Bournemouth University

Restoration of hand and arm function to people with tetraplegia as a result of damage to the spinal cord in the neck through the use of functional electrical stimulation (FES)

Lalitha Venugopalan

A thesis submitted to Bournemouth University in partial fulfilment of the requirements for the degree of Doctor of Philosophy

July 2017

Abstract

Functional Electrical Stimulation (FES) therapy is a widely used rehabilitation technique to improve the hand functions of people with spinal cord injuries (SCI) and stroke. Two of the upper limb FES devices – the NeuroControl® Freehand System and the NESS H200 have received FDA approval and have been successfully commercialised. At the time of writing, out of the two devices, only NESS H200 was commercially available but the use of rigid arm splint limited the number of people who could functionally use the device. A new four channel upper limb FES device called the TetraGrip was developed during this research work. This device was controlled using an IMU based shoulder position sensor strapped across the contralateral shoulder and did not use a rigid arm splint. This allowed flexibility in electrode position and more people were able to use the system. The device was programmed to perform two hand movements – the key grip and the palmar grasp. Besides these functional modes, it was programmed to generate an exercise sequence that alternated between the palmar grasp and key grip movements. The device was tested on fourteen able bodied volunteers who used the shoulder position sensor to operate the device. This study was helpful in establishing the repeatability and reproducibility of the device and also helped in improving the device based on the feedback from users. This study also helped in exploring the possible combination of electrode positions for achieving functional movements. It was then clinically tested on two people with C6 tetraplegia who participated in a twelve week long study. The volunteers used an Odstock® Microstim to exercise the desired muscles for four weeks and then came back to the clinic once a week for eight weeks to use the TetraGrip. They were assessed using outcome measures such as the grip strength test, the box and block test and the grasp release test. As the study progressed, both the volunteers showed improvements in their ability to perform the specified tasks using key grip and palmar grasp movements and on the last day of the study, they were able to perform activities of daily living using the TetraGrip such as holding a pen and writing and holding a fork and eating lunch.

Table of Contents

List of Figures

List of Tables

List of Abbreviations

ABV	Able Bodied Volunteer
ADL	Activities of Daily Living
AdP	Adductor Pollicis
APB	Abductor Pollicis Brevis
ARAT	Action Research Arm Test
AREF	Analog Reference
ASIA	American Spinal cord Injuries Association
ATP	Adinosine Tripospate
BCI	Brain Computer Interface
BGS	Belgrade hand Grasp System
BR	Brachioradialis
CNS	Central Nervous System
ECRL/ECRB	Extensor Carpi Radialis Longus/Brevis
EDC	Extensor Digitorium Communus
EEG	Electroencephalography
EMC	Electromagnetic Compatibility
EMG	Electromyography
FC	Flight Controller
FCR	Flexor Carpi Radialis
FCU	Flexor Carpi Ulnaris
FDA	Food and Drug Administration
FDP	Flexor Digitorium Profundus
FDS	Flexor Digitorium Superficialis
FES	Functional Electrical Stimulation
FI	Flexor Indicis
FIM	Functional Independence Measure
FPL	Flexor Pollicis Longus
GRT	Grasp Release Test
ICSHT	International Classification of the Surgery of the Hand in Tetraplegia
IMU	Inertial Measurement Unit

IntFES	Intelligent Functional Electrical Stimulator
ISNCSCI	International Standards for Neurological Classification of Spinal Cord Injury
LED	Light Emitting Diode
LVDT	Linear Variable Differential Transformer
MeCFES	Myoelectrically Controlled Functional Electrical Stimulation
MEMS	Micro Electro Mechanical System
MES	Myoelectric Signals
MMI	Man Machine Interface
MRC	Medical Research Council
OP	Opponens Pollicis
PD	Posterior Deltoid
PT	Pronator Teres
RAHFT	ReJoyce Automated Hand Function Test
ROM	Range of Motion
RWTHS	Rehabtronics Wireless Triggered Hand Stimulator
SCI	Spinal Cord Injury
SCIM	Spinal Cord Independence Measure
TMS	Transcranial Magnetic Stimulation
WCTS	Wrist extension Controlled Thumb flexor Stimulation
WCWS	Wrist extensor Controlled Wrist extensor Stimulation

Preface

This PhD is funded by Bournemouth University and INSPIRE, a charitable institution for people with spinal cord injury. The research work for this PhD was undertaken at the National Clinical FES Centre at the Salisbury District Hospital, which has been providing FES service since 1984. This department has been sponsoring and providing honorary contracts to PhD students associated with the Bournemouth University or University of Southampton. The technical and clinical findings from these research works have been used to improve the existing FES devices and developing new devices.

Dedication

This research work is dedicated to all the people with tetraplegia who are eagerly awaiting a take home FES device to improve their hand function and help them regain independence in performing their activities of daily living.

Acknowledgement

I take this opportunity to thank my supervisors Prof. Ian Swain, Dr. Jon Cobb and Dr. Paul Taylor for their unconditional support and guidance during this research work. I would like to thank all my supervisors for their valuable comments and guidance during each and every stage of this research work.

Next, I would also like to take this opportunity to thank the people in The National Clinical FES Centre at the Salisbury District Hospital, Salisbury, for all their support, guidance and encouraging words. I would specially like to thank Dr. Earl Merson and Mr. Robert Batty for all their help, guidance and support with the design of the TetraGrip. I would also like to thank both the able-bodied volunteers and the tetraplegic volunteers who volunteered to participate in this research work and without whom, it would have been impossible to achieve the results and validate this study.

Next I would like to thank INSPIRE, A Charitable Foundation for people with Spinal Cord Injury and the Bournemouth University for their support and the generous funding this research work. As an international student, it would have been very difficult for me to continue this research work without their generosity.

Last but not the least, I would like to thank all my lovely friends and family members, especially my late father, Mr. V. Venugopalan, my mother, Mrs. Chitra Venugopalan, my brother, his wife, my nephew, my in-laws and my husband Dr. Santhosh Seshadhri, for believing in me and encouraging me to chase my dreams.

.

Author's Declaration

The work presented in this thesis is my own. Some of the assembled parts belong to Odstock Medical and are listed below:

The Stim Engines are developed by the department of New Product Development of the Odstock Medical and were reprogrammed to suit the TetraGrip

The OML boost circuit for supplying power to the stim engines were also developed by the department of New Product Development at the Odstock Medical.

The volunteer information sheets in Appendix C were based on a template document in use at the Odstock Medical.

Chapter 1 Introduction

1.1 Background

The human spinal cord is a bundle of nerves, protected by the vertebral column, which connects the brain to the rest of the body. An injury to the spinal cord can lead to permanent damage to the nerves as this will block the signals to and from the peripheral nerves to the brain and can thus affect everything below the level of the lesion The spinal cord changes at approximately T12 (12^{th} thoracic vertebra). Above T12 it is part of the central nervous system where it is able to process its own signals, whereas below T12 it is part of the peripheral nervous system. Hence any injury above T12 is an upper motor neuron injury whereas below that point is a lower motor neuron injury. Some of the common reasons for a spinal cord injury (SCI) are traffic accidents, knife injuries, gunshot injuries, falls and sports injuries (Nas et al. 2015). SCI not only results in loss of independence and physical function, but can also affect breathing, cardiovascular, bowel and bladder functions in an individual. Other complications may involve pressure sores and autonomic dysreflexia (Nas et al. 2015).

An injury to the spinal cord in the cervical region (neck area) leads to a condition called **Tetraplegia** and an injury in the thoracic, lumbar and sacral regions leads to a condition called **Paraplegia**. Tetraplegia is a condition which is defined as the partial or complete paralysis of all four limbs and paraplegia is a condition that is defined as the partial or complete loss of functions below the waist.

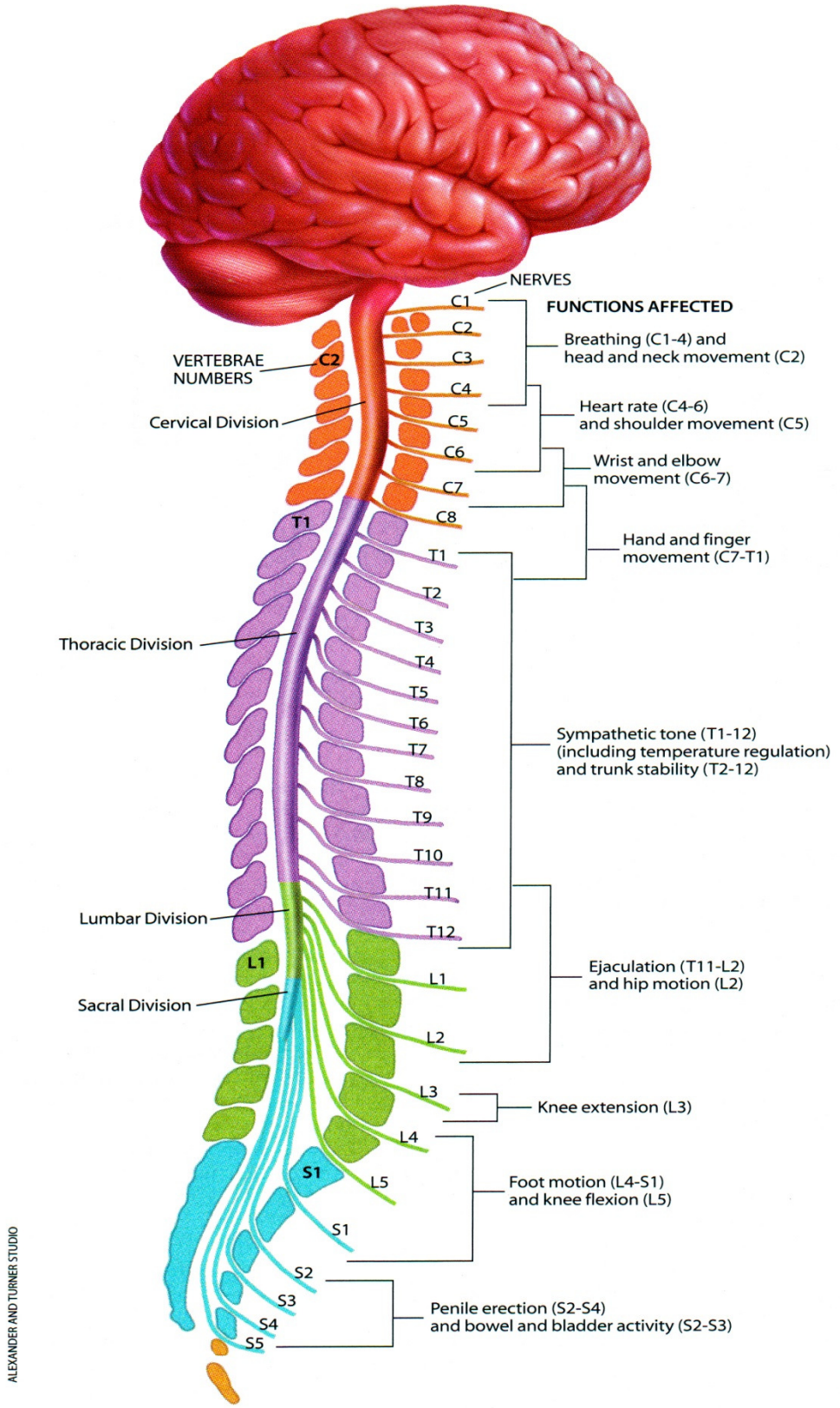


Fig 1-1: Spinal Cord and its functions (Alexander&TurnerStudio 2015)

According to Apparalyzed, a non-commercial website designed to promote SCI awareness, nearly 1200 people in the UK are paralysed as a result of SCI every year and there are approximately 40,000 people living with the effects of SCI (Apparelyzed Spinal Cord Injury Peer Support 2014).

Figure 1-1 provides a detailed description of the spinal nerves and their functions. An injury to the spinal cord at any level affects the functions mentioned at that level and the levels below the point of lesion. The extent of the loss of function after a SCI depends on the level of injury and the completeness of the injury (Nas et al. 2015) and this is determined by a scale defined by the American Spinal cord Injuries Association (ASIA) called the ASIA scale (summarised in table 1-1). A person with a C5 complete spinal cord injury will not have any of the functions mentioned in the figure 1-1 below the level of C5. If the injury is C5 incomplete, then the person will have some residual functions below the level of lesion. Whether a person has complete or incomplete SCI is identified during the post injury evaluation. A detailed description about the complete and incomplete SCI is provided in Chapter 2.

Impairment Scale	Description
A: Complete	No Sensory or Motor function preserved in the Sacral segments S4-S5
B: Incomplete	Sensory but no motor function below the neurological level and extends through the sacral segments S4-S5
C: Incomplete	Motor functions are preserved below the neurological level and majority of key muscles below the neurological level have a muscle grade less than 3
D: Incomplete	Motor functions are preserved below the neurological level and the majority of the key muscles below the neurological level have a muscle grade greater than or equal to 3
E: Normal	Sensory and motor functions are normal

Table 1-1: Description of the ASIA impairment scale (Kirshblum et al. 2011)

A person with SCI (complete or incomplete) has to undergo intensive rehabilitation in order to preserve the residual function and gain some

independence while performing the activities of daily living (ADL). Their rehabilitation routine involves intensive physiotherapy and occupational therapy. The physiotherapists encourage them to participate in sports like swimming, archery and wheelchair rugby as this provides people with SCI an opportunity to socialise with each other. A physiotherapist also helps in wheelchair rehabilitation which involves transfer from the wheelchair to the toilet, the bed, the bath and other places (Savić 2003). Occupational therapy includes exercises that target improving the hand functions of a person with tetraplegia.

These improvements are assessed using various outcome measures specifically defined for the upper limb rehabilitation. Often other orthosis such as splints or an electrical stimulation device is recommended if the occupational therapists think the person with SCI would benefit from it and that the use of an orthosis will improve their ability to perform their ADL better. If an electrical stimulation system is used to provide or enhance missing function, such as dorsiflexion of the foot when walking or restore hand function it is usually referred to a Functional Electrical Stimulation device or FES device for brevity. The term FES will be used throughout this thesis.

