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Design and development of a low-cost biphasic charge-balanced functional electric stimulator and its clinical validation

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Abstract

Functional electric stimulators that produce near-ideal, charge-balanced biphasic stimulation waveforms with interphase delay are considered safer and more efficacious than conventional stimulators. An indigenously designed, low-cost, portable FES device named InStim is developed. It features a charge-balanced biphasic single channel. The authors present the complete design, mathematical analysis of the circuit and the clinical evaluation of the device. The developed circuit was tested on stroke patients affected by foot drop problems. It was tested both under laboratory conditions and in clinical settings. The key building blocks of this circuit are low dropout regulators, a DC–DC voltage booster and a single high-power current source OP-Amp with current-limiting capabilities. This allows the device to deliver high-voltage, constant current, biphasic pulses without the use of a bulky step-up transformer. The advantages of the proposed design over the currently existing devices include improved safety features (zero DC current, current-limiting mechanism and safe pulses), waveform morphology that causes less muscle fatigue, cost-effectiveness and compact power-efficient circuit design with minimal components. The device is also capable of producing appropriate ankle dorsiflexion in patients having foot drop problems of various Medical Research Council scale grades.

Keywords: neuromuscular stimulation, voltage regulators, muscle, biomechanics, operational amplifiers, biomedical equipment
Keywords: low-cost biphasic charge-balanced functional electric stimulator, low dropout regulators, DC–DC voltage booster, single high-power current source OP-Amp, zero DC current, current-limiting mechanism, safe pulses, waveform morphology, muscle fatigue, cost-effectiveness, compact power-efficient circuit design, ankle dorsiflexion, foot drop problems

1. Introduction

Many stroke survivors have to depend on physical exercise for recovery. Physiotherapy is one of the

traditional ways of achieving this. However, functional electrical stimulation (FES) devices have recently been used to provide involuntary exercise using peroneal nerve stimulation to the patient affected by foot drop problems due to stroke (hemiplegia). The World Health Organization quotes 'with aid of assistive technologies, people with a loss of function are better able to live independently and participate in their societies. However, in many low-income and middle-income countries (including India), only 5-15% of people who require assistive devices and technologies have access to them' [1]. The annual incidence of strokes in India approaches 1 million cases per annum. In view of the potential demand due to the high numbers of current FES users in India, and that there are no approved indigenous FES devices currently available on the market, an Indian government national rehabilitation hospital (NIOH Kolkata) supported this work to develop an indigenous device (referred as InStim). The main design criteria were cost-effectiveness, safety and efficacy. Before starting to design this FES device, we reviewed the recent literature on advances in stroke rehabilitation and found that FES device technology is evolving but requires improvement. Furthermore, recent guidelines from the National Health Science (NHS-UK) on neurological disorders emphasise that 'FES device technology is still evolving and requires improvement in device design to enhance efficacy of treatment and to meet patient's safety concerns' [2]. Safety and efficacy of the stimulation is dependent on the characteristics and nature of the stimulation waveforms, design of stimulation protocol, size of the electrode and current densities within safe limit [3]. Traditionally, FES devices used transformer and switching MOSFET in their output driver stage. This type of architecture has the following disadvantages: (i) it produces a uniphasic, unbalanced anodic/cathodic charge; (ii) it causes a large rise and fall time of stimulation pulses; (iii) it produces unwanted high-voltage spikes in the output due to line frequency noise; (iv) output waveforms have a + /– average DC current; (v) the morphology of the pulse is distorted and is not rectangular charge-balanced biphasic as ideally expected [4]. These problems lead to inappropriate firing of neurons or excessive excitability of neurons causing more muscle fatigue or insufficient dorsiflexion due to inconsistent motor unit recruitment.

It also involves patient safety issues such as tissue damage [5]. FES devices used for foot drop are ideally expected to produce perfect charge-balance stimulation waveform, as it is considered to be both safe and efficacious. It delivers equal Faradaic and non-Faradaic charge hence ideal for a patient's safety and it also reduces the fatigue of stimulated muscles by optimum muscle activation [5]. However, it is difficult to achieve charge-balanced stimulation. FES technologists and clinical researchers are working on these directions. To solve these problems Cheng *et al.* (2004) were the first to propose DC–DC architecture to boost the voltage instead of using transformer-MOSFET scheme. While designing the proposed 'InStim' FES device, we took inspiration from the technological advancements in implanted microstimulators that successfully produced a balance charge for safe neural stimulation [6] using ASIC/FPGA-based DC–DC booster and low current pump-based driver stage topology by making necessary changes to meet high-voltage–high-current requirements of surface neural stimulation.

