An Intelligent System for Automatic Footdrop Correction in Stroke Patients using FES: A Pilot Study

Naveen Gangadharan, Sivakumar Balasubramanian, George Tharion, Judy John,
Thangavelu Senthilvelkumar, Suresh Devasahayam

Abstract— Initial post-stroke hemiparesis is common in stroke patients that might lead to motor impairments of the contralateral limbs. They usually are presented with impaired ankle-foot function, commonly termed as footdrop / dropfoot. Their gait is associated with foot slap, toe-drag and hip-circumduction. Despite the research in post-stroke rehabilitation that has brought in various technical insights to footdrop correction, there is still want of evidence-based rehabilitation guidelines because of limited understanding of the mechanisms leading to footdrop and its correction. This paper presents a study with main objectives being 1) to develop a low-cost inertial motion sensor-based footdrop correction system that uses Functional Electrical Stimulation (FES) as intervention, and to assess the effectiveness of the system in correcting footdrop with manual stimulation using a press button, and 2) propose an algorithm based on the above results to automate the stimulation timing of the device. Six healthy subjects and two stroke survivors were recruited for the study. Studies related to FES-based footdrop correction has always presented problems pertaining to an efficient way of achieving a normal gait. There are lesser evidences on the parameters of stimulation including the timing of stimulation which is a prime factor to achieve a smooth normal gait pattern which this study has taken into consideration. The results of this study show that such a device is expected to help stroke survivors with footdrop to walk with enough clearance. The tibial tilt angle, tibial angular velocity and forefoot normal acceleration components have been used to simulate the automatic stimulation ON/OFF pulse and the algorithm is found to work for the controls recruited, which proves the feasibility of automating the stimulation using sensor-based swing phase detection. The positive feedback about the device has also shown a direction towards the future work this work demands to completely automate the system and make a reliable, low-cost, user friendly footdrop correction device.

Index Terms— FES (Functional Electrical Stimulation), footdrop, gait analysis, IMU (Inertial Motion Sensor), Madgwick algorithm, peroneal stimulator, stroke rehabilitation, tibialis anterior stimulation, walkaide.

1 Introduction

Stroke survivors are often presented with contralateral hemiplegia if there is damage to the corticospinal tract and there will be persistent distal weakness, one such case being dropfoot. The subject will not be able to actively dorsiflex the foot during the swing phase of the gait. Hip circumduction, steppage gait, toe dragging, reduced gait speed, and higher fall risks are usually presented as the consequences. As compared to the conventional AFOs that limits ankle mobility leading to contractures, discomfort and unfavourable aesthetics, FES has emerged as one of the effective means of achieving active ankle dorsiflexion during the swing face, helping the stroke survivors to attain good foot clearance and achieve a natural gait [7] [8] [9]. A peroneal nerve stimulator can be used to stimulate the common peroneal nerve innervating the tibialis anterior responsible for the ankle dorsiflexion [10] [1].

The peroneal stimulator design has been in research for decades to develop a more user friendly, light weight, more reliable, and economical orthotic device. The early 1990s witnessed use of surface electrodes and foot switches (either open/ close mechanical switch or force sensitive resistors) with limitations of being required to be worn along with a stable foot wear or some other means holding the switch and the major drawback was the inappropriate firing of the switch due to poor contact during the hemiplegic gait. The entire set up was not convenient to use on daily basis. To overcome these limitations, sensors with accelerometers and gyroscopes, that can detect the joint orientation and the timing of stimulation for dorsiflexion can be used to calculate gait kinematics obtained from the sensor data [11] [12]. This presented study is on the development of a sensor-based footdrop correction device using FES with manual mode of triggering stimulation, being tested on normal volunteers and stroke patients. The data collected has been used to propose an algorithm for automatic footdrop correction where the stimulation timing is decided based on the manual stimulation data [16]. This would be the first step towards the design and development of a user friendly, motion sensor-based dropfoot correction system with FES device, having a manual control and an automatic control. The commercial available model of this kind of a footdrop correction system has been reviewed by the users with the following drawbacks: i) the device stimulation timing accuracy does not take into account the situations where a user sits by bending the knees and the device wrongly stimulates detecting the tibia tilt, ii) there is no provision to switch back to the manual control mode from the automatic mode if the user decides to switch. This study would be an attempt to check the feasibility of such a device adapted to Indian settings in terms of cost, provision for barefoot wearing and accuracy.

2 Methods

The apparatus comprised of a multichannel stimulator that

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was used to stimulate the common peroneal nerve innervating the tibialis anterior, a sensor master control board to collect the gait kinematics from two inertial measurement units, one placed on top of forefoot and the other on tibia, a hand-held manual switch to switch ON/OFF the stimulator, Fig. 1 shows the principle.

