Investigation of controllable multi electrode based FES (functional electrical stimulation) system for restoration of grasp

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Abstract

Functional electrical stimulation (FES) applied via surface electrode can be used for hand rehabilitation particularly for enabling grasp in patients with stroke or spinal cord injury. The use of multi-pad electrode and multi-channel electrical stimulator will improve the effectiveness of conventional FES. Such a system consists of a multi-pad surface electrode and a matching multi-channel stimulator. This system will allow the targeting of the motoneurons which activate muscle groups to produce corresponding functional movements of the hand.

In this thesis we introduce a new system which consits of a multi-electrode pad and matching multi-channel electrical stimulator. The multi-electrode electrode system is composed of small pads that can be activated individually. This composite electrode allows the targeting of motoneurons that activate corresponding muscle groups and produce various functional movements. Our multi channel stimulator can provide controlled spatial distribution of the electrical charge that is delivered to the motoneurons. The results were used to design prototype neuroprosthesis to enable improved restoration of functional grasp.

The device was tested on a C5 tetraplegic person and four healthy subjects. The results show that the multi-pad electrodes provide good selectivity and can be used for generating a functional grasp. The results also shows that the effect of stimulation varies from person to person reflecting inter subject anatomical variation. The findings from this study are of importance for the application of transcutaneous electrical stimulation in the home and clinical environments.

KEYWORDS: Functional electrical stimulation, neuroproshthesis, multi-pad electrode, paralysed hand

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Chapter 1

Introduction

1.1 Background

Neurorehabilitation is a sub area of rehabilitation, which aims to aid recovery of a nervous system injury and restore any functional alteration resulting from it. Functional electrical stimulation (FES) is an important technique with in Neurorehabilitation which can provide artificial control over the peripheral nervous system that is compromised after stroke or spinal cord injury (SCI)[1, 2]. In short, FES is a way of bridging disconnected or damaged neuronal paths between the brain and the extremities. FES is a method of applying low level electrical currents to the body thereby artificially activating the peripheral nervous system to restore or improve impaired function. Full systems that allow restoring functional movements by using FES techniques are called neuroprosthesis. A neuroprosthesis applies electrical stimulation (FES) to the motor branches of the peripheral nerve by which paralyzed muscles are electrically stimulated to produce muscle contraction, replacing the electrical signals coming from the brain through the injured spinal cord[3]. FES has been used for rehabilitation purposes for long[4, 1, 5, 6]. FES based grasping systems have existed in the research settings for the last few decades. Various combinations of FES systems have been in use for regaining grasp and release function. One example is the use of FES with a splint for grasp[7, 8]

Common problems in many existing FES systems are 1.) Insufficient selectivity, 2.) Discomfort, 3.) Quick muscular fatigue. Most of these problems can be eliminated or reduced by the use of multi-pad electrode instead of a large single electrode[7, 9, 10]. The suggestion to use multi-pad electrodes was introduced in parallel with the development of multi-channel electrical stimulator for the arm and control of patients with tetraplegia or stroke[11, 12]. The results when applying multi-pad electrode show that the required electrical charge can be delivered in a distributed manner so that the user feels less discomfort than with large surface electrodes[13]. In this thesis I present the development of a well controllable FES grasping system consisting of multi-pad electrode and multi-channel electrical stimulator, with user interface for selecting various stimulation parameters and electrode shape configuration[4].

1.2 Clinical significance

Neuroprosthesis for grasp are most frequently used in patients with stroke or spinal cord injury, to restore grasping function. In the case of SCI subjects, the sub population that benefits the most from the device for grasping is cervical level (C5-C6) complete SCI subjects. Restoration of hand grasp is essential for achieving a high level of independence in ADL in these patients. Usually they have the function of the proximal upper limb muscles sufficiently to perform reaching tasks, while it is difficult for them to voluntarily perform grasping and holding of objects. The neuroprosthesis can be permanently used as an assistive device in these patients to perform activity of daily living (ADL) including grasping. A limited number of cervical level spinal cord injury patients use tenodesis orthosis, which is used for doing minimal manipulation due to passive force developed between index finger and thumb due to wrist extension. Many of these patients are unaware of the use of neuroprosthesis for regaining grasp in ADL[6, 14].To apply FES neuroprosthesis in SCI subjects one has to ensure there should not be a major degree of motoneuron or nerve root damage of the muscles to be stimulated. In general, the C5-C6 complete SCI subjects frequently will come under this group of subjects and that is why neuroprostheses have been found effective in these subjects.

In stroke subjects functional ailment won't usually seen be in both hands. Hence, in these subjects the hand function of the more affected arm is not as critical as in the case of SCI subjects. Stroke subjects have a prevailing weakness or lower tone of the muscles that need to be stimulated and have no motor neuron or nerve root damage. Unlike the SCI subjects, stroke subjects often feel discomfort during the electrical stimulation, because they have only weakness of muscle but their sensory mechanisms are intact. Therefore, it is crucial to select an optimum stimulus strength without causing much unpleasant sensation. It is also important to consider that muscle spasm seen in stroke subjects can affect them in performing grasping task. Considerable number of cervical level SCI subjects suffer from partial or complete peripheral nerve damage around the lesion (motoneurons and nerve-roots), and one has to determine the extent of this damage as it restricts the application of FES[15, 16]. Peripheral nerve damage is normally assessed by means of neurographic recordings[17].

1.3 Motivation

The main motivation to carry out this project is the prevalence of differently abled people with partial or complete loss of hand function due to spinal cord injury or stroke. Another reason is feedback obtained from patients, therapists and physicians about previous work done by our group, including (a) myoelectric controlled motorized prosthetic arm, a prosthetic arm controlled by subtle muscle contractions from the residual limb and (b) motorised tenodesis hand orthosis for cervical level spinal cord injury people, an assistive device for producing passive force at fingers due to active extension of wrist. These devices turned out to be very useful assistive devices among patients in Rehabilitation institute, CMC-Vellore.

1.4 Goal and Structure of Thesis

Several development steps were required to reach the goal of a fully controllable neuroprosthesis that is able to improve hand function especially grasping in stroke or SCI. The feasibility of applying neuroprosthesis for grasping using functional electrical stimulation for improving grasping in the phase of rehabilitation has already been mentioned. This thesis focuses on resolving a number of scientific , clinical and engineering questions about neuroprosthesis.The broad research goal of this thesis project was to achieve control of hand function using multi-electrode, multi-channel FES. This goal was achieved by the design of required stimulators and electrodes and the measurement of digit and wrist movement.

The thesis is structured in five chapters. The second chapter gives an overview of the physiological aspects of electrical stimulation, a catalogue of the important forearm muscles responsible for hand functions and an overview of some of the currently available and obsolete neuroprostheses.

The third chapter is the methodology chapter, which gives details of the technical aspects of multi-channel electrical stimulator and multi-pad electrode. It also addresses the experiment methods used for measuring hand movement during FES.

The fourth chapter gives the results. The results obtained from four healthy subjects as well as one C5 tetraplegic patient are summarized. The fifth chapter contains the discussion of the results, and the sixth chapter gives the conclusion and possible future work.

Chapter 2

Physiological aspects of electrical stimulation

This chapter gives a general and brief review of the principles of neurophysiology, and external stimulation of excitable tissue so that the fundamentals of FES can be understood. In addition some clinical applications of FES are also explained in this chapter.

2.1 Human nervous system

The human nervous system is divided into two parts. They are the central nervous system and the peripheral nervous system. The Central nervous system consists of the brain and spinal cord whereas the peripheral nervous system consists of the roots of the spinal cord, cranial and autonomic nerves and their branches which are the peripheral nerves. The brain is the central processing area where all the information are processed and stored. The spinal cord is the channel through which the information from the brain flows. The nervous system has two types of cells: neurons or nerve cell and glial cell. Glial cells are not directly involved in information transmission and signal processing but they have a vital role in supporting and nourishing neurons. The motor system is the subsystem of the nervous system responsible for motor action and manipulation of the environment. The sensory system is the subsystem of the nervous system formed by sensory neurons which obtain information about the environment.

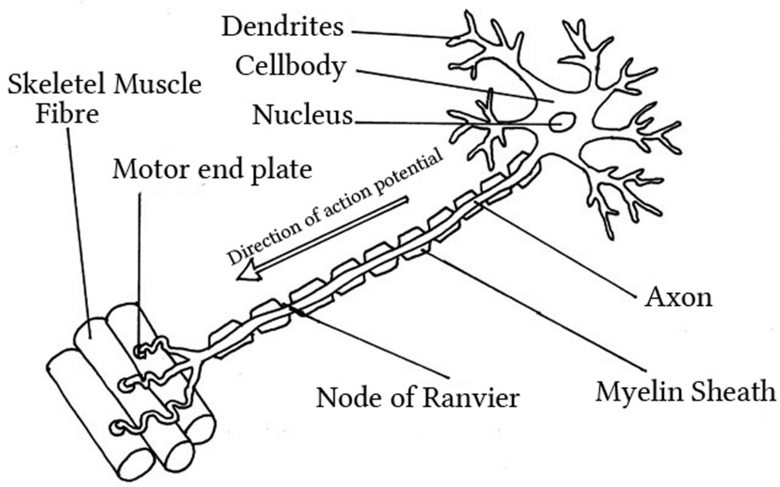


Figure 2.1: Structure of a neuron

2.2 Motor system

The motor system is the mechanical aspects by which our nervous system interacts with the external world. Skeletal muscle is divided into fascicle, which is further divided into muscle fibers. A typical muscle is controlled by a group of motor neurons. A group of muscle fibers innervated by a single motor neuron is called a muscle unit and a muscle unit together with its motor nerve is called motor unit [18, 19].

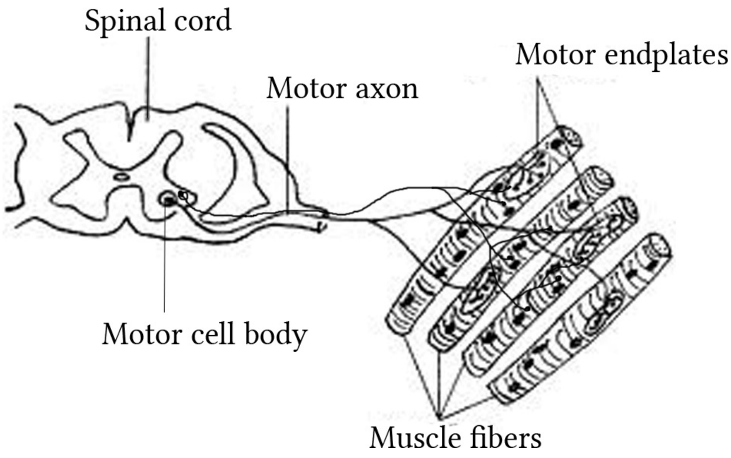


Figure 2.2: Motor unit.