2. Disadvantages of current approaches and solutions required

We have listed all the relevant prior arts on FES designs in Table 1. There are only a few articles that revealed the complete FES circuit design. Most of them used traditional transformer-MOSFET architecture. The schematics of clinically validated (using studies on stroke patients with foot drop) designs for producing safe, efficacious and biphasic charge-balanced stimulation are not available in the public domain. A few research groups have worked on parts of FES design, notably the output driver stage; however, limitations as mentioned in Table 1 were studied in detail to develop the proposed design. Many of the designs documented within the published literature do not give details about clinical validation, efficacy of the circuit or detailed specification of the output waveform. Owing to these reasons, we felt it was necessary to design a new FES circuit (InStim).

Table 1

Prior art on FES device designs and their shortcomings

Reference no.	Design method for output driver stage and other details on schematic	Charge balancing method	Maximum current, mA	Validation (skin model/patient)
[7]	2 Op-AMP Howland current pump. − current output limited up to 25 mA	BBP UUP	25	Y/N
[8]	transistorised Wilson current mirror, − computer-controlled	BUP(trapezoid)	110	N/N
[9]	transistor-based,	BUP	100	N/N
[10]	OP-AMP + transformer	UUP	74	Y/N
[11]	single Op-Amp current source	BBP	120	N/N
[12]	MOSFET + transformer	NR	NR	N/Y[a]
[13]	multi-Op-Amp output driver additional safety circuit	BUP	120	Y/N
[14]	not disclosed, transistorised pulse generation schematic given	BBP	100	N/Y[a]
[15]	MoSFET + transformer	UUP	80	Y/Y

UPP: uniphasic charge unbalanced pulses, BUP: biphasic charge unbalanced pulses, BBP: biphasic charge-balanced pulses.

[a]Clinical test of the device performed on healthy subjects instead of stroke patients (device efficacy also not evaluated). P: partial, Y: yes, N: no, NR: not reported.

3. System design (FES device: InStim)

In this Letter, we present a FES device design for producing perfect, rectangular, charge-balanced stimulus output with near-zero DC level. This design also features a mechanism to limit the current at a safe level. Unlike most designs documented in the published literature, the proposed design is both laboratory and clinically tested with a cohort of stroke patients, thereby demonstrating its proven safety and efficacy. The following system requirement specifications were used to design a new FES device after a survey of the currently available FES devices and researcher recommendations [16].

4. Stimulator specifications

The designed stimulator delivers combinations of short duration (180 μs) and high-current (up to 60 mA) charge-balanced biphasic pulses with frequencies of 40 Hz. Interphase delay of 20 μS was kept between the anodic and cathodic phases as per the best practice recommended for biphasic pulses. These pulses are applied via a 6 cm diameter electrode placed proximal to the peroneal nerve. The pulse

rise time was kept very short (2 μs) so that the charge contained in the stimulation pulses would be close to the ideal (ideal charge in each pulse = PW × *I*). For safety purposes, the maximum current limit was kept at 60 mA, which is a safe limit for stimulus delivery via 10 cm × 5 cm electrodes [3]. Considering the maximum current limit of 60 mA, the output voltage level needed was calculated as 120 V, assuming the skin resistance to be 2 kΩ. ($V = I \times RP = 60\ mA \times 2\ k\Omega = 120\ V$) [4]. Fig. 1 shows a block diagram for the indigenous FES device, InStim, illustrating the four stages detailed below. On the basis of these specifications, a circuit was realised using the SPICE-based design and simulation software TINA-TI (Texas Instruments Inc., USA) and implemented accordingly. The detailed schematic is shown in Fig. 2. The schematic of the FES device is divided into five blocks: (i) power-management unit (PMU), (ii) input stage, (iii) the combined microcontroller unit, input–output interface and associated controls, (iv) feedback and (v) the output driver stage. All five sections are described below.

