Design of FES based muscle stimulator device using EMG and insole force resistive sensors for foot drop patients

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Abstract

In the presented research, design of functional electrical stimulation (FES) based muscle stimulator device has been described which is used to correct and enhance the gait activity of foot drop patients. The device mainly comprises of FES unit for electrical pulse generation, an electromyography (EMG) sensor V3 for feedback system and insole force-sensitive resistive sensors (FSR) to control ON/OFF timing of device. The device controls the ankle flexion without excessive eversion or inversion of foot (i.e. balanced flexion) by stimulation of common peroneal nerve and tibialis anterior muscle (TA). The efficiency of device is assessed by evaluating gait temporal and spatial parameters (TSP's) and 3-dimensional gait kinematics (ankle flexion) of footdrop patients by "Peak Motus Motion Measurement System". It has been found that use of FES stimulator increases the walking speed by 19%, cadence by 7%, step length by 11% and stride length by 15.5%. In addition, it is also observed that stride time, stance time, step time, single support time and double support time is decreased by 5%, 17%, 22%, 15% and 18% respectively. Moreover, kinematics analysis of foot shows that the device prevented the footdrop up to 30° by controlling the ankle flexion and extension magnitude. Thus, the obtained results suggest that the proposed FES based stimulator device provides enough stimulation to peroneal nerve required for stable gait activity of footdrop patients. Copyright © 2018 VBRI Press.

Keywords: Foot drop, functional electrical stimulation (FES), muscle stimulator device, force-sensitive resistive sensors (FSR), gait temporal and spatial parameters (TSP's), 3-dimensional gait kinematics, tibialis anterior muscle, peroneal nerve.

Introduction

Stroke is among the main causes of motor function disability [1-3], such as shortening and stiffening of muscle fibers along with alterations in type of muscle fibers [4, 5]. Foot drop is one of the post-stroke effects [6-8] which severely affect the normal life activities of stroke patients. It involves insufficient activation of dorsiflexor muscles due to calf muscle spasticity, nerve suppression or muscle weakness [9]. Normally foot drop patients undergo "toe drag" during their gait cycle and have problem in swing phase due to weak dorsiflexion (ankle flexion). Several devices are used for the treatment of foot drop condition, which mainly comprises of ankle foot orthosis (AFO) [10-11] and functional electrical stimulation (FES) based devices [12-17]. The use of AFOs can prevent foot dragging but normally they are not preferred; as they restricts the range of motion of ankle and are also uncomfortable to use [18]. Hence, FES based device could be a better alternative for AFOs, as they enhanced the activation of ankle flexor muscles and reduces the muscle atrophy [19]. Moreover, chronic FES improves level of cardiovascular fitness [20-22], lessens spasticity [23-24], recovers mobility [25, 12] and allows patient to perform rehabilitation exercises [26]. Additionally, use of FES stimulation also enhanced the neurological changes and motor learning occurs in the central nervous system which leads to an effective change in gait activity with time [27]. Thus, it is evident that the advantages and health benefits of FES make it a preferable treatment over AFOs for foot drop. Previously, FES based stimulator has been designed by Sabut *et al* [28] but in that work, time duration for FES pulses has not been taken into consideration and fixed duration FES pulse has been provided to every patient. As level of stimulation needed by every patient differs, therefore, it is not appropriate to apply same duration pulse to every patient. Furthermore in another research study [29], FES pulse has been given in continuous mode which can cause "accommodation phenomena" in dorsiflexor and as a result muscle will stop responding to applied signal in effective manner. Additionally, in [30, 31] the presented foot drop stimulators are invasive which involved an open surgery to implant them. Thus, in our presented research, we have proposed non-invasive design for FES based muscle stimulator. Also parameters for both FES time duration and FES selective