2.3 External stimulation of Excitable tissue

When a stimulating current passes between a pair of electrodes placed near a nerve it flows in the tissue and some of it flows along the surface of the nerve. The nerve surface current results in a trans membrane current from which proceed initiation and propagation of an action potential.

For example, when a pair of stimulating electrodes is placed on the skin near where the ulnar nerve is located as shown in figure 2.3, current flows through entire tissue from one electrode to another. There is a longitudinal current flowing through the nerve which results in a transmembrane current. And if this current exceeds the necessary threshold an action potential (AP) will be initiated[20].

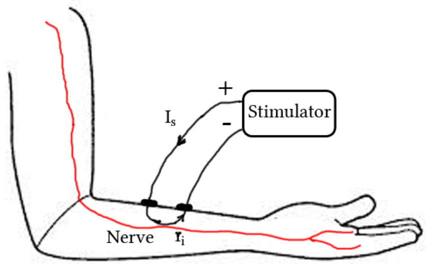


Figure 2.3: Action of stimulator to a nerve

When motor nerves are stimulated in between the neuron and the axon terminal, an AP propagates towards the end of the axon that is innervating a muscle (orthodromic propagation) and an AP propagates backwards towards the cell body of the motoneuron (antidromic propagation)[21]. FES is typically concerned with orthodromic propagation as they generate muscle contractions in order to produce the desirable body function. Figure 2.4 illustrates the direct stimulation of a motorneuron which innervates the target muscle. In the case when the APs are generated by the central nervous system (natural activation), the cell body receives AP driven inputs from dendrites, it sums the excitatory and inhibitory post-synaptic potentials, processes them and if the cellular potential is large enough generates an output AP. Following stroke or SCI the motorneurons do not receive any input from the central nervous system therefore paralyzing muscle function. FES provides a substitute for the natural functionality by artificially generating the required APs to elicit the desired muscle/limb function.

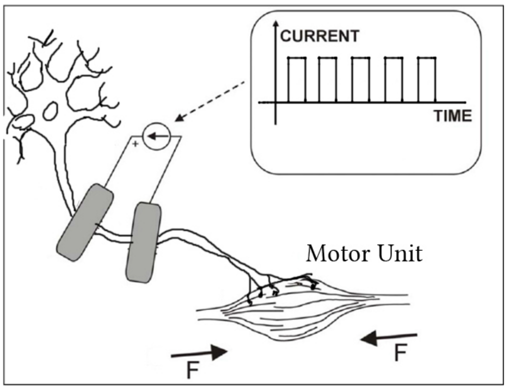


Figure 2.4: Illustration of motorneuron stimulation

2.4 Principal forearm muscles for grasping

The principal muscles for controlling independent volitional movements of the wrist, fingers (digits 2-5) and thumb (digit 1) are described below. The extrinsic muscles end in tendons which pass under the retinaculum at the wrist, and articulate the various digits of the hand. Small intrinsic hand muscles (e.g. the lumbricales) provide flexion of the meta carpo phalagial (MCP) joints with simultaneous extension of the distal inter phalagial (DIP). These are the forearm muscles responsible for various hand movements.

The existing devices for improving grasping are able to restore or improve two grasping styles: the lateral and palmar grasp[14]. The lateral grasp is used to hold thin and flat objects such as paper, keys, or disk. Whereas palmar grasp is for holding bigger and heavier objects such as bottles, cans etc. The palmar grasp is generated by first generating the opposition of thumb and the palm, which is followed by coinciding flexion of both the thumb and the fingers. The lateral grasp is generated by finger flexion to provide opposition, which is then followed by the thumb flexion. Finger flexion is performed by stimulating the flexor digitorum superficialis (FDS), and the flexor digitorum profundus(FDP). Finger extension is obtained by stimulating the extensor communis digitorum(ECD). Stimulation of the thumb's thenar muscle or the median nerve produces thumb flexion. Details of the various forearm muscles are tabulated in the following tables

2.5 Neuroprosthesis for grasping

The upper limb has 30 degrees of freedom. Almost all existing assistive devices or neuroprosthesis aim to improve grasping function, mainly hand opening and closing. In addition to these there are a few other devices that can control elbow movement. Currently available neuroprosthesis use either implanted or surface electrodes for stimulation. A few of the important systems are briefly explained below.

2.5.1 Freehand system (Cleveland)

P H Peckam from Case Western Reserve University and his collaborators started with the restoration of hand function in tetraplegic subjects using FES. It used percutaneous intramscular electrodes to stimulate the peripheral nerves various muscles of hand. The main difficulty in these system were about 10% breakage of electrodes and occasional infections[22].

2.5.2 NEC FESmate FES system

Sendai FES group led by Y. Handa developed microcomputer controlled neuroprosthesis for grasping. It is a PC programmable FES system consisting of a personal computer and an 8-bit microcontrolled stimulator with 16 D/A stimulator and 3 A/D channels was developed. The stimulation pattern for various channel derived from a standardized EMG data from able bodied subjects.

The centre for sensory-motor interaction in Aalborg university (SMI) developed neuroprosthesis for the restoration of lateral hand grasp using natural sensory feedback. First they used Freehand system from Cleveland group. After experiencing some problem in the electrodes the NEC electrode system was developed[23].

2.5.3 The Handmaster

It is the last version of a hybrid orthopedic-neuroprosthesis device developed in Israel and distributed by Bioness Inc. The system is used to generate grasping function in tetraplegic and stroke subjects. The concept is simple, it only has 3 channels that stimulate the finger flexors, finger and wrist extensors and thumb flexion. These 3 electrodes are controlled with a push button that enables hand opening and closing. The device is composed of two parts: the hard plastic orthosis and the wireless control unit, which is a handheld remote control box that allows users to adjust stimulation level and turning on and off. One of the disadvantages of the handmaster is that it does not provide the possibility of adjusting electrode position because they are fixed to the orthosis. In addition, the orthosis is so stiff and it does not permit pronation or supination when users wear the device[8].

2.5.4 The Bionic Glove

This neuroprosthesis was developed by Prochatzka in University of Alberta and it the was designed for SCI patients who have wrist flexion and extension but cannot grasp successfully. The neuroprosthesis consists on a neoprene fingerless glove provided with a sensor (an inductive linear variable displacement transducer) on the palm to detect wrist position. It is no longer in use[24].

2.5.5 ETHZ- Paracare

This neuroprosthesis was developed in ETH Zurich and it was aimed at both stroke and SPI subjects. It is based on the use of the Compex Motion stimulator, which allows a wide variety of custom made programs and integration of any sensor or sensory systems. Although the system permits great flexibility for a broad number of applications, donning and doffing the device is complicated[7].

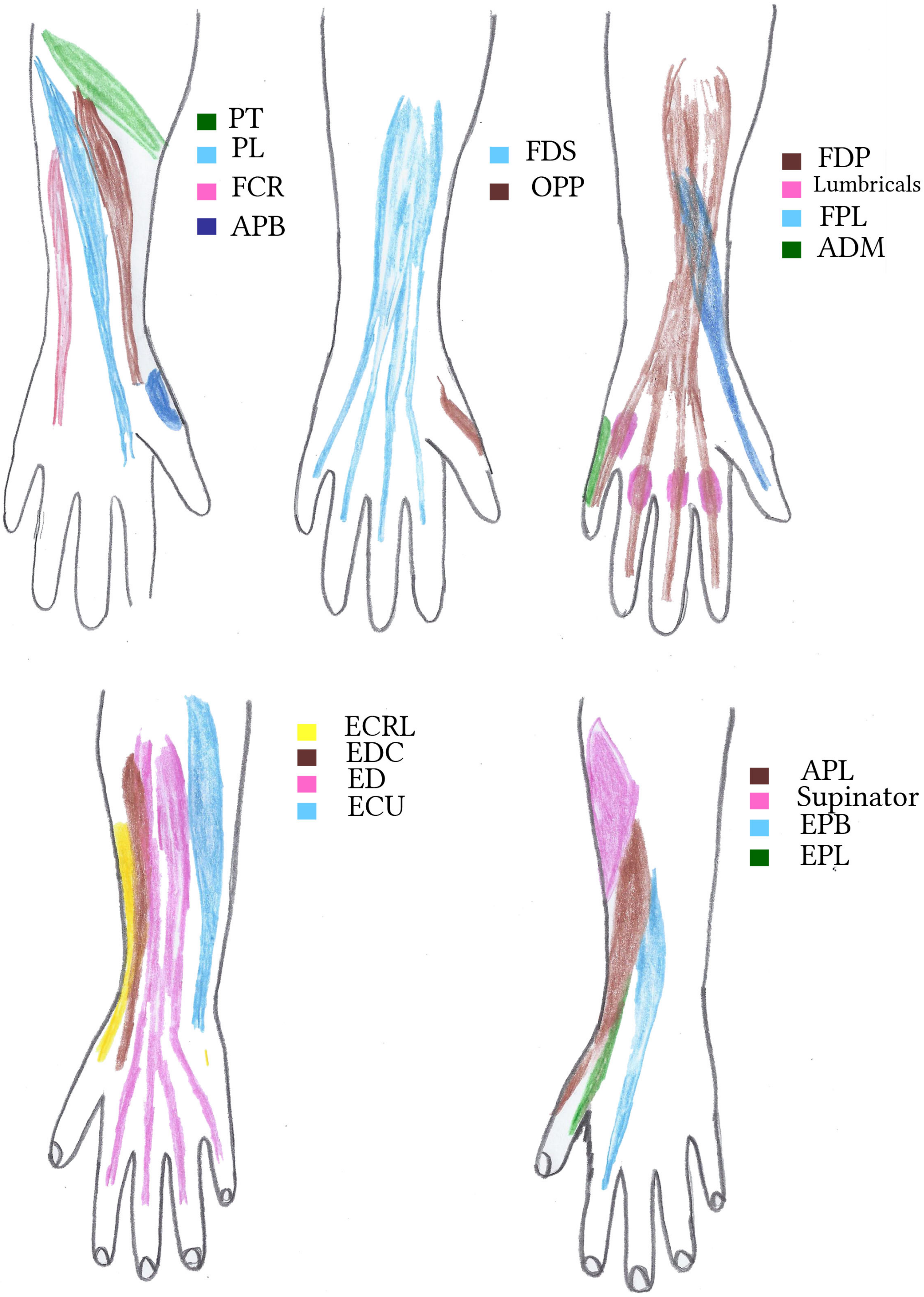


Figure 2.5: Location of some important muscles from Table 2.1 and 2.2

Table 2.1: Flexor muscle groups

Muscle		**Nerve**	**Function**
Superficial flexors			
Pronator Teres	PT	Median	Pronation of the palm such that it faces backwards; weak flexion of the arm
Flexor Carpi Radialis	FCR	Median	Wrist flexion and abduction (with extensors)
Palmaris Longus	PL	Median	Tenses palmar fascia to help resist distal shear forces; May help with wrist flexion
Flexor Carpi Ulnaris	FCU	Ulnar	Wrist flexion (with FCR) and wrist adduction (with ECU) for ulnar deviation
Palmaris Brevis	PB	Ulnar	Tightens palm of hand to assist with grasping (involuntary)
Flexor Pollicis Brevis	FPB	Median and Ulnar	Flexes base of thumb
Abductor Pollicis Brevis	APB	Median	Abduct thumb
Middle flexors			
Flexor Digitorum Superficialis	FDS	Median	Flexion of middle phalanges of digits 2-5
Opponens Pollicis	OPP	Median	Opposes thumb .
Deep flexors			
Flexor Digitorum Profundus	FDP	Median and Ulnar	Flexion of distal phalanges of digits 2,5.
Flexor Pollicis Longus	FPL	Median	Flexes phalanx of thumb and some wrist flexion.
Abductor Digiti Minimi	ADM	Ulnar	Abducts and flexes the little finger.
Flexor Digiti Minimi Brevis	FDMB	Ulnar	Flexes little finger.
Lumbricals	L1	Median and Ulnar	Simultaneous flexion of MCP with extension of PIP.