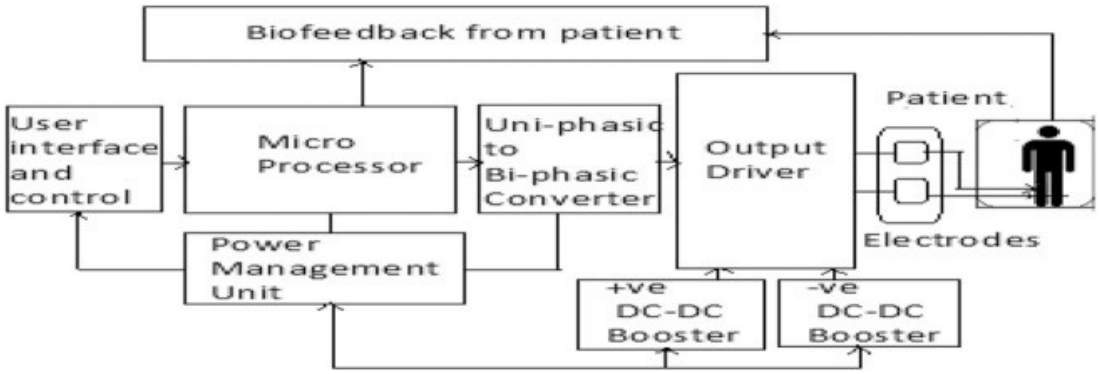

Figure 1

Block diagram of the indigenous FES device InStim

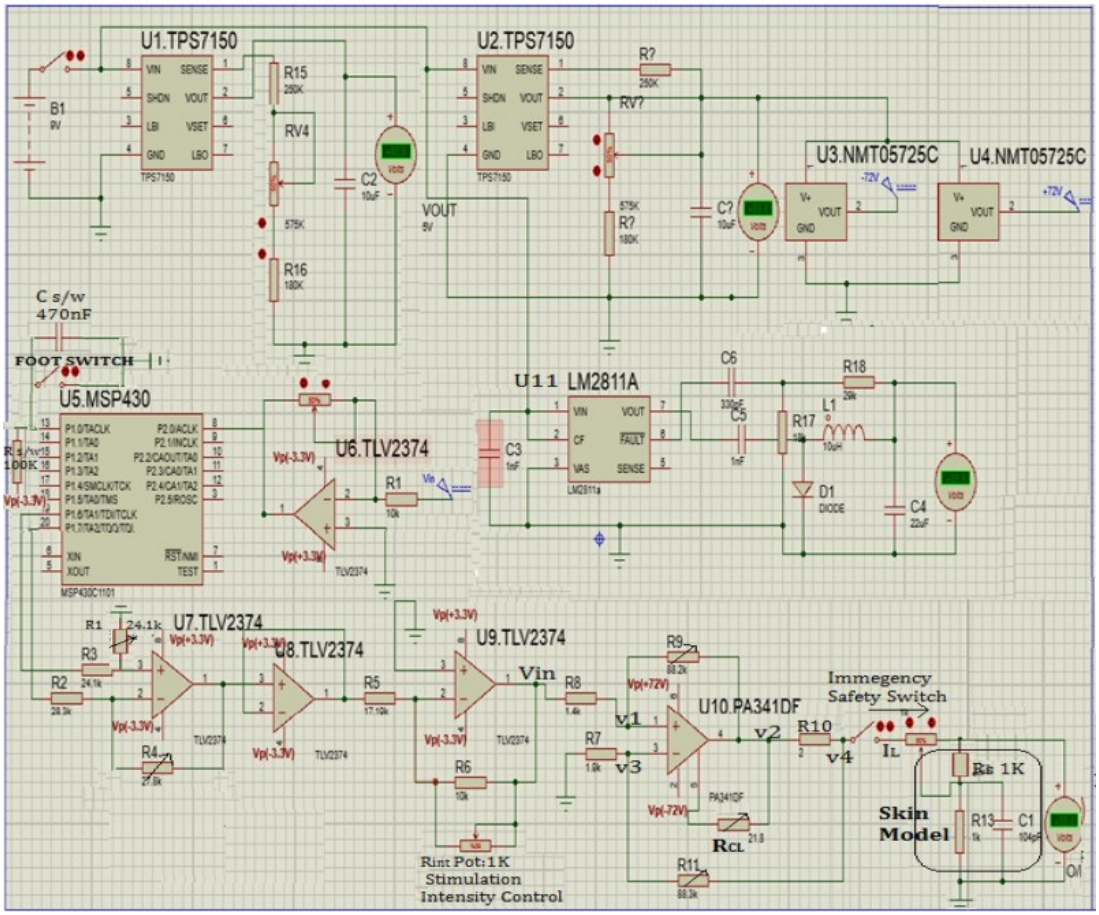

Figure 2

Schematic of the indigenous FES device ‘InStim’

4.1. PMU [low drop-out (LDOs) and DC–DC boost converter]

The PMU functions to supply the required voltage to all circuit parts. It consists of three LDO regulator ICs (U1, U2 and U11), two DC–DC boost converter ICs (U3 and U4) and some additional components. Of the three LDOs, two (U1 and U11) are used for generating ±3.3 V while the third (U2) provides the required input supply (+5 V) to the DC–DC boost converter ICs.

Stimulators are required to produce high-voltage, short duration pulses. A peak-to-peak pulse of more than 100 V is required to achieve appropriate ankle dorsiflexion in foot drop patients. Two DC–DC boost converters (U3 and U4) are used to boost the voltage to a desired level (±72 V). The boosted voltages act as high-voltage positive rail (+72 V) and high-voltage negative rail (−72 V), respectively, for the output driver stage. LDOs were used as they have an ultra-LDO voltage, resulting in reduced power consumption and enhanced efficiency as well as increased battery life of the device. The PMU unit was designed with a mechanism to monitor the battery levels, allowing notification of the user via a red LED when the device requires recharging or the battery needs replacement.