The use of electrical stimulation for pain relief dates back to 15 AD where torpedo ray fish were used to deliver electric shocks to cure gout pain and headaches (Gater et al. 2011). In 1780, Luigi Galvani demonstrated that electrical impulses in the nerves were passed to the muscles and thus caused their contraction. The research into the use of electricity for therapeutic purposes continued in the 19th and 20th century, which resulted in the development of devices like defibrillators and cardiac pacemakers. These advances led to the better understanding of the peripheral nervous system which in turn made it possible for researchers to develop stimulators targeting specific requirements for a person with SCI (Gater et al. 2011).

The use of phrenic nerve stimulator for assistance in breathing and the use of FES for improving the bladder and bowel functions in people with SCI are

some of the applications for FES documented in the literature (Ragnarsson 2008; Gater et al. 2011). Besides these applications, FES has also been used for standing in people with paraplegia and upper limb rehabilitation for people with tetraplegia (Ragnarsson 2008).

The use of upper limb FES is beneficial for people with a lesion at or below C5 if the injury is complete. For people with incomplete SCI, an initial assessment has to be done to evaluate the availability of muscles before subjecting them to FES. The successful use of FES is subjected to the satisfaction of certain prerequisites which can be evaluated during the initial assessment. The volunteer has to have muscle strength greater than or equal to 3 in the scale defined by the Medical Research Council (MRC) called the MRC scale (described in detail in chapter 2). Another important pre-requisite for the use of FES is that the target muscles should not be denervated, which can happen at, or just below the level of the lesion. The use of FES will be successful only if the peripheral nerves innervating the target muscles are intact.

The two main hand movements required by people with tetraplegia are the key grip and the palmar grasp movements. The key grip movement is necessary for grasping smaller objects like a pen and a fork, while the palmar grasp movements are required for grasping larger objects like a glass or a juice can. These two movements are described in greater detail in Chapters 3 and 6. Another pre-requisite for using upper limb FES for rehabilitation is the availability of muscles to generate functional key grip and palmar grasp movements. Once the volunteer satisfies all these pre-requisites, they are appropriate to FES therapy.

The upper limb FES devices for people with tetraplegia were broadly classified as implanted, percutaneous and surface FES devices, based on the type of electrodes. Implanted FES devices used epimysial electrodes, which were placed directly on the target muscle, or nerve cuffs placed around the appropriate nerve for delivering the electrical impulses. The advantage of using an implanted FES device is that it eliminates the requirement of the

precise placement of electrodes on a daily basis. However, the cost of the surgery for implanting the device and the rehabilitation associated with it are the major disadvantages of using an implanted system.

The percutaneous electrodes are placed such that the electrode part is implanted inside the body but the connectors for the electrodes are outside the skin which makes these electrodes partially implanted. The advantages of using these electrodes are the same as the implanted electrodes but the main disadvantages of using a system with this type of electrode are the high chances of infection and cost as an invasive surgery is required to implant the electrodes. The cost of the FESMate, a percutaneous FES system, was approximately $10,000 in the early 1990s (Triolo et al. 1996).

Surface FES systems mostly use commercially available surface electrodes for delivering the impulses. The advantages of using these devices is that they are simple to use and can be set up on people immediately if they are suitable for the use of FES. The major drawback of using surface electrodes is the requirement for precise placement of the electrodes. The two upper limb FES devices that were approved by the Food and Drug Administration (FDA) for use in people with tetraplegia and commercially available are summarised here and a detailed literature review is presented in Chapter 3 of this thesis.

The NeuroControl® Freehand System, marketed by NeuroControl Corp., was an eight channel implanted FES device. This device was used in numerous clinical studies involving people with C5/C6 tetraplegia and it was observed during the course of these studies that the volunteers were able to perform the specified tasks much more efficiently with the help of the NeuroControl® Freehand System (Taylor et al. 2002). The device was implanted on more than 250 people with tetraplegia after being approved by the FDA (Kilgore et al. 2008). NeuroControl Corp. stopped manufacturing this device in the year 2001 and went out of business in the year 2007 (Venugopalan et al. 2015). The researchers who developed the Freehand System have developed a

'Next Generation Freehand System' which is currently undergoing intensive clinical trials (Memberg et al. 2014a).

A number of FES device using surface electrodes are described in the literature. Out of these devices, the NESS H200 is the only commercially available and FDA approved device. This is a three channel FES device that uses a rigid arm splint to hold the electrodes in position. Once the device is properly set up, the volunteer wears the arm splint and turns the device ON with the help of a push button and starts using the device. This design has reduced the donning and doffing time tremendously as it eliminates the need for precise placement of the electrodes (Snoek et al. 2000).

A number of upper limb FES devices are discussed in great detail in Chapter 3 which raises a question: Why do we need another upper limb FES device? The answer to this question is discussed in the next section.

1.2 Need for Another Upper Limb FES Device

With the unavailability of the NeuroControl® Freehand System, the NESS H200 became the only FDA approved commercially available upper limb FES device. However, this device was not suitable for everyone because the rigid arm splint held the wrist in a fixed position. This makes it difficult to use where the person already uses a tenodesis grip. A tenodesis grip uses the fact that as the person dorsiflexes their wrist the fingers are inclined to close. This is impossible if the wrist is held in a fixed position as is the case with the H200. The rigid arm splint reduces the donning and doffing time but it does not allow flexibility in the electrode placement. Also it is difficult to design an arm splint that can fit a variety of hand sizes and the arm splint of the NESS H200 was available in only one size and hence did not fit everyone (Venugopalan et al. 2015).

Since no other upper limb FES devices for people with SCI was available at the time of writing, there is an urgent requirement for an upper limb FES

device that can be used by a wider range of people. This device needs to be efficient in improving the hand and arm functions while using it and at the same time needs to be flexible enough to allow the user to utilise any residual functions. This device should provide the user the necessary freedom to choose the hand function they want to perform at any given time and should allow the user to adjust their grasp strength while performing a task of their interest. Hence the selection of optimal man-machine interface was necessary as well.

If such a device is successfully developed, then it will bring important changes to the life of people with tetraplegia. These changes are discussed in the next section.

1.3 Importance of the Proposed Research

A person with C5/C6 tetraplegia usually uses modified cutlery for consuming food and uses a special pen for writing or uses a special finger support that holds the pen for them. If the proposed FES device is developed successfully, it might help a person with tetraplegia in performing ADLs like holding a pen and writing or holding a fork and having their dinner. Use of FES would provide an individual with tetraplegia independence in performing many of their ADL, which would have otherwise been very difficult. The proposed device will not only improve the user's ability in performing tasks, it will make them less dependent on their carers which would be a big morale booster for both the user and their family. The main target of this research is to develop a FES device that will allow flexibility in the electrode placement, minimise the number of electrodes as much as possible, can be used by a wider group of people with tetraplegia and is not very expensive to develop. The formulation of the research aim and the research objectives for this research work is summarised in the next sections.

1.4 Research Aim

The main aim of this study is:

To explore the possibility of developing a multi-channel upper limb FES device controlled using a man-machine interface that can be used by people with C5/C6 tetraplegia for improving their hand function and to study the user's ability to control the device efficiently in order to perform the required task.

The objectives of this research in order to fulfil the abovementioned aim is summarised in next section.

1.5 Research Objectives

The following are the main objectives of this thesis in order to fulfil the research aim:

- **Objective 1:** To explore different sensors in order to provide a reliable input for the user to control the device.
- **Objective 2:** To develop a control system which uses the input from the sensor and allows the user to operate the device without undue conscious effort.
- **Objective 3:** To develop a multichannel upper limb FES device that can stimulate the corresponding muscles for key grip and palmar grasp movements with the help of the defined control signals.
- **Objective 4:** To study the performance of the device and the shoulder position sensor when used by a person with C5/C6 tetraplegia and to evaluate the performance of the device in improving their upper limb functions.

1.6 Research Outcome

This research will provide results on the performance of a MMI to control an upper limb FES device. This MMI will not be in direct contact with the user's skin which will eliminate the possibility of skin irritation caused due to the sticky tapes used to attach the sensor to the user's skin. Minimising the number of wires will reduce the chances of the sensor breakdown as well.

At present, there are two FES devices that are commercially available for upper limb application and one of the devices is suitable only for certain group of people. The other does not have much clinical evidence to suggest that it improves the hand functions of people with SCI. If the results from this research show that the proposed stimulator helps in regaining the upper limb functions for people with tetraplegia, then the idea can be used to develop a future upper limb FES device that can be used by a wider range of people with tetraplegia.

The device will not use a rigid arm splint which will allow the end user to use preserved movement (if available), such as the tenodesis grip along with the use of FES to enhance their upper limb function. In order to hold the wrist in a stable and neutral position, the use of co-contraction of the muscles of the forearm will be explored. This concept has not been used in any of the existing upper limb FES devices and hence adds novelty to this research work.

1.7 Outline of the Thesis

A brief description about the upper limb muscles, spinal cord and SCI and the rehabilitation associated with SCI is provided in Chapter 2.

Chapter 3 provides a detailed literature survey of the upper limb FES devices used for the rehabilitation of people with tetraplegia. This chapter provides a detailed description of these devices, the clinical studies involving them and

their commercial availability. It then determines the choice of control system and the selection of the sensor for controlling the upper limb FES device.

Chapter 4 describes the shoulder position sensors that were explored during this research work and describes the selection of the possible shoulder position sensors.

A comparison between the possible shoulder position sensors, the experiments performed and the selection of the shoulder position sensors are described in Chapter 5.

Chapter 6 provides describes the device design of the device called the TetraGrip in great detail. The hardware design and the modes of operation of the device are described in this chapter.

Chapter 7 provides information about the protocols for the clinical testing of the TetraGrip. This device was first tested by able bodied volunteers and then by tetraplegic volunteers. The protocols for both these experiments are summarised in this chapter.

Chapter 8 analyses the results obtained from both the experiments. This chapter is split into two main sections: the results obtained from the able bodied volunteers is summarised in the first section and the results obtained from the tetraplegic volunteers is summarised in the second section.

A detailed discussion of the results and the observations made during the clinical study are presented in Chapter 9.

The conclusion of this research work is presented in Chapter 10 and the possible future works are also highlighted in this chapter.

Chapter 2 Anatomy and Physiology of the Intact Skeletal Muscle, Spinal Cord Injuries and the Associated Rehabilitation

2.1 Background

A brief description of the anatomy of the upper limb muscles along with the physiology of the muscle contraction is presented in this chapter. The chapter then describes the SCI and the rehabilitation procedures a person undergoes after the SCI in detail. A brief description of how the Functional Electrical Stimulation (FES) works, the stimulation parameters, the types of electrodes and the devices used for upper limb rehabilitation is also summarised in this chapter. It concludes by identifying the need for this research work.

2.2 The Upper Limb Muscles

The human hand is a complicated and robust system capable of performing a number of grasps and fine manipulation. It consists of at least 18 joint articulations controlled by over 30 muscles (Segil and Weir 2015). These muscles are innervated by the nerves that originate from the cervical vertebral level of the spinal cord and hence damage to the spinal cord in the neck region can impair many of the hand functions. There are a number of muscles in the upper limb which can be broadly divided into two categories: the upper arm muscles and the forearm muscles. Figures 2-1 to 2-5 summarise the muscles in the upper limb.

The main upper arm muscles are:

- Biceps Brachii: Flexes and supinates the forearm

- Triceps: Extends the forearm
- Brachioradialis (BR): Flexes the arm

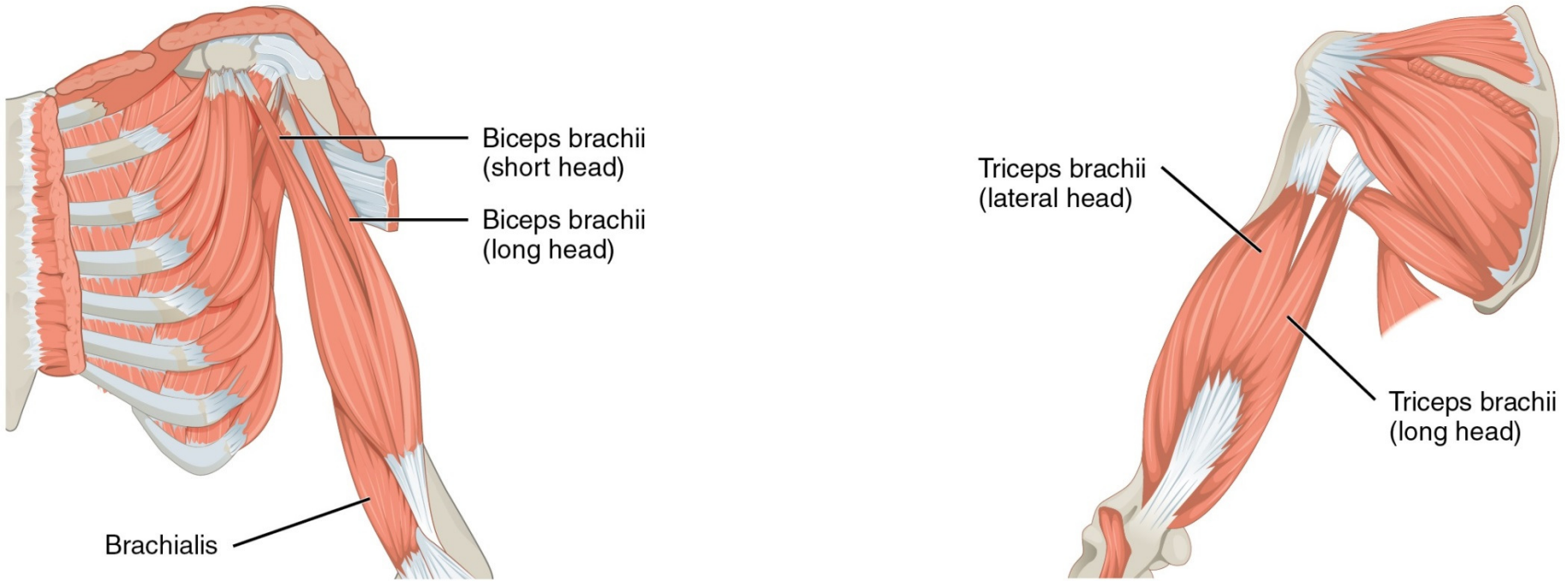
The main muscles of the forearm are:

- Flexor Carpi Radialis (FCR): Flexion and radial deviation of the wrist
- Flexor Carpi Ulnaris (FCU): Flexion and medial deviation of the wrist
- Flexor Digitorium Superficialis (FDS): Flexion of the middle phalanges. Continued action causes wrist flexion
- Flexor Digitorium Profundus (FDP): Flexion of the interphalangeal joints along with the wrist and the metacarpophalangeal joints.
- Extensor Carpi Radialis Longus/Brevis (ECRL/ECRB): Extends the wrist and causes radial deviation of the hand
- Extensor Digitorium Communus (EDC): Extension of the fingers and the continued action can cause wrist extension

The main muscles controlling the thumb are:

- Flexor pollicis longus (FPL): flexes the phalanges of the thumb.
- Adductor Pollicis (AdP): Adducts the thumb (moves the thumb towards the index finger)
- Abductor Pollicis Brevis (APB): Abducts the thumb (Moves the thumb perpendicular to the hand)
- Opponens Pollicis (OP): Helps in thumb opposition (Moves the thumb towards the little finger)

The physiology of the contraction of these muscles is explained in the next section.



