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DEVELOPMENT OF A GAIT RE-EDUCATION SYSTEM IN INCOMPLETE SPINAL CORD INJURY

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***Objective:* The aim of the paper is to present the development of a system for swing phase restoration in patients with incomplete spinal cord injury.**

***Methods:* The functional electrical stimulation based gait re-education system comprises a sensory system, a system providing cognitive feedback and a motor augmentation system facilitating and correcting the movement of the swinging extremity. Mathematical algorithms estimate swing quality and classify the swing phase of walking into 3 levels, termed cognitive feedback, which is provided to the patient as an auditory signal. A single-channel peroneal functional electrical stimulation was applied as a motor augmentation system to provide the patient with the motor assistance required. The important novelty of the proposed system is that motor assistance is provided only at the level that enables the patient to perform a good swing.**

***Results:* The developed system was tested in a patient with incomplete spinal cord injury, with C4–5 lesion, whilst walking on a treadmill. The results show that the automated sensory-driven functional electrical stimulation augmentation system, providing only the minimal assistance required based on the subject's performance, is a viable approach that successfully releases a therapist from the task of delivering properly timed stimulation of adequate intensity in assisting the swing phase of walking.**

Key words: central nervous system, electrical stimulation, sensory system, gait re-education, treadmill walking.

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INTRODUCTION

Over the last few decades there has been a trend of increasing numbers of incomplete spinal cord injuries (SCI), where one leg is usually considerably more affected than the other. One of the main goals of rehabilitation in paretic individuals is improvement of walking ability. Within the last 10 years novel methods of neurological rehabilitation have been developed which take into account the plasticity of the injured central nervous system (CNS). A general methodological framework has been developed which emphasizes that sensory and motor augmentation should be set at the level that enables the execution of the practised task, thus facilitating the reorganization of the injured CNS, leading to functional improvement. When the functional task is walking, treadmill training with partial body weight support (BWS) is the method that has been developed over the years and is used today in most rehabilitation environments. Several large-scale controlled clinical studies (10) have proven the efficacy of the approach in acute as well as chronic conditions. Unfortunately, the major deficiency of the proposed method is that it requires a therapist to assist the walking subject. The therapist sits alongside the treadmill assisting the stepping movements of the paretic leg, which involves the therapist in strenuous work under ergonomically unfavourable conditions. Additionally, the assistance provided by the therapist is variable. This variation is even more pronounced with greater training time and increasing fatigue of both the therapist and the walking subject.

Different robotic systems have been developed (GaitTrainer (8), LOCOMAT (5)) providing symmetrical and repeatable gait-like training on a treadmill. Unfortunately, as these devices have limited degrees of freedom the walking practice is also somewhat restricted. In addition, these devices are expensive. A viable alternative to the mechanical powered orthosis is functional electrical stimulation (FES), which has a long tradition as an orthotic and therapeutic aid in the rehabilitation of walking after paraparesis (1). Direct stimulation of motor neurones, artificial activation of spinal neural circuits and stimulation of dermatomes have been employed successfully to augment artificially the movement of the affected lower extremity, usually during the swing phase. Years of clinical practice have shown that a single-channel peroneal stimulation is adequate assistance for correcting the condition of foot-drop or provoking flexion of the hip, knee and ankle in people with incomplete SCI.

It was therefore a natural step to combine the method of treadmill BWS training with single-channel FES, aiming to relieve the therapist from the task of manually assisting movement of the paretic extremity. Hesse (7) and Field-Fote (6) have clinically tested the above approach successfully and have demonstrated that such a practice has even better results than classical treadmill with BWS walking training when the application of FES is carefully controlled. Their experience has shown that such a combination of treadmill training with BWS and FES can only be effective when an experienced therapist manually controls the timing and intensity of the stimulation and

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visually evaluates the quality of the swings performed and continuously provides verbal feedback to the walking subject.

These findings motivated us to develop a system of multiple sensors for walking assessment and provision of cognitive feedback (4) with the goal of making the training process more objective and thereby also repeatable. The system developed enabled acquisition and assessment of the quality of the swing phase of walking while training on the treadmill. The system was tested in a person with an incomplete SCI level C4–5 injury and the results have shown that: (i) the subject was able to voluntarily improve the swing and thereby also improve their walking; and (ii) the timing of FES triggering was crucial, meaning that auditory feedback was also an important cue to the therapist who controlled the triggering and the intensity of the single-channel FES system augmenting the swinging of the paretic extremity.

The above work indicates the need for a fully automated sensory driven FES augmentation system that, based on the processed information acquired by the sensory system, apart from assessing and evaluating the swing phase and providing cognitive feedback signal to the patient, would also determine the proper timing and intensity of stimulation. The neuro-rehabilitation training incorporating automated FES augmentation, which depends on patients' performance, could further maximize the efficacy and quality of training.