4.2. Input stage (uniphasic-to-biphasic pulse converter and driver)

The input stage receives uniphasic waveforms from the microcontroller port and converts them to the

biphasic waveform. It consists primarily of two operational amplifiers (U7, U8), with U7 configured as the differential amplifier, and U8 as the buffer/driver. The buffer at the end of this stage is responsible for impedance matching and maximises morphological consistency in stimulation waveforms.

4.3. Microcontroller unit, input–output (I/O) interface and associated controls

The microcontroller unit generates a sequence of pulses with a specified frequency and duration. It uses a microprocessor, pulse width controller circuit and foot switch to achieve this task. The microprocessor (U5) used was ultra-low power MSP430F2013 (Texas Instruments Inc., USA). This microprocessor has low-power modes, drawing as little as 0.5 μA in standby mode. The microprocessor was programmed to generate two independent uniphasic pulse sequences with +3.3 V amplitude on two pins of port 2 (pins 1.7 and 1.6). These pulses are then transmitted to the biphasic pulse conversion unit. The control unit consists of a mechanism to adjust the intensity, frequency and foot switch to control the duration of the stimulus pulse. The I/O region regulates the LED indicator, power switch and safety switch. The amplitude of the pulse is adjusted using a rotory potentiometer R_{pot} of amplifier U9. R_{pot} is the feedback path of an inverting operational amplifier (U9) and is used specially for intensity control so that it will not be necessary to do in output driver stage current pump circuit and that impedance is not disturbed. To adjust stimulation parameters, a rotary knob is provided instead of a menu-based system, a sophisticated graphical user interface. A decision was made to minimise the cost of the device and to keep it simple.

4.4. Feedback

The feedback element consists of foot sensors to capture walking information or gait cycle of the patients. The tactile switch was used as a foot sensor as shown in Fig. 2. The microprocessor receives feedback information from the foot sensor (tactile switch) and it controls the stimulation output (switching stimulation on–off, that is, pulse timing modulation). The foot switch was placed under the heel of the inside sole of the shoe under the hemiplegic foot. When the patient lifts the limb for walking, the foot switch becomes off and the corresponding control signal is fed to the microprocessor (μP). The program in the μP generates stimulation pulses that are further fed to the current pump output driver stage. When patients place their foot on the ground, the foot switch becomes closed. In this case, the program in μP detects this event and switches the stimulation pulses off.

4.5. OP-Amp-based output driver state

The output driver stage is based on current pump topology. A high-voltage, high-current voltage-to-current converter operational amplifier U10 (PA341DF; Cirrus Logic, USA) having high compliance voltage was selected for this stage. The output of the driver stage was applied to the patient via stimulation electrodes (oval 10 cm × 5 cm, make Cefar Compex, UK). The output driver stage avoids unwanted DC levels in the output transistor-based designs.

The drive unit has a current-limiting mechanism incorporated for improved safety of the patient. Driver OP-Amp uses a simple external resister R_{CL}, to adjust current, and can be easily adjusted to the stimulus requirements associated with the treatment of numerous conditions. Equation (8) illustrates the relationship between the current-limiting resistance (R_{CL}) and the maximum permissible current level. Furthermore, the circuit was designed to minimise components, and is associated with a low printed circuit board footprint. For the high-current, high-voltage output driver stage positive and negative rails (supply) of ±72 V were provided from the DC–DC boosters U3 and U4. The compliance voltage required was twice the maximum output voltage (i.e. 144 × 2 = 288 V). Hence for the output driver stage we have selected a suitable high-voltage operational amplifier PA341DF (Cirrus Logic, USA) which has a very high compliance voltage (800 V) well above the compliance requirement.

4.6. Output driver stage design and performance testing

To investigate the relationship between input voltage and output current of the driver stage we evaluated the circuit transfer function by doing nodal voltage and current

$$\begin{aligned}(V_{\text{in}} - V_1)/R_8 + (V_2 - V_1)/R_9 = 0;\\ I_{\text{L}} = (V_2 - V_4)/R_{10} + (V_3 - V_4)/R_{11}\end{aligned} \tag{1}$$

$$\begin{aligned}(V_4 - V_3)/R_{11} + V_3/R_7 = 0; V_3 = V_1\\ \text{iL} = -V_{\text{in}}(R_9/(R_8 \ * \ R_{10}))/(1- \in)\end{aligned} \tag{2}$$

where $\in = R_{12}((R_9R_7-R_8R_{10}-R_8R_{11})/R_8R_{10}(R_7+R_{11}))$

$$\text{iL} = -V_{\text{in}}.(R_9/(R_8 \ * \ R_{10})) \tag{3}$$

when ratio R_9/R_8 sets equal to R_{11}/R_7

$$\text{iL} = -0.5 \ * \ V_{\text{in}} \ * \ (R_9/R_8) \tag{4}$$

when R_{10} set at 2 Ω

$$\text{iL} = -20 \ * \ V_{\text{in}} \tag{5}$$

R_9 and R_8 are fixed at 80 k and 2 k, respectively, (6)

iL = 0 mA, when V_{in} = 0v; iL = 60 mA, when V_{in} = 3 V (7)