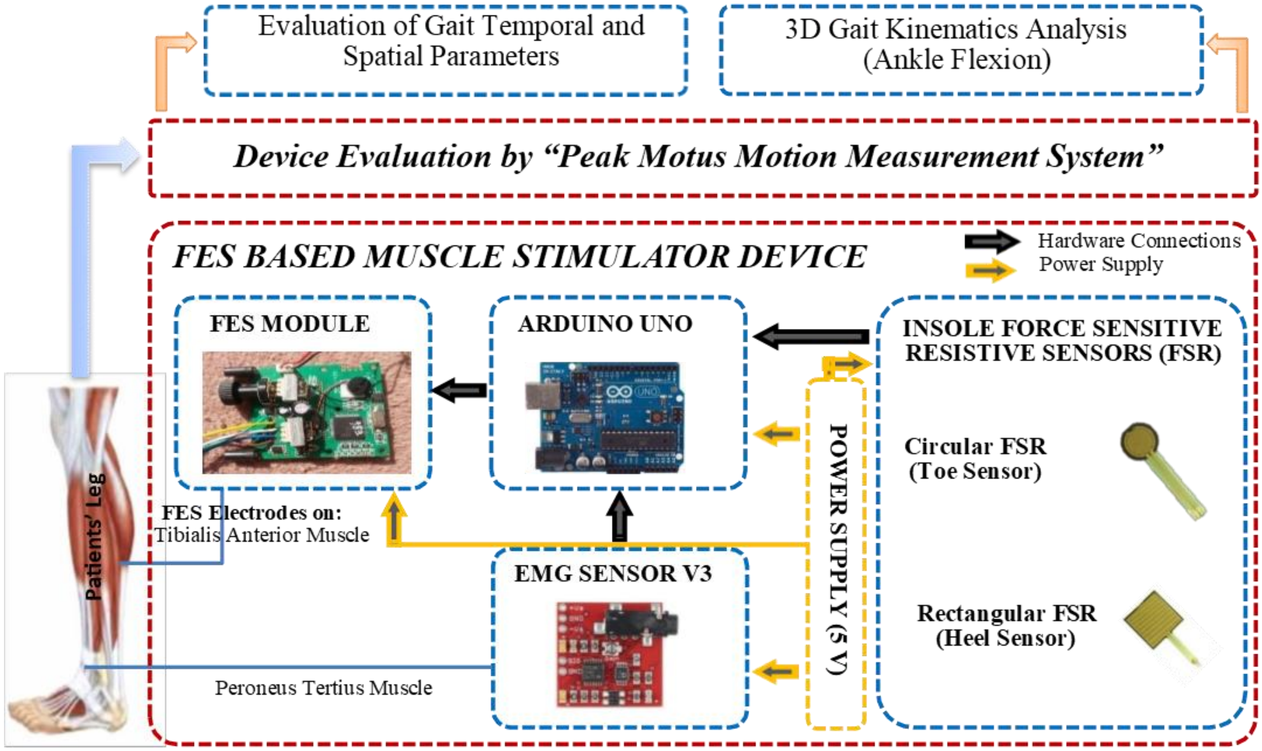


Fig. 1. System Architecture of FES Based Muscle Stimulator Device.

mode are considered and adjusted via feedback control system provided by EMG sensor. The results show that device usage has activated the ankle flexor muscles that helped in producing more balanced and stabilized gait.

Materials and methods

FES stimulator design and working

The schematic representation of overall methodology adopted in designing FES based muscle stimulator device for foot drop patients has been shown in **Fig. 1**. The device mainly comprises of power supply, FES pulse generator module, electromyography (EMG) sensor V3, insole force- sensitive resistive (FSR) sensors and Arduino microcontroller **(Fig. 2)**.

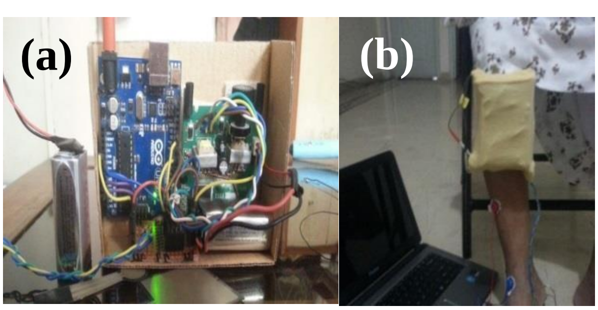


Fig. 2. (a) FES Based Muscle Stimulator, (b) Stimulator Application to Subject.

For a portable and rechargeable system, a 7.2 V lithium ion battery is used which provides power to microcontroller, EMG sensor, FSR sensors and FES module. The main unit of device is FES pulse generator, which produces electrical stimulus pulses of between 20 and 250 μsec at a frequency of 30-100 Hz, with current amplitudes of up to 100 mA. FES pulse generator is connected to tibialis anterior muscle via electrodes which provides surface stimulation of the common peroneal nerve and causes dorsiflexion (ankle flexion). The stimulator also encompasses EMG sensor which is connected with three electrodes; two of them are located on the peroneus tertius muscle and one ground electrode is placed on the fifth phalangeal joint. Initially, the EMG signal of normal person muscle (Peroneus Tertius muscle) is monitored and stored in the microcontroller which acts as a reference for analyzing patients' muscle activity. Hence, EMG sensor monitors the myoelectric activity of patient and sends the signal to microcontroller, where it is compared with reference data. The comparison provides the approximate idea about level of stimulation required to perform dorsiflexion. Hence, based on feedback received from EMG sensor, Arduino controls the amplitude, time and frequency of FES stimulation. Moreover, the maximum output range of current amplitude and time period is calibrated according to subjects' condition and their level of comfort. "MATLAB Support Package for Arduino" is used to interface with controller for analyzing and configuring the operating parameters range) of the device. Another important feature is ON/OFF mechanism of device, which is controlled by insole FSR sensors. These sensors act as a "Foot Switch" and are placed under heel (rectangular FSR) and toe (circular FSR) of the foot. The heel and toe rise will indicate the initiation of swing phase, which is detected by microcontroller and causes the stimulation of FES electrodes. Whereas, on heel strike the foot switch will detect the end of swing phase and stops the FES stimulation.