METHODS

Control strategy

The backbone of the approach we propose consists of 2 feedback control loops, the cognitive feedback loop and the FES control loop (Fig. 1). In the first and more important feedback loop the patient is part of the strategy. The processed sensory information, which represents the estimated swing quality information, is provided as auditory feedback. The swing quality estimation is based on multisensor integration. Data assessed from knee goniometer, accelerometers and gyroscope are used to determine the numerical value (4), which represents a comparison with the desired reference swing. The reference swing movement could be captured either from the less affected lower extremity of the patient with SCI or determined as the trajectory of the lower extremity in a neurologically intact individual. The numerical value is provided to the patient as auditory feedback at 3 different levels. The levels are presented as 3 different frequencies. The low frequency indicates an adequate to poor swing, the middle frequency indicates a sufficient swing and the high frequency represents a good performed swing phase. The feedback described is simple enough to be understood during walking and enables the patient voluntarily to improve the swing of his affected lower extremity. A more detailed description of the sensory system developed and processing algorithms utilized is provided in (4).

The FES control loop is based on the assessed sensory information and the swing phase quality. The sensors provide the information necessary to determine the moment of triggering of the electrical stimulation. Since we use single channel peroneal nerve stimulation to provoke the flexion response, i.e. simultaneous hip and knee flexion and ankle dorsiflexion, we have to make sure that the moment of triggering will take place before the initial swing phase. The swing phase can be divided into pre-swing, initial swing phase, mid-swing and terminal swing (9). We defined the appropriate moment of FES triggering using the information from the knee goniometer. When knee flexion occurs, the heel-off phase takes place and from numerous trials this appeared to be the most adequate triggering moment for peroneal stimulation.

Swing quality (4) is the term used to describe the correlation between the actual and the desired trajectory of the swinging limb and is the most important parameter used to control the stimulation amplitude. The stimulation amplitude is pre-set by the physiotherapist at the beginning of the session and depends on the observed deficiencies of a particular subject. During treadmill walking the quality of the swing phase is estimated and on the basis of this information the stimulation amplitude is adjusted. After every swing phase the quality estimate is stored. The user can pre-set the number of swings required for stimulation amplitude adjustment. When the pre-set number of good swings is performed, the stimulation amplitude is decreased. A succession of good swings means that the patient has managed to walk adequately; therefore the level of FES motor augmentation can be decreased. Conversely, in the case of a number of successive poor swings, the level of FES motor augmentation was not sufficient and did not allow the subject to perform adequately. Therefore, the stimulation amplitude is increased.

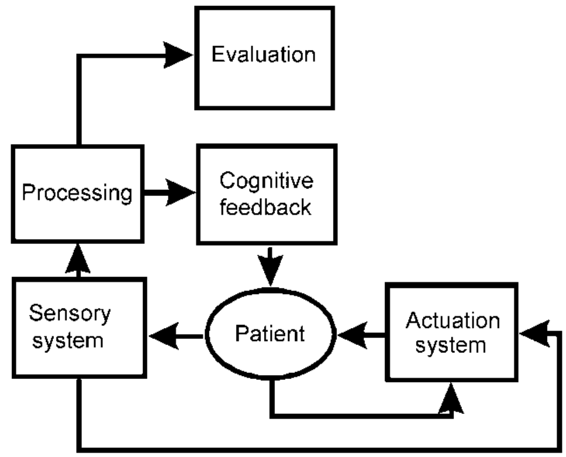

Fig. 1. The concept of functional electrical stimulation gait re-education. Two loops are presented. The automatic actuation control loop is supported by a sensory system and the cognitive feedback loop includes the patient and his voluntary activities.

Instrumentation

The developed system (Fig. 2) was applied to a patient with incomplete SCI and tested in the rehabilitation centre. Most of the processing was managed by personal computer (PC, Pentium III 500 MHz), based on a Windows platform. The supervisor software, enabling set-up of the triggering and initial stimulation intensity, was programmed in Matlab/Simulink and C++. Signals were assessed by a multi-sensor device (4), consisting of 2 pairs of single cross-axial accelerometers and a gyroscope encased in a plastic housing. The rectangular device box was placed on the shank of the patient using 2 Velcro straps in the longitudinal axis aligned with the shank. Misalignment of the device in the longitudinal axis had no significant effect on results. Goniometers were placed at the ankle and knee joints in order to assess knee and ankle angle trajectories. The ankle goniometer had no other function than measurement, while the knee goniogram was used to trigger the FES and was also implemented in the sensory integration algorithm. The algorithm estimated the quality of the swing phase (4). The term "quality" here expresses the level of agreement with the chosen reference swing. The competent information is the acceleration trajectory of the foot. The user-friendly software provided several options to pre-set the required knee angle and thus the moment of triggering, the required knee flexion for good swing phase, the number of swings required for automatic stimulation amplitude adjustment and the parameters of the FES. We chose the clinically well-accepted single channel surface peroneal nerve stimulation with the following parameters, stimulation frequency 20 Hz, pulse width 200 μs and current 35 mA.