Table 2.2: Extensor muscle groups

Muscle		Nerve	Function
Superficial Extensors			
Branchioradialis	BRL	Radial	Stabilizes elbow joint during rapid flexion and extension.
Extensor Carpi Radialis Longus	ECRL	Radial	Wrist extension and abduction. Acts in synergy with the finger flexors to help form strong fist.
Extensor Digitorum Compoundus	EDC	Radial	Base of phalanges of digits 2-5; Finger extension.
Extensor Digiti Minimi	EDM	Posterior Interosseous	Extension of little finger at all joints.
Extensor Carpi Ulnaris	ECU	Radial	Wrist extension and abduction.
Deep extensors			
Supinator	SUP	Posterior Interosseous	Acts alone to move palm anteriorly.
Abductor Pollicis Longus	APL	Radial	Thumb abduction and extension of phalanx.
Extensor Carpi Radialis Brevis	ECRB	Radial	Wrist extension and abduction.
Extensor Pollicis Longus	EPL	Radial	Thumb Extension.
Extensor Pollicis Brevis	EPB	Radial	Thumb extension and abduction; Wrist abduction.

Chapter 3

Methodology: Materials and Experimental Procedures

The primary aim of this research was to develop a stimulation system that fulfills the goal of selective stimulation of forearm flexor and extensor muscle groups. This chapter describes our multi-channel stimulator, array electrodes and experimental protocols used on healthy individuals and patients.

3.1 Instrumentation design and development

The hypothesis is that it is possible to achieve various functional movements of the hand by activating combinations of the muscle groups in the hand by the use of multiple electrodes with individual current control. The design has multiple cathodes with individual current control and the anode is common. The stimulator should have provision for setting various parameters for the experiment including pulse amplitude, pulse width, frequency, duration and selection of particular output channel. The overall aim was to develop a stimulator using the latest embedded technology to make an energy efficient, portable system for our FES system using multi-electrode stimulation of the forearm. The design is based on the previous versions of single channel stimulator developed in our lab.

3.1.1 Design of electrical stimulator

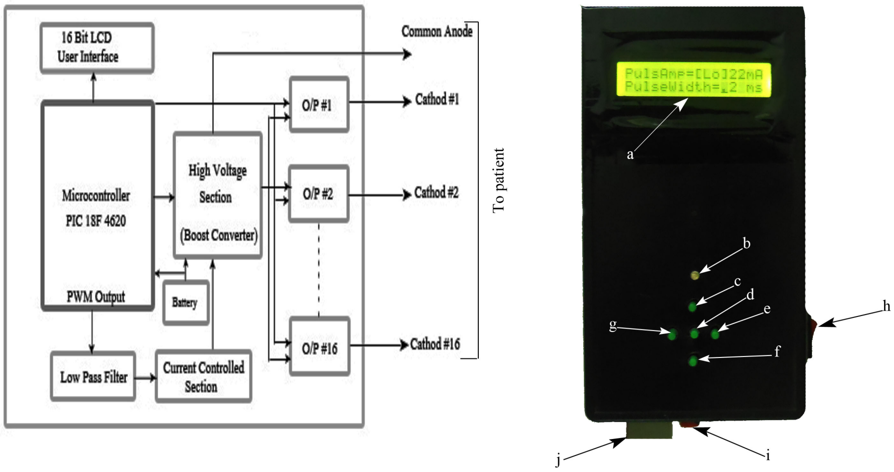


Figure 3.1: Multi channel stimulator: block diagram(left panel) and front panel of the stimulator (right panel).

In the figure 3.1, the letters at the right panel represents a) LCD display, b)Indication LED, c)Increment button, d)Trigger button,e)Parameter selection button,f)Decrement button,g)Parameter selection button, h) Power ON switch, i) Anode connector, j)Cathode connector

The user interface consists of a 16 bit LCD display and set of five push button switches for controlling and selecting various stimulator parameters. There is an LED indicating the status of stimulation. A power ON switch is also provided. Connection to the multi-cathode array is a flat cable of 16 wires , and a single wire connection for the anode.

3.1.1.1 Block diagram description

The block schematic of the stimulator is shown in figure 3.1. The functionality of each stages is explained below.

- **Microcontroller unit**: The stimulation parameters processing logic is implemented in a microcontroller. PIC18F4620 is a versatile 8-bit microcontroller from Microchip™. This controls the the boost converter section for generation of high voltage, the current of the output section, and the user interface comprising a 16 bit LCD display, and push button switches .

- **High Voltage Section**: High voltage generation is achieved by an on-demand DC-DC boost converter. The key principle that drives the boost converter is the tendency of an inductor to resist changes in current by creating an opposing magnetic field. A Super capacitor is used to provide the current surge during the high voltage conversion. In figure 3.2 the MOSFET acts as an active switch controlled by the microcontroller.When the active switch is ON , the inductor stores some energy by generating a magnetic field and when the active switch is OFF , the stored energy will be transferred to the output capacitor. At the end of this ON-OFF cycle charge across the output capacitor builds up. This stored charge serves as the power source for high voltage section. The high voltage build up across the capacitor depends upon number of factors such as amount of energy transferred from inductor to capacitor, value of inductor and capacitor and number of charge pulses. The switch is controlled by the microcontroller.

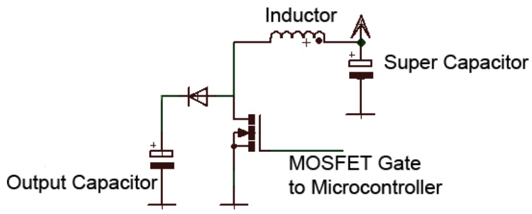


Figure 3.2: High voltage section

- **Current controlled output sections**: The high voltage stored in the capacitor is used to power constant current output sections. Constant current pulse is achieved by the two transistors shown in figure 3.3. The base voltage of the upper transistor controls the output current. The PWM output of the microcontroller passed through a low-pass filter acts as a Digital-to-Analog converter. This variable voltage from the D/A is given to the base of the upper transistor to control the current pulse amplitude of the stimulus. A 16 channel stimulator has 16 current controlled output sections. The stimulus pulse duration is determined by a binary (TTL) pulse given to the lower transistor. Depending on the value of reference voltage a controlled value of output current (collector current) is possible. Selection of the output is done by controlling switching signals to each of the current controlled sections.

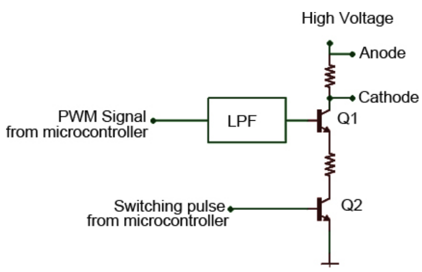
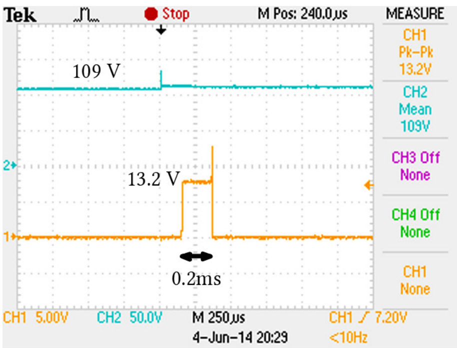


Figure 3.3: Low pass filter and current controlled section

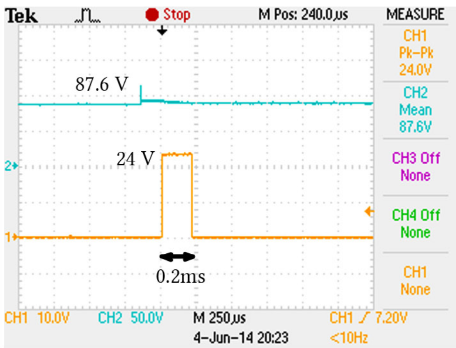
- **Power supply**: The system power supply was designed with a DC-DC boost converter as already described. The high voltage section can produce a maximum voltage of around 240V. The requirements of each device meant that a battery voltage of 4.8V was used as input. The battery pack used was made up from 4 serially connected AA 1.2V NiMH rechargeable batteries, each capable of 2.4Ah of charge.

3.1.2 Current and Voltage waveforms

Figure 3.4shows the waveform recorded on the oscilloscope while testing the stimulator. Here channel 1 (shown in yellow trace) corresponds to the stimulus pulse across 1kΩ load resistor and channel 2 (Blue trace) is the voltage across high voltage capacitor. The number of pulses are fixed in order to get a stable fixed high voltage.



(a)



(b)

Figure 3.4: Screen shots of current and voltage waveforms on oscilloscope

3.1.3 Calibration procedure for stimulator

The calibration procedure for stimulator includes setting of proper duty cycle in the microcontroller for the pulse width modulated signal that will become a corresponding DC voltage level at the output of low pass filter (D/A conversion) for each of the current values. The output of the LPF which is the D/A output will act as the reference voltage for our aforementioned current controlled section. In the calibration procedure it is required to tabulate various values of duty cycle, LPF output voltage and output of the 1kΩ load resistor. A sample set of reading is shown below based on our actual calibration procedure.

PWM Duty Cycle(%)	LPF output (V)	Voltage across 1kohm(V)	Calculated current(mA)
8	0.694	5	5
10	0.921	8	8
12	1.02	12	12
13	1.15	16	16
14	1.26	20	20
15	1.48	25	25

Table 3.1: Calibration values

3.2 Multi-pad Electrode Design and Fabrication

We have developed a customized 16 field multi-pad electrode which is also called an array electrode for dorsal and volar forearm stimulation. The design sketch of the developed array electrode is shown in figure 3.5 (a) and (b). Ethaflex was used as the base material because of its flexibility. Depressions are made on the Ethaflex with hot punching and silver discs of 1cm diameter were placed in to these depressions. Conductive foam cut to the same size as the silver disc was stitched on to each silver disc. This foam over each electrode could be soaked in saline to make a comfortable, flexible electrode array. Wires from a flat cable are soldered on to the back of silver disc. Two sections of Ethaflex sheet (each consisting of four sets of electrode plus conductive form) are attached together with an elastic band making the electrode array stretchable to fit different forearm girths. Velcro at the ends of the electrode band was used for attachment and fixing firmly around the forearm.The centre to centre distance between two electrode positions is about 2cm and the total length is about 20 cm.