Left upper arm muscles (anterior lateral view)

Left upper arm muscles (posterior view)

Fig 2-1: The Upper Arm Muscles (OpenStax 2013)

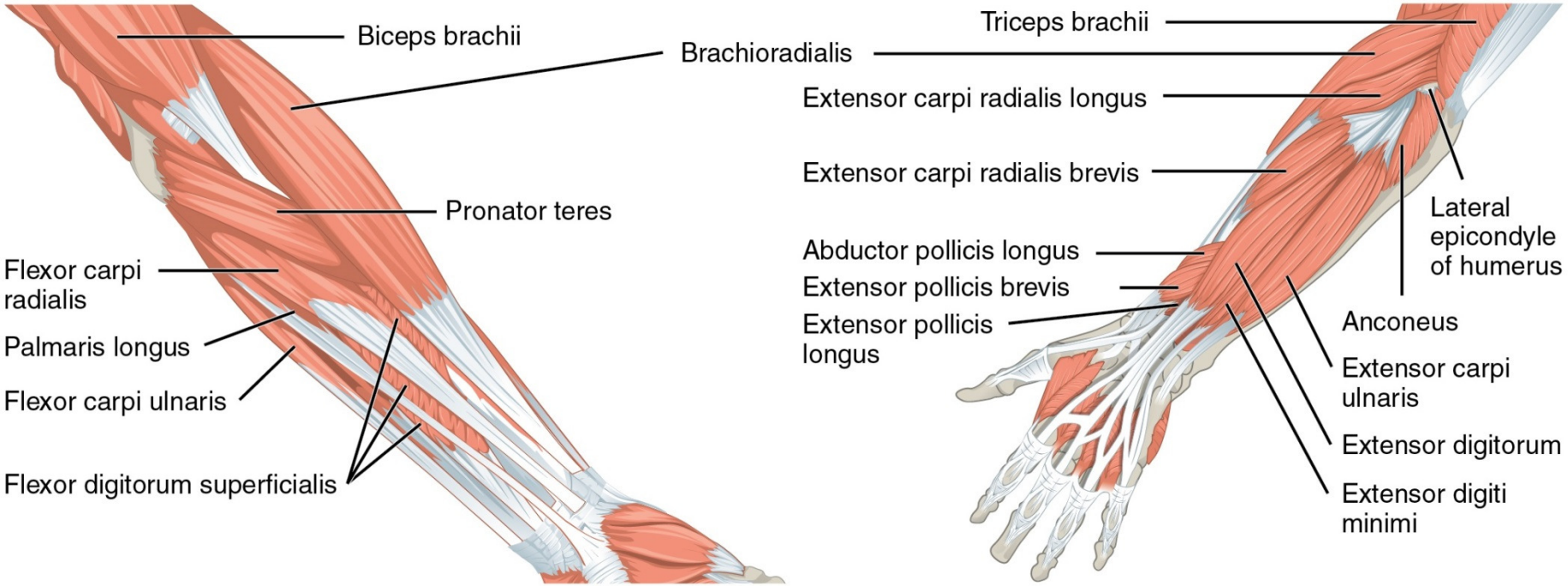


Fig 2-2: The Superficial Forearm Muscles (OpenStax 2013)

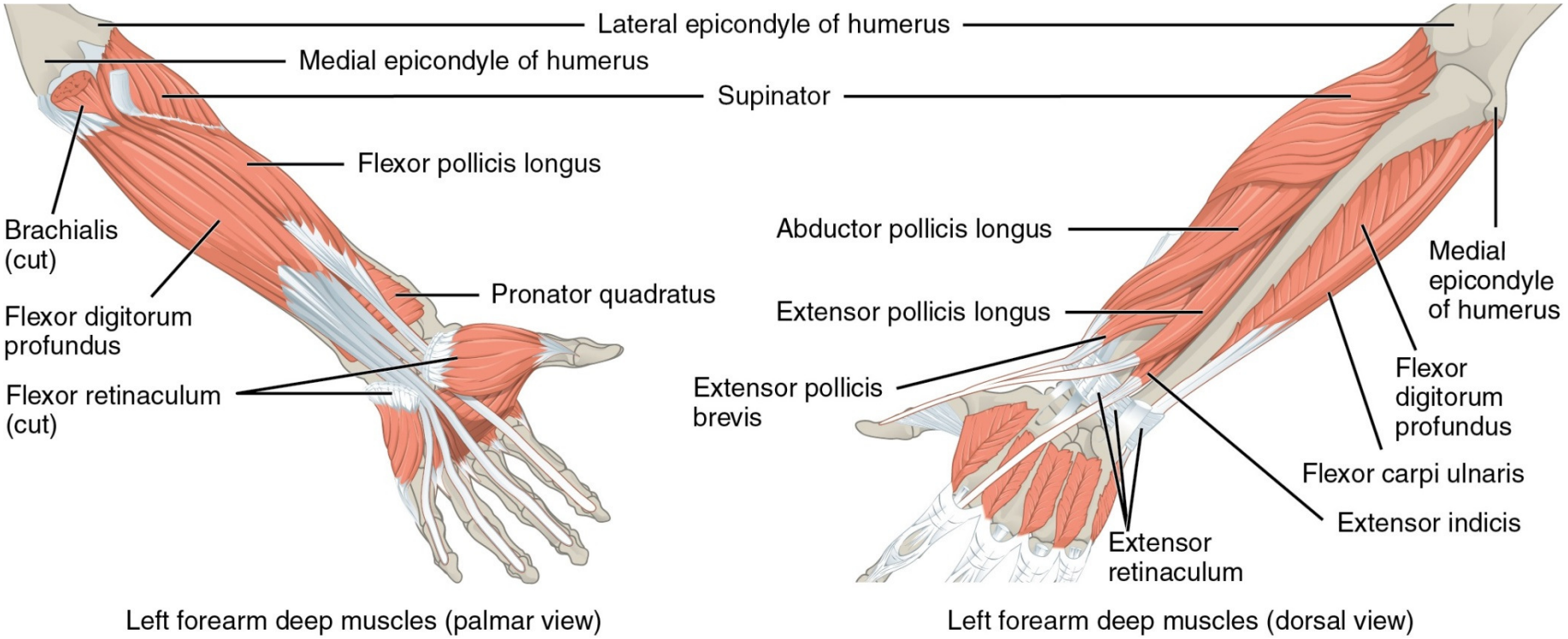


Fig 2-3: The deep forearm muscles (OpenStax 2013)

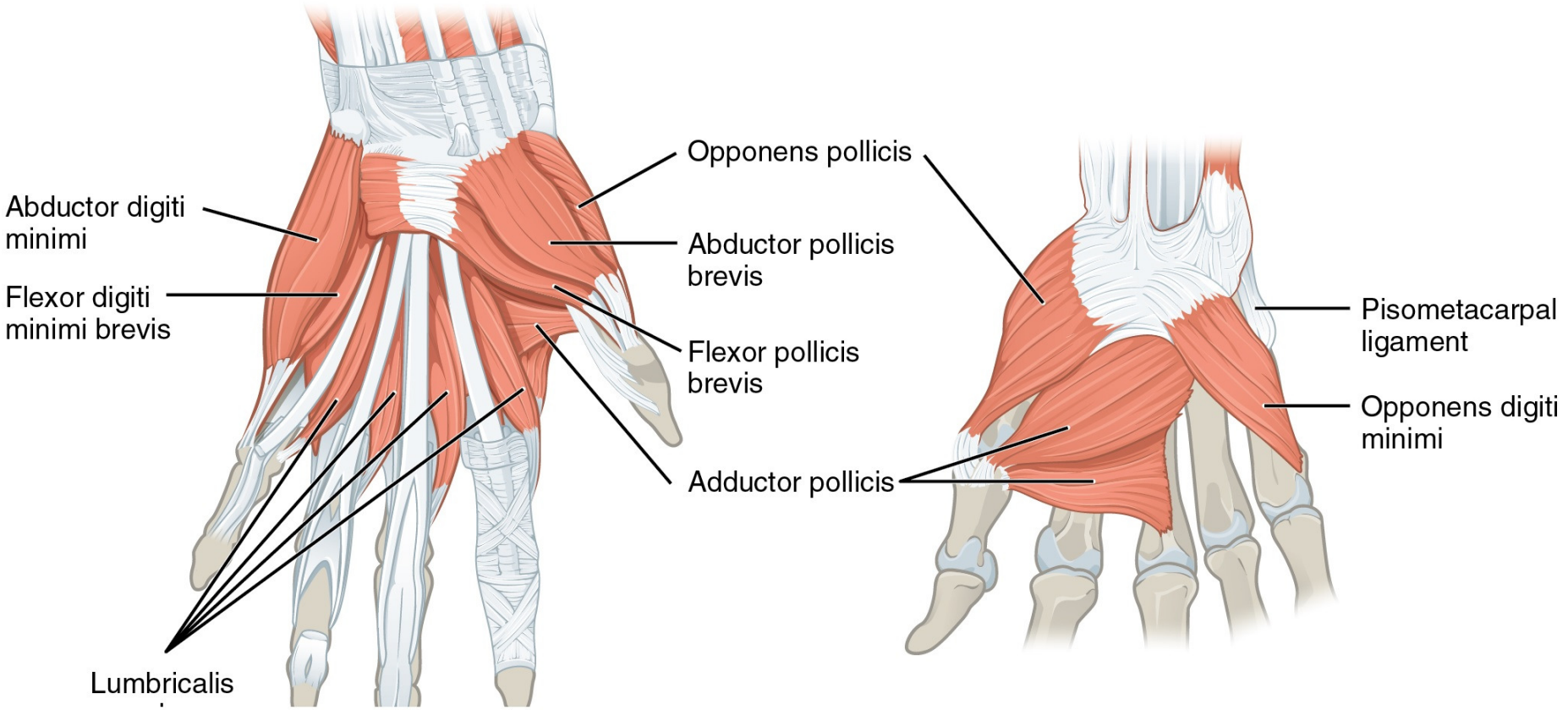


Fig 2-4: The muscles in the hand (OpenStax 2013)

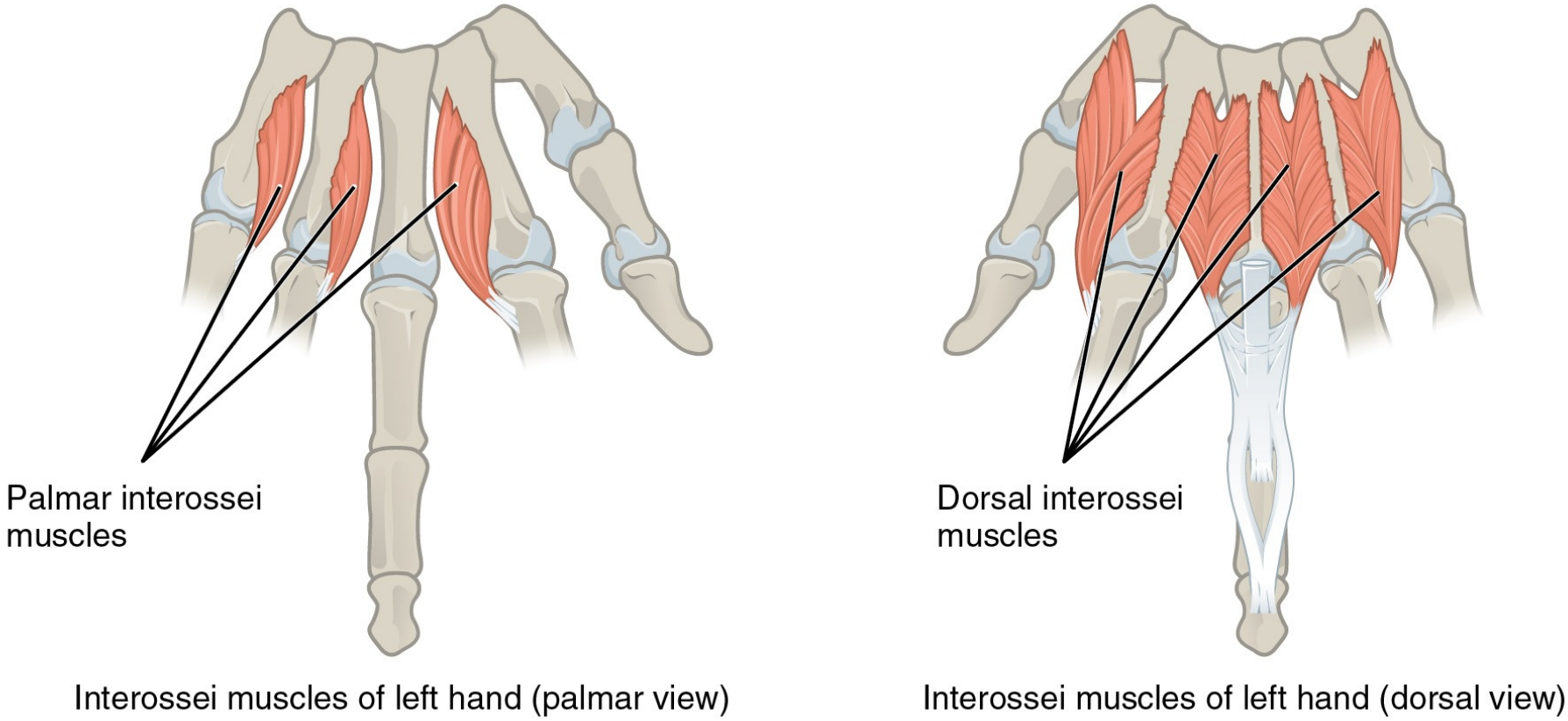


Fig 2-5: The Interossei Muscles of the Hand (OpenStax 2013)

