A Reliable, Insole-Embedded Gait Phase Detection Sensor for FES-assisted Walking

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A Reliable, Insole-Embedded Gait Phase Detection Sensor for FES-assisted Walking

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Abstract

This paper presents a new gait phase detection sensor (GPDS) embedded in an insole and clinical results of its use in conjunction with a functional electrical stimulation (FES) system for patients with a dropped-foot walking dysfunction. The GPDS (sensors and processing unit) is entirely embedded in a shoe insole and detects four phases of the gait cycle in real time: stance, heel-off, swing and heel-strike. The instrumented GPDS insole consists of a miniature gyroscope that measures the rotational velocity of the foot with respect to the ground and three force sensitive resistors that measure the force load on the shoe insole at the heel and the metatarsal bones. The extracted gait phase signal is transmitted from the embedded microcontroller to the electrical stimulator and is used in a finite state control scheme to time the electrical stimulation sequences. The electrical stimulations induce contractions in the paralyzed muscle-groups leading to a more normal motion of the impaired leg. Quantitative gait analysis of the performed walking experiments proved the effectiveness of the system. This combined GPDS sensor and stimulation system has the potential to improve the functional benefit and comfort of use for FES-assisted walking for a wide range of gait disabilities after brain-stroke, spinal-cord injury or neurological diseases.

Keywords: locomotion, gait phase detection, neuromuscular stimulation, gyroscope, microcontroller, biomedical signal processing

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I. INTRODUCTION

Since the early 1960s it has been demonstrated by many research centers that functional electrical stimulation (FES) can be used effectively to assist individuals with walking deficiencies as a result of damage in the central motor nervous system [1]. FES systems consist of an electrical stimulator, which sends electrical pulses via self-adhesive surface electrodes or implanted electrodes to selected muscles of the leg. This stimulus produces artificial contractions of the targeted muscles at selected times during the gait cycle.

Correct timing of the applied stimulation within the gait cycle, is crucial for the functional effectiveness of this system. The simplest way to control the timing of the stimulations is by manually pressing a push-button once for each step [2]. Although the simplicity is beneficial, this control method requires the subject's uninterrupted attention and coordination and offers limited synchronization with the gait cycle events and is practically limited to a single event indication per gait cycle. To improve this situation, automatic triggering methods have been proposed. These methods are based on sensors ranging from simple foot switches placed in the shoe insole to inclinometers, goniometers, gyroscopes and accelerometers. Electrodes for electromyography and implanted nerve cuff electrodes for afferent nerve signal recording have also been used [3-6]. Despite this range of sensors, the available triggering methods are still insufficiently reliable for everyday use and many patients who benefit from an FES system during their rehabilitation in the clinic, stop using it when they return home. Progress must be pursued by improving the functional outcome as well as the user-friendliness and reliability of the FES equipment. In this paper we present a new, reliable, real-time gait phase detection system (GPDS) for FES walking applications. This device has been miniaturized to fit inside a shoe insole.

An important practical aspect of a gait phase detection system is that the system must be insensitive to disturbances caused by non-walking activities. In daily activities, walking is interrupted by short non-walking activities, such as standing, sitting, shifting the weight from one leg to the other, sliding of the feet, etc. It would be very impractical if the gait phase detection system needed to be continuously turned on and off to avoid stimulations during non-walking activities. Systems relying on force sensors alone, or inclinometers attached to the shank, do not comply with the above demand. Various designs have been proposed in the past, in particular: Skelly et al. [3] presented a fuzzy, rule based gait event detector and concluded that two force sensitive resistors (FSR) per insole were sufficient for gait event detection during walking. The robustness however to non-walking activities is questionable. Williamson et al. [4] reported excellent detection reliability when using three accelerometers attached to the shank and a machine-learning algorithm to detect the real time transitions between five phases of the gait cycle. However, no results were presented for a use of this system with an FES system. The Salisbury-group (U.K.) has administered to several hundred patients with a dropped foot the Odstock dropped foot stimulator (ODFS). This single channel stimulator is controlled by a simple foot switch usually placed beneath the heel [5]. The foot switch indicates the heel-off and the heel strike phases. The subject must keep the foot-switch depressed when they stop walking to avoid false stimulation triggers. After a short period of inactivity the stimulator shuts down and must be turned on again to continue operation.