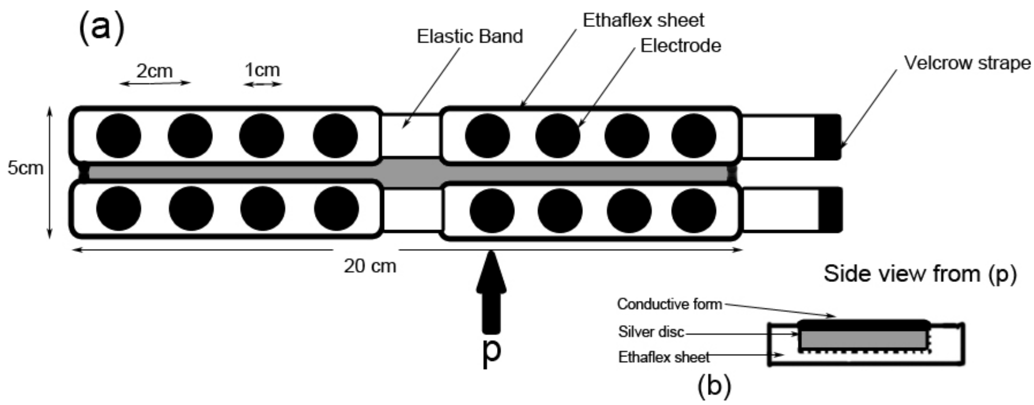


Figure 3.5: Design draft of multi-pad electrode sleeve, (a) top view and (b) side view from position ‘p’

Figure 3.5‘shows actual arrangement of electrode sheet including Ethaflex sheet , silver electrodes and conductive form, elastic band etc. Figure 3.6 shows a photograph of our custom made button silver electrode with provision to stitch conductive foam (figure 3.7 (b)) into it.

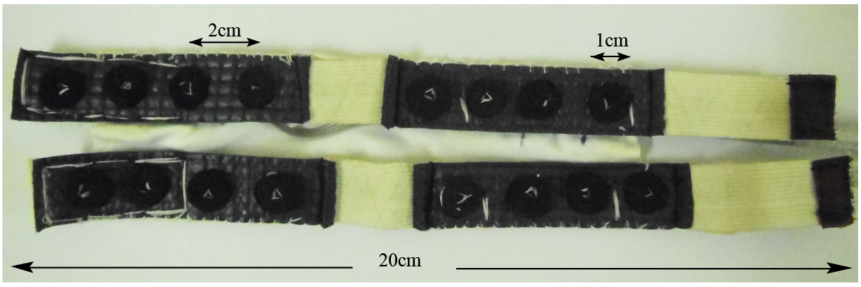


Figure 3.6: Making of multi-electrode sheet

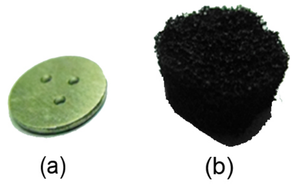


Figure 3.7: (a) Shows raw silver electrode and (b) conductive foam

3.3 Experiments

This subsection describes various aspects of multi- electrode stimulation on the forearm muscles. The effect of stimulation using the above described array electrode and multichannel stimulator on patients as well as healthy subjects was studied to understand electrode positioning, stimulation discomfort etc.

3.3.1 Electrode Placement

This subsection describes the placing procedure for our custom made multi-pad electrode sleeve and common anode. The optimal position for placement of multi-pad electrode is should take into account the following factors.

1. Targeted functional movement.
2. Displacement of the electrode due to motion.
3. Entire coverage of forearm flexor and extensor muscle groups.

A commonly practiced procedure is to place anodic electrode (+) distal to the targeted muscle groups that is covered by cathodic electrode (-). Multi-padded cathode is positioned at a distance almost 5 cm from the elbow of the subject. A common anode in the form of wrist band is placed above the wrist at the carpal tunnel position of the forearm. The position of the multi-electrode cathode is in such a way that the dorsal aspect of the forearm including electrode numbers 1 to 4 as shown in figure 3.8. The use of Ethaflex and elastic band inside the electrode garment makes it more flexible.

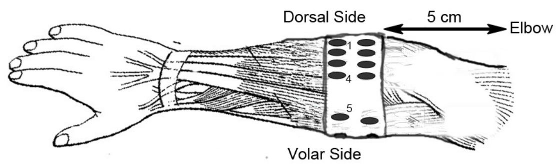


Figure 3.8: Placement of electrode band over forearm

The dorsal side of the forearm contains most of the extensor muscle groups and the volar side has the flexor muscle groups. When the finger flexors are stimulated at the positions shown in figure 3.9. Muscle groups such as flexor digitorum superficialis and flexor digitorum profundus will be activated and that will result in contraction of various fingers excluding thumb. The effect of stimulation of each of these electrodes will vary among individuals according to their inter anatomical variation.

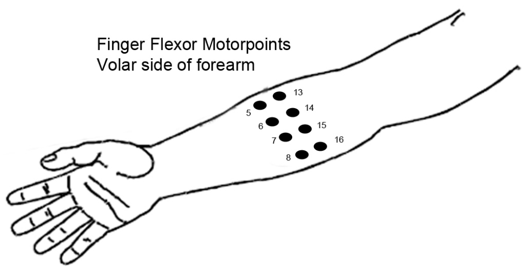


Figure 3.9: Electrodes on the volar side of forearm for flexor motor points

3.3.2 Protocol Design

The aim of the experiments was to record the effect(functional movement) of stimulation of each electrode positioned at sixteen different points on the multi-pad electrode garment, and also any variation with different stimulation parameters, on healthy subjects as well as on spinal cord injury patients. A pilot study has been conducted on 4 healthy individuals and one patient with C5/C6 tetraplegia. The protocol of the experiment was as follows: The subject was made to sit with the test hand properly placed on a table and the multi-pad electrode was fixed on the forearm covering anatomically the finger flexor muscle and wrist extensor muscle groups. After setting various parameters electrical stimulation was administered to the predetermined muscle groups for flexion and extension. The motor effects of stimulation was measured using motion tracking (Leap Motion^{TM}) device and a video camera. By analysing the data collected from the devices, the angle covered by the fingers and wrist, force could be determined. Healthy individual were asked to don the device according to approximate anatomical location of wrist extensor and finger flexor muscle groups. Experiment results from healthy individuals are helpful for determining various stimulation parameters for subsequent trials on patients. The experiment setup is shown in figure 3.10.

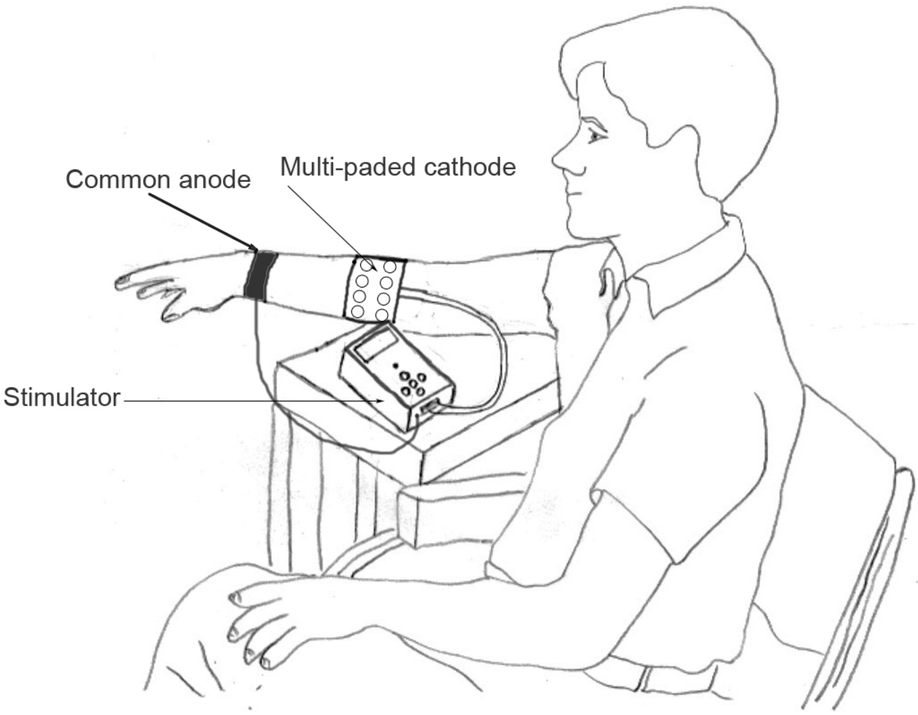


Figure 3.10: Experimental setup

3.3.3 Experiment in detail

1. Four healthy subjects from co-workers in the lab and one patient with C5-C6 tetraplegia from the inpatients from the Rehabilitation Institute were recruited.

2. Subjects were recruited based on the inclusion and exclusion criteria mentioned in Table 3.2.

3. Informed consent was taken from each subject or patient.

4. The physical attributes of the subject (forearm length, wrist length, forearm segment circumference etc.) were recorded.

5. Recruited subject/patient was asked to do the following.

   (a) Sit on chair with hand resting on a table and electrode was placed on the forearm with enough conductive gel.

   (b) FES multi-pad electrode was attached to the forearm with Velcro and common anode will be attached to the carpal bone area.

6. Various parameters such as current strength, pulse width, frequency, duration, pulse train control were set.

7. One electrode was selected at a time out of the sixteen in the array. Pulse amplitude was fixed at around 22mA for normal subject and 35mA for patients in order to achieve adequate contraction of finger and wrist muscle.

8. Pulse width of 0.2ms and frequency of stimulation of 16Hz were used to get a fused tetanic contraction of muscles.

9. Movement of the wrist and finger flexion were captured with a video camera and motion tracking device(Leap Motion).

10. The procedure is repeated for all the electrodes numbered 1 to 16 and the whole experiment was repeated a couple of days after the initial experiment to establish reproducibility of the results compared to the same subject.

Inclusion Criteria	Exclusion Criteria
For patients	
C5-C6 tetraplegic patients.	Poor skin condition electrode placement area.
Minimal spasticity and contracture of wrist muscle.	Severe contracture of wrist and finger joints.
Upper limb passive range of motion should be within normal limit.	Chronic infective diseases.
Age group: 18 years and above	Chronic Kidney, Heart or Lung diseases.
For normal subjects	
Any age and sex.	Use of pacemaker and Neurological disease

Table 3.2: Inclusion and Exclusion criteria of the study

Chapter 4

Results

During the design process of our FES system including multi-channel stimulator and multi-pad electrode, the system tested was in the laboratory for the implementation of a new user interface and control for the stimulator. In the development process the stimulator was calibrated with electronic test and measurement instruments in order to set exact current levels. It has been ensured to maintain the pulse shape of the current signal. Experiments have been done on four healthy individuals and one C5 tetraplegic patient, and the results are described in the following subsections.