2.3 Physiology of Muscle Contraction

The upper limb muscles are skeletal in nature and consist of two contractile proteins: A thin actin filament which has the active binding sites and the thick myosin filament which has protrusions called the myosin heads. When a nerve impulse reaches the neuromuscular junction, a neurotransmitter called Acetylcholine is released which is responsible for numerous chemical reactions which expose the active binding sites of the Actin. The myosin heads get attracted to the exposed active binding sites and form a cross bridge and pulls the actin filaments at the expense of an Adenosine Triphospate (ATP) molecule thereby causing the muscle contraction. The myosin head detaches from the active site of the actin when an ATP molecule binds back to it. This process repeats as long as the muscle needs to be contracted which depends upon the incoming nerve impulse. This method of muscle contraction is called the Sliding Filament Theory (figure 2-6).

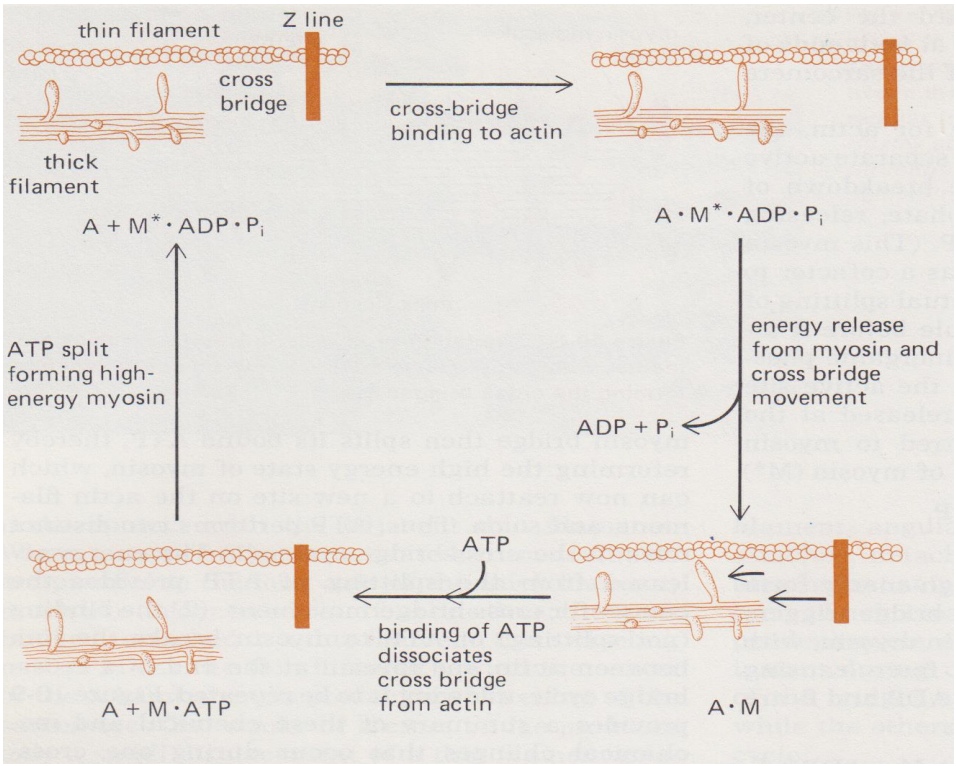


Fig 2-6: Physiology of muscle contraction: Sliding Filament Theory (Huxley and Niedergerke 1954; Huxley and Hanson 1954)

A group of motor neurons and the skeletal muslces innervated by them is called a motor unit (Figure 2-7). These motor units work together to coordinate the contraction of a skeletal muscle. The amount of tension developed by the muscle depends upon the number of activated muscle fibres in it and the force produced by each of them. .

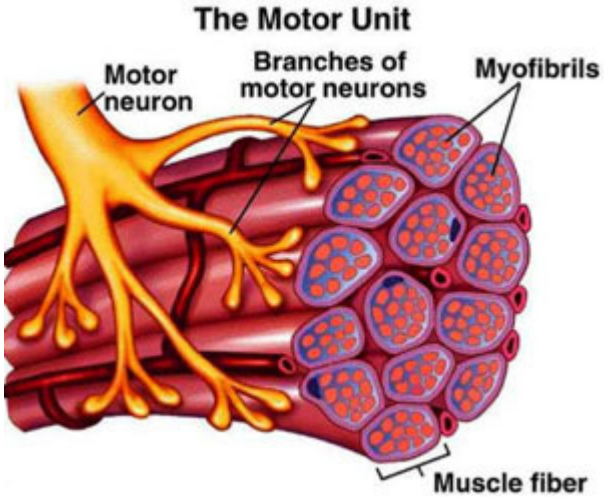


Fig 2-7: A Motor Unit in a Skeletal Muscle (Waterbury 2007)

In order to reduce the fatigue, the motor neurons fire asynchronously. This allows one motor neuron to rest and replenish its ATP concentration while another fibre is contracting. By this mechanism, the muscle achieves smooth contraction without excessive fatigue.

Based on the rate at which a given muscle fibre splits an ATP molecule, the skeletal muscles are categorised into three types:

- Slow twitch: These muscle fibres have a slow speed of contraction and are resistant to fatigue.
- Fast twitch, resistant to fatigue: These muscles have a fast rate of contraction but have rich blood supply and are hence resistant to fatigue.
- Fast twitch, fatiguable: These muscles have high ATPase activity with low oxidative capacity and therefore they fatigue quickly.

The contraction times of the skeletal muscles vary from 10 ms (fast fibres) to 100 ms (slow fibres).Though the action potential lasts only for a short period (1-2 ms), the mechanical response lasts for over a 100 ms. It is possible that a second action potential is generated during this period. The resultant force will be a summation of the two twitch responses. The contraction is called tetanic contraction if the potentials arrive at a sufficient rate. A rate of 20-25 pulses/second is needed to produce a tetanic contraction in slow fibres and a rate of 100 pulses/second is needed for fast muscle fibres. The stored energy available in the form of an ATP decides duration for which a muscle remains in tetanic contraction. The tension in the muscle will be reduced if the ATP concentration decreases. A muscle fatigues when it fails to maintain the force during sustained or repeated contractions.

Some skeletal muscles contain predominantly one type of muscle fibres and some others contain a mixture of all three muscles types. The proportions however vary depending upon the usage. For example, the postural muscles tend to be slow twitch fatigue resistant type, whereas those in the arms tend to have more number of fast twitch fatiguable fibres. When using electrical stimulation, the training regime should be well planned as the naturally occurring asynchronous firing of motor nerves is not available when external electrical stimulation is used.

When a muscle is stretched the muscle spindles produce an output and this is carried along the Ia and II afferent fibres to the spinal cord where they have an excitory effect on the motor neurons from the same muscle. This causes the muscle to contract and hence return the muscle to the original length before the stretch occurred. It is thought that this reflex is an important part of the bodies control mechanism used to maintain the stable position of the bodies joints. Evidence of this control loop can be seen by performing an H reflex test. The Ia afferents are slightly larger than the motor neurons that are carried in the same nerve bundle. This means their excitation threshold is lower than the motor neurons. If a nerve bundle is stimulated at low intensities it is possible to only activate the Ia afferents. The nerve impulse produced travels up the nerve to the spinal cord where a synapse is made

with the motor neuron. This activity excites the motor neuron and the nerve impulse generated, travels down the nerve to the muscle, exciting a muscle twitch and its associated EMG. This is called the H reflex, named after the physiologist who discovered it, Hoffman. The delay between stimulation and EMG response is equal to the transition time for both nerves. As the stimulation intensity is increased, direct recruitment of the motor nerve occurs which generates two nerve impulses and one travels down the nerve to the muscle. The resultant EMG response is termed the M (Motor) wave. The second impulse travels up the nerve (antidromic) to the spinal cord. If an antidromic nerve impulse occurs on the same nerve as the H reflex, the nerve impulses annihilate each other and the H reflex dose not course and EMG response. For this reason, as the stimulation intensity increases the M wave increase in size while the H reflex decreases.

After SCI, this complex control of the muscle contraction is lost and replicating the same with external electrical stimulation is not possible. Thus programming a stimulator to reproduce the fine movements of fingers and hand is not possible using external electrical stimulation.

The action potentials in the muscles are generated using one of the following mechanisms:

- Stimulation by a nerve fibre
- Stimulation by hormones and local chemical agents
- Spontaneous electrical activity within the muscle membrane itself

The action potential in the skeletal muscles is generated when the respective motor neuron gets excited. These motor neurons are myelinated nerve fibres (figure 2-8).

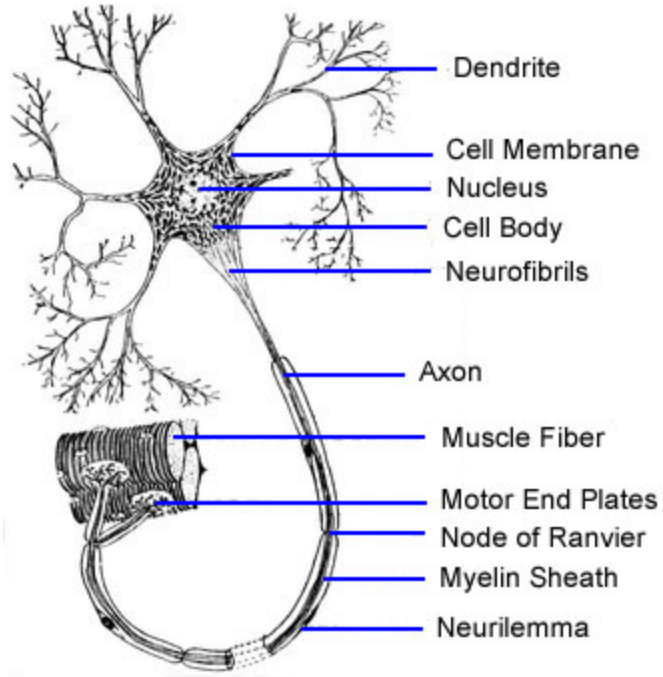


Fig 2-8: A Detailed Diagram of a Motor Neuron (Kidport 1998)

The axon of a motor neuron is located in the brain stem or the spinal cord. It subdivides into many branches when it approaches the muscle and each of these branches connects to a single muscle fibre. When they reach the muscle surface, the axons lose their myelin sheath and divide into fine terminal ends which lie in the grooves on the surface of the muscle. The area under the terminal portion the axon is called the motor end plate. The point where the axon terminates is called the neuromuscular junction and the area of greatest concentration of neuromuscular junction is called the **motor point**.

Motor points are important for electrical stimulation because muscle contraction can be easily initiated if the electrodes are placed at the motor point. Motor neurons carry information from the brain or the spinal cord to the peripheral organs. The spinal cord works as a messenger between the brain and the peripheral nervous system. It takes the sensory information from the

peripheral nerves and delivers it to the brain and takes the motor information from the brain and delivers it to the peripheral organs. An injury to the spinal cord can affect various functions of the body. The effect of SCI and the rehabilitation associated with it is discussed in the next section.

2.4 Spinal Cord Injuries: Classification and Associated Rehabilitation

The spinal cord is well protected by the vertebral column. But trauma from motor vehicle accidents, fall, sports injuries or violence can cause SCI. Based on the level and extent of damage; various activities of the human body are affected. The SCI can be classified as Complete and Incomplete. Incomplete SCI are those in which there is some sensory or motor function preserved below the level of neurological injury. The ASIA has defined an impairment scale called the ASIA impairment scale (Grundy & Swain, 2002). The degree of impairment is graded in 5 groups as summarised in the table 1-1 in Chapter 1.

The grade of the muscles used in the ASIA impairment scale is based on the Medical Research Council (MRC) scale are summarised in the table 2-2.

Muscle Grade	Description
0	Total Paralysis
1	Palpable or visible contraction
2	Active movement, full range of motion (ROM) with gravity eliminated
3	Active movement, full ROM against gravity
4	Active movement, full ROM against gravity and moderate resistance in a muscle specific position
5	(Normal)Active movement, full ROM against gravity and full resistance in a functional muscle position expected from an otherwise unimpaired person
5*	(normal) active movement, full ROM against gravity and sufficient resistance to be considered normal if identified inhibiting factors (i.e. pain, disuse) were not present
NT	Not testable (i.e. due to immobilization, severe pain such that the patient cannot be graded, amputation of limb, or contracture of > 50% of the normal range of motion).