Our concept for gait phase detection was first presented in [7]. It is based on the use of a miniature gyroscope sensor in addition to three force sensitive resistors placed on the shoe insole. In a previous study [7] the gait phase detection algorithm that was used, proved to be very reliable under many different indoor and outdoor, walking and non-walking conditions. In this paper, we present the miniaturization of this system, its combination with and FES system and its clinical use as a walking neuroprosthesis. In particular, the sensors and the microprocessor have been entirely embedded in a shoe insole. This system is currently used in our clinic in combination with the Compex-Motion FES stimulator [8] to assist incomplete (hemiplegic) spinal cord injured subjects in improving their walking performance. Kirtley [9] presented a similar instrumented insole with an embedded microcontroller, a gyroscope, five FSRs, a three-axis accelerometer and a radio-frequency transmitter. The insole does not provide the gait-phases in real-time, but transmits the raw data to a PC, which then analyses the gait dynamics and kinematics.

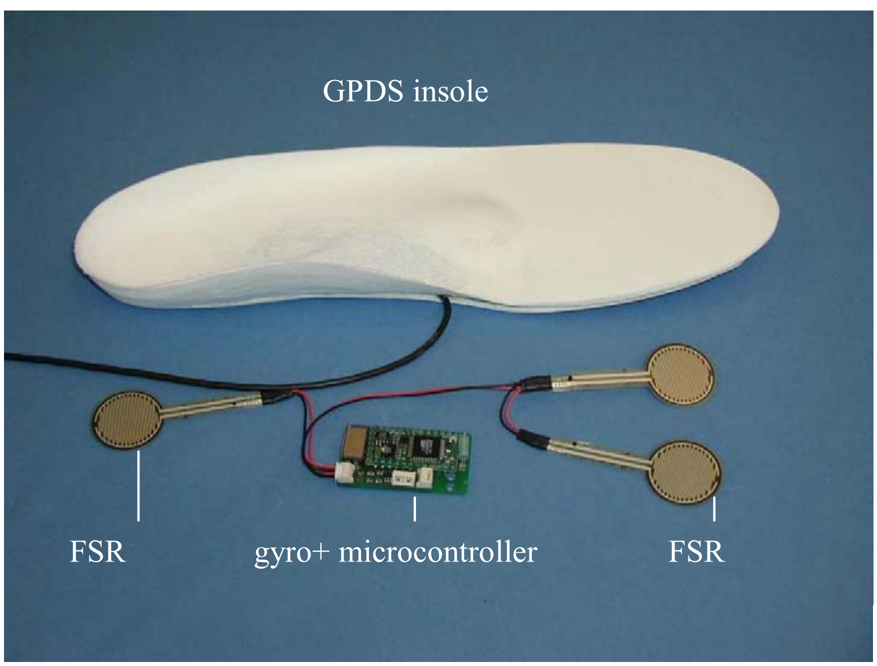

Figure 1: Shown here is the instrumented GPDS insole (white) and next to it displayed the embedded components.

II. THE GAIT PHASE DETECTION SENSOR (GPDS)

A. Hardware

The GPDS is embedded in an anatomically shaped shoe insole (Bauerfeind AG. No.21270/5), shown in figure (1). The four gait phases are detected using a combination of two types of “off-the shelf” sensors:

1) Flat, circular (diam. 2.5 cm) non-linear force sensitive resistors (FSR Interlink El. Inc. 152NS)

2) A miniature (15.5×8.0×4.3 mm^3) gyroscope (ENC-03JA Murata, Japan), used to measure rotational velocity of the foot with respect to the ground in the sagittal plane.

The FSRs were fixed on the bottom side of the insole, one underneath the heel and two underneath the first and fourth heads of the metatarsal bones. Two (instead of one) FSRs were used underneath the metatarsal heads to deal with asymmetric loading due to irregular ground or pathologic gait. Since FSRs are not precision sensors (specified 25% part-to-part repeatability), they were only used as two-state switches to indicate when weight was applied to them and when not, which was achieved by measuring the voltage drop across each FSR connected in a voltage divider circuit. Their specified switching time delay was 1 ms. The FSRs alone could not distinguish between true walking and weight shifting from one leg to the other, nor could they provide any information about the foot condition during the swing phase.