4.1 Study on healthy individuals

Laboratory based trial on healthy individuals was done as a preparation for trials on patients, in order to get an idea about placement of electrode , stimulation levels etc. This study was carried out on four healthy individuals during May 2014. Written informed consent approved by the Institutional Review Board of CMC- Vellore was obtained. The multi-electrode cathode was wrapped around the forearm and held with Velcro. The common anode was placed at the wrist. Stimulating parameter values were; current amplitude of 20mA, pulse width of 0.2ms, and frequency of 16Hz. Stimulation was administered through each electrode one at a time for a duration of 2seconds each. The motor effects of stimulation were measured using a video camera, and by analyzing the video data, the direction and extent of movement was determined. Movement data was also collected using a Leap Motion^{TM} motion analyzer. However, the data from this was poor as the detection of the digits was often wrong. The device is meant for rough gesture detection which requires fairly approximate digit detection. With customized software to optimize the frame rate and error rate, the device may be more useful – but that was not done in this thesis. Therefore, the Leap Motion data was only used as supporting data for the video measurements.

The set of figures shown the result of the joint angle produced at meta carpo phalangial (MCP) joint, proximal inter phalangial (PIP) joint and wrist joint. Positive angle represents the extension of that particular joint and negative angle represents flexion. Figure 4.1 represents the movement of fingers at MCP , PIP and combined MCP , PIP joints.

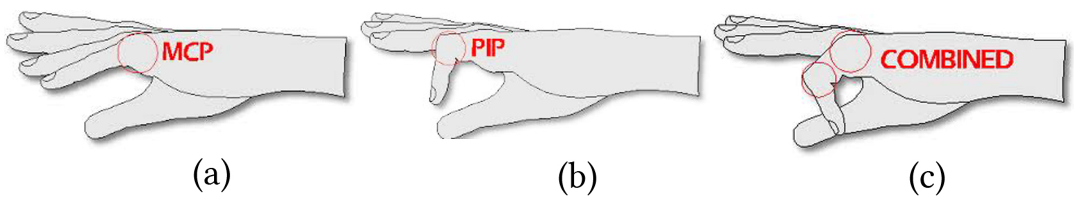
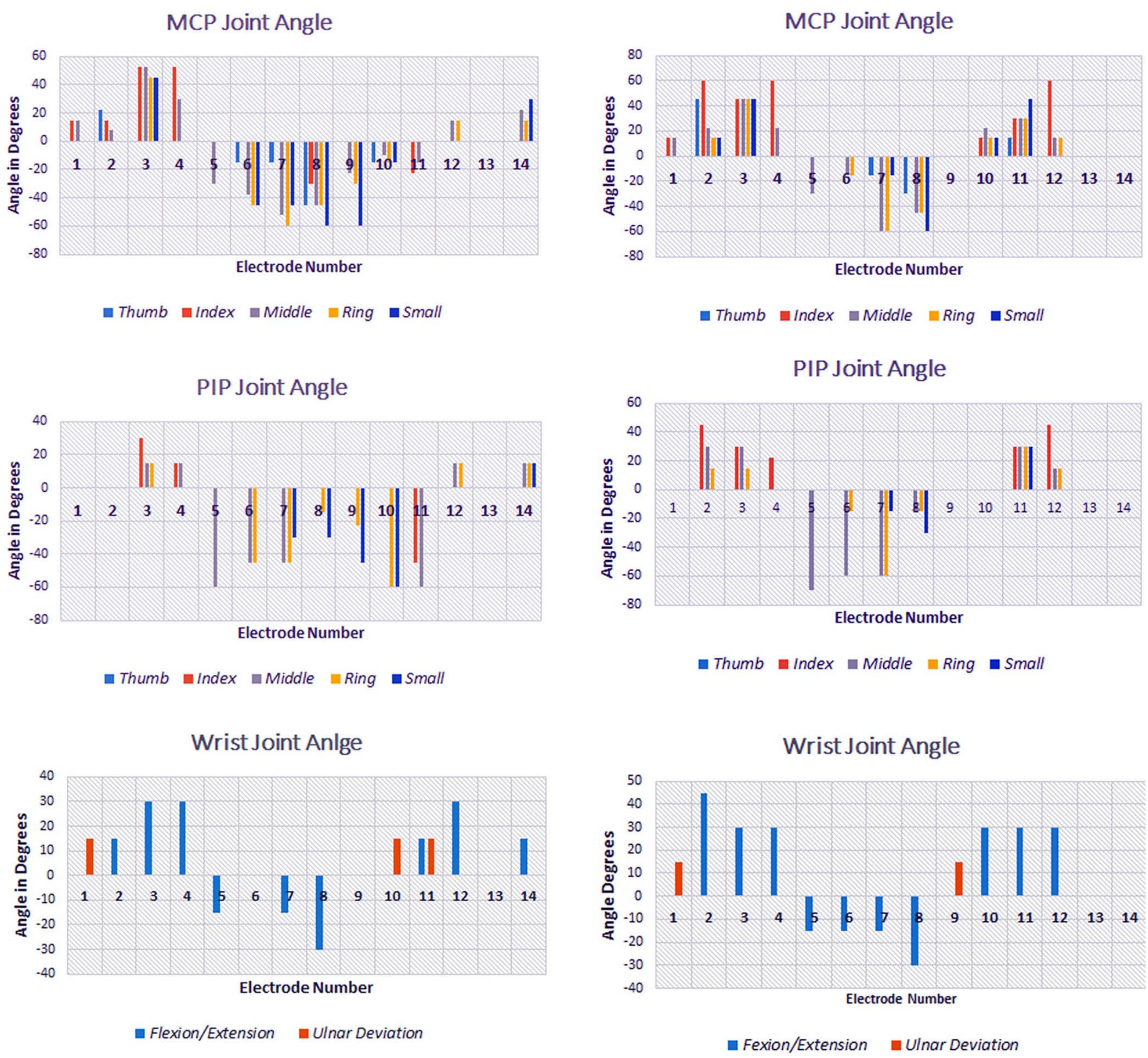


Figure 4.1: Movement of fingers at MCP, PIP and combined

Figure 4.2 shows the result of stimulation of electrode number 1 to 14. Figure (a) corresponds to subject 1 and (b) corresponds to subject 2. Similarly figure 4.3 for subject 3 and 4. The movement of finger can be analyzed at two joints namely MCP and PIP, the first two graphs represents the result of stimulation at MCP and PIP for thumb, index, middle, ring, small and fingers.

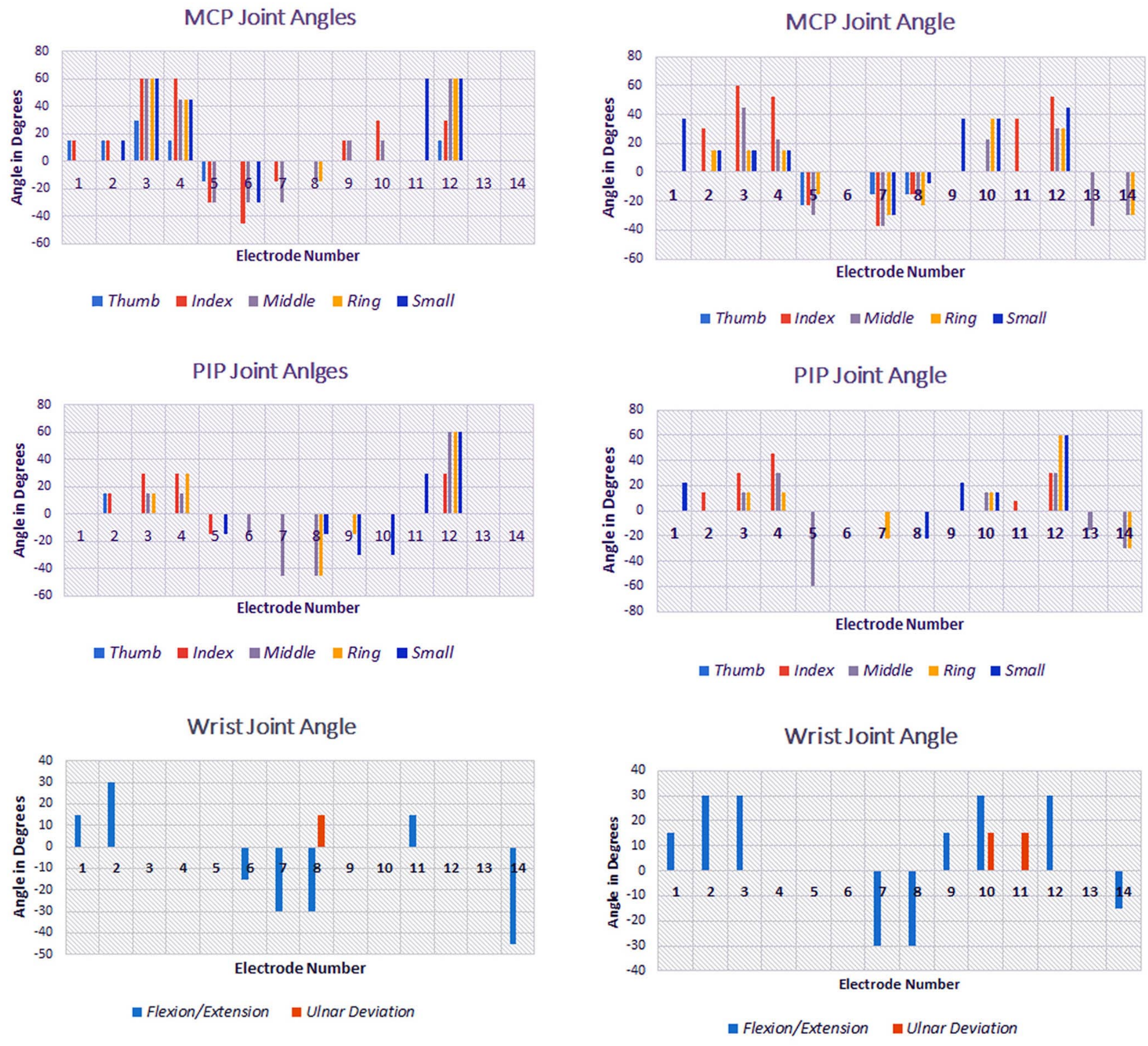
In the wrist joint angles graphs., blue bars represents flexion/extension and red bars represent ulnar deviation. As we can see there are some electrodes which cause only ulnar deviation or a combination of ulnar deviation and flexion of wrist. As far as grasping is concerned, excessive ulnar deviation is undesirable.