Table 2-1: The muscle grades based on the MRC scale (Kirshblum et al. 2011)

A spinal cord lesion in the neck region often results in **tetraplegia** where the person with SCI often loses partial or total function of all the four limbs. A detailed description of the loss of functions at various levels is provided in figure 1-1 of Chapter 1. A person with SCI often undergoes intensive rehabilitation in order to enable them to perform some of the ADL independently. The ADL include tasks such as personal hygiene (brushing teeth, being able to dress), drinking from a cup or glass, writing, using a telephone, picking up a book etc. The rehabilitation for a person with SCI includes physiotherapy and occupational therapy which are discussed in the next section.

2.4.1 Physiotherapy and Occupational Therapy

The physiotherapy exercises aid a person with SCI in breathing, coughing and in maintaining the range of movements in the limbs. The physiotherapist also helps a person with SCI with the wheelchair rehabilitation by teaching them how to use the wheelchair and how to transfer from the wheelchair to the bed, the toilet, the bath and other places. Various sporting activities can assist in balancing, strength and fitness. The physiotherapists encourage the person with SCI to participate in activities like swimming, table tennis, snooker, darts and archery as these activities will not only improve their coordination and hand functions but will also help them in socialising with other people once they leave the hospital (Savić 2003).

The occupational therapy helps the person with SCI in gaining physical and psychological independence in performing some of the ADL. Occupational therapy includes performing tasks that improve the hand function of a person with SCI and outcome measures are used to assess their performance in regular basis. The occupational therapist also assists the person with SCI in overcoming the difficulties in performing their ADL by providing alternative methods and equipment that will help them with personal care, domestic tasks and communication. Often, occupational therapy can be more effective if a person with SCI undergoes tendon transfer surgery to stabilise some of

the arm functions. Some of the most commonly performed tendon transfer surgeries are summarised in the next section.

2.4.2 Functional Hand Surgery for People with Tetraplegia

Re-constructive surgeries are often suggested to the people with tetraplegia in order to restore some of the functional activities of the limb. One of the most common goals of this surgery is to provide pinch and grasp functions of the hand and restore elbow functions. The principle of this kind of re-constructive surgery is a technique called tendon transfer. In a tendon transfer surgery, the tendon from an active or functional muscle is transferred to joint having no function in such a way that it restores the function of this joint. Multiple tendon transfer surgeries can be done for restoring more than one function but these surgeries have to be performed one at a time. Hence it is highly likely that an individual may undergo more than one surgery for restoring some of the hand functions.

The main component for selecting the appropriate candidate for tendon transfer surgery is the evaluation of strength and sensation of the upper limb. The International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) provides a generalised degree of impairment after SCI but the main limitation of the ISNCSCI is that it does not provide adequate information on all upper limb muscles and sensations (Dunn et al. 2016). Hence a more specific International Classification for Surgery of the Hand in Tetraplegia (ICSHT) has been defined specifically for the hand assessment purpose. Table 2-2 shows a comparison between ISNCSCI and ICSHT(Dunn et al. 2016). The ISNCSCI and ICSHT define that the minimum strength of a muscle for a tendon transfer should be at least 4 out of 5 in order to be able to move the joint against gravity. The ICSHT was further modified to record the sensory functions as well using the two point discrimination method.

Abbreviations: PD-Posterior Deltoid; BR-Brachioradialis; ECRL- Extensor Carpi Radialis Longus; ECRB- Extensor Carpi Radialis Brevis; PT- Pronator Teres; FCR Flexor Carpi Radialis

ISNCSCI	Level of SCI	ICSHT
Elbow extensors	C5	Group 0 No muscles for transfer
Wrist extensors	C6	Group 1 BR Group 2 ECRL Group 3 ECRB
Elbow Extensors	C7	Group 4 PT Group 5 FCR Group 6 EDC
Finger Flexors	C8	Group 7 EPL Group 8 Partial Digital Flexors Group 9 Lacks only intrinsics
		Group X Exceptions

Table 2-2: Comparision between ISNCSCI and ICCST (Dunn et al. 2016)

The most commonly performed tendon transfer surgeries are summarised in the table 2-3.

Level	ICSHT	Desired function	Possible reconstructive procedure
C5	0	No muscles available for transfer	
	1	Elbow extension	PD to Triceps or Biceps to Triceps
		Wrist extension	BR to ECRB
		Key grip	FPL tenodesis, Split distal FPL tenodesis
C6	1-3	Elbow extension	PD to triceps or biceps to triceps
		Key grip	BR to FPL or FPL tenodesis, Split distal FPL tenodesis
		Thumb Extension	EPL tenodesis
		Gross grasp	BR to FDP or ECRL to FDP
		Gross release	EDC tenodesis
C7	4-7	Key grip	BR to FPL or PT to FPL, Split distal FPL tenodesis
		Gross grasp	ECRL to FDP or PT to FDP
		Gross release	PT to EDC
C8	8-9	Thumb opposition	ECU to FCT to FPL using FDS

Table 2-3: List of commonly performed tendon transfer surgeries (Dunn et al. 2016)

Often people who have undergone tendon transfer surgery are recommended the use of FES to further enhance their hand functions. FES is briefly discussed in the next section.

2.5 Functional Electrical Stimulation (FES)

FES is a technique of using electricity to activate the nerves supplying the muscles of the limbs that have been paralysed, to produce useful or purposeful movement. The paralysis can be due to the damage to the CNS as a result of SCI, head injury, stroke or other neurological disorders. Stimulating current is applied to the motor units through the active and the common electrodes placed at the motor and the reference points respectively (figure 2-9). This establishes an electric field between the two electrodes and the ions generated due to the electric filed create a current. This ionic flow across the nerves generates action potential which propagates along the nerve causing the muscle contraction.

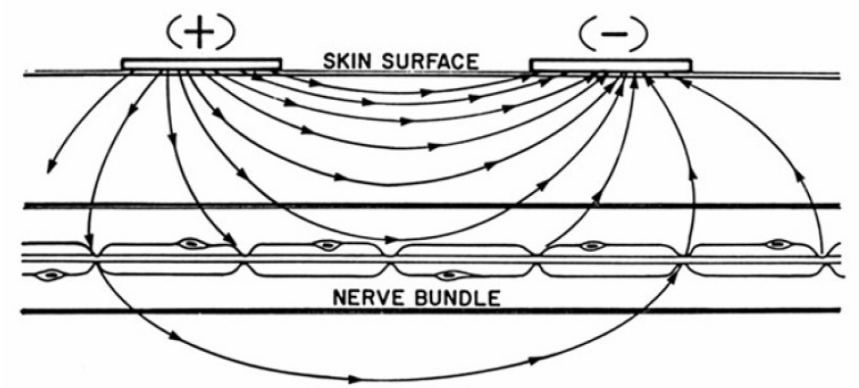


Fig 2-9: Principle of Functional Electrical Stimulation (Benton et al. 1993; Bajd and Munih 2010)

The current flowing per unit area, also known as the current density, is inversely proportional to the size of the electrode. Hence smaller electrodes result in higher current density. Also, the current density is high at the interface between the tissue and the electrodes and decreases as the current travels deeper. The distance between the active and the indifferent electrode depends on the depth of stimulation and hence affects the current density. If

the point of stimulation is closer to the surface, then the electrodes are placed closer to each other. On the other hand, in order to stimulate deeper sites, the electrodes need to be placed away from each other (Bajd and Munih, 2010). The current density can also be changed by keeping the distance between the electrodes constant. This can be achieved by modifying the stimulation parameters listed out in the next section.

2.5.1 Stimulation Parameters

The stimulation parameters for adjusting the current density at the site of delivery of the stimulation pulse are: the pulse amplitude and duration, the pulse frequency or the pulse repetition rate, the ON-OFF times, the ramp times and type of the waveform. These stimulation parameters are discussed in the following subsections in detail.

2.5.1.1 Pulse amplitude and duration

The pulse amplitude is set indirectly by setting the current for the channel(s) of the stimulator. It has to be higher than the threshold of excitability of the stimulated tissue and this can be ensured while setting up the device. When the pulse amplitude is just above the threshold value, then the nerve fibres nearest to the electrode are excited. But when the amplitude is increased beyond the threshold value, then some additional nerve fibres farther away from the electrodes get excited as well which can cause co-contraction or unwanted stimulation response.

The duration for which the stimulation is kept ON in a particular channel depends upon a parameter called the stimulation duration. This is a very important parameter especially in multichannel FES devices where the stimulation envelope is generated by sequencing the ON times for the all channels.

2.5.1.2 Pulse frequency

The pulse frequency determines the number of action potential per unit time. Therefore, the quality of evoked motor response is influenced by the frequency of the pulse. Skeletal muscle under neurological control achieves tetanic contraction at a frequency as low as 6-8 Hz as the muscle fibres are recruited asynchronously. However FES recruits the muscle fibres synchronously and therefore requires higher frequency pulses in order to achieve the desired muscle contraction. A contraction similar to tetanic contraction can be achieved with 20-30 Hz frequency with the help of FES. However with increase in frequency of the stimulation pulse, the fatigue increases due to the synchronous recruitment of the muscle fibres (Lynch and Popovic 2008).

2.5.1.3 ON/OFF Times or Duty Cycles

The ON time is the duration for which the stimulator is ON and the duration for which the stimulator is OFF is called the OFF time. During the ON time, the stimulator delivers a train of pulses with specified amplitude, duration and frequency. The length of OFF time defines the period for rest and recuperation for the stimulated tissues before the next stimulus is delivered. This is usually used to maintain uniform muscle contractions over extended periods of time. The ON/OFF times should be chosen according to the treatment regime and the patient's fatigue response to the stimulation regime.

2.5.1.4 Ramp Times

The ramp times are used to gradually recruit motor units rather than stimulating all the motor units at once. The ramp effect can be created by either gradually increasing the amplitude of the pulse or increasing the pulse width of the pulse train. The ramp down time allows the limb to return to a resting position gradually and in a controlled manner. Gradual recruitment of

the motor unit also reduces the fatigue caused due to Slow ramps are more comfortable and because they produce a slower stretch of the antagonist muscles and hence are less likely to cause a stretch reflex and so cause spasticity (Benton et al. 1993; Lynch and Popovic 2008).

2.5.1.5 Waveforms

The commonly used stimulator waveforms are monophasic, asymmetric biphasic and symmetric biphasic waveforms. Figures 2-10 to 2-12 show all the three waveforms.

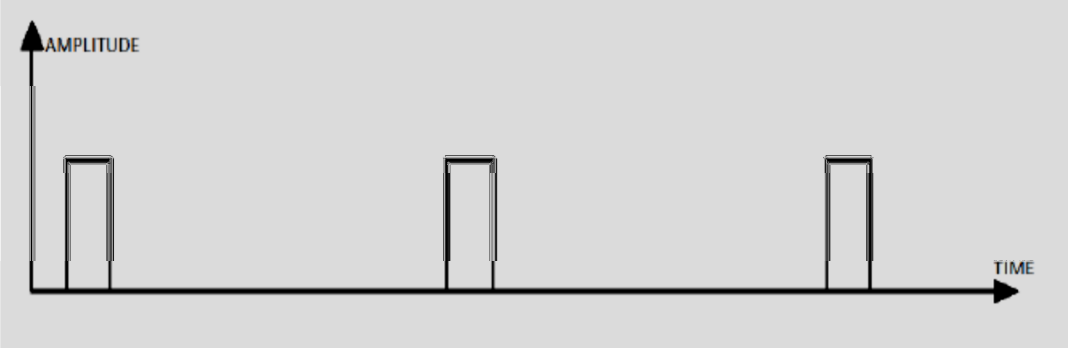


Fig 2-10: Monophasic Waveform (Broderick et al. 2008)

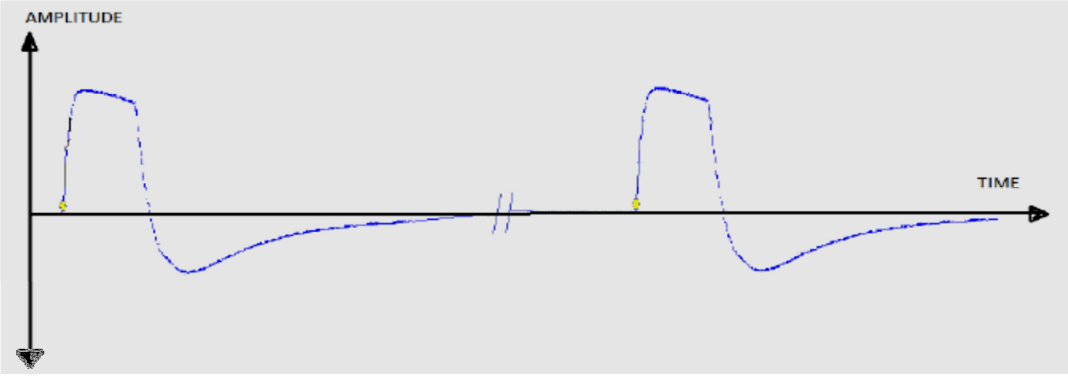


Fig 2-11: Asymmetric Biphasic Waveform

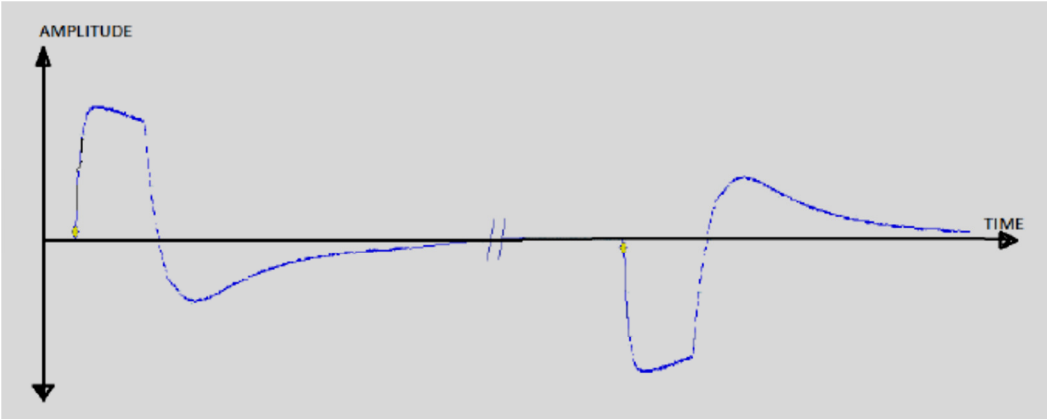


Fig 2-12: Symmetric Biphasic Waveform

With a monophasic waveform, the ions flow in only one direction. This can cause electrode deterioration and skin irritation. In an asymmetric biphasic waveform, the ions flow in both directions which allow each of the electrodes to serves as a cathode during a cycle of the waveform. In this type of waveform, the tissue is depolarised during one cycle and gets repolarised during the opposite cycle and hence minimises the risk of skin irritation. In a symmetric biphasic waveform, the current flows in one direction and then reverses as a mirror image in opposite direction. The magnitude and duration of the current in both directions remain the same. This allows the electrodes to act as a cathode for alternate cycles. The types of electrodes used for upper limb FES stimulation are summarised in the next section.