RESULTS

One male patient with incomplete SCI (height 1.75 metres,

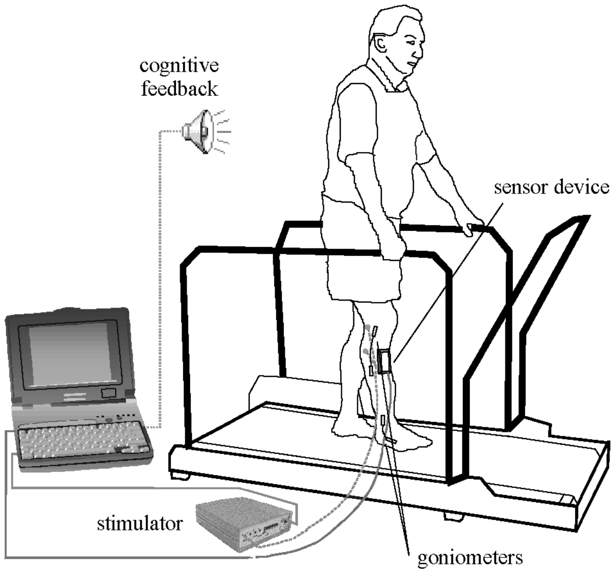

Fig. 2. Functional electrical stimulation re-education set-up. The multisensory system is attached to the shank of the patient. Data processing carried out by a personal computer, which provides cognitive feedback and controls the electrical stimulation, triggering and intensity.

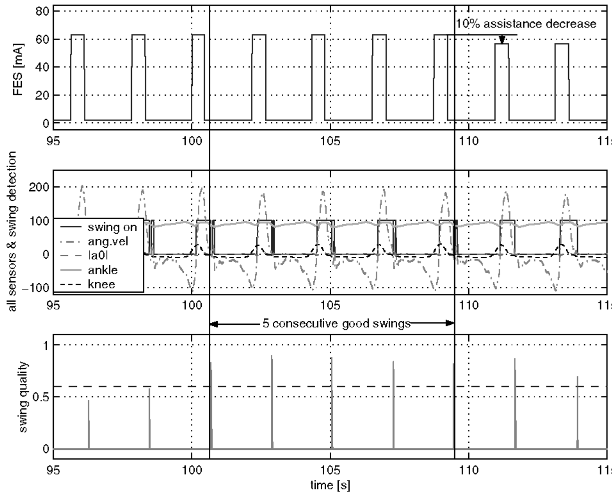

Fig. 3. The presence and the intensity (in mA) of electrical stimulation (upper diagram). The middle diagram shows all the assessed signals. "Swing on" presents the swing phase detection, which is based on gyroscope signal ("ang. vel") that assesses the angular velocity of the shank. The diagram shows both goniograms, the "knee" and the "ankle", and the acceleration ("|a0|") signal. In the lower diagram the swing quality is presented. After pre-set number (5) of consecutive good swings the stimulation intensity was decreased.

weight 84 kg, age 30 years) with C4–5 lesion, Asia classification C (4 months before measurement) was involved in the development, testing and case study validation of our approach. He was not able to walk due to inability to perform a swing movement without FES and was a regular peroneal stimulator, MicroFES^{TM} (The Jozef Stefan Institute), user for 1 month. MicroFES^{TM} is a 1-channel electrical stimulator, triggered by the shoe insole, with a pair of electrodes applied over the common peroneal nerve.

His FES assisted treadmill walking was considered satisfactory and was recorded as a reference gait pattern. This was done in the first session of the treadmill when the patient was walking with MicroFES^{TM} on both lower extremities. The goal of further treadmill training sessions, which were all performed on the same day, was to explore functioning of the completely automated sensory driven FES augmentation system. The computer controlled electrical stimulator, as described in (4), replaced the MicroFES on the patients' right lower extremity. The patient had to walk with the self-selected pre-set speed of the treadmill (0.5 km/h) and concentrate on the cognitive feedback signal. The goal of the subject, being the essential element of the first closed loop as shown in Fig. 1, was to perform in a way that resulted in good swings. The task of the second, automated closed loop, was to process data assessed by the multisensor device, and control the triggering moment and intensity of FES. At the beginning of the training session the physiotherapist pre-set the stimulation parameters, the required knee flexion in the swing phase and the required number (5) of good/poor swings for the automatic change of the stimulation intensity (10%). The intensity was also limited to prevent too much FES assistance.