(a) (b)

Figure 4.2: Joint angles at MCP joint, PIP joint, Wrist joint (a) healthy subject 1, (b) healthy subject 2

In MCP and PIP joint angle graphs; light blue corresponds to flexion or extension of thumb, red corresponds to index finger, gray corresponds to middle finger, yellow is ring finger and dark blue corresponds to small finger. In the wrist joint angle blue corresponds to flexion or extension of wrist and red corresponds to ulnar deviation of wrist.



(a) (b)

Figure 4.3: Joint angles at MCP joint, PIP joint, Wrist joint for (a) healthy subject 3, (b) healthy subject 4

Figure 4.4 shows the mean and SD values for all 4 normals in a single figure.

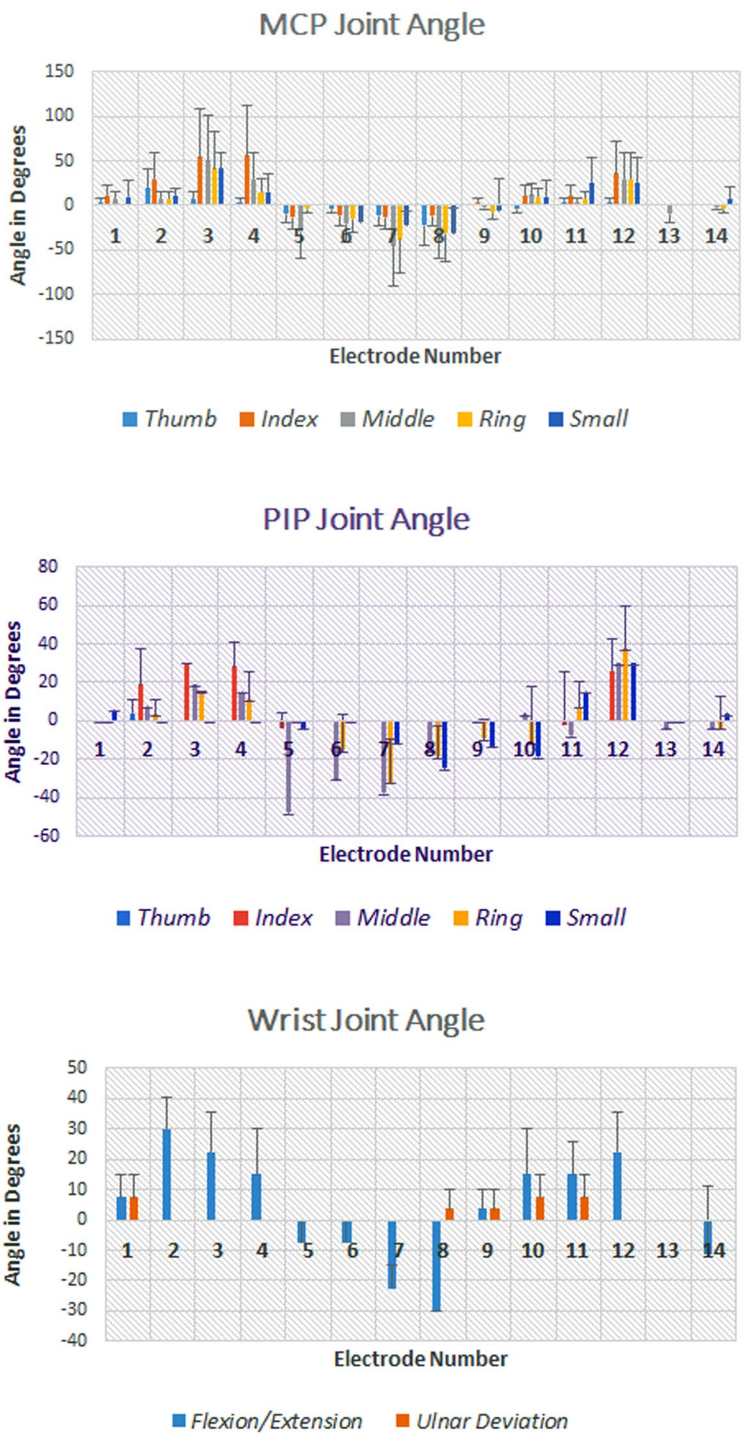


Figure 4.4: Mean and Standard deviation of joint angles for all 4 healthy subjects

4.2 Study on C5 Tetraplegic Patient

The result of stimulation on a C5 tetraplegic patient , with complete loss of wrist function is tested with our FES system. The current amplitude level of around 33mA , pulse width of 0.2ms and 16Hz were applied. The result of stimulation is shown in figure 4.5. Regarding the stimulation comfort; at some positions (5,12,13,14) the subject experienced discomfort even at lowest current amplitude of 5mA. As shown in figure 4.5, other that aforementioned electrode locations, it is quite evident that our device can impart good amount of contractions at MCP, PIP and wrist joints. Also when analysing the wrist joint, the occurrence of ulnar deviation is also quite minimal or zero.

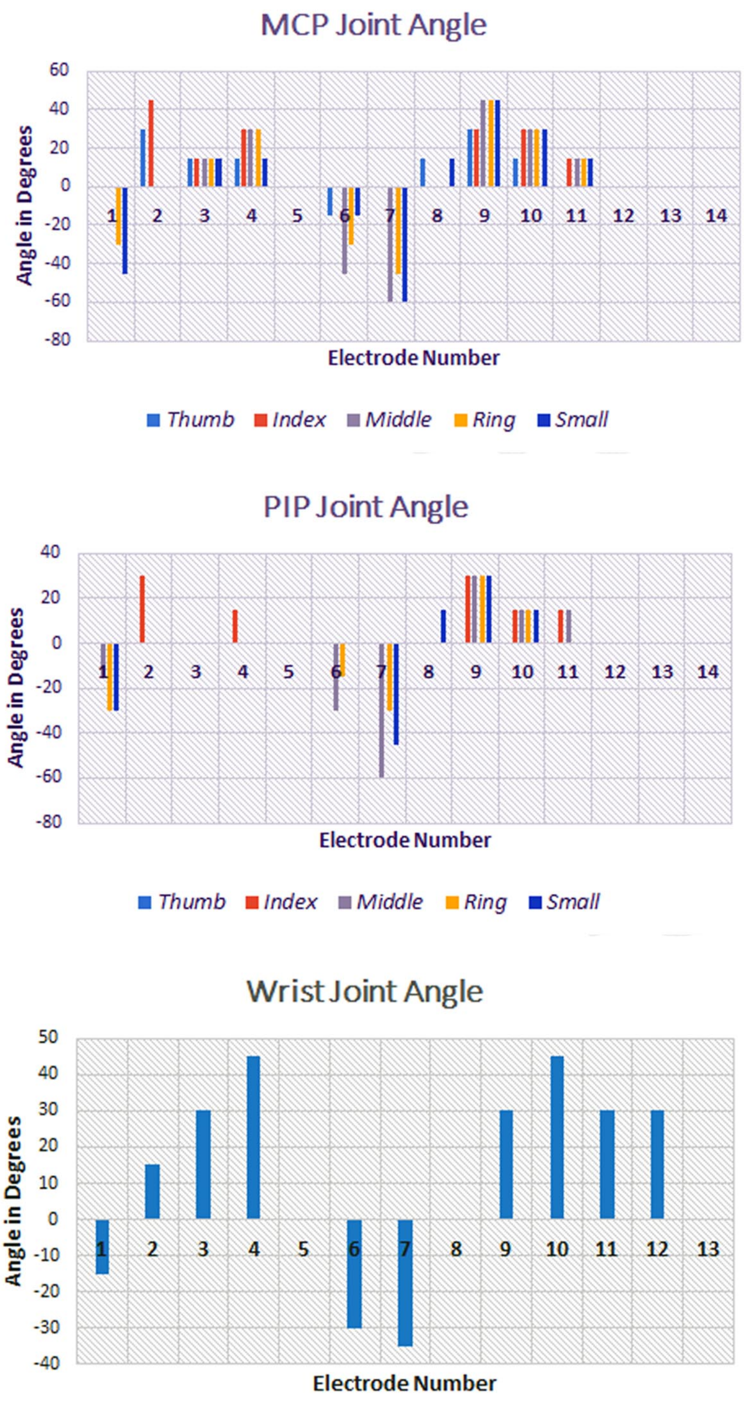


Figure 4.5: Joint angles at MCP joint, PIP joint, Wrist joint for (a) C5 Tetraplegic patient.

Chapter 5

Discussion

In the work presented in the thesis we have presented the use of multi-electrode stimulation for fine control of hand function using electrical stimulation. We have developed the entire system including multi-channel stimulator and multi-electrode band. The range of movement at the various joints during individual electrode stimulation depends on the spatial location of the nerves under the electrodes.

The study was conducted on 4 healthy individuals and one C5 tetraplegic patient. All participants tested were able to achieve finger movement by stimulation, as measured through stimulated range of motion measurements. The tetraplegic participant in this study had no finger motion without the neuroprosthesis; therefore, any finger motion was an improvement over baseline.

The design of our stimulator is novel and very versatile and is compact in size and easy to adjust the parameters because of improved user interface. The stimulator delivers rectangular current pulses to the targeted nerve or muscle. The charging time of our stimulator is not good enough to charge up the capacitor such that its voltage remains at 200V for large loads. Thus for higher rates of stimulation that is more than 8Hz, the stimulation intensity decreases slightly. This is being taken care of in subsequent designs in the lab.

The multi-electrode is an important component of our FES system. The electrode shape, presence of conductive form, dimension of electrode, arrangement on flexible band have considerable influence on the outcome of stimulation. No design of FES system for hand control is complete without addressing the design of electrode. Different types of electrode configurations were made during the development of this work.

During pronation and supination of the forearm, the position of the tissue under the skin changes and that can affect the stimulation. This is an important issue for the future improvement of the device. Our finding suggest that it is possible to form a pattern of electrodes corresponding to produce accurate movement for grasping. However this pattern will vary person to person depends upon their inter subject anatomical variation.

Chapter 6

Conclusion and Future work

6.1 Conclusion

As a part of the thesis we have built and tested an FES system for improving the hand function , especially grasp in patients with paralysed hand. The following are the main features of our system:

1. A sixteen channel electrical stimulator capable of generating rectangular current pulses, with range of parameter adjustments.

2. A flexible, easy to use multi-electrode band capable of stimulating major forearm muscles corresponds to finger flexor and wrist extensor.

3. The system can work for several days with four standard AA Ni-MH rechargeable batteries.

Our approach to a multi-electrode based system for improving hand function is based on idea that it is possible to do selective stimulation over forearm muscles responsible for finger flexion and wrist extension. The fact that it is possible to do so has been demonstrated quite convincingly using surface electrodes. The entire system runs on four numbers of standard Ni-MH rechargeable battery. We have developed and tested a system which can selectively administer electrical current into forearm muscle groups. Some experiments have been conducted on healthy subjects to validate various parameters before doing patient trials. The system is ready for more detailed validation on humans. In addition, our system tested on one C5 tetraplegic patient with complete loss of wrist function and the results were presented in chapter 4 in detail, and the results are promising.