$I_{\text{Limit}} = V_{\text{BE}}(0.6)/R_{\text{CL}}$, when R_{CL} = 10 Ω current limit set as 60 mA (8)

From the above relationships, it is evident that the input voltage (V_{in} 0–3 V) to drive stage controls the output stimulation current (range 0–60 mA). The values of resisters required to generate this current range (0–60 mA) were derived from the above relationships. The detailed schematic of the device is provided as a supplemental section of this Letter. The above output driver circuit design produces a safe, charge-balanced biphasic stimulation pulse sequence as shown in Fig. 3*b*, which is close to the ideally expected stimulation waveform as shown in Fig. 3*a*. The output current accuracy of the output stimulus waveform was 98% when compared with test values over the range of 1–60 mA with pulses of 180 μs or longer. The rise time for square pulses is <3 μs, as expected from the charge-balanced stimulator.

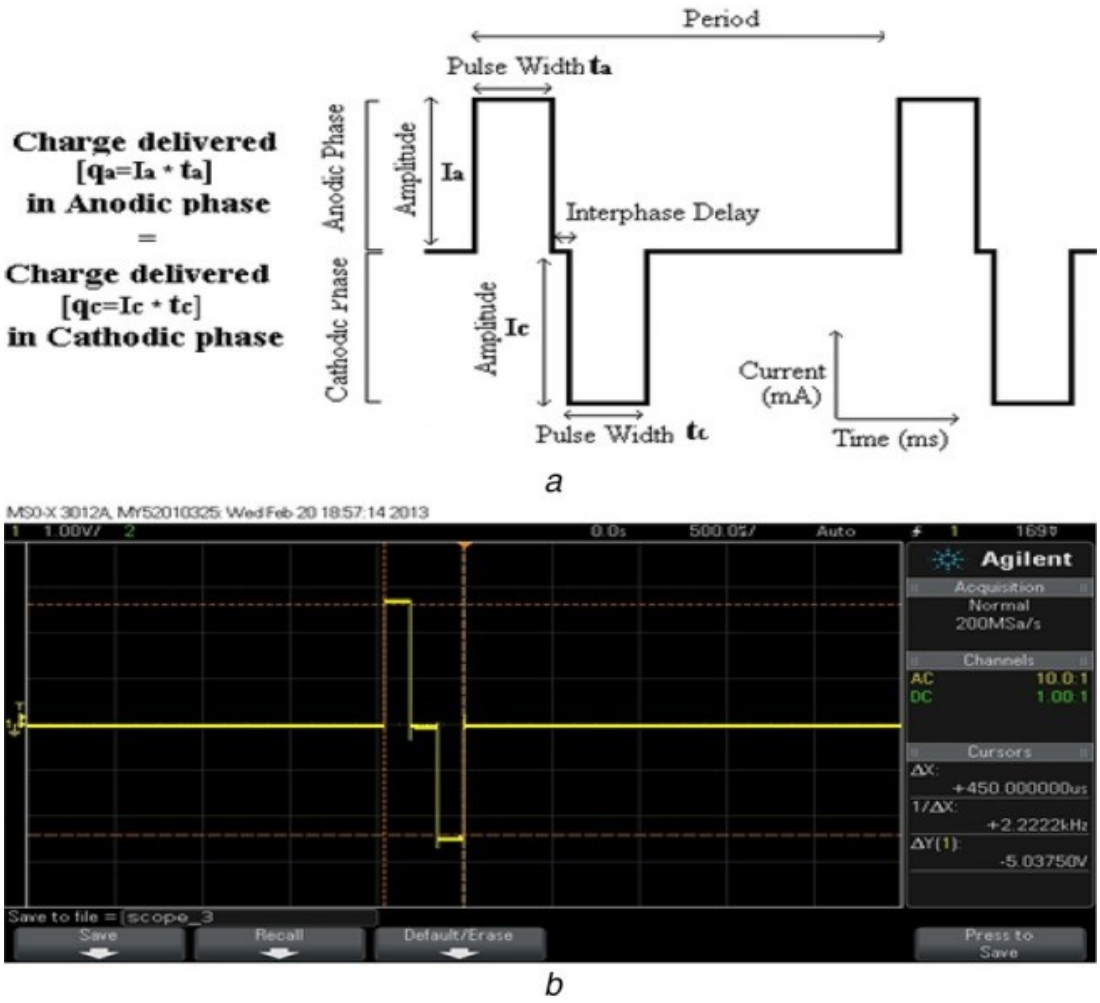

Figure 3

Output driver stage design and performance testing

a Ideal output expected from the stimulator for providing safe and efficient treatment

b Indigenously developed FES device 'InStim output

Improvements seen as compared with previous architectures were: (i) biphasic charge-balanced rectangular stimulation waveform with equal anodic charge and cathodic charge; (ii) lower rise time and fall (decay) time of pulses; (iii) absence of unwanted DC level and spikes; (iv) constant output irrespective of changes in skin impedance; (v) pulse morphology unaffected by the change in skin impedance; (vi) wave parameter stimulation frequency (40 Hz), maximum output current (60 mA), pulse width (360 μs) and interphase delay of 20 μs are required in a FES device for foot drop. The above pulse characteristics provide safety to patient, avoid muscle damage, cause minimum muscle fatigue and generate optimum firing of the neurons for efficacious electrostimulation treatment