The gyroscope measured the rotational velocity by sensing the mechanical deformation caused by the Coriolis force on an internal vibrating prism. The gyroscope signal was filtered by a third-order band-pass filter (0.25–25 Hz) with a 20-dB gain in the pass-band. The frequencies outside the pass-band were filtered out because they were not related to the walking kinematics. The filtered signal was used to directly estimate the angular velocity of the foot, and at the same time, it was integrated to estimate the angle or inclination of the foot relative to the ground. The angular velocity and inclination are used individually separate parts of the gait phase detection algorithm. A resetting mechanism was built in the algorithm to avoid accumulation of drift errors in the integrated signal. This algorithm reset the foot inclination to zero during the stance-phase when all three FSRs were loaded. No calibration of the sensors was needed prior or during their use. A detailed discussion of the gyroscope signal processing and the effect of varying ambient temperature on the gyroscope performance was presented in [10]. The sensor signals were sampled at a frequency of 100 Hz.

The gyroscope, amplifier and band-pass filter were integrated together with a microcontroller on a small electronic circuit board (dimensions: 30mm × 49mm ×7.7mm), which was embedded in the anatomically shaped foot-arch of the insole. The depression for the device was created by removing material from the insole. The sensing axis of the gyroscope was oriented perpendicular to the sagittal plane, in order to measure rotations of the foot in that plane. A slim custom aluminum housing was used to protect the components of the circuit board from external loads. The FSRs were connected to the circuit board using flat micro-connectors (Molex Inc., USA).

A low-cost BX-24 microcontroller board (NetMedia Inc., USA) was used for signal acquisition, processing and implementation of the gait-phase-detection algorithm. This device incorporated a low-power ATMEL microcontroller with floating point math capability, 16 standard I/O pins, of which eight could be used as ADC with 10 bit resolution. The microprocessor could be programmed conveniently in visual basic. A thin plastic protective layer (1 mm) was glued to the bottom of the insole to protect the FSRs and the electronic circuit board from direct contact with sharp or potentially hazardous objects. The total thickness of the fully instrumented insole was less than 6 mm, at the heel and below the metatarsal bones. Twelve instrumented insoles were fabricated in different sizes: small, medium, large and extra-large (36, 38, 41, 45 respectively in European sizes).

The gait phases were then used to trigger functional electrical stimulation sequences and were transmitted via a direct cable connection as discrete voltage states from the embedded microcontroller to the programmable electrical stimulator Compex-Motion (Compex SA, Switzerland) [8]. Power was supplied to the GPDS through the same cable used for data transmission.

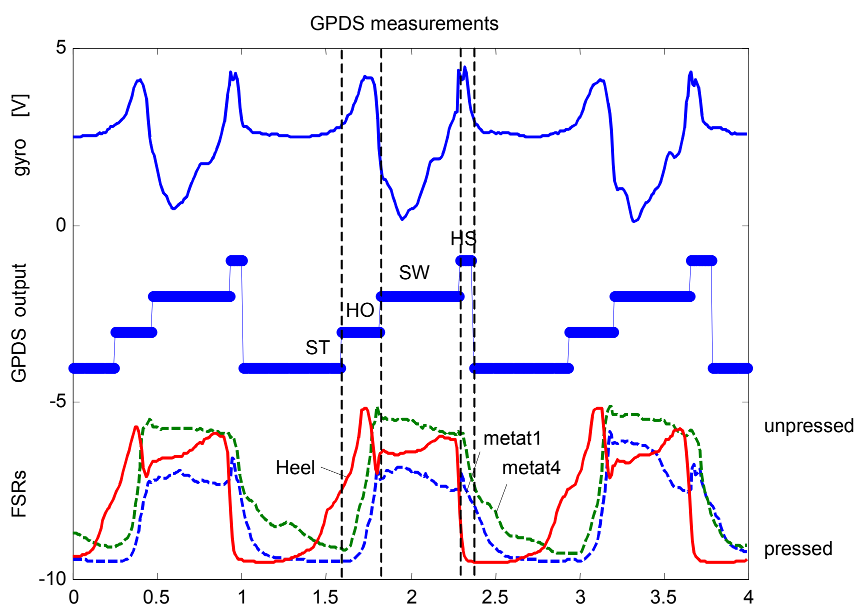

Figure 2: Sensor signals and GPDS output during three steps. top=gyroscope, middle=GPDS, bottom=FSRs; ST=stance, HO=heel-off, SW=swing, HS=heel-strike, (figure lended from our previous publication [7], where the same sensors and processing algorithm were used).