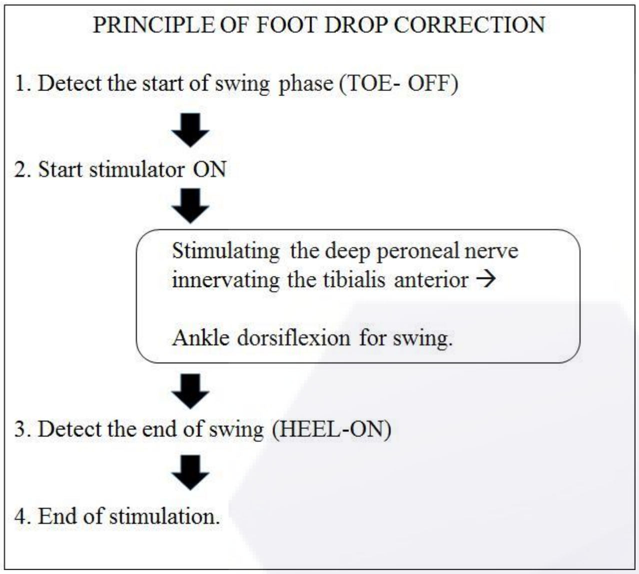

Fig. 1. Principle of footdrop correction using FES

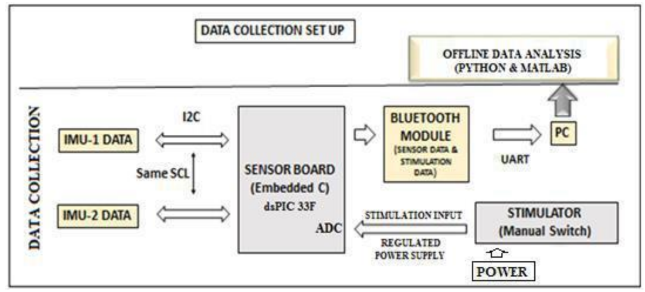

Fig. 2. Sensor master control hardware

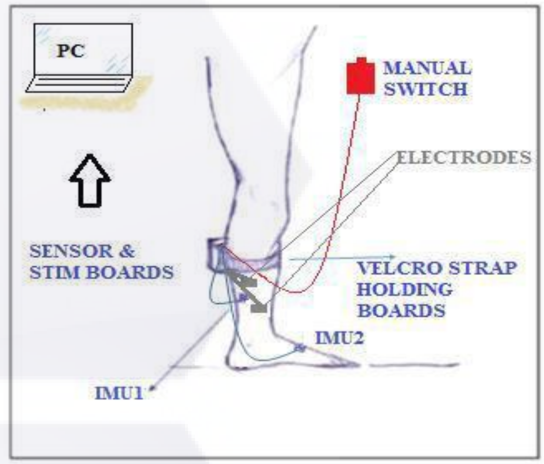

Fig. 3. Stimulator at the level of deep peroneal nerve

2.1 Sensor Master Control Board

The sensor master control board houses a digital signal microcontroller, dsPIC33FJ128GP804 (16 bit), from Microchip, 2 Inertial Measurement Units (IMUs) and a Bluetooth module, Fig. 2 and Fig. 3. Inertial Measurement Unit (IMU): MPU-9250 from Invensense was used to measure linear acceleration and angular velocity of lower limb segments. Sensor communication to the controller was established with I2C at 400 kHz. I2C, Bluetooth and ADC: For the device, I2C bit banging was implemented to interface the IMUs, while UART has been used to interface with the Bluetooth module and ADC for collecting stimulation ON/OFF timing pulse data. Bluetooth 2.0 +EDR zmodule from Bluegiga Technologies was used. The data was collected in PC at a frequency of 100Hz.

2.2 Stimulator Board

A 4-channel constant current stimulator (CMCstim, developed in-house) with independent channel control was used for the study, Fig. 4. It has mainly 4 sections: the controller, the high voltage section, the output current controlled section and power supply. One out of the 4 channels were used for stimulating the deep peroneal nerve responsible for the swing phase ankle dorsiflexion to correct dropfoot. One channel was kept for gastrocnemius/soleus plantart flexion push off, for future research. The high voltage section can build up voltage up to 240V.

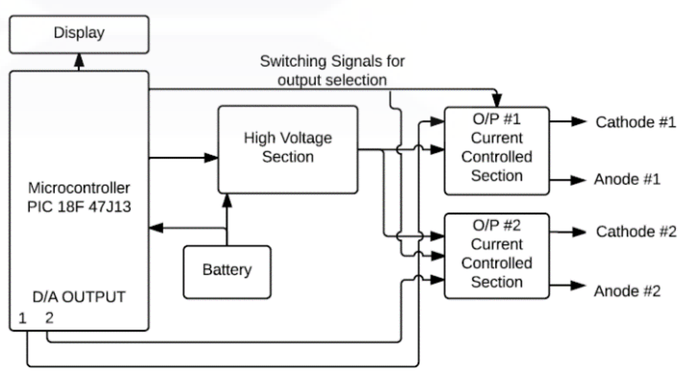

Fig. 4. Stimulator block diagram

- *Naveen Gangadharan worked on this for MS Thesis, Christian Medical College (CMC) Vellore and SCTIMST Trivandrum, India, (2016). E-mail: navpournami@gmail.com*
- *Suresh Devasahayam, Head & Professor, Bioengineering, CMC Vellore*
- *Sivakumar Balasubramanian, Professor, Bioengineering, CMC Vellore*
- *George Tharion, Professor, Physical Medicine & Rehabilitation, CMC Vellore*
- *Judy John, Professor, Physical Medicine & Rehabilitation, CMC Vellore*
- *Thangavelu Senthilvelkumar, Lecturer, Physiotherapy, Physical Medicine & Rehabilitation, CMC Vellore*

The stimulation parameters (biphasic/monophasic pulses, pulse amplitude, pulse width and frequency) can be preset as required to produce enough dorsiflexion for foot clearance and stimulation can be initiated using the manual hand-held button (up to 0-80 mA, 0-40Hz, 0-0.5ms). The stimulator is powered using rechargeable Nokia battery, 3.7V, 1020mAh. Adhesive gel pad electrodes were used. The stimulator could be extended upto 8-channels.