2.6 Types of Electrodes used in Upper Limb FES

The electrodes used in upper limb FES devices are broadly classified as: implanted electrodes or epimysial electrodes, percutaneous electrodes and surface electrodes. The epimysial electrodes are completely implanted and can be precisely placed on the target muscle. The use of epimysial electrodes has the following advantages:

- It eliminates the need for precise placement of the electrodes every time the user dons the device.

- The response to FES is better as it allows precise placement of the electrodes. The size of the electrode is also smaller compared to the surface electrodes which reduce the effect of co-contraction of the neighbouring muscles.
- They are cosmetically more appealing as neither the electrodes nor the connecting wires are visible.

Percutaneous electrodes have advantages similar to that of the implanted electrodes except that they are not cosmetically appealing. This is because the electrodes are implanted but the connectors pierce through the skin and are connected to an external stimulator. There are some disadvantages of the systems using implanted or percutaneous electrodes such as:

- The surgery for implanting the system or the electrodes makes the user susceptible to infection.
- The post-surgery recovery time is significant and the user would not be able to undergo any FES related rehabilitation during this time.
- The surgery and the rehabilitation associated with it are expensive compared to using a surface stimulation device.

There are several disadvantages of using a system with surface electrodes such as:

- Precise placement of the electrodes for optimum FES response is often challenging.
- Since surface electrodes are much larger in size compared to the epimysial electrodes, they cause co-contraction of the muscles surrounding the target muscles which sometimes leads to undesirable responses.
- The user or the carer has to precisely place several electrodes during the setup process.
- The surface electrodes wear out over a period of time and require periodic replacement. If the user uses too much moisturiser around

the site of stimulation, the electrodes wear out quickly which affects the response to electrical stimulation.

However surface electrodes are still popular because of the following reasons:

- It allows the clinician to try different electrode positions at any given time and modify the settings of the device accordingly and get the best possible response.

- Another advantage of using the surface electrodes is that the FES based rehabilitation for the suitable candidate can be started soon after the initial assessment as an outpatient procedure.

Some of the disadvantages of using the surface electrodes can be overcome by marking the area of the electrode placement and providing the user photographs of their arm with the electrodes. This would help the user or their carer with the precise placement of the electrodes. The user is asked to use less moisturiser or avoid the use of the same if they can and apply water to the surface of electrodes after use and place them in the package provided as this would improve the life of the electrodes. Co-contraction of the neighbouring muscles however remains an issue but it can be managed by modifying the settings and by finding the best possible electrode position. A brief description of the use of FES for upper limb rehabilitation is presented in the next section.

2.7 FES for upper limb rehabilitation

The human hand is capable of performing a number of grasp movements which are summarised in the figure 2-13. A number of muscles need to contract in a coordinated manner for a human hand to achieve these grasp movement. When electrical stimulation is used, it is not possible to isolate and stimulate a large number of muscles and achieve these movements. In

conditions such as SCI, many of these muscles may not respond to electrical stimulation at all. Therefore, two grip patterns, the key grip and the palmar grasp were chosen because: these grasp patterns allowed a person with SCI to perform their ADL and could be closely replicated with the use of electrical stimulation (Taylor et al. 2002; Kilgore et al. 2008). . The key grip movement is used to grasp finer objects like a pen or a fork. The palmar grasp movement on the other hand is used to grasp larger objects like a juice can, a cup or a book. Strengthening these two grips will enable a person to perform ADL like brushing their teeth, eating their meal, have a drink and socialise with people (Taylor et al. 2002; Kilgore et al. 2008; Memberg et al. 2014b).

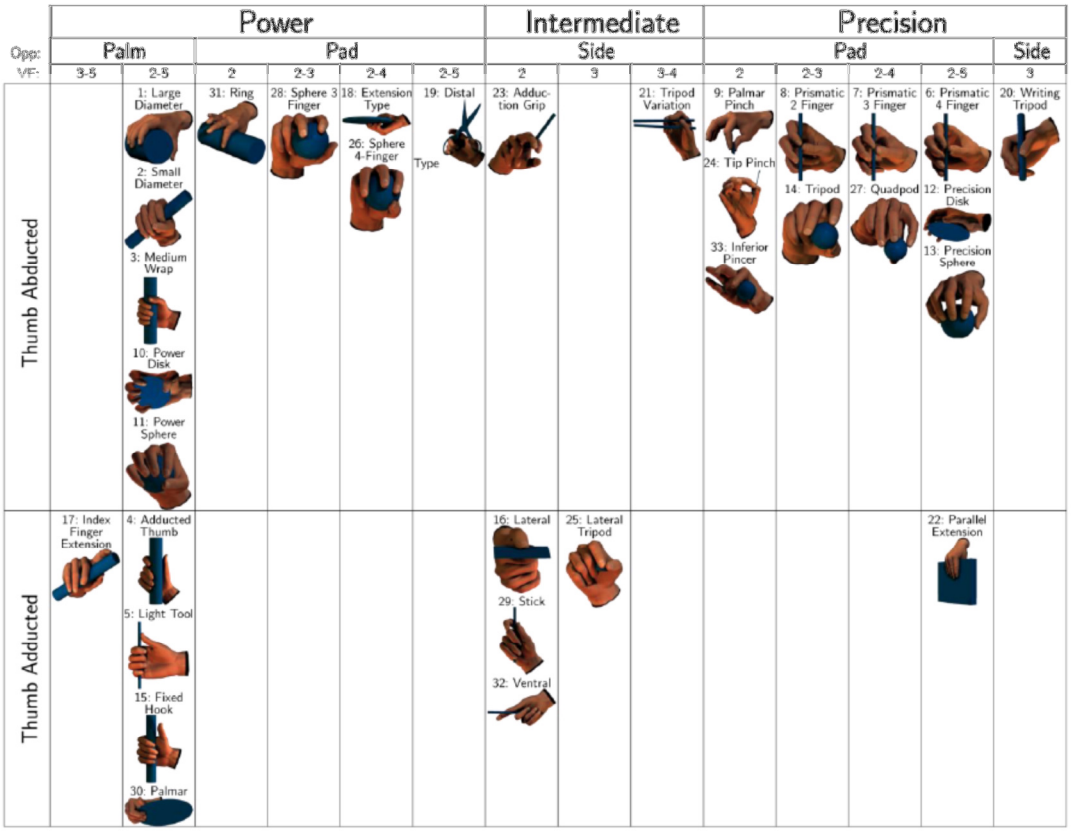


Fig 2-13: Human hand grasp patterns (Feix et al. 2016)

A FES device consists of: the main stimulator, a man-machine interface (MMI) to control the device and the electrodes to deliver the impulses. The devices used for upper limb rehabilitation were used either for strengthening the targeted muscles (exercise mode) or help the individual perform the tasks functionally (functional mode). The user used a MMI to manipulate the

operation of the device which was interpreted by the stimulator and sent out stimulation impulses to the target muscles through the electrodes (Bajd and Munih 2010). The most commonly used MMIs were push buttons (Snoek et al. 2000) and electromyography (EMG) signals (Thorsen et al. 2006; Kilgore et al. 2008).

The main disadvantage of using a push button as a MMI is that it can only be used to switch ON or OFF the stimulation and does not allow the user to fine tune their grasp while the stimulation is ON. The use of EMG signals allow the user to adjust the grasp strength but it increases the number of electrodes which can be disadvantageous especially with a surface system as it increases the number of electrodes the user has to precisely place. A detailed literature on the MMIs used for controlling an upper limb FES device is presented in the next chapter. With the advancement in Micro Electro Mechanical Systems (MEMS) technology, it has become possible to develop miniature movement sensors also known as the inertial measurement units (IMUs). The possibility of using these IMUs as a MMI for an upper limb FES device is explored in this thesis.

2.8 Summary

This chapter briefly describes the anatomy of the upper limb muscles and the physiology of muscle contraction of skeletal muscle. It then discusses the spinal cord, effects of SCI at the neck region and the effect it has on upper limb functions. The loss of function based on the level of injury is also discussed here which helps in understanding the residual functions in a particular group of people and helps in deciding the rehabilitation. It then describes the classification of the SCI according to the ASIA scale and discusses the outcome of the rehabilitation an individual undergoes after a SCI. The chapter provides a brief description of the principle of FES, which is one of the rehabilitation therapy used to improve the upper limb functions of a person with SCI. A detailed literature review of the FES devices used for upper limb rehabilitation is presented in the next chapter.

Chapter 3 Upper Limb FES devices: A Review

3.1 Introduction

The field of electrical stimulation is not new as around 400 B.C, torpedo fish and rubbed amber were used to generate electrical stimulation to treat a wide range of conditions from headache to arthritis (Bajd and Munih 2010). Great advances in electronics have made it possible to build multichannel stimulators that are compact and easy to use on a daily basis. For a stimulator to be described as safe to use by a disabled person the following criteria must be met (Swain 1992).

- The system should be fail safe and should not cause any harm to the user.
- It should be simple to put on and to use.
- It should aide the user to gain independence or provide therapeutic benefits.
- The system should be repeatable and effectively reproduce the functions it is designed for.
- The user should be able to understand the limitations of the device and exploit it in the best possible way.

From the mid-1980s, research on upper limb FES resulted in the development of devices that produced clinically significant results. Some of these devices became commercially available as well. A detailed description of these devices is given in the next section.

3.2 Review of Upper Limb FES devices

The main parts of an upper limb FES device are the stimulator, a MMI that allows the user to manipulate the system according to their use and the electrode system. A detailed description of the upper limb FES devices that have shown clinically significant results is presented below.

3.2.1 The NeuroControl® Freehand System

The NeuroControl® Freehand System (figure 3-1) was developed at the Case Western Reserve University and marketed by the NeuroControl Corp, Cleveland Ohio. The device consists of an implantable eight channel stimulator which is powered externally. The user controls the device using a shoulder position sensor which is fixed to the contralateral shoulder (Taylor et al. 2002; Mulcahey et al. 2004; Kilgore et al. 2008).

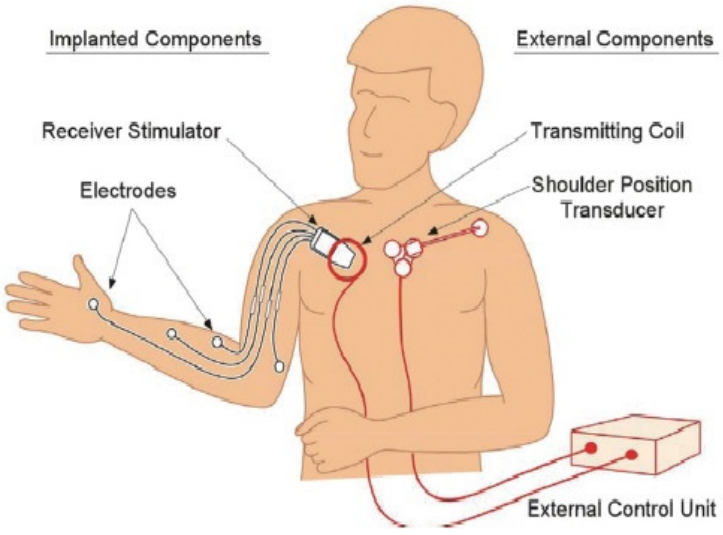


Fig 3-1: The NeuroControl® Freehand System (Kilgore et al. 2008)

This device allowed the user to perform key grip (lateral pinch) for holding smaller objects such as a pen or a fork and palmar grasp (palmar prehension) for grasping larger objects such as a glass of water or a bottle (Kilgore et al. 2008). It received power when the button on the shoulder

switch was activated and a quick shoulder elevation turned the stimulation ON. The user then useed shoulder protraction/retraction to adjust the grip and once they were confident about the grip, they “LOCKED” the device in its current state by another quick shoulder elevation (Mulcahey et al. 2004). The device was programmed to perform palmar prehension to start with. But if the user pressed the power switch in the shoulder position sensor for a short duration, then the system went into the key grip mode (Buckett et al. 1988).

In order to get a good hand grasp, electrodes were placed on the following muscles: FDS and FDP for finger flexion, EDC for finger extension, flexor pollicis longus (FPL) and extensor pollicis longus (EPL) for flexion and extension of the thumb, AdP and abductor pollicis brevis (AbPB) for thumb adduction and abduction (Kilgore et al. 2008). Most of the users underwent tendon transfer surgeries for additional stability and increased upper limb functions.