B. The gait phase detection algorithm

The gait phase detection algorithm detects, in real-time, the transitions between the following four phases of the gait cycle: *stance, heel-off, swing, heel-strike* (see Fig. 2 and 3). The loop frequency of the algorithm 100 Hz was equal to the sensor sampling frequency. The algorithm is a knowledge- and rule-based algorithm, which allows a total of seven different transitions (T1-T7) between the four gait phases, as illustrated in Figure (3). The algorithm was programmed in Visual Basic and executed on the BX-24 microcontroller, embedded in the insole. Details about the rules, which govern the transitions from one gait-phase to another, as well as handling of special cases of pathologic gait, are given in [7].

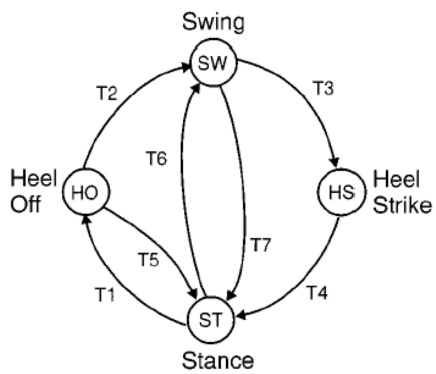

Figure 3: The GPDS divides the walking cycle into four gait phases: stance, heel-off, heel-strike, and swing. The arrows T1–T7 illustrate the possible transitions between the gait phases.

C. Robustness of algorithm

The gait phase detection algorithm reliably identified the transitions between *stance, heel-off, swing*, and *heel-strike* for a wide range of normal and pathological gait styles. In the study presented in [7], the reliability of the GPDS was evaluated using ten able-bodied subjects and six subjects with walking impairments. In that study it was shown that the employed gait phase detection algorithm was reliable under diverse conditions such as walking on flat and rough terrain (grass, earth and snow), walking on inclinations and on stairs. The algorithm was also very robust against non-walking perturbations such as shifting of the weight from one leg to the other, sliding the feet, standing up and sitting down. The detection success rate for both groups of subjects for walking on level ground, slopes, and irregular terrain were above 99%. In the case of the stair climbing and descending tasks, the GPDS achieved detection rate above 99% for able body subjects and above 96% for subjects with impaired gait. The performance of the GPDS was verified using an optical motion analysis system (Vicon 370 Oxford Metrics Ltd., U.K.) or based on comparison of the GPDS output signal and raw sensor signals. The system was tested in both indoor and outdoor environments and it was shown that its detection performance was independent of the ambient temperature (tested range: 0°C to 25°C). Additionally, the GPDS was tested at different walking and running speeds (0.5 to 13 km/h fast jogging) and detected the four gait phases with the same reliability.

III. Experimental Case Study

The purpose of the experimental study presented here was to quantitatively measure the benefit of the combined GPDS-FES system. Although the detection performance results for our GPDS algorithm per-se have been presented in [7], its combination with an FES system has only recently been validated and is presented here for the first time. In particular, we were interested in determining if the timing of the stimulation was appropriate for different walking speeds and ground inclinations. Two subjects, with incomplete spinal cord injuries participated in the study (level of lesion: T10 subject A, C6 subject B). As a result of their spinal cord injury, the subjects suffered from a unilaterally dominated paraplegia (one leg affected). Without FES, subject A could walk independently using crutches but with a typical dropped-foot gait pattern, while subject B due major deficits in hip and knee flexion used a wheel-chair almost exclusively in daily life. An informed consent to participate in this study was obtained from the subjects and the local Ethics Committee approved the experimental protocol.