2.3 System Calibration

There are two IMU sensors used for the study, one placed on the tibia and the other placed on the foot. Static calibration is done by aligning the corresponding axis of the sensor with the world coordinate axes and then by measuring the acceleration and gyroscope values with changes in orientation of sensor, Fig. 5. Dynamic calibration has been done against simple and double pendulum [15] [22] [23], Fig. 6 and standard video gait analysis (*PhaseSpace Motion Capture*, Rehabilitation Institute, Christian Medical College, Vellore). To calibrate the sensors, the system was fitted on to the subject along with the LED markers and the sensor data collection was done along with the standard gait analysis. The position of the sensors is as in Fig. 7. The accelerometer data and the gyroscope data from the IMUs placed on the tibia and the forefoot are used to find the rotation angles along x, y, z axes of the respective sensor, to determine the position of the tibia and forefoot, in terms of angles with respect to ground, using Madgwick algorithm [21] [14] [24]. The Figs. 5, 6, 8 show the calibration results. The same sensor orientation on tibia and forefoot was used throughout the study.

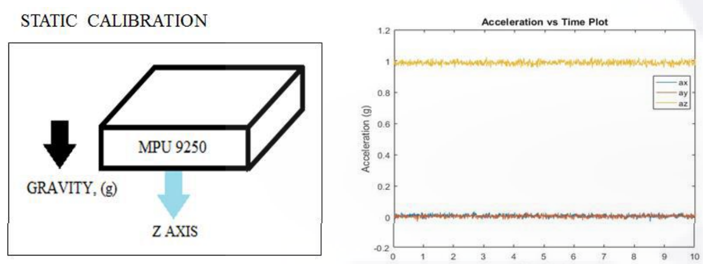

Fig. 5. Static calibration (only z-axis shown)

2.4 Subjects

6 normal volunteers (4M, 2F: age 22-25yrs) and 2 stroke patients (2M, 45 and 55yrs, from Vellore, Tamil Nadu, India) were recruited for the study. A few stroke subjects had to be excluded from the study as they exhibited spasticity.

Inclusion Criteria: At least 1 stroke more than 8 weeks before enrollment, resulting in dropfoot who can walk 5 meters with support, age greater than or equal to 18 years, history of independent function prior to stroke, including walking with assistive device, adequate cognition and communication abilities (> 21/30 on Mini Mental State Examination MMSE), ankle dorsiflexion with test stimulation while sitting and standing, adequate knee and ankle stability during gait with stimulation.

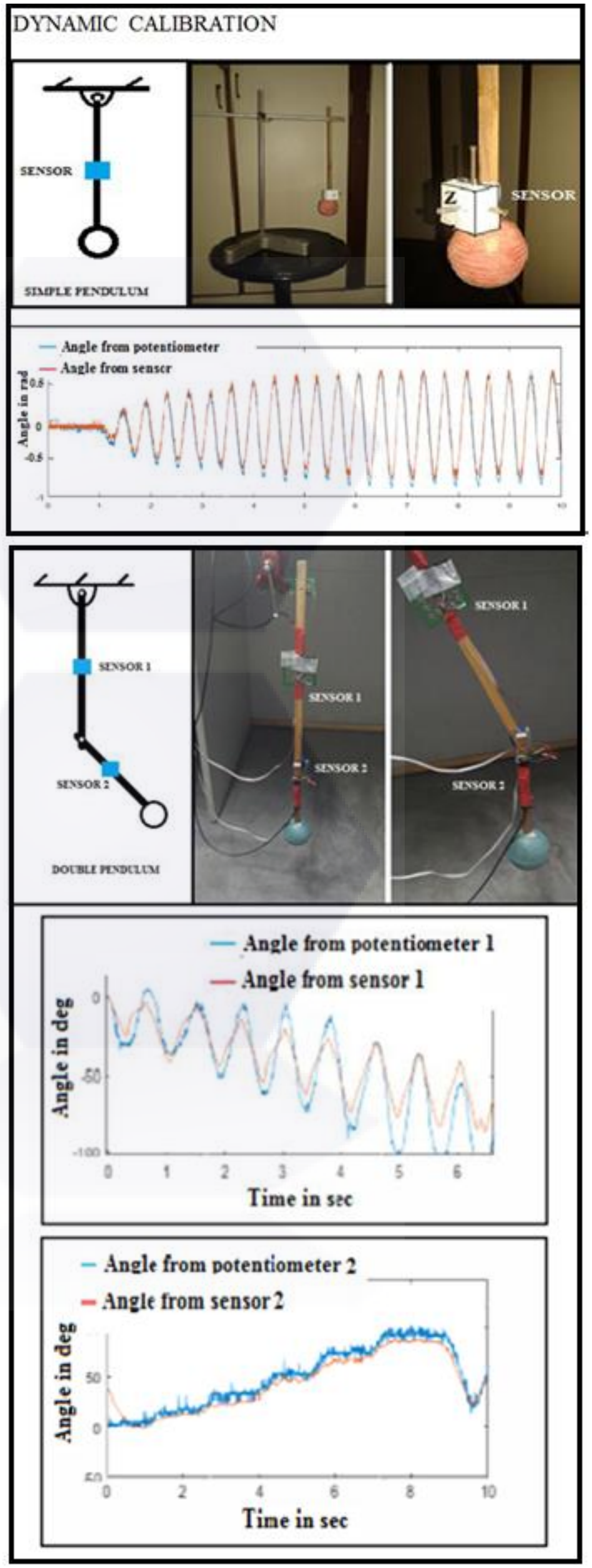

Fig. 6. Dynamic calibration using pendulum

Exclusion Criteria: Any condition which can be a contraindication for using FES were excluded, such as: pregnancy, implants like cardiac pacemaker/ implants generating electrical signals/implants in lower limb having metal parts/ vagal nerve stimulator; local conditions limiting wearing of FES were excluded, such as: venous stasis/ history of lower extremity ulcer/ chronic skin condition/ excessive pain/ swelling/ severe injuries in affected leg, pre-existing orthopaedic condition that could limit ambulatory progress (eg: arthritis, total hip/knee replacement, limited ROM etc); Cases of peripheral neuropathy/ lower motor neuron injury/ equinus contractures and patients with severe hemineglect/ absence of stereognosis were excluded.