The NeuroControl® Freehand System was used in a number of clinical studies before it was commercialised. In one of the studies, the efficacy of this system was evaluated by implanting it in nine people with C5-C6 tetraplegia and accessing the role of the device in restoring lateral and palmar grasp. The assessment was validated by monitoring the results of Grip Release Test (GRT), ADL, grip strength test and two-point discrimination. Seven of the nine subjects reportedly used the device on a daily basis and the results of this study showed statistically significant improvement in their grip and grasp ability. Also 3 out of the 4 users who had some sensory ability before the device was implanted showed improvement in the two point discrimination (Taylor et al. 2002).

A multi-centre clinical trial with over three years of follow up on 50 FES users revealed that 49 of the users showed improvement while performing ADL with the device than without (Peckham et al., 2001). The NeuroControl® Freehand system became the first hand grasp device to get the FDA approval. It was CE marked and implanted on over 200 patients with C5-C6 tetraplegia worldwide.

Based on the results obtained from the clinical studies, it is safe to state that the NeuroControl® Freehand System has had life changing impact on its users. The device provided its users an increased independence while performing their ADL (Kilgore et al. 2008). But there were some breakdown issues with the shoulder position sensor and the external transmitter coil (Venugopalan et al. 2015). Since the shoulder position sensor was one of the most used components of the device, it was subjected to lot of wear and tear which wore out the wire connecting the sensor to the control unit causing the sensor to malfunction. The external transmitter coil had a similar problem because the wire and the connectors were not robust enough when compared to the wear and tear they were subjected to. Also there were some complaints of skin irritation by the users caused due to the double sided sticky tape used to fix the shoulder position sensor to the contralateral shoulder (Taylor et al. 2002; Venugopalan et al. 2015).

NeuroControl Corp. decided to stop manufacturing the device in 2001 for commercial reasons but continued to provide limited support to the users until 2007 when the company went out of business. The Cleveland FES Centre and the National Clinical FES Centre, Salisbury, UK continue to provide any possible support to the surviving users in the USA and the UK (Venugopalan et al. 2015). A next generation freehand system has been proposed by the same research group which is discussed in the next section.

3.2.2 Implanted Stimulator Telemeter (IST-12)

After the NeuroControl® Freehand System, the group at the Case Western Reserve University in Cleveland, Ohio, proposed an EMG-controlled implanted stimulator (figure 3-2) called the Implanted Stimulator Telemeter (IST-12) also called the next generation Freehand System. This stimulator consists of twelve intramuscular electrodes for stimulation and two epimysial EMG recording electrodes and an external control unit (Kilgore et al. 2008; Knutson et al. 2013). Besides the electrodes it had a circuit that was

hermetically sealed in a titanium capsule and a coil for power and transmission. It delivered constant current, charge balanced, biphasic pulses. The current amplitude varied between 0 and 20 mA and the frequency of the signal was 12 to 18 Hz with a pulse width of 0-200 µs (Memberg et al. 2014b).

EMG signals from a distal muscle, typically the ECRL or the Br was used to control the grasp, opening and closing while EMG signal from a more proximal muscle such as the trapezius or the platysma was used to provide the state commands such as the system ON/OFF and the grasp pattern selection. All of the EMG electrodes for controlling the device were placed on the ipsilateral muscles. This allowed the user to use FES bilaterally (Kilgore et al. 2008).

This device was initially implanted in three people with SCI all of whom also underwent tendon transfer surgeries. The control signal was customised according to the participant's requirements and it was reported that all three of the participants showed improvement in their ability to perform ADL (Kilgore et al. 2008).

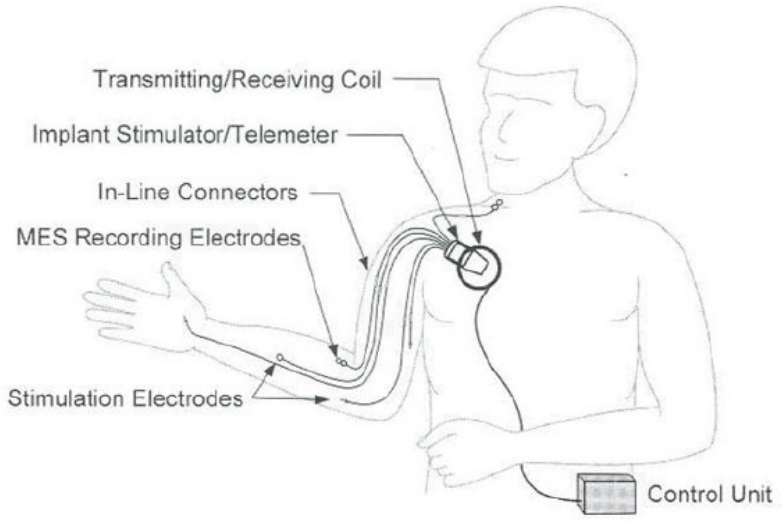


Fig 3-2: The Implanted Stimulator Telemeter (IST-12) (Kilgore et al., 2008)

This device was also implanted in a stroke patient. The user didn't show much improvement initially as the EMG based control strategy didn't work properly. The control strategy was replaced by a push button. This was more convenient for the user and showed significant improvement in the range of movements and the ability to perform ADL during the subsequent review sessions (Knutson et al. 2012).

In another study, two of the IST-12 stimulator were used to form a 24 channel stimulator and used it to restore the hand and arm function of individual with high-level tetraplegia (C4 and above). This 24 channel stimulator was implanted on two individuals and spiral nerve cuffs were used to stimulate the muscles of the upper limb. Both the individuals were using the device for two and half years and were able to perform ADL with some limitations (Memberg et al. 2014)

3.2.3 The NESS H200 (The Handmaster)

The NESS H200 (previously known as the Handmster) is an FDA approved FES device invented by Prof. Roger Nathan and his group in Ben-Gurion University, Israel (Nathan and Ohry 1990). It is now manufactured and marketed by the Bioness Inc. This is a three channel device that uses surface stimulation and consists of two parts: the stimulator and the forearm splint which holds the electrodes in place (Fig 3-3). The first channel controls EDC, the second channel controls FDS and FDP and the third channel controls the thumb position.

Three exercise modes and two functional modes are pre-programmed in the stimulator (Snoek et al. 2000). Exercise modes provideed repetitive stimulation to the specified group of muscles in order to build muscle strength. The functional modes helpedthe user to perform key grip and palmar grasps. Handmaster targeted the following muscles: FDS, EPB, FPL, EDC and thenar muscles (Snoek et al. 2000).

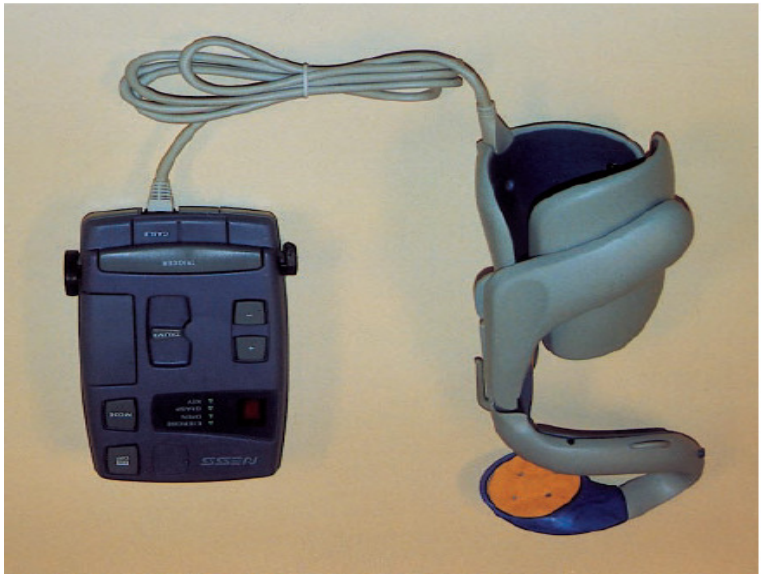


Fig 3-3: NESS H200 (The Handmaster) (Snoek et al., 2000)

The user pressed a button to trigger the stimulation. In palmar grasp mode, the extensors were stimulated and after a predefined time interval, the flexors were simultaneously stimulated. The stimulator was programmed to switch off the extensor stimulation after a predefined delay while the flexors were stimulated till the user pressed another button that stoped the stimulation. For the palmar grasp the AbPB was stimulated and for the key grip the EPB is stimulated. The user was able to steer the position of the thumb by adjusting the proportion of EPB and AbPB. A similar sequence was followed for achieving key grip. The stimulation amplitude was adjusted by the clinician while setting up the device. The subject used a sliding resistor to control the position of the thumb (Popovic et al. 2002b).

The NESS H200 has shown some clinically significant results. In one of the studies, 18 stroke survivors were asked to use this device for a period of ten weeks and their muscle tone and motor scores were monitored. Of the 18 people, 15 completed the study and showed significant improvement in their muscle tone and motor scores. The group was further divided into two subgroups: people with initial Fugl-Meyer Motor Assessment (FMA) score less than 35 (more impaired) and the other initial FMA more than 35 (less impaired). It was also observed that the group with initial FMA more than 35 showed more improvement at the end of the study (Hendricks et al. 2001).

In another study, ten people with tetraplegia were asked to use this device and their progress was monitored. Out of the ten, three people couldn't use this device either because the stimulation of the key muscles was not possible or because the splint was too tight to fit their arm. Out of the remaining seven, one person couldn't use the device functionally due to the presence of finger flexion contractures. This person used the device for therapeutic purpose and at the end of the training period, the finger contractures of the metacarpophalangeal joints were reduced from 50 to 10 degrees. Out of the remaining six, two were able to achieve just a palmar grasp while the remaining four were able to achieve both key grip and palmar grasp (Snoek et al. 2000).

This device is predominantly used by stroke survivors for exercise. The main advantage of this device is the ease with which it can be donned and doffed. However the main disadvantage of this device is that it does not allow the u to the people with SCI to use a tenodesis grip (if available). It also does not allow sufficient flexibility in choosing the electrode positions (Popovic et al. 2002b).

With all its limitations, the NESS H200 was the only commercially available upper limb FES device at the time of writing. It was updated to the NESS H200 Wireless Hand Rehabilitation System in 2013 (Bioness 2013).

3.2.4 The Bionic Glove

The Bionic Glove (Prochazka et al. 1997), developed by Arthur Prochazka and the group at the University of Alberta, was a fingerless glove that sensed the voluntary wrist flexion/extension and stimulated the muscles controlling the fingers and thumb to either grasp an object or release it. This device could be donned and doffed independently with minimal help (Prochazka et al. 1997). The electrodes were first placed at the area of stimulation and the conductive areas in the internal surface of the glove made automatic contact with the electrodes. The electrical pulses were delivered via these electrodes

to the targeted muscle causing the muscle to contract (Prochazka et al. 1997).

The stimulator was a battery operated device which was located in a pocket on the glove (figure 3-4). There were buttons provided in the control unit that enabled the user to select the modes of operation. Based on the buttons pressed and the position of wrist, which was detected by a Linear Variable Differential Transformer (LVDT) that was fixed along with the stimulator, the course of action was decided. If the wrist was flexed, then the device stimulated the finger extensors to open the hand. On the other hand, if the wrist was extended, then the device stimulated the finger flexors to close the hand. This is known as a **powered tenodesis grip** (Prochazka et al. 1997). This device was only suitable for people with C6 tetrplegia or similar users who were able to flex and extend their wrist voluntarily. (Venugopalan et al. 2015).

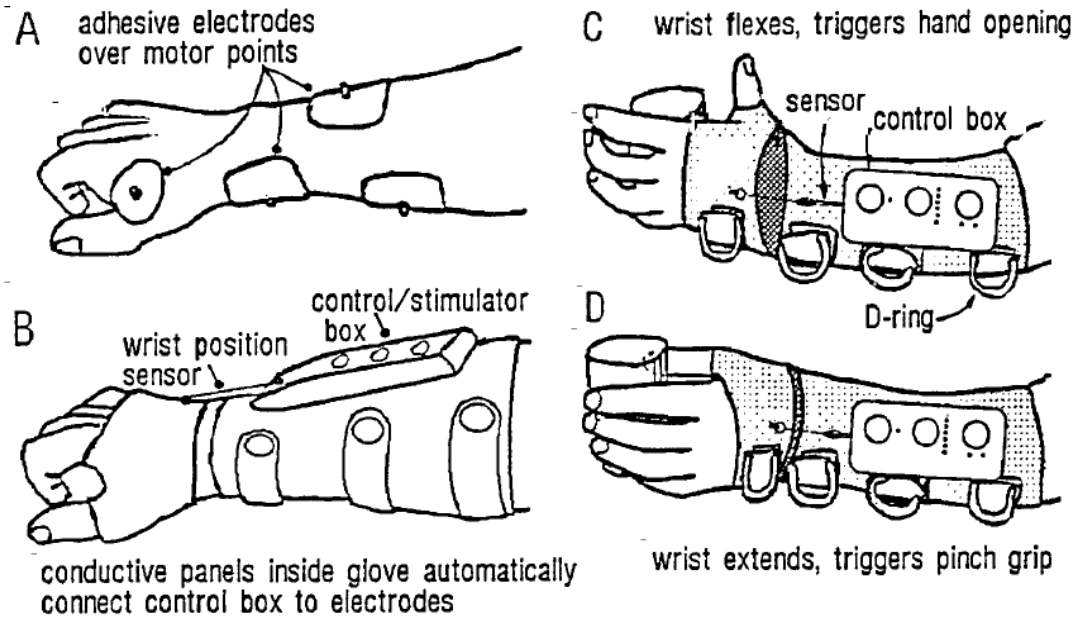


Fig 3-4: The Bionic Glove (Prochazka et al. 1997)

The glove was made of elastic material called neoprene with small perforations for ventilation. The glove had four Velcro straps with D-rings that were used to hold the garment tightly in the hand and forearm.