The experiment consisted of the following tasks, which were carried out on a treadmill:

1) Walking horizontally at three speeds: slow, normal, fast. (subj. A: 1.2, 2.0, 2.5 km/h and subj. B: 0.6, 0.9, 1.4 km/h)

2) Walking downhill (-15% inclination), normal speed

3) Walking uphill (15% inclination), normal speed

4) Non-walking activities: shifting the weight from one leg to the other, standing up, and sitting down

The "normal" walking-speeds were initially self-selected by the subjects and were then enforced by the treadmill speed. We also asked the patients to verbally express their opinion about the comfort/usefulness of the system. Subject A used two stimulation channels for a balanced dorsal flexion of the ankle (stimulated muscles: ext. dig. longus and peroneus tertius). Subject B used two stimulation channels for the stimulation of the peroneal nerve (to elicit the flexion reflex) and the activation of the tibialis anterior muscle. The stimulation started at the detection of the heel-off phase and terminated at the detection of the heel-strike phase. Both subjects had previous walking training with a manually or GPDS triggered FES system, once a week during the previous three months, but had no particular muscle training.

The bilateral hip, knee and ankle joint trajectories as well as the foot-clearance were recorded using the optical motion analysis system Vicon (Vicon Motion Systems Ltd., UK) with five cameras and fifteen reflecting markers, placed on standard body locations. The output signal of the GPDS was collected synchronously to the Vicon measurements, in order to measure the phase detection delay.

IV. EXPERIMENTAL RESULTS

The combined GPDS-FES system worked successfully and offered great functional benefit to both subjects, in all of the above-listed conditions (1-4).

A comparison of the joint trajectories of the impaired and non-impaired sides based on the Vicon measurements is presented in figure (4).

Joint trajectories

Figure (4) displays ankle joint trajectories obtained from subject A during 10 sequential steps of horizontal walking. The two graphs on the top show the ankle joint trajectories without FES, the non-impaired side on the left and the impaired side on the right. When comparing both sides in the swing phase (~ 60%-100% of the gait cycle) the foot's plantar flexion on the impaired side is larger by almost 10 degrees. Additionally, during the swing phase an oscillation of the foot can be observed, which is explained by the paralysis of the distal leg muscles, which fails to stabilize the foot. The bottom graphs of figure (4) show the ankle joint trajectories during walking with FES. In the non-impaired side, no significant change is observed. On the impaired side, two benefits can be noted: (a) the excessive plantar flexion of the affected foot during the swing phase has been reduced to normal levels, (b) the undesired oscillations of the foot during swing, although not completely eliminated, are reduced from an average of 8.3 degrees to 2.4 degrees in peak-to-peak amplitude. This is explained by the FES induced activation of the dorsal extensors of the foot. The comparison of the graphs shows that the application of FES leads to a greater similarity between the impaired and non-impaired sides and therefore to an overall more "normal" gait pattern.