The results show the assessed gait parameters, the presence of FES its intensity and the estimated swing quality during the selected training session (Fig. 3). The swing quality estimation took place at the end of each swing phase. The algorithm (4) was based on correlation with the reference signal (0 = poor, 1 = excellent) and returned a numerical value presented in the lower chart of Fig. 3. The figure also shows how the pre-set number of good swings (5) decreased the intensity of electrical stimuli (the upper diagram) by 10%.

The patient focused on the cognitive feedback audio signal and attempted to improve his swing in order to maintain symmetrical walking. When the pre-set number of consecutive good swings had been performed, the stimulation intensity was decreased (Fig. 4). In contrast the stimulation level increased in the case of the pre-set number of poor swings. In all other cases (various successions of good, sufficient or poor swings) the stimulation intensity was not changed. The pre-set demand for swing classification was the swing quality value; during these measurements the swing quality value was set to 0.6. Figure 4 shows the gait re-education system performance and the FES assistance needed during walking. During the first phase of this gait training session the swing quality varied in such a way that the stimulation level remained unchanged. In the further course of the session an improvement in performance can be observed, resulting in a decreased level of FES support. In the interval from 150 and 200 seconds there is a decrease in swing quality that resulted in an increase in FES support, which enabled the subject to restore adequate swing performance and again reduce the level of FES assistance.

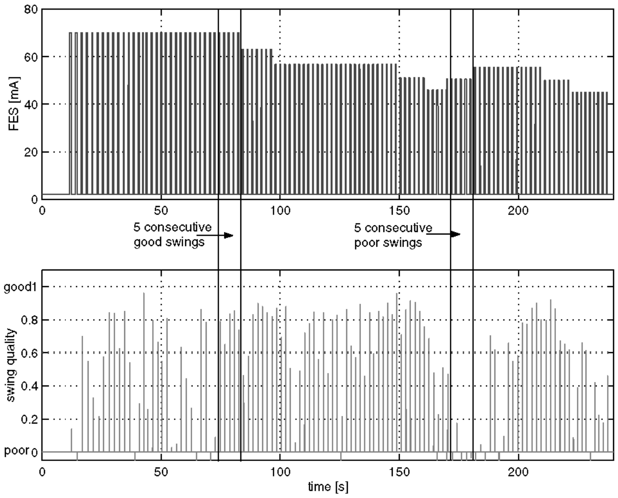

Fig. 4. The effect of the good/poor swings on the stimulation intensity. When the patients' swing phase became good/poor the requirement for functional electrical stimulation assistance was decreased/increased.

DISCUSSION

In our earlier development of a gait re-education system for use in incomplete paraplegia the aim was to involve the patient in the rehabilitation process (1) by using cognitive feedback supported by an artificial multisensor system. Triggering of the single-channel FES system augmenting the swing phase was left either to the patient or the therapist. We also tested the possibility of the walking subject adjusting the intensity of the electrical stimuli by a special control lever (3). Our earlier work (2) and the experiences of Hesse at al. (7) and Field-Fote (6) exposed the need for automated triggering and intensity adjustment of the FES system augmenting the swing in order to improve the repeatability of the training conditions where the level of FES support is adjusted to a level suitable for the walking subject's performance. The main focus of the work presented in this paper was therefore to develop the sensory driven automated FES augmentation system and explore the functioning of such a system in a clinical setting involving a neurologically impaired subject.

The results of our case study clearly show that the proposed approach of sensory driven automated FES augmentation of the swinging extremity can be successfully incorporated into gait treadmill training. The recordings presented in Fig. 4 clearly demonstrate the interaction of the walking subject and the state of the sensory driven FES augmentation system. From the gait performance it appears that the walking subject was indeed an active participant in the gait re-education process as the level of FES augmentation was reduced in the first phase of the training session and thereafter varied around the level that appeared to be needed. The main achievement of such training is that the walking subject receives not only the cognitive feedback information, which is needed to improve performance on a conscious level, but also relevant sensory feedback that is input to the spinal neural circuits at the spinal level as the level of FES support is related to the gait performance. The patient expressed that he was very contented with the device as he was released from the need to monitor visually the movement of his extremities. Thus he could move in a straight line and focus on the auditory feedback. At the same time the automatic control of the electrical stimulation provided the assistance required.

In conclusion, rather comprehensive and repeatable gait-training conditions are achieved, which should have impact on the increased quality of walking, and might also have shortened the duration of the gait re-education treatment required. By developing and testing the described gait re-education system we are in a position to evaluate further the presumed effectiveness of the approach in controlled clinical trials. Further development of the gait re-education system will focus on substitution of the knee goniometer information, needed to determine the triggering moment of the FES system. The triggering will be accomplished through an adequate processing algorithm, which will derive the necessary information from the multisensor system. This will further simplify clinical utilization of the developed system.

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