2.5 Protocol

This pilot study was conducted on normal volunteers and then on patients with foot-drop, caused by stroke. There were two parts for the study, as shown in Fig. 9. After sensor calibration using simple pendulum and double pendulum procedures, and after correlating the data with video gait analysis on an even floor, the data collection was done using manual stimulation for normal subjects and stroke patients, wherein the subject will trigger the stimulator at the start of the swing phase (pre-swing) of gait using a hand-held press button. The sensor data set along with the manual switch timing data were used to find the control parameters for automatic stimulator switch control algorithm, to be used in the automatic (auto) mode. The second phase is the pilot study of the auto mode based on this algorithm. This has not been implemented in the controller in this study but has been validated through simulation. The system is to be evaluated for two modes of operation, manual and automatic modes. In manual mode, the user should trigger the stimulator at the start of the swing phase of gait using a hand held press button as in part 1. Now, the user can switch to the auto mode to automatically trigger the FES during the pre-swing to achieve active dorsiflexion based on the stimulation control parameters from manual mode. The second phase integration could be a future work. The following were the clinical trial procedures followed for data collection:

Baseline Recording: After subject recruitment, the calibrated sensor system was placed such that one sensor on the shank, one on the dorsal aspect of the forefoot and sensor board at the calf level to which these sensors are interfaced. The subject was asked to walk continuously without stimulation for about 4-6 meters, on an even floor. The following parameters are calculated: tibial angle, foot dorsiflexion angle, walking speed, walking symmetry and stride length from the calibrated data which becomes the baseline values.

Manual Stimulation Phase: Next, the recruited subject was asked to sit on chair with the CMC stimulator (CMCstim) placed along with sensor board and strapped on to the lower limb at the calf level as shown in Fig. 12 below the pad electrodes at the level of deep peroneal nerve innervating the

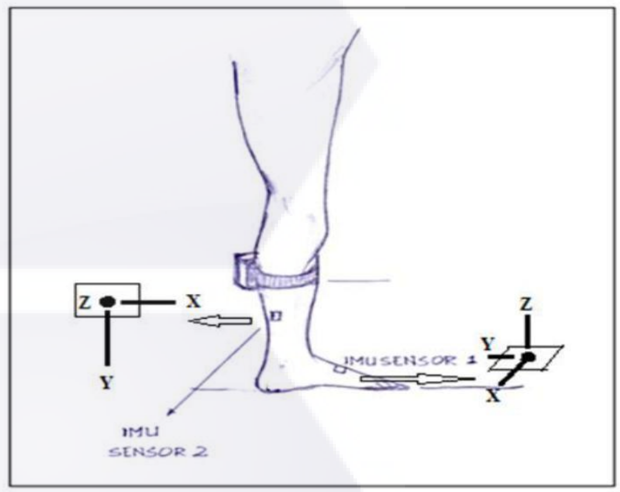

Fig. 7. Calibrated against CMC Gait Lab LED based 8-Camera Gait Analysis System (standard)

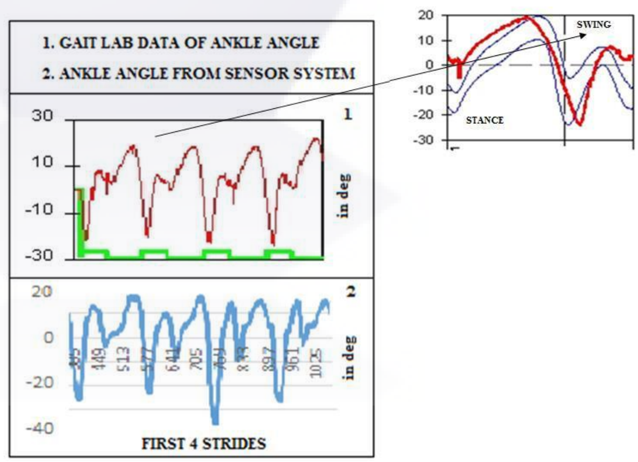

Fig. 8. Calibrated results against CMC Gait Lab

Mean maximum ankle angle during swing phase from gait lab data = 8-10 degrees,

Mean maximum ankle angle during swing phase from IMU sensor data= 10-12 degrees,

Mean minimum ankle angle during swing phase from gait lab data = -22 degrees= Mean minimum ankle angle during swing phase from IMU sensor data