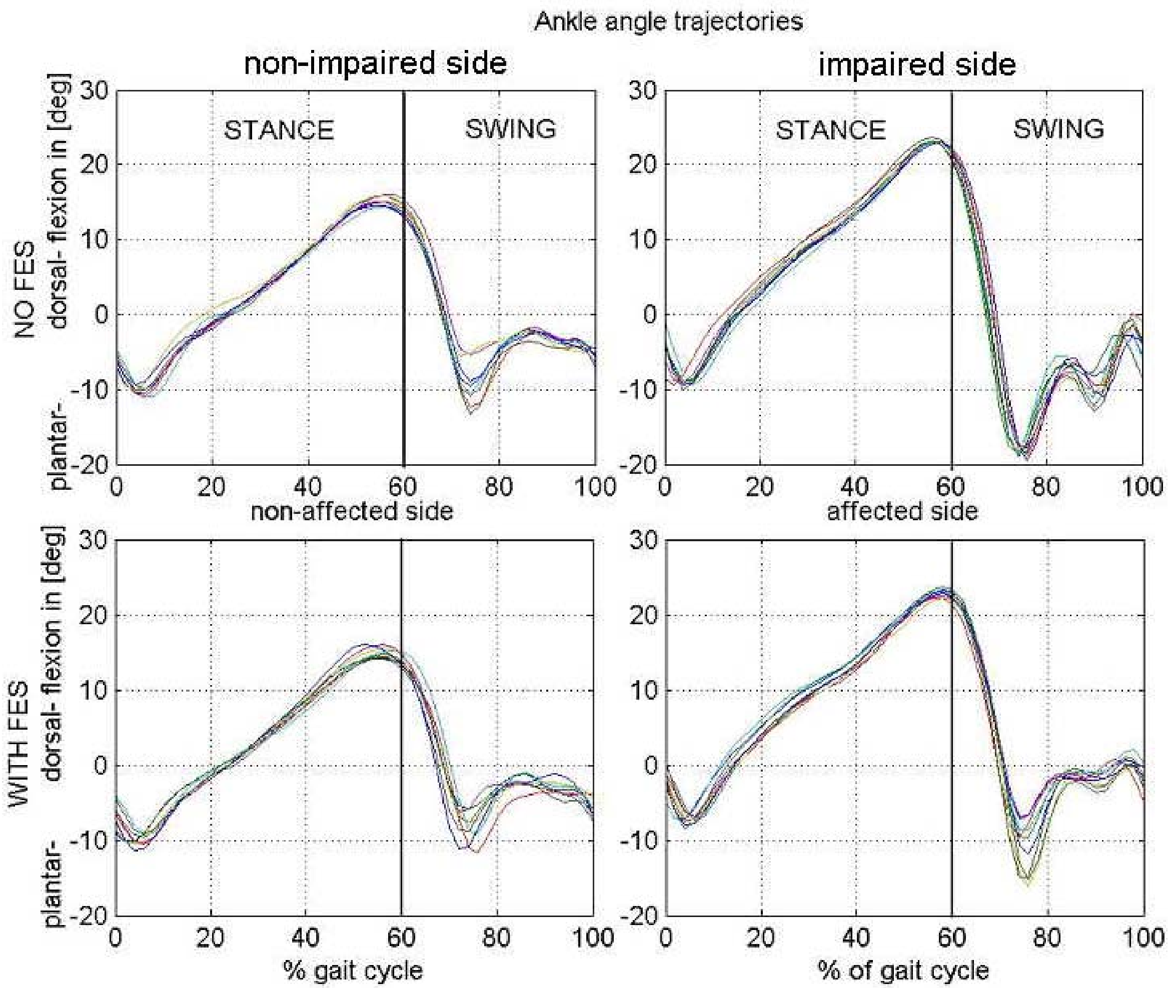

Figure 4: Ankle trajectories of 10 steps at 2.0 km/h, Left: <u>non</u>-impaired side, Right: impaired side;

top row: <u>without</u> FES, bottom row: <u>with</u> FES

For subject B, the application of the GPDS + FES system offered similar benefits. As shown by the illustration in figure (5), the application of FES reduced the excessive plantar flexion of the foot during the swing phase, from 10 degrees to 0 degrees, and provided a better clearance. Overall, the application of FES led to a quantitatively greater similarity of the impaired and non-impaired gait cycles and the subject could comfortably increase his walking speed from 0.6 to 1.4 km/h.