Gait analysis

In order to perform a gait analysis experiments, 6 foot drop patients (age between 40 and 50) were selected.

Following criteria were established for selection of subject:

(1) Suffer from footdrop because of upper motor neuron injury and can be corrected by peroneal nerve stimulation.
(2) Must have good tolerance against external stimulation sensation.
(3) Able to walk comfortably at least 20 meters with use of walking aids.
(4) Subjects with mental issues, implantable devices and pregnant condition were excluded.

Gait temporal and spatial parameters (TSP's) and 3D gait kinematics were analyzed using "Peak Motus Motion Measurement System". Reflective markers were positioned on ankle, toe and knee of foot drop affected leg (figure. 3). Gait parameters and kinematics were monitored during treadmill walking in two conditions:

(1) Without FES device
(2) With FES device

The subject walked for 1 minute in each condition with a rest of 5 minutes between them. The speed of treadmill was fixed to 1 km/h for subjects with FES device and adjusted to 0.6 km/h without FES, because the patients could not walk faster without external assistance.

TSP's are evaluated in terms of walking speed, cadence (No. of steps/minute), step length (distance between successive heel contacts of opposite feet), stride length (distance between two consecutive heel contacts of the same foot), stride time (duration for the completion of a gait cycle), stance time (duration when the foot is on the ground), step time (duration for the completion of a right or left step), single support time (duration when only one foot is on the ground) and double support time (duration when both feet are in contact with the ground simultaneously during gait cycle), since these parameters are the main gait identifiers [32]. Whereas in gait kinematics, magnitude of ankle flexion is assessed. Ankle flexion (θ_{AF}) is an angle between ankle-knee axis and foot (toe-ankle axis) and its neutral position (0°) corresponds to foot perpendicular to ankle-knee axis **(Fig. 3).**

Experimental results and analysis

Evaluation of Gait Temporal and Spatial Parameters

In order to validate the device performance, 6 footdrop patients were selected and their gait is monitored with and without FES device. The mean values of temporal and spatial parameters with pre and post usage of FES device are presented in **Table 1**. The result shows an improvement in gait efficiency of subjects with an increase in speed (19%), cadence (7%), step length (11%) and stride length (15.5%), along with decrease in stride time (5%), stance time (17%), step time (22%), single support time (15%) and double support time (18%).

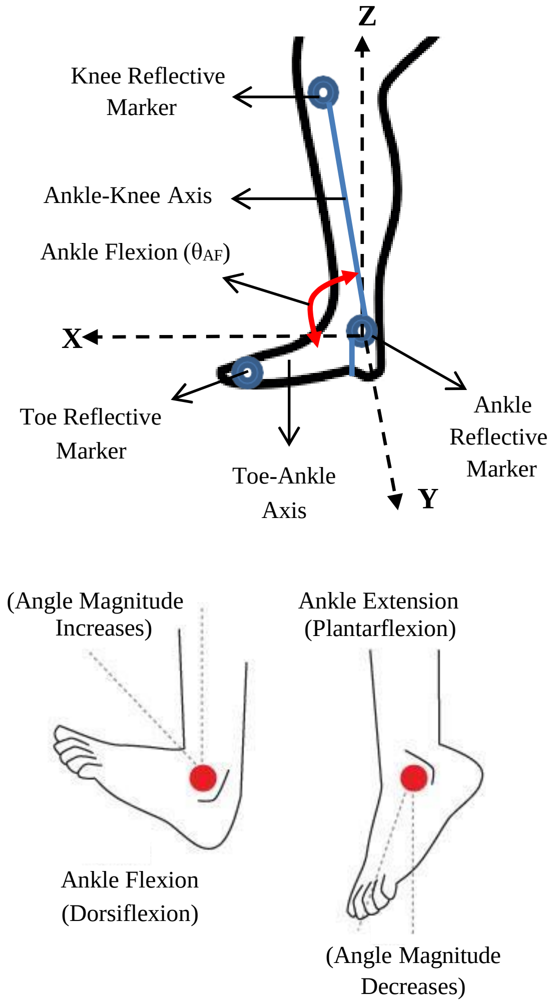


Fig. 3. Marker Placement and Foot Biomechanics Overview for Gait Analysis.