If unbalanced charge is observed in the output waveform, to overcome this issue two precautions were taken during the design of the circuit. First, in the biphasic pulse generation stage (subtracted stage after microprocessor, OP-AMP U7) two variable potentiometers R_1 and R_4 are provided to adjust the difference if any in anodic and cathodic charges. Second, in the last stage output driver stage variable

resisters (R_9 and R_{11}) are provided to adjust the charge in anodic and cathodic pulses independently by manually adjusting the potentiometers. These arrangements made certain that output pulse is always biphasic charge balanced.

5. Results

This section describes the results of laboratory and clinical testing of the proposed FES device (InStim*)*. In the laboratory, output stimulus wave parameters were monitored using the skin model as shown in Fig. 4; the device safety was also evaluated [17]. The device efficacy was assessed by measuring the degree of ankle dorsiflexion caused by stimulation, and the fatigue level of the stimulated muscle due to stimulation.

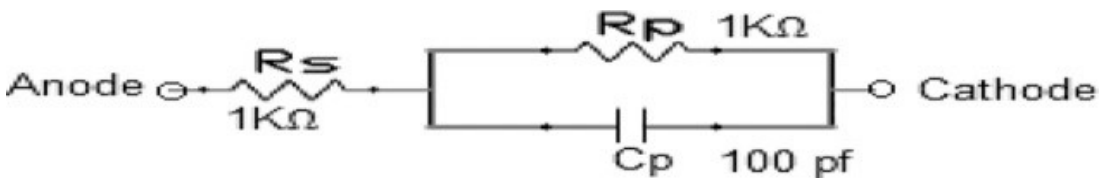

Figure 4

Skin model used for testing the safety of the device

5.1. Laboratory testing

The waveforms obtained at the output (cathode–anode) terminal of the device were observed using an oscilloscope (InfiniiVision, Agilent Inc., USA). The obtained output waveform and its characteristics are described in Fig. 3*b*. The correlation between the ideal and the InStim device waveforms was 0.98. The output waveform was also observed at various pulse widths, pulse durations and current amplitudes. The important wave parameters' (intensity, frequency, DC voltage, root mean square (RMS) current) values were within expected values. Table 2a shows the various stimulation intensity levels adjusted by the stimulation control knob and the corresponding output RMS current and DC voltage present in the output stimulus waveform. Moreover, the output waveform characteristics (amplitude and timing) were measured using an oscilloscope are shown in Table 2b.

Table 2a

Laboratory test (skin model) results of the indigenously developed FES device (InStim)

Sr	Stimulation intensity, mA	Stimulation frequency, Hz	Output RMS current, mA	Output DC voltage, mA
1	25	40	0.73	−0.07
2	35	40	1.55	−0.07
3	40	40	2.18	−0.07
4	45	40	2.64	−0.08
5	50	40	2.79	−0.08

Table 2b

Various amplitudes and timing characteristics of output waveform measured using an oscilloscope

Parameters (magnitude)	Value	Parameters (time)	Value
Pk-Pk, V	144.6	period, ms	24.8
Maximum,V (anodic)	72.2	frequency, Hz	40.1
Minimum,V (cathodic)	−72.4	+width (μs) (anodic)	179
Top, V (anodic)	72	−width (μs) (cathodic)	180
Base, V (cathodic)	−72	inter pulse interval	20
Over, %	0.28	duty, %	1.5
Average-cyc, mV	−754	rise, μs	5
DC RMS, mV	160	fall, μs	8
AC RMS, V	0.81	duty, %	1.44

5.2. Patients' safety

It is evident from Table 2a that this output stimulation waveform contains minimal levels of DC output voltage, which avoids risk of stimulated muscle damage of the patient. Besides, a 0.5 μF capacitor between the subject and the stimulator was provided. It ensures that even in the event of stimulator failure, no more than 72 μC ($C * V = 0.5$ μF * 144 V) of net charge will be transferred to the subject. This is less than the maximum safe charge of 520 μC for human body surface stimulation. Thus this design avoids the delivery of high-voltage power supplies directly to the stimulating electrodes. Moreover, the current-limiting feature in the output driver stage of the stimulator provides safety to the

patient. Extra safety is provided to the user through a controlled emergency safety-switch by which the patient can disconnect himself from the stimulator by pressing it.