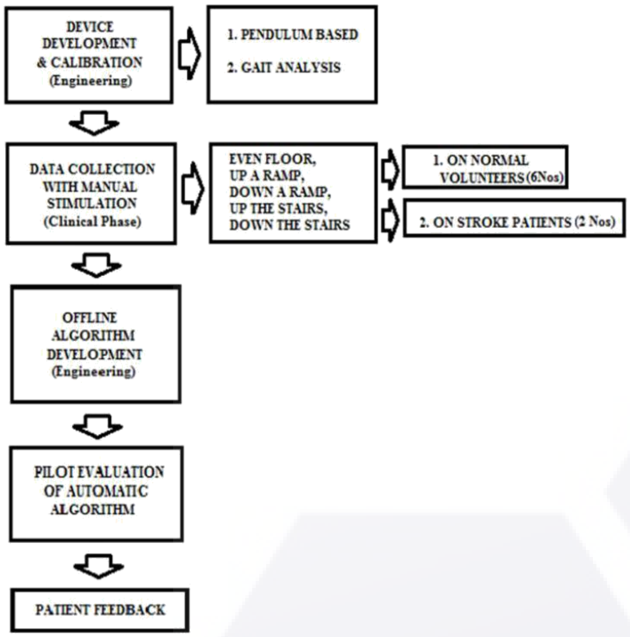

Fig. 9. Study Protocol

tibialis anterior muscle. The sensors were still positioned on the shank, the top of foot of the affected limb at the predetermined anatomical positions. The stimulation parameters were set according to the subjects' comfort level to produce enough dorsiflexion of forefoot. A FES control switch for the stimulator (CMC Stim) was to be triggered ON/OFF by the subject at the start of gait swing phase. Stimulation was given to the electrodes on each button press. With set parameters, the subject was asked to walk on different platforms - even floor, up a ramp, down a ramp, upstairs, and downstairs, Fig. 10. Sensor data was collected for 4-6m continuous walking. The sensor data along with manual stimulation timing was used as the data set for automatic stimulation algorithm development. This was manual data collection phase.

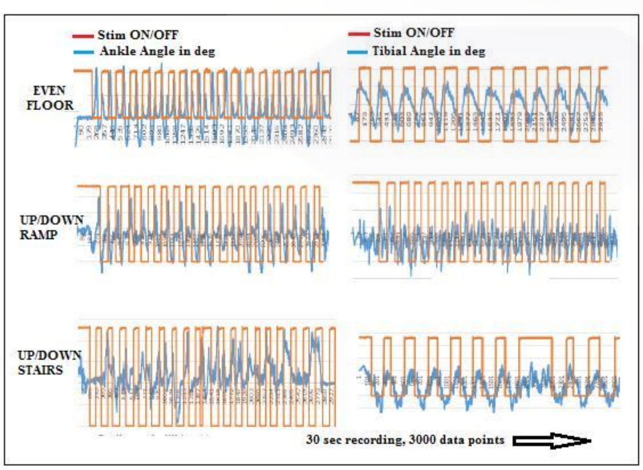

Fig. 10. Terrain comparison

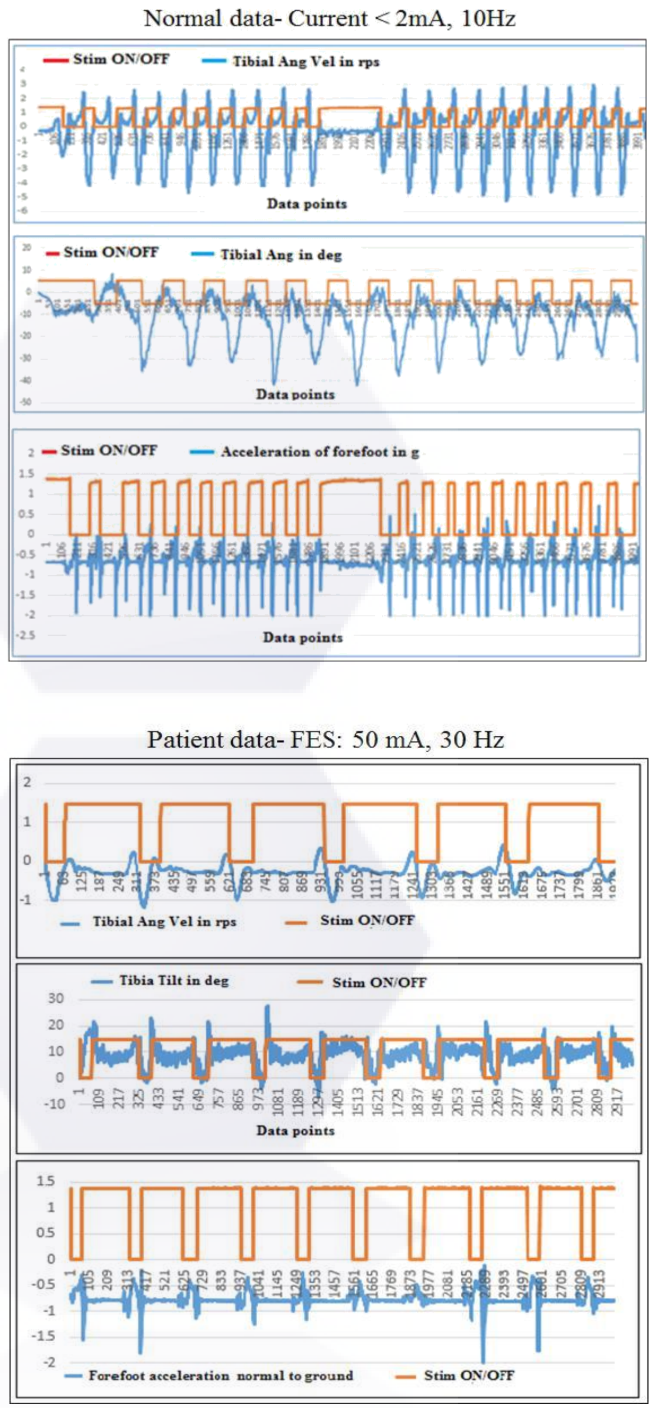

Fig. 11. Normal data and patient data

Algorithm Development for automatic mode: This was implemented offline based on the sensor and stimulation ON/OFF data collected from the Manual Stimulation Phase to determine gait kinematic parameters for automatic swing phase detection. Analysis was done using python and MATLAB.