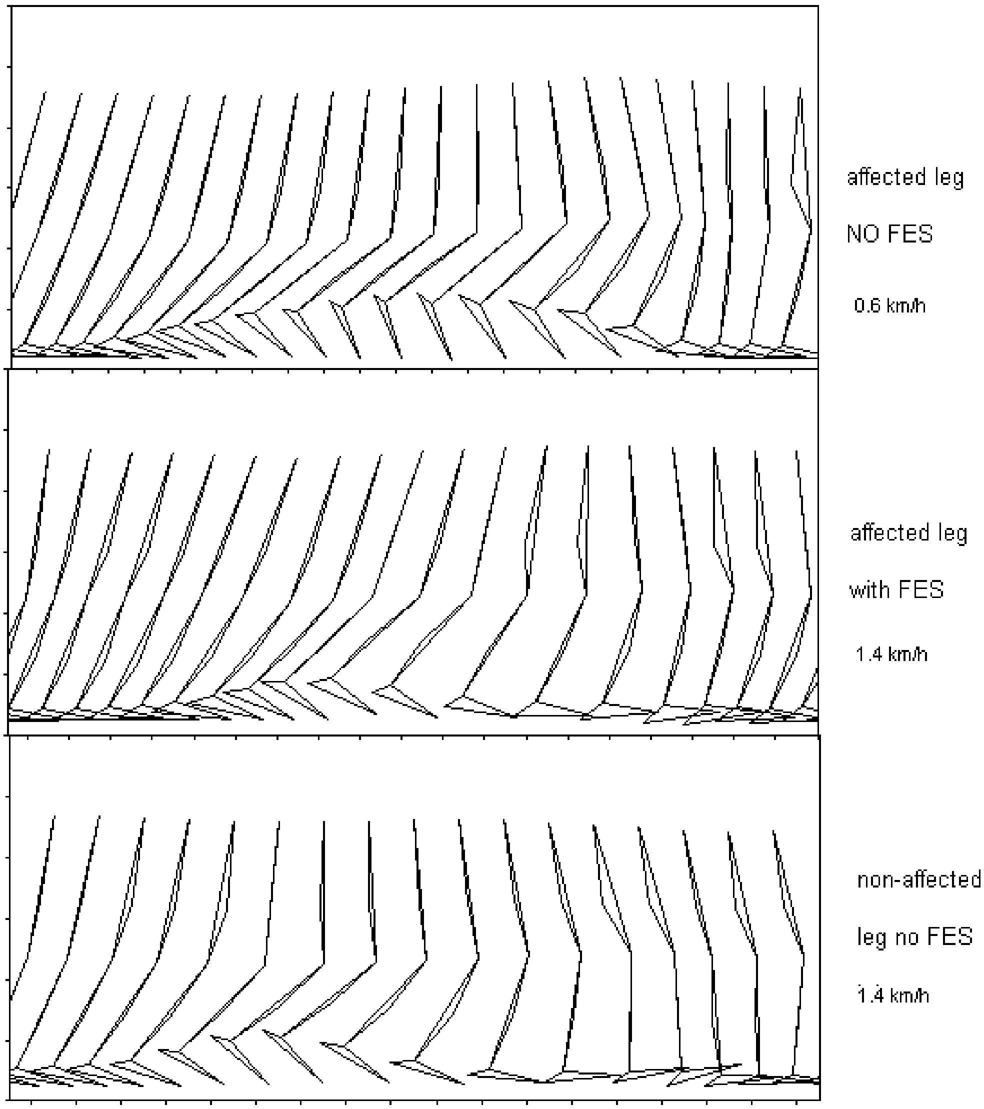

Figure 5: Measured leg motion for subject B; top = no FES; middle = with FES; bottom = non-impaired leg

Both subjects reported that walking with the FES system was less tiring and safer than without FES. For both, the use of FES stimulation allowed them to significantly increase their walking speeds (subj. A: from 1 to 1.5 km/h, subj. B: from 0.6 to 1.4 km/h). The subjects further expressed a clear preference for the automatic, GPDS-triggered FES system in comparison to a manually triggered one, which they had used earlier in our hospital. This preference was associated with the elimination of the need to concentrate on giving precise manual trigger timings, while concentrating on their walking. Most importantly, the GPDS did not generate false triggers during standing, shifting of the weight from one leg to the other, sitting down or rising from a seated position. During these instance simpler systems consisting only of force sensors would fail. Also, the subjects did not need to worry about turning off and on the system every time they stopped or started walking. The gait phase detection delay of the GPDS (< 70 ms) proved to be sufficiently small for the above-described applications and walking speeds.

V. DISCUSSION AND FUTURE DIRECTIONS

The positive results obtained in the above-described experiments and our clinical experience indicate that the GPDS provides increased comfort to the FES user. The stimulation being triggered automatically leaves the hands and the mind free to be used for other things. The fact that the GPDS works robustly on flat, rough or inclined terrain and the fact that it does not generate false triggers increases the comfort and the confidence the user has in the system. Faster walking speeds that overcame the double stance phase were a directly result. We hope that in the near future, the GPDS system may be commercialized[1] and may gain wide acceptance among experts and clinicians for FES walking applications.

Future developments are expected to continue in the following directions: adding wireless communication between the instrumented insole and the functional electrical stimulator, studying long-term effects on patient walking performance, and finally, using the gait phase signal and the gyroscope signal not only as a trigger to time pre-programmed stimulation sequences, but as a direct feedback signal in a closed-loop FES control scheme. As suggested by Veltnik et al. [11] two orthogonal gyroscopes could serve to control the plantar- and dorsi-flexion as well as the eversion and inversion of the foot.

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