next stride. The resulting output trajectories $\alpha_1$, $\beta_1$ of the second stride exhibit clearly better foot lift and less inversion. Therefore, the controllers perform only minor adaptations of the FES parameters in the following strides.

For each patient, similar trials with different initial profile heights are performed. If, for example, the initial FES parameters are chosen conservatively high to assure a safe (but exaggerated) foot lift during the first stride, then a foot motion with too large foot pitch $\alpha_0$ and roll $\beta_0$ is induced. Thus, the stimulation intensities $\mathbf{u}_{\alpha,0}$, $\mathbf{u}_{\beta,1}$ are reduced before the next stride. Just as before, we find that the deviations of foot pitch and roll are reduced quickly to the physiological range that is observed in healthy subjects’ gait. Across the four patients and throughout a large number of trials, this convergence required at most two strides.

Due to the natural fluctuation of many FES parameters and gait parameters, tracking accuracies below the few-degrees level are not achieved in any of the trials. However, more than fifty further walking trials confirm that the controllers quickly achieve the desired foot motion. Moreover, we find that, by persistent adaptation, the physiological foot motion is maintained, even when the patient modifies his/her walking style (for example by increasing knee flexion during swing phase and decreasing cimrculation). In walking trials with a duration of up to ten minutes, we find that setting constant intensity profiles leads to a slow deterioration of the foot motion, which is caused by muscular fatigue. When the ILC is activated, it compensates these time-variant effects by automatically raising the intensities as much as needed to maintain the desired foot motion.

For all four patients, the trials yield similar results and findings. Since this contribution only aims at providing a proof of concept rather than a clinical study, the characteristics of each individual are not analyzed in detail. It is, however, important to note that the iterative learning process leads to highly individualized FES parameters that may vary largely from one patient to the next (and often from day to day within one patient), even if the same FES parameterization and reference trajectories are used. Fig. 10 illustrates this fact using the example of the roll angle control results obtained in the four different patients.

Fig. 9. Experimental results of ILC with polar-type FES parameters in a drop foot patient. (a) Starting from non-individualized values, the controller adjusts the FES parameters from stride to stride and thereby achieves the desired foot motion during swing phase. Dots mark heel-off and initial contact of each stride. (b) The deviations (root-mean-square errors) from the desired pitch and roll trajectories are reduced to the ranges found in healthy subject data within at most two strides.

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In the previous section, we furthermore found that the individualized patterns change from one patient to the next and often from day to day within one patient. In current clinical practice, however, the same stimulation pattern is used day after day. In some cases, this might lead to acceptable results, but it will hardly ever yield optimal results. Previous studies found that the required amplitude varies “from day to day due to a number of factors: changes in skin resistance due to sweating or dryness of the skin, condition of electrodes and fatigue and changes in resistance to dorsiflexion caused by spasticity of the calf muscles” [30].

Beyond this, some of the patients participating in the current evaluations reported that their muscle tones, and thus their foot motions, change when they get nervous, for example while crossing a street. The significance of such short-time changes should be subject of further studies. The proposed setup with a foot-mounted inertial sensor facilitates such investigations.

With respect to time-variant FES dynamics, we found in the previous section that changes in the subject’s walking style and fatigue-related changes are automatically compensated. It should be noted that when and to which extent fatigue occurs depends on the individual patient and on the FES parameters. The muscles of well-trained patients will obviously fatigue later than those of subacute stroke patients, who might nevertheless benefit from using the proposed system during early rehabilitation. Regardless of the individual patient, the onset of fatigue might be delayed by reducing the stimulation frequency from 50 Hz to 25 Hz, for example. All described mathematical methods work equally well at this reduced stimulation frequency.

We believe that the proposed system and the experimental results represent a technological breakthrough in drop foot treatment. However, every technological milestone should be followed by an elaborate clinical evaluation. The grade of improvement should eventually be judged in light of improvements for the patients. Hence, future studies should focus on outcome measures with strong clinical relevance and on patients’ perception. It is an open medical research question to which extent clinical outcomes are improved by an automatic intensity optimization, by reducing excessive eversion and by delaying the onset of fatigue. Regarding usage of the adaptive drop foot stimulator as an everyday-support device for chronic drop foot patients, further developments and evaluation studies are advisable, especially with respect to activities of daily living or to walking stairs and slopes.

Finally, we shall note that foot drop is often accompanied by weak knee flexion or other gait impairments. Therefore, it should be a longtime goal to support not only dorsiflexion and eversion of the foot. Additional inertial sensors might be employed to determine ankle and knee joint angle [31] and additional FES channels might be employed to support, for example, ankle plantarflexion (push-off) and knee flexion.

7. Conclusions

FES-based drop foot treatment via surface electrodes has been considered. Benefits of a closed-loop approach were discussed, as well as the challenges arising from the multidimensionality of this task and from large delays and disturbances. We proposed a three-electrode setup that allows us to recruit m. tibialis anterior and m. fibularis longus via two independent FES channels without violating the zero-net-current requirement. We then characterized the domain of admissible stimulation intensities that is defined by the patient’s maximum tolerated intensities. A nonlinear decoupling scheme was applied to facilitate decentralized iterative learning control of foot pitch and roll with independent input saturation limits and anti-windup. Experimental trials with drop foot patients revealed that predefined pitch and roll angle trajectories are achieved by the controller within only two steps of learning.
Unlike existing drop foot stimulators, the proposed system adapts the electrical stimulation to the needs of a specific patient on a specific day with a specific electrode placement and maintains a physiological foot motion even in the presence of disturbances.

**Ethical approval**

Informed consent of the patients was obtained and the trials have been approved by the ethics committee of Charité Universitätmedizin Berlin (Number EA2/015/13).

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**Competing interests**

None declared.

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**References**


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