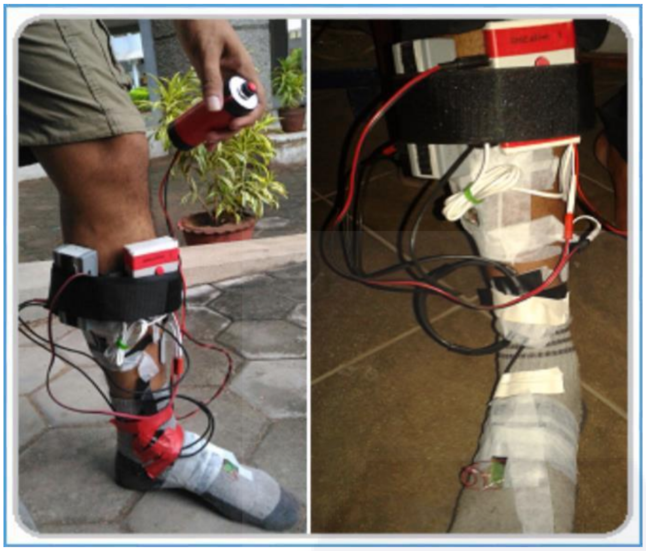

Fig. 12. Device in clinical trial

3 Results

The trials were carried out on 4 terrains: Even floor, Up a ramp, Down a ramp, Up the stairs, and Down the stairs, to verify which data would be ideal to find a correlation between stimulation ON/OFF timings and gate phase tibial and ankle orientations [25]. Tibial and Ankle Angles with respect to the ground were calculated for different terrains for one subject using Madgwick algorithm. To analyze the stimulation ON/OFF timing correlation with various gait parameters, the data from even floor case was utilized to eliminate errors that might arise due to terrain constraints, parameters that could match exactly stimulation ON/OFF pulse edges were used in the algorithm for automating stimulation.

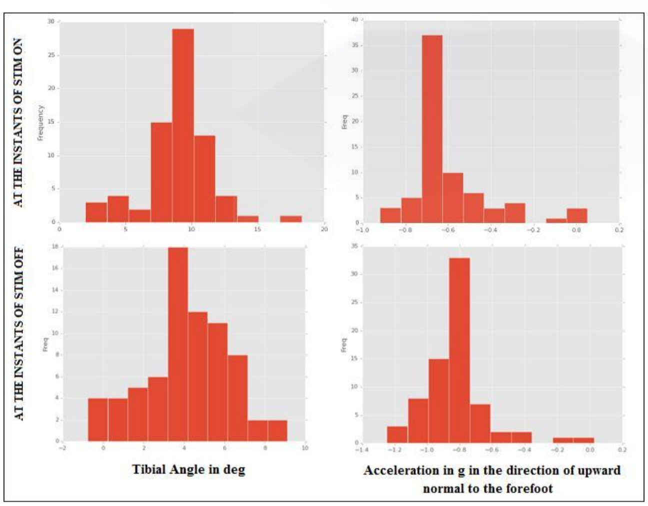

Fig. 13. Pre-swing detection parameters

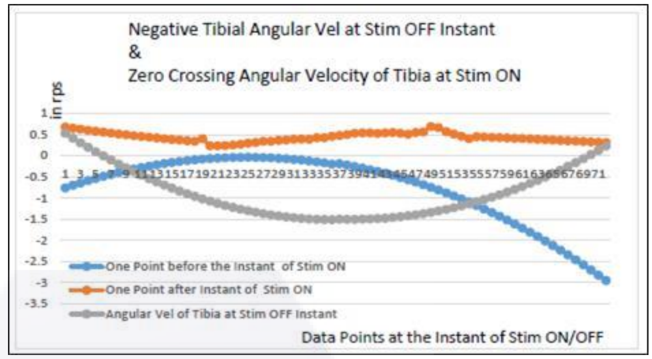

Fig. 14. Pre-swing detection parameters

The tibial tilt angle as observed from the gait pattern, Fig. 11 and Fig. 13, show that the tibia/shank has a backward tilt from the vertical position at the time of toe-off (start of swing) and a forward tilt from vertical at the heels on (terminal stance marking end of swing). This was used as one potential parameter to detect swing phase.

Pre-swing detection: Just the tibial angle change, as threshold for generating the stimulation ON/OFF pulse resulted in the swing phase misses. This was due to the variations in the tibial angles during a normal gait. Hence, to ensure that the automatic stimulation pulse generation algorithm covers all strides without missing any preswings, one more parameter was used for detection, which is the tibial angular velocity which has the property of zero-crossing at toe-off as per the control data analyzed, Fig. 14.