5.3. Skin model test results

Before applying the stimulation to the patient, researchers have recommended to use a skin model for evaluating the safety and performance of the device [17]. Output stimulation waveforms of the developed device with different frequencies and amplitudes were applied on a skin model as shown in Fig. 4. It was observed that high frequencies produce higher RMS voltages. For an optimally safe stimulation, the DC voltage in the output waveform is expected to be zero to avoid the risk of skin burns as shown in Table 2a

5.4. Power requirement of a pulse sequence

Let us consider that a patient is stimulated with maximum current capacity (I_p = 60 mA) with standard output voltage (V_p = 72 V) and the frequency of stimulation used is 40 Hz, with anodic and cathodic pulse width of 180 µs each and that the inter-pulse interval is kept as 20 µs. In this case the power required to deliver a train of biphasic pulses to the tibialis anterior muscle of the patient is around 0.065 W.

5.5. Clinical test results

To determine efficacious and a safe InStim stimulator for clinical use, four stroke subjects with foot drop due to stroke were recruited randomly at a clinical site (National Institute of Orthopedically Handicapped-NIOH Kolkata). Each subject was stimulated using both the indigenously developed stimulator InStim and the comparator stimulation device MegaXp (Cybermedic Corp., Korea). The experimental protocol features a one-hour interval between stimulations. During stimulation, the cathode was fixed above the peroneal nerve, while the anode was attached to the tibialis anterior (TA) muscle of the patient. Stimulation was applied for 30 min at an intensity level appropriate to produce sufficient dorsiflexion of the ankle. The goal of this experiment was to test the efficacy of the InStim stimulator by assessing dorsiflexion [range of motion-(ROM)] and muscle fatigue associated with application of the stimulus waveform, and comparing it with an existing device.

Power provided by pulses to the TA muscle of the patient is around 0.065 W

$$V_{\text{rms}}\ \text{of biphasic pulse} = \sqrt{(V_{\text{rms}}\ \text{of anodic pulse})^2 + (V_{\text{rms}}\ \text{of cathodic pulse})^2}$$
$$V_{\text{rms}}\ \text{of biphasic pulse} = \sqrt{(V_p\sqrt{D_A})^2 + (V_p\sqrt{D_C})^2} \quad (9)$$

where $D_A = D_C$, duty cycle of anodic and cathodic pulses

$$V_{\text{rms}}\ \text{of biphasic pulse} = V_p$$
$$\text{Power of biphasic pulse train} = V_p \times I_p \times D \quad (10)$$

where D is the duty cycle of the entire pulse train

$$D = \frac{\text{Anodic pulse width } 180\,\mu\text{s} + \text{Cathodic pulse width } 180\,\mu\text{s} + \text{Interpulse width } 20\,\mu\text{s}}{\text{Pulse Period (on+off Duration)}}$$

$$D = \frac{380\,\mu\text{s}}{24\text{ ms}};\ D = 0.15$$

$$\text{Power of biphasic pulse train} = V_{\text{p}} \times l_{\text{p}} \times D = 72\text{ V} \times 60\text{ mA} \times 0.015$$

$$\text{Power of biphasic pulse train} = 0.065\text{ W}$$

ROM is a very important parameter to find the dorsiflexion capability of a foot drop patient [18]. A goniometer was used to assess the active ROM following stimulation to determine whether sufficient dorsiflexion of the ankle has been achieved. The ROM measures shown in Table 3 reveal that the balanced-change pulses produced by InStim appropriately excites the nerves to produce a level of dorsiflexion, sufficient for ankle movement as required for normal gait. A difference in the degree of ankle dorsiflexion achieved was noted between InStim and MegaXP, with the indigenous device evoking an ankle dorsiflexion 15° more than that seen when using the existing market comparator device. This is attributable to the use of a charge-balanced biphasic pulse system over the unbalanced-charge pulses as used in current devices [4].

Table 3

Clinical outcomes of a comparison between existing FES (MegaXP) device and the indigenous FES device (InStim)

Patient no	MRC grade[a]	Stimulation intensity, mA	Active ROM, deg		Dimitrov fatigue index (FI_{nsm})		Skin burn
			Mega-XP	In-Stim	Mega-Xp	In- Stim	
1	1	25	45	60	410	214	no
2	2	35	40	55	530	291	no
3	3	40	35	50	789	402	no
4	4	45	30	45	678	326	no

[a]MRC (Medical Research Council Scale for muscle strength): grade5: muscle contract normally against full resistance, grade 0:no movement.

Note: The above results are for stimulation frequency = 40 Hz (frequency recommended in the scientific literature for effective treatment of food drop problems.