6.2 Future work

This FES system can be used in portable as neuroprosthesis. The instrument requires some enhancements. The first one is the requirement of a proper control switch for operating this assistive device. This system may consist of an ultra portable stimulator that can be placed on the forearm itself with a sensor control using an inertial motion sensor with a wireless link attached to the stimulator. The second aspect is the requirement of further study on patient, the initial results of our device on patients shows significant improvement in their hand movement, this has to be validated with further studies with higher sample size.

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Appendix A

IRB approval

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

Ethics Committee Registration No : ECR/326/INST/TN/2013 issued under Rule 122D of the Drugs & Cosmetics Rules 1945, Govt. Of India.

Dr. George Thomas, D Ortho., Ph D.,
Chairperson, Ethics Committee

Dr. B. Antonisamy, M.Sc., Ph D., FSMS, FRSS.,
Secretary, Research Committee

Prof. Keith Gomez, B.Sc., M.A (S.W), M.Phil.,
Deputy Chairperson, Ethics Committee

Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho
Chairperson, Research Committee & Principal

Dr. Nihal Thomas,
MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

April 09, 2014

Dr. Vinil T. C
Post Graduate Trainee
Department of Bioengineering
Christian Medical College, Vellore 632 002

Sub: **Fluid Research grant project:**
Investigation of controllable multi electrode based FES (functional electrical stimulation) system for restoration of grasp.
Dr. Vinil T. C, Bioengineering, Dr. Suresh Devasahayam, Bioengineering, Dr. George Tharion, Physical Medical and Rehabilitation, Dr. Navin B. P, PMR, CMC.

Ref: IRB Min No: 8685 [INTERVEN] dated 26.02.2014

Dear Dr. Vinil T. C,

The Institutional Review Board (Silver, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Investigation of controllable multi electrode based FES (functional electrical stimulation) system for restoration of grasp." on February 26th 2014.

The Committee reviewed the following documents:

1. IRB Application format
2. Curriculum Vitae' of Drs. Vinil T. C, Suresh Devasahayam, George Tharion, Navin B. P
3. Informed Consent form (English, Tamil & Malayalam)
4. Information Sheet (English, Tamil & Malayalam)
5. No of documents 1-4

The following Institutional Review Board (Research & Ethics Committee) members were present at the meeting held on February 26th 2014 at 9.45 am in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

Ethics Committee Silver, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

Name	Qualification	Designation	Other Affiliations
Dr. B. Antonisamy	M.Sc, PhD, FSMS, FRSS	Professor, Biostatistics, Member Secretary, Research Committee, IRB, CMC, Vellore	Internal, Statistician
Dr. Vinod Joseph Abraham	MBBS, MD, MPH	Professor, Community Medicine, CMC, Vellore	Internal, Clinician
Dr. Suresh Devasahayam	BE, MS, PhD	Professor of Bio-Engineering, CMC, Vellore	Internal, Basic Medical Scientist
Dr. L Jeyaseelan,	M. Sc, PhD, FRSS	Professor, Biostatistics, CMC, Vellore	Internal, Statistician
Dr. B. Poonkuzhali	MSC, PhD	Professor, Haematology, CMC, Vellore	Internal, Basic Medical Scientist
Dr. Anuradha Bose	MBBS, DCH, MD,MRCP, FRCPCH	Professor, Child Health, CMC, Vellore	Internal, Clinician
Dr. Sukriya Nayak	MBBS, MS	Professor, General Surgery, CMC, Vellore	Internal, Clinician
Dr. Molly Jacob	MBBS, MD, PhD	Professor, Biochemistry, CMC, Vellore	Internal, Clinician
Dr. Anil Kuruvilla	MBBS, MD, DCH	Professor, Child Health, CMC, Vellore	Internal, Clinician
Dr. Sathya Subramani	Md. PhD	Professor, Physiology, CMC, Vellore	Internal, Clinician
Mrs. Pattabiraman	B. Sc, DSSA	Social Worker, Vellore	External, Lay person

Prof. Keith Gomez	BSc, MA (S.W), M. Phil (Psychiatry Social Work)	Student counselor, Loyola College, Chennai, Deputy Chairperson, Ethics Committee, IRB, Chennai	External, Lay Person & Social Scientist
Mr. C. Sampath	B. Sc, BL	Legal Expert, Vellore	External, Legal Expert
Dr. P. Zachariah	MBBS, PhD	Retired Professor, CMC, Vellore	External, Clinician
Rev. Dr. T. Arul Dhas	M.Sc, BD, DPC, PhD(Edin)	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Dr. Binu Susan Mathew	MBBS, MD	Associate Professor, Clinical Pharmacology CMC, Vellore	Internal, Pharmacologist
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M. Phil, BL.	Sr. Legal Officer, CMC, Vellore	Internal, Legal Expert
Dr. Nihal Thomas	MD MNAMS DNB(Endo) FRACP(Endo)FRCP(Edin) FRCP (Glasg)	Secretary IRB (EC)& Dy. Chairperson (IRB), Professor of Endocrinology & Addl. Vice Principal (Research), CMC, Vellore	Internal, Clinician

We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any **adverse events** occurring in the course of the project, any **amendments in the protocol and the patient information / informed consent**. On completion of the study you are expected to submit a copy of the **final report**. Respective forms can be downloaded from the following link: http://172.16.11.136/Research/IRB Polices.html in the CMC Intranet and in the CMC website link address: http://www.cmch-vellore.edu/static/research/Index.html.

Kindly provide the total number of patients enrolled in your study and the total number of withdrawals for the study entitled: "Investigation of controllable multi electrode based FES (functional electrical stimulation) system for restoration of grasp. " on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

Yours sincerely,

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD.,MNAMS.,DNB(Endo),FRACP(Endo),FRCP(Edin),FRCP(Glasg)
Vice - Principal (Research) - Reg. No. 43983
Christian Medical College, Vellore - 632 004.

CHRISTIAN MEDICAL COLLEGE
VELLORE
INDIA
NOT TO BE MINISTERED UNTO BUT TO MINISTER

Cc: Dr. Suresh Devasahayam, Bioengineering, CMC, Vellore

Ethics Committee Silver, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

Appendix B

Consent forms

- English
- Malayalam
- Tamil

Patient Information Sheet

Study Title: Testing of the feasibility of using artificial stimulation to control finger flexor and wrist extensor in patients with C5/C6 tetraplegia.

Principal Investigator: Vinil T C

You are being requested to participate in a research to study feasibility of using artificial stimulation to control finger flexor and wrist extensor which are dominant contributors in grasping. The rationale for this study is to develop a controllable device for restoring grasp in tetraplegic patients.

The study will help to define control parameters for future design of FES (Functional Electrical Stimulation) based grasping device for tetraplegic individuals. This system when built would help to perform various functional tasks in these individuals.

If you agree to participate in this study, you will be required to cooperate with us in The Rehabilitation Institute, CMC Vellore. You will be asked to don a multi electrode pad on your forearm. You will be assisted to sit on a chair with your hand placed on a table. FES (which involves applying low level electrical currents externally for performing a functional task) will be administered to preselected muscles of your forearm and resultant forces/movement generated would be recorded. You may be asked to repeat similar procedure by changing the electrode position and thereby recording the various movements of wrist as well as fingers. The whole procedure will be repeated a couple of days after the initial experiment to ensure reproducibility of the results. Clinician will be available during this procedure.

Participation in this study is not likely to cause harm to your health in any foreseeable manner. Electrical Stimulation procedure is known to strengthen and tone the muscles and also aids in improving blood flow and reducing muscle disuse atrophy.

The data collected and analysed may be useful for the future investigations and would be helpful in finding out an optimal electrode configuration for various functional tasks such as grasping an object. There is no participation fees required to be paid by the subject /patient.

Your participation in this study is totally voluntary and you have the full freedom to withdraw your participation from the study at any point of time. Confidentiality would be maintained in handling your personal and medical history. Data would be stored and accessed against hospital numbers of patients and would be accessed by only the people involved in the study.

You are requested to please co-operate with the procedure during the study so that the data collection process would be easy and accurate.

If you have any further questions, please ask Mr. Vinil T C, Dept. of Bioengineering, CMC Vellore (Tel: : +91-4162285098 (O)). Email: viniltc@cmcvellore.ac.in)

Informed Consent form to participate in a clinical trial

Study Title: Testing of the feasibility of using artificial stimulation to control finger flexor and wrist extensor in patients with C5/C6 tetraplegia.

Study Number: __________

Subject's Initials: __________ Subject's Name: _____________________

Date of Birth / Age: ________

Please initial box

(Subject)

(i) I confirm that I have read and understood the information sheet dated ________ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: ____/____/_____

Signatory's Name: ______________________________ Signature:

Or

Representative:_______________
Date: ______/______/_______
Signatory's Name: _____________________________________
Signature of the Investigator: ___________________________
Date: ______/______/_______
Study Investigator's Name: ____________________________
Signature of the Witness: _______________________________

Date:______/______/________
Name of the Witness: __________________________________

പഠന തലകെട്ട് : വിരലുകളുടെയും കൈപത്തിയുടെയും ചലനശേഷി വീണ്ടെടുക്കാൻ സഹായകമായ കൃത്രിമ വൈദ്യുത ഉത്തേജന ഉപകരണത്തിന്റെ പ്രാരംഭ പരീക്ഷണം .

പ്രധാന ഗവേഷകൻ: വിനിൽ .ടി . സി

ഈ പഠനത്തിലേക്ക് നയിക്കുന്ന പ്രധാനകാരണം, കൈപത്തിയുടെ പ്രവർത്തനം വീണ്ടെടുക്കാൻ ഉതകുന്ന ഒരു ഉപകരണം വികസിപ്പിക്കുക എന്നതാണ്. ഈ പഠനം വഴി, മേൽ പറഞ്ഞ ഉപകരണത്തിനെ നിയന്ത്രിക്കുന്ന വിവിധങ്ങളായ ഘടകങ്ങൽ മനസിലാക്കുവാനും ഭാവിയിൽ ഇത്തരം കൈകൾ തളർന്ന രോഗികളിൽ, കൈയുടെ പ്രവർത്തനം പുനരിജ്ജീവിപ്പിക്കാൻ ഇത് സഹായകമാകും. ഇതുവഴി ഇത്തരം വ്യക്തികൾക്ക് വിവിധങ്ങളായ കാര്യങ്ങൾ സ്വമേധയാ നിർവഹിക്കാൻ സാധ്യമാകുന്നു.