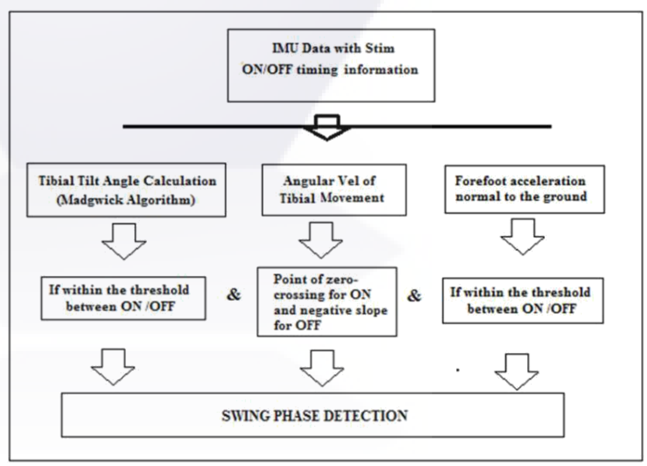

Fig. 15. Automation algorithm

End of swing phase detection: Similarly, tibial angle threshold along with negative going angular velocity of tibia can be used as the end of swing phase. These parameters varied in case of some stroke patients due to either lack of a proper tilt angle or because of unstable limb motion. However, an additional parameter could be found out through trials that could predict if the limb is advancing besides the above-mentioned parameters, the acceleration component normal to the forefoot which was even observed for the stroke survivors, Fig. 13. Algorithm to detect swing phase based on these 3 parameters (tibial angular velocity, tibial tilt angle, forefoot normal acceleration component) was implemented (Fig. 15) and validated by simulating a stimulation trigger ON/OFF pulse waveform and then superimposing the generated pulse waveform over the actual manually given stimulation ON/OFF data (from manual stimulation data collection phase).The results were promising as discussed in the below Figs. 16, 17, showing the ability of the algorithm to automatically correct footdrop using FES, once implemented in the controller.

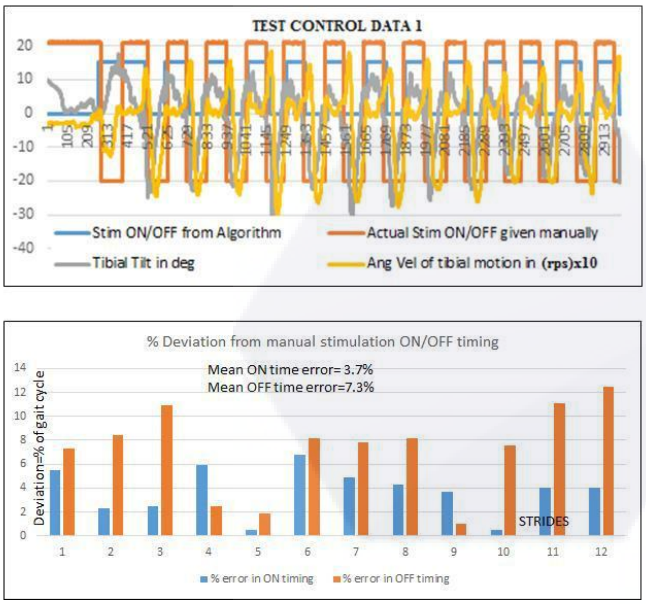

Fig. 16. Test control validation 1

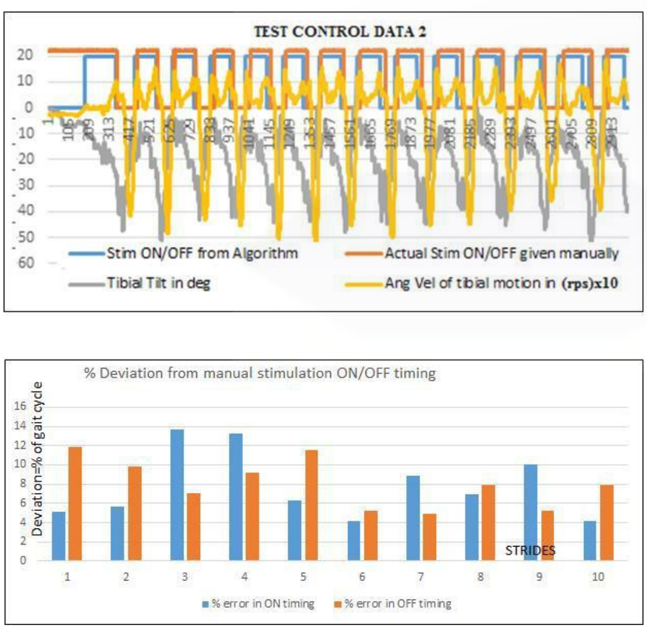

Fig. 17. Test control validation 2

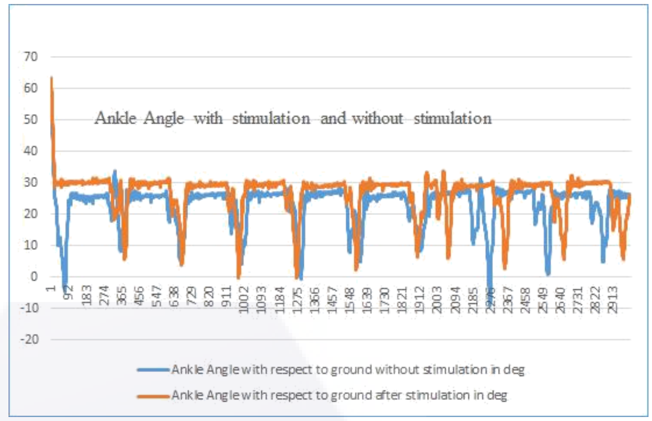

Fig. 18. Increased dorsiflexion in patient 1, with device

TABLE 1
Gait Kinematics Compared

Trial no:	Walking speed without stimulation	Walking speed with stimulation
1	3m in 1min	5m in 1min
2	2.5m in 1min	4m in 1min
3	3.5m in 1 min	5.3m in 1min
	Stride length without stimulation	Stride length with stimulation
1	16cm	24cm
2	15cm	23cm
3	15cm	23cm
	Spatial asymmetry without stimulation	Spatial asymmetry with stimulation
1	0.2	0.1
2	0.2	0.09
3	0.2	0.09

Most patients during the study couldn't complete the trials because of pain sensation to high currents, though the footdrop correction results were in congruence to what was proposed. Some of them presented high spasticity and had to be excluded. The results obtained from the stroke patients are shown in Figs. 18 and 20 and Table 1. Swing phase detection algorithm was also validated for one patient who could complete the trial, Fig. 19. The parameters were: current= 50mA, rectangular pulse width= 400us, frequency= 30Hz.