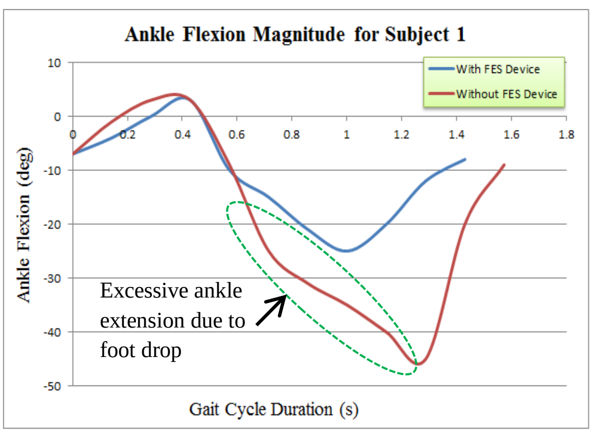
Table 1. Mean values of TSP's with and without FES Stimulator Device.

PARAMETERS	WITHOUT FES	WITH FES	PERCENTAGE CHANGE
Speed (cm/s)	45.86 ± 5	54.43 ± 5	18.6% Increase
Cadence (steps/min)	86	92	7.0% Increase
Step length (cm)	32	35.5	11.0% Increase
Stride length (cm)	56	64.7	15.5% Increase
Stride time (sec)	1.66	1.58	5.0% Decrease
Stance time (sec)	1.2	1	16.6% Decrease
Step time (sec)	0.69	0.54	22.0% Decrease
Single support time (sec)	0.53	0.45	15.0% Decrease
Double support time (sec)	0.67	0.55	18.0% Decrease

Thus, it is observed that the FES stimulator device allows selective control of muscle activation; restoring walking mobility and provides an overall improvement in gait of foot drop patients.

3D Gait Kinematics Analysis

Furthermore, a 3D walking kinematics is analyzed to compare the gait behaviour with and without FES stimulator device. **Fig. 4** demonstrates the ankle flexion magnitude of two subjects with means gait cycle duration (mean of 15 gait cycles of footdrop affected leg i.e. from heel strike to heel strike of affected leg) before and after use of device. In foot drop condition ankle extension is more during swing phase and ankle flexion is not adequate due to weaken ankle flexor muscles. Hence, it is evident from **Fig. 4** that without FES device, subject is not able to flex the ankle properly and have higher ankle extension. At the end of gait cycle (during swing phase), the ankle flexes because the foot becomes free and is pushed freely in forward direction. Whereas, the use of FES device controls the ankle extension (up to 30°) and produces balanced gait with stable ankle flexion in less stride time (gait cycle duration).



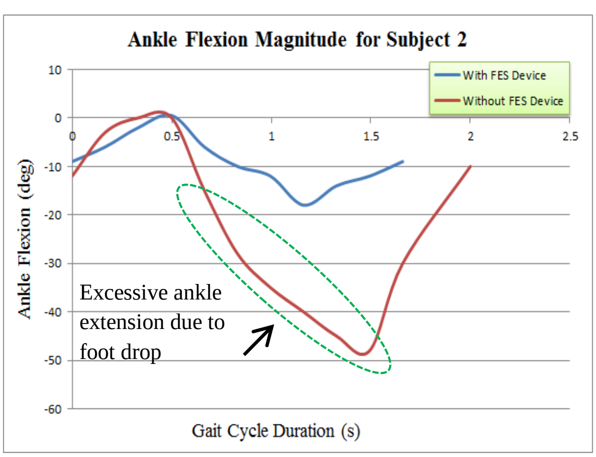


Fig. 4. Average Ankle Flexion Angle during 15 Gait Cycles of Foot Drop Affected Leg i.e. From Heel Strike to Heel Strike of Affected Leg (With and Without FES).

Conclusion

The objective of this research is to design and test the effectiveness of FES based stimulator device for footdrop patients. Device performance was assessed on a set of subjects by evaluating their gait TSP's and ankle kinematics with and without FES stimulation. Mean TSP's results show that FES stimulator has remarkably improved the gait activity of subjects and enhanced their walking speed, cadence, speed length and stride length within limit of 7% to 19%. In addition, device also reduces the stride time, stance time, step time, single support time and double support time by 5% to 22% and hence provides overall improvement in walking posture. Furthermore, 3D kinematics analysis of foot demonstrates that usage of FES stimulation limits the ankle extension within certain range of motion and produced more balanced and stable ankle flexion, thereby correcting the footdrop by 30°. Moreover, 5 subjects (out of 6) have experienced back pain while walking without FES device, because they were not able to lift their affected foot properly and have to throw their legs forward. They reported that their strength is improved with FES stimulation and it also lessens their back pain during walking. This shows that FES based stimulator device is a preferred and reliable treatment for footdrop patients and such devices will also provide remedy for other mobility disorders along with footdrop correction.

Supporting information

Supporting informations are available from VBRI Press.

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