വെല്ലൂരിലെ സി .എം .സി പുനരധിവാസ (റീഹാബിലിറ്റെഷൻ) കേന്ദ്രത്തിൽ നടക്കുവാൻ പോകുന്ന ഈ പഠനത്തിന്റെ നടപടിക്രമം : താങ്കളെ ഒരു കസേരയിൽ ഇരുത്തിയ ശേഷം കൈത്തടയിൽ അനേകം വൈദ്യുത ചാലകങ്ങൾ ഘടിപ്പിച്ചിരിക്കുന്ന ഒരു ഷീറ്റ് ധരിപ്പിക്കുന്നു. വളരെ ചെറിയ തോതിലുള്ള വൈദ്യുതി മുകളില പറഞ്ഞ ഷീറ്റിലെ ചാലകങ്ങളിലൂടെ കടത്തിവിടുന്നു, അതേസമയം വിരലുകൾക്കും കൈപത്തിക്കും ഉണ്ടാകുന്ന ചലനം രേഖപെടുത്തുന്നു. പ്രഥമ പഠനം കഴിഞ്ഞ് സമാന്തര ഫലം ലഭിക്കുന്നുണ്ടോ എന്നറിയാൻ വീണ്ടും പഠനം ആവർത്തിക്കുന്നതാണ്. ഒരു ഡോക്ടറുടെ സേവനം ഇതിനിടയിൽ ലഭ്യമാണ്. ഈ പഠനത്തിലുള്ള പങ്കാളിത്തം നിങ്ങളുടെ ആരോഗ്യത്തെ ഒരുതരത്തിലും ഹാനികരമായി ബാധിക്കുന്നില്ല , അതോടൊപ്പം പേശികൾ ചുരുങ്ങുന്നത് തടയുകയും ചെയ്യപെടുന്നു.

ഈ പഠനത്തിൽ നിന്ന് ലഭിക്കുന്ന വിവരങ്ങളും , വിശകലനങ്ങലും ഉപയോഗിച്ചുകൊണ്ട് ഒരു പുതിയ കൃത്രിമ വൈദ്യുത ഉത്തേജന ഉപകരണത്തിന്റെ വികസനത്തിനും അവ ഇത്തരം തളർച്ച അനുഭവിക്കുന്ന രോഗികളിൽ വിവിധങ്ങളായ പ്രവർത്തനങ്ങൾ സ്വമേധയ ചെയ്യുവാനും സഹായകമാകുന്നു.

പങ്കെടുക്കുന്ന വ്യക്ത്തിയിൽ നിന്ന് യാതൊരു ഫീസും ഈടാക്കുന്നതല്ല . ഈ പങ്കാളിതത്തിൽ താങ്കൾക്ക് പൂർണ്ണ സ്വാതന്ത്ര്യം ഉണ്ടായിരിക്കുന്നതാണ് , അതിനാൽ എപ്പോൾ വേണമെങ്കിലും ഇതിൽനിന്ന് പിന്മാറാവുന്നതാണ്.

രോഗപരമായും വ്യക്തിപരമായുമുള്ള വിവരങ്ങൾ ഈ പഠനത്തിൽ ഉൾപ്പെടുന്നവർ മാത്രം കൈകാര്യം ചെയ്യുന്നതായിരിക്കും.

ഞങ്ങളുടെ ഈ ഗവേഷനത്തിന്റെ വിവര ശേഘരണ കൃതയതയ്ക്കു താങ്കളുടെ സഹകരണം ആവശ്യപ്പെടുന്നു.

കൂടുതൽ വിവരങ്ങൾക്ക് ബന്ധപ്പെടുക : വിനിൽ . ടി . സി (Tel: : +91-4162285098 (O)). Email: viniltc@cmcvellore.ac.in)

സമ്മതപത്രം

പഠന തലകെട്ട് : വിരലുകളുടെയും കൈപത്തിയുടെയും ചലനശേഷി വീണ്ടെടുക്കാൻ സഹായകമായ കൃത്രിമ വൈദ്യുത ഉത്തേജന ഉപകരണത്തിന്റെ പ്രാരംഭ പരീക്ഷണം .

പ്രധാന ഗവേഷകൻ: വിനിൽ .ടി . സി

പഠന നമ്പർ: ....

പങ്കെടുക്കുന്ന വ്യക്തിയുടെ പേര്: ....

ജനനതിയതി / വയസ്സ്: ....

1. മേല്പ്പറഞ്ഞ വിവരങ്ങൾ ഞാൻ,..................................തിയതി വായിക്കുകയും മനസ്സിലാക്കുകയും ചെയ്തു. ഇതെപറ്റിയുള്ള ചോദ്യങ്ങൾ ചോദിക്കാൻ അവസരം ലഭിച്ചിട്ടുണ്ട്.
2. ഞാൻ ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നത് എന്റെ ഇഷ്ടപ്രകാരമാണ്. അതിനാൽ എന്റെ ആരോഗ്യപരമായും നീതിപരമായുമുള്ള ഒരു അവകാശങ്ങളേയും ബാധിക്കാതെ ഏതുനേരത്തും ഇതില്നിന്നു പിന്മാറാൻ സാധിക്കും എന്ന് ഞാൻ മനസിലാക്കുന്നു.
3. ഈ പഠനത്തിന്റെ പ്രയോജകനും അദ്ദേഹത്തിന്റെ കൂടെയുള്ളവർക്കും. നീതിശാസ്ത്ര സംഘടനക്കും എന്റെ ആരോഗ്യ റെക്കോർഡുകൾ പരിശോധിക്കാൻ സാധിക്കുന്നതാണ്. ഞാൻ ഈ പഠനത്തിൽ നിന്ന് പിന്മാറിയാലും ഈ പഠനത്തിനും പിന്നീടുള്ള പഠനങ്ങൾക്കും ഇത് പഠനവിധേയമാക്കാവുന്നതാണ്. ഈ പഠനത്തിനായി ഞാൻ നല്കിയ വിവരങ്ങൾ മൂലം മൂന്നമതൊരാൾക്കു എന്നെ തിരിച്ചറിയാൻ സാധിക്കില്ല എന്ന് ഞാൻ മനസ്സിലാക്കുന്നു.
4. ശാസ്ത്രീയമായ പഠനങ്ങൾക്കായി ഈ പഠനത്തിൽ നിന്നുള്ള വിവരങ്ങൾ ഉപയോഗിക്കുന്നതിനു ഞാൻ ഒരു തടസ്സമാവില്ല.
5. ഈ മേൽപ്പറഞ്ഞ പഠനത്തിനായി പങ്കെടുക്കാൻ പൂർണ്ണമായി ഞാൻ സമ്മതിക്കുന്നു.

ഈ പഠനത്തിൽ പങ്കെടുക്കുന്ന ആളുടെയോ അയാളുടെ നിയമാനുസൃതമായ പ്രതിനിധിയുടെയോ ഒപ്പ്.

തിയതി ....

ഒപ്പിട്ടയാളുടെ പേര് ....

പരിശോധകന്റെ ഒപ്പ് ....

തിയതി ....

സാക്ഷിയുടെ ഒപ്പ് ....

തിയതി ....

സാക്ഷിയുടെ പേര് ....

<u>நோயாளின் தகவல் தாள்</u>

ஆய்வு தலைப்பு : பக்கவாதம் கொண்ட நோயாளிகளுக்கு மின் தூண்டல் மூலம் கை விரல்களை செயல் படுத்தி பொருள்களை பிடிக்கச் செய்வது குறித்த ஆய்வு.

முதன்மை ஆய்வாளர் : வினில் T C

இந்த ஆய்வின் நோக்கமானது, செயற்கை மின் தூண்டல் மூலம் பக்கவாதத்தினால் கை, கால் செயல் இழந்தவர்களின் கை விரல்களை இயல்பு நிலையில் செயல்படுத்தி பொருள்களை பிடிக்க வைப்பது. செயற்கை தூண்டல் என்பது, மிக குறைந்த மின்சாரம் அளித்து செயலிழந்த உறுப்பை செயல்ப்படுத்த வைபதாகும். இவ்வாறுச் செய்வதால், செயல்படாத விரல்களை, செயல்படுத்தி எந்த ஒரு பொருளையும் பிடிக்க வைக்கும் முயற்சியில் இந்த ஆய்வு செய்யப்படுகிறது.

இந்த ஆய்வின் மூலமாக, செயற்கை தூண்டல் சாதனத்தின் இயல்பையும், அதன் செயல்பாட்டு அம்சத்தையும் கண்டறிய உதவுகிறது. மேலும், இந்த ஆய்வு மூலம் பக்கவாததினால் கை, கால் செயலிழந்த மனிதர்களுக்கு பொறுத்தி அவர்களுக்கு மறுவாழ்வு அளிக்க உதவுகிறது.

எனவே, இந்த ஆய்வில் பங்குபெருமாறு உங்களை வேண்டுகிறோம். இந்த ஆய்வில் நீங்கள் பங்குபெற்றால், உங்கள் முலங்கையில் ஒரு மின் பட்டை பொருத்தப்படும். பின், அதன் மூலமாக, குறைந்த மின்சாரம் அளிக்கப்பட்டு, அதன் விளைவாக ஏற்படும் விரல் அசைவை கண்காணிக்கப்படும். இந்த சோதனைகள் அனைத்தும், மருத்துவர்கள் மற்றும் தொழில்நுட்ப வல்லுநர்கள் முன்நிலையில் நடைபெறும். செயற்கை மின் தூண்டல் அளிபதனால், உங்களுக்கு எந்த ஒரு ஆபத்தோ, பின் விளைவுகளோ ஏற்படாது. இதனால், உங்களின் தசைகளின் வலிமை கூடும், இரத்த ஓட்டம் சீராகும். இந்த ஆய்வில், பங்கு பெருவதர்க்கு கட்டணம் ஏதும் வசூலிக்கபடாது.

இந்த ஆய்வில் பங்குபெருவது என்பது, முற்றிலும் தங்கள் சொந்த முடிவே, பங்குபெற வேண்டும் என்று எந்த ஒரு நிர்பந்தமோ, கட்டாயமா இல்லை. தங்களுக்கு விருப்பமில்லை என்றால், எந்த கட்டத்திலும் விலகி கொள்ளலாம். தங்கள் குறித்த தகவல்கள் மற்றும் ஆய்வின் போது பெறப்படும் தகவல்கள் அனைத்தும் பாதுகாப்பாக வைக்கப்படும். மேலும் தங்கள் இரகசியத்தன்மை பராமரிக்கப்படும். இந்த ஆய்வில் பங்கு பெற விரும்பினால், முழு மனதுடன் பங்கு பெற வேண்டும். ஆய்வின் போது, தாங்கள் தரும் ஒத்துழைபை கொண்டே ஆய்வுத் தகவல்களை துறிதமாகவும், துல்லியமாகவும் பெறமுடியும். வேண்டுமானால், மருத்துவர் தங்களை இரண்டு அல்லது மூன்று நாட்களுக்கு வந்து செல்லும் படி கூருவர்.

உங்களுக்கு இந்த ஆய்வை பற்றி மேலும் சந்தேங்கள் அல்லது கேள்விகள் இருந்தால், இவரை தொடர்பு கொள்ளவும்.

திரு. வினில் T C, பயோ இன்ஜினியரிங் துறை, சி.எம்.சி, வேலூர்.
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Appendix C

Circuit schematic of multi-channel electrical stimulator