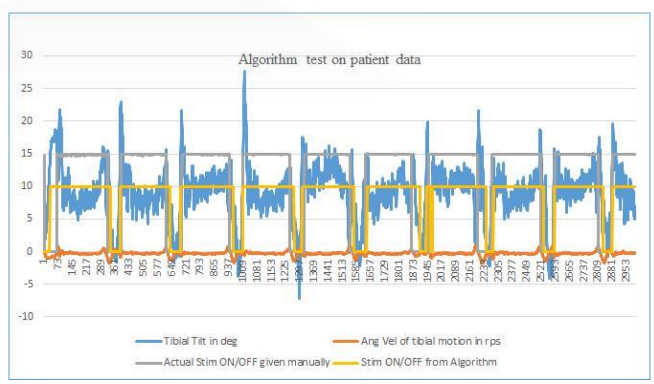

Fig. 19. Algorithm validation on patient 1

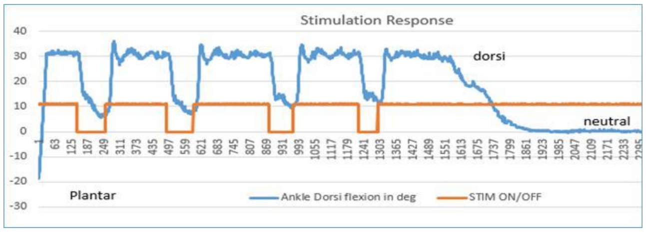

Fig. 20. Increased dorsiflexion in patient 2, with device

4 Discussion

In this study, feasibility of automating a dropfoot correction system using FES as intervention has been presented. The instrumentation includes a calibrated IMU sensor system, a 4-channel stimulator (only two channels programmed for the user). The study was carried out in two parts. First part was implementing the manual stimulation mode in which the subject can give stimulation to the ankle dorsiflexors using a press button during the swing phase to correct dropfoot. Following this, the gait kinematics from the controls were collected using IMU sensors placed on shank and forefoot and were correlated with the stimulation ON/OFF timings and an algorithm was proposed to automate the stimulation ON/OFF based on the gait phase determined from the sensor system.

The algorithm is such that, the stimulation timing can be precisely tailored to everyone's gait pattern and can adapt to changes that might occur during gait by taking three kinematic parameters, tibial tilt, tibial angular velocity and forefoot normal acceleration component. Having the sensor-based gait phase detection unlike footswitch system makes it convenient for the users not having to wear any kind of footwear. The design is such that the entire system is low cost and easily wearable. Presented results were from 6 controls and 2 patients. Once properly validated with higher sample size, the automatic stimulation mode algorithm if implemented in the controller, the device can be customized for a normal gait with effective dropfoot correction. The simulation shows that algorithm works only if there is a tibial tilt. For the patients with no tibial tilt, may be foot switch/force sensors would be useful to detect toe-off.

The algorithms used to find the shank and the ankle angles and hence the gait phases need to be implemented in the controller for real time gait phase detection. Hence, the future work would demand implementation of online learning of the stimulation ON/OFF pulse waveform pattern from the manual stimulation and then to automate the FES during swing phase of gait based on this data. Once implemented, manual and auto modes can be available for the users. One of the limitations is the time constraints faced during the study. Once the feasibility is proved on enough subjects, the next level is to have a cost effective, easy to use, accurate system for automatic footdrop correction using FES for the Indian population. The stimulation timing accuracy can be improved using two sensors as compared to the commercial alternative [5] which is way expensive. But with a tilt parameter alone, it should be possible to trigger ON/OFF the stimulator once the subject enters swing phase as shown by the study. That may make system simpler ergonomically as well as computationally. In that case, one tilt sensor can be incorporated on the stimulator board and thus the extra sensor control board can be avoided.

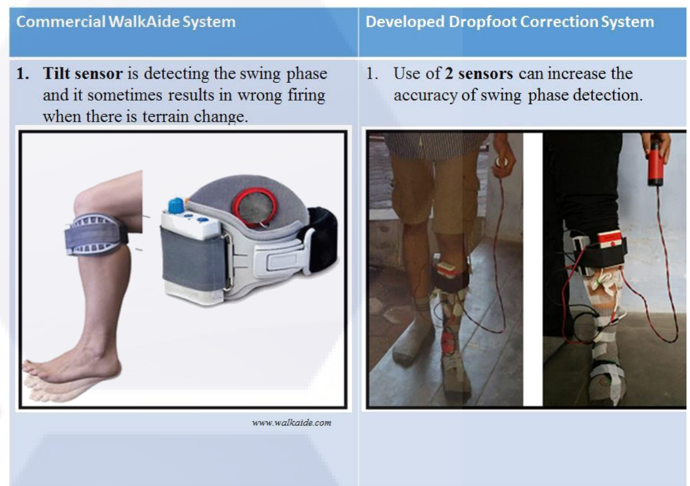

Fig. 21. Device comparison with walkaide device

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