Muscle fatigue is a decrease in force due to sustained stimulation [19]. The FES device causing less muscle fatigue can be used for a longer amount of time for electrotherapy. Surface electromyogram (sEMG) analysis is a good measure to evaluate the extent of muscle fatigue due to stimulation. We acquired sEMG from the TA muscle of each patient, before and after application of the FES stimulus.

For sEMG recording biosignal acquisition device, PowerLab (AD Instruments, Australia) was used. During sEMG acquisition, subjects completed 15 repetitions of a hemiplegic limb foot-extension exercise, lifting 75% of their one-repetition maximal voluntary isometric contraction (MVC). In recent literature, the Dimitrov spectral index of muscle fatigue (FI_{nsm}) is recommended for an accurate estimation of peripheral muscle fatigue, as it gives more accurate results, in comparison to other evaluation parameters [20]. FI_{nsm} is calculated as follows

$$\mathrm{FI}_{\mathrm{nsm}} = \frac{\int_{f1}^{f2} f^{-1} \cdot \mathrm{PS}(f) \cdot df}{\int_{f1}^{f2} f^{k} \cdot \mathrm{PS}(f) \cdot df}$$

where PS(f) is the EMG power spectrum, calculated using Fourier transform and $f^1 = 1$ Hz and $f^2 = 500$ Hz. FI_{nsm} indices are calculated as the ratio of spectral moments of order (−1) and order, $k = 2$. sEMG data was acquired before the stimulation and also after the stimulation. Using acquired sEMG data, the Dimitrov index (FI_{nsm}) was calculated using the above equation. The relative change in spectral index FI_{nsm} post-FES showed an increase against the pre-FES value, reflecting peripheral muscle fatigue. The maximal change of FI_{nsm} (Dimitrov fatigue index) observed for the comparator device (MegaXp) was approximately eightfold, whereas the indigenous InStim device provoked a fourfold increase. This difference fatigue index between the two devices was significant ($p < 0.01$). This analysis validates that the InStim stimulator device causes less muscle fatigue in patients by recruitment of appropriate motor units for producing synchronous ankle dorsiflexion patterns. The reason for this was using the pulse characteristics close to the ideal [6].

6. Discussion and conclusions

The goal of this Letter was to develop a safe, charge-balanced, low-cost, portable stimulator (InStim), and test its efficacy in stroke patients with foot drop.

As already explained in Table 1, although the device developers have worked on a variety of schematics, most of them are not tested in a clinical set-up. The National Health Science, UK, in its FES guideline suggested that FES device technology is evolving and there is need for improvement in the efficacy and safety of the devices by leveraging the latest techniques. We have tried to fill the existing gap in the literature by translating the laboratory-developed device into a clinical set-up. Hence, this Letter is useful for electrostimulation rehabilitation engineers. It discloses the FES design that caters to the need of improvement in safety and delivers close to ideal stimulation waveform with enhanced clinical efficacy. Moreover, the developed device is cost-effective and meets the requirements of the population of developing counties.

We attempted to resolve the shortcomings in the existing designs (refer Table 1). The DC–DC converter-based power management and single OP-Amp output driver current source architecture were used to achieve near-ideal biphasic (anodic–cathodic) charge-balanced waveform without the presence of spikes with precise control over the current, pulse timing with current-limiting features. Laboratory test and waveform measurements confirmed the absence of DC level in the output stimulus waveform. The skin model confirmed that InStim device delivers constant current and is successful in limiting it within a safe current range as required in foot drop patients.

Clinical testing of the device was conducted to assess the efficacy and to identify any potential adverse events. ROM measurement demonstrates that the device produces sufficient dorsiflexion of the ankle in

stroke patients exhibiting foot drop within a range of MRC grades (0–4). Quality of the stimulation waveform caused lower levels of muscle fatigue. Analysis of sEMG data acquired following InStim stimulation showed it produced approximately half the muscle fatigue than a similar device. The device can be used for the long-duration treatment with minimal adverse effects. Thus given the evidence, the efficacy and safety of the 'InStim' device for use in patients with foot drop having a range of MRC grades are validated.

6.1. Clinical implications

Although the stimulator is designed for correcting foot drop in stroke survivors, by incorporating small modifications in its design, researchers working in the rehabilitation domain can easily adopt it to spinal cord injury and cerebral palsy conditions.

7. Acknowledgments

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8. Declaration of interests

The authors report a patent "Charge Balanced Self Adjusting Electrical Stimulation for Correcting Foot Drop Problem",(Ref: 1255/KOL/2013) (filed) Dated:04-11-2013 pending.

9. Ethical approval and registration of clinical trial

The study is approved by ethical committee of IIT Kharagpur-India and NIOH Kolkata-India. The details of trial registration are available at www.ctri.gov.in [CTRI/2012/09/003019] and also at WHO's International Clinical Trial Registry Platform http://apps.who.int/trialsearch/Trial.aspx?TrialID?CTRI/2012/09/003019]

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