In one of the studies as a part of multi-centre clinical trials, the Bionic Glove was clinically tested on twelve people with SCI at C5-C7 who used the device for six months or more for performing their ADL such as brushing their hair, brushing their teeth, using a fork and pouring from a one litre juice box. The daily use of this device improved power grasp when compared to passive tenodesis and increased the range of movement of the hand. A significant improvement was seen while performing a manual task with the help of this system (Popović et al. 1999). This study concluded that the Bionic Glove improved the independence of an individual with tetraplegia if their Functional Independence Measure and Tetraplegia Index of Functions before using the device were 20% and 50% respectively (Popović et al. 1999).

The Bionic Glove was commercialised by Neuromotion Inc. Canada as the Tetron Glove (Prochazka et al. 1997). The multi-centre clinical trial of the Bionic Glove was never completed as the company went out of business in 1999 and the IP was acquired by Rehabtronics Inc. Canada (Venugopalan et al. 2015).

The use a LVDT as a wrist position sensor limits the use of the device to only those who can flex and extend their wrists and hence the device was redeveloped so that it can be used by a wider range of people with neurological disabilities (Venugopalan et al. 2015). The new device called the Rehabtronics Wireless Triggered Hand Stimulator (RWTHS) is described in the next section.

3.2.5 The Rehabtronics Wireless Triggered Hand Stimulator (RWTHS)

The Rehabtronics Wireless Triggered Hand Stimulator (figure 3-5) is similar to the Bionic Glove but instead of a LVDT, it uses a wireless earpiece that is programmed to control the FES device using tooth clicks. This device has been used in a few clinical studies.

In one of the studies, this device was used by 13 participants with SCI who were divided into two groups. Five of the participants completed the study by using the device bilaterally therefore the treatment groups had a group size of nine. Both the groups were subjected to two types of treatment named Treatment 1 and Treatment 2. In Treatment 1, the volunteers were required to play track ball based computer games for strength training followed by FES treatment. In Treatment 2, the volunteers used the Rehabilitation Joystick for Computerised Exercise (ReJoyce) to play computer games associated with ADL followed by FES therapy. Treatment 1 was called the Conventional Exercise Therapy and Treatment 2 was called the ReJoyce Exercise Therapy (Kowalczewski et al. 2011).

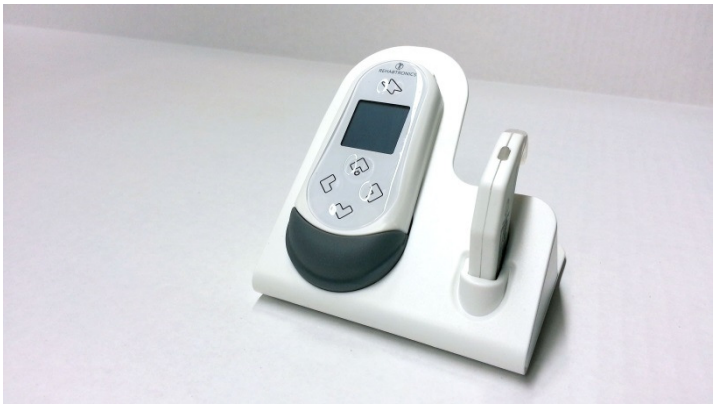


Fig 3-5: The Rehabtronics Wireless Triggered Hand Stimulator (Venugopalan et al. 2015)

This study was a block randomised control trial where the participants in Group 1 received Treatment 1 followed by a month of washout period and Treatment 2. The order of the treatment was reversed for the Group 2. The primary outcome measure used in this study was Action Research Arm Test (ARAT) and the secondary outcome measures used were grasp and pinch forces and the ReJoyce Automated Hand Function Test (RAHFT). This study concluded that the ARAT and RAHF scores of the volunteers improved after Treatment 2 when compared to Treatment 1 (Kowalczewski et al. 2011).

In another study, eleven chronic stroke survivors used the device for an hour a day, five days a week for six weeks for performing exercises. The primary

outcome measure for this study was ARAT score and the secondary outcome measures were the quantitative test for upper limb functions performed in the workstation the grasp force measurements and the neuroplasticity was assessed by measuring the cortical excitability using Transcranial Magnetic Stimulation (TMS). This study found out that the volunteers showed improvements in their ARAT scores which indicated reduction in spasticity and improvement in the muscle strength. However the volunteers did not show any improvement in their TMS scores which indicated that there was no improvement in their cortical excitability. The study also showed that the volunteers with intermediate functional scores improved the most (Buick et al. 2015).

3.2.6 The Belgrade Grasp System (Actigrip)

The Belgrade Grasp System (BGS), developed by Dr. Dejan Popovic and his group at the University of Belgrade, is a four channel FES device designed to be used by stroke survivors (figure 3-6). This device provideed additional reach function along with the grasp function. Three of the channels were used to stimulate the muscles for grasping while the fourth channel was used for stimulating triceps brachii. This allowed the user to extend the arm and reach for the object (Popovic and Popovic 1998).

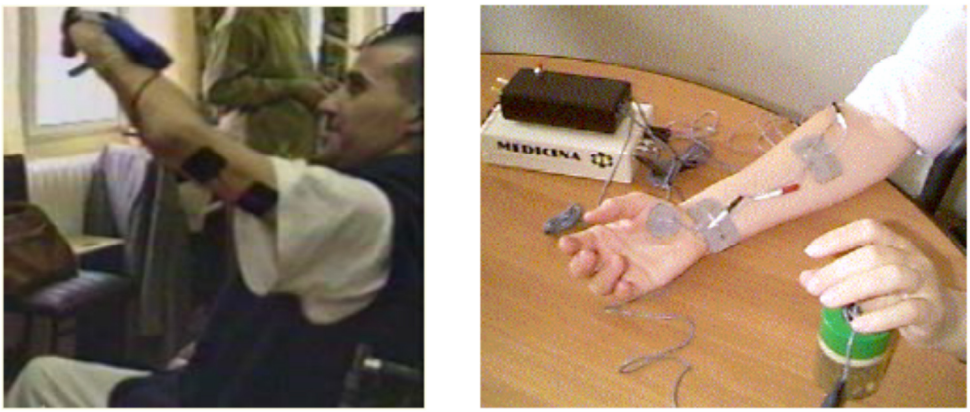


Fig 3-6: The Belgrade Reach and Grasp System (Popovic et al. 2002b)

The opening or closing function of the hand was controlled by a push button. The BGS performed the reaching function by measuring the subject's

shoulder velocity with a goniometer and generating a synergistic elbow motion by stimulating the triceps brachii muscle such that this motion resembled the able-bodied subject's shoulder-elbow coordination.

This device was commercialised by Neurodan A/S (Alborg, Denmark). Neurodan was later acquired by Otto Bock who decided to discontinue the development of surface upper limb FES device at that time. The hardware used in the BGS has been used by the UNA Systems, Belgrade, to develop UNA4 and UNA5 which have been used for FES applications (Venugopalan et al. 2015).

3.2.7 The FESmate

The FESmate was a percutaneous system developed by NEC, Japan. It was a programmable multichannel system capable of delivering 30 channels of electrical stimulation. The user used a push button to start the stimulation. When the button was pressed, a trapezoidal stimulation envelope was generated which contracted the necessary muscles to generate the desired hand function. This envelope was derived from the EMG signals recorded from able bodied volunteers who were asked to perform the specified tasks. The stimulation envelope for a number of activities were programmed in the stimulator and the user used a push button to trigger the stimulation (Popovic et al. 2002b).

Around 500 people (both SCI and stroke) were evaluated for the clinical trials of this device and around 92 received therapeutic electrical stimulation and 23 received FES. The technology of this device was unquestionably advanced but the cost of this device was approximately $10,000 in the year 1991, which included the costs for 15 electrodes, implantation and associated medical treatment (Triolo et al. 1996). The use of percutaneous electrodes, however, increased the risk of infection. This device was not marketed outside Japan and was exclusively used only for research purpose (Shimada et al. 1996; Triolo et al. 1996).

3.2.8 The ETHZ ParaCare System

The ETHZ ParaCare system (figure 3-8) was a portable walking and grasping system developed by the Automatic Control Laboratory at the Swiss Federal Institute of Technology Zurich (ETHZ) and the Paraplegic Centre at the University Hospital Balgrist, Zurich. It was a programmable device that was customised according to the user's need by using a rapid prototyping system. This programmable device was controlled using any of the following: discrete EMG signals, proportional EMG signals, a sliding potentiometer or a push button.

The proportional EMG signal was used by people with SCI who were able to voluntarily protract and retract the contralateral shoulder. Contracting the anterior deltoid caused finger and thumb extension and contracting the posterior deltoid caused finger and thumb flexion. The amplitude difference between the anterior and posterior deltoid determined the force of the grasp.

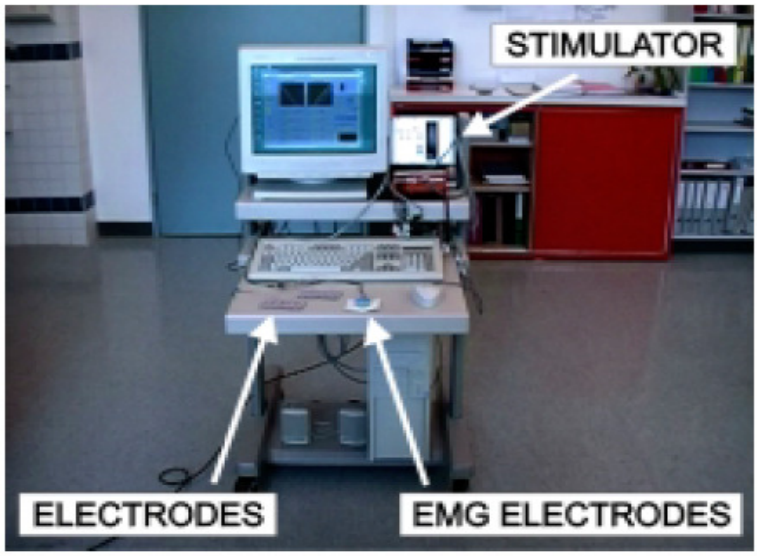


Fig 3-7: ETHZ ParaCare Rapid Prototyping System (Popovic et al. 2000)

Discrete EMG signal was used by patients who voluntarily controled a muscle but were not able to contract it gradually or maintain a contraction for specified period of time. Here, the volunteer contracted or relaxeed a muscle to generate the ON/OFF signals. The user was expected to generate a

specified sequence of signal to command the stimulator to perform a specified task.

A push button was used by the users who were not or did not want to use EMG. In this case, the button was pressed for the first time to cause the hand to close. When the user pressed the button for the second time, the hand started to open and remained open for two seconds. If they wanted the hand to remain opened for longer duration, the button was pressed once every second. This control technique was not very user friendly and was less effective when compared to the Discrete EMG signal.

The proportional EMG signal was used by people who were able to voluntarily protract and retract their shoulders. These movements of the shoulder either opened or closed the hand and the extent of open/close was proportional to the strength of the EMG signal in each of the direction. A sliding potentiometer on the wrist was useful for people who were not capable of the using proportional EMG method. In this method, the hand is opened if the slider was pushed in one direction and closed when the slider moved in the opposite direction. The resistance of the potentiometer determined the grasp force.

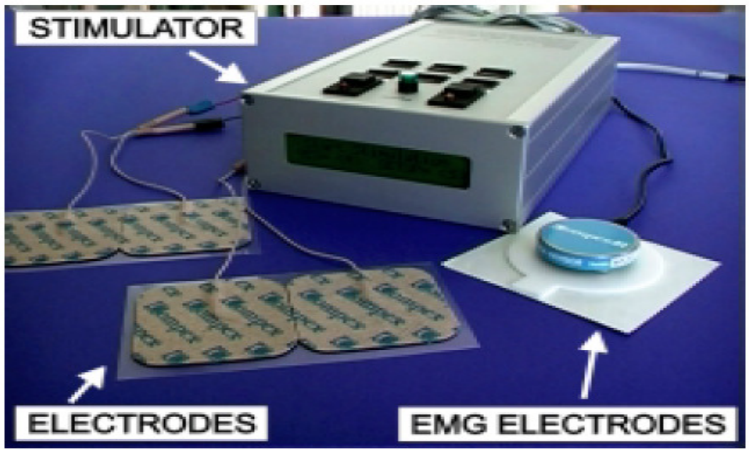


Fig 3-8: ETHZ ParaCare Portable FES system (Popovic et al. 2000)

This device was clinically tried on eight people with SCI. Out of the eight participants; four were able to generate the desired control signals. They used the device for performing tasks such as pouring liquid from a bottle into

a glass, grasping a telephone receiver, grasp an apple and eat, pick up a tooth brush and brush the teeth and other ADL (Popovic et al. 2000). The remaining four decided not to use the device for various reasons. One of the volunteer was not very stable emotionally and refused to cooperate with the research group while another volunteer had good grasp without FES and the remaining two had previously received FES therapy and did not receive any benefit from using the neuroprosthesis (Popovic et al. 2000).

One of the major disadvantages of this device was that it took around seven to ten minutes to don and doff (Popovic et al. 2002b). During the clinical testing of this device, it was found that the device proved to be bulky and hence was not ideal as a take home device. Also it did not qualify for CE marking and FDA approval as the hardware did not totally comply with the ISO 60601 standards. Hence this device was not commercialised. However the software of the ETHZ ParaCare preformed to the expected standards during the clinical studies. Hence the researchers took the idea further by incorporating the software of this device with the hardware platform provided by Compex SA, Switzerland and developed another FES device called the Compex Motion (Venugopalan et al. 2015). A detailed description of this device is provided in the next section.

3.2.9 The Compex Motion

The Compex Motion (figure 3-9) was a transcutaneous (surface) FES device and has four biphasic current regulated stimulation channels and two analog input channels which was configured to measure the output voltage of sensors such as goniometers and inclinometers. This device was developed as a custom-made neuroprosthesis, a neurological assessment device, a muscle exercise system or an experimental set up device for physiological studies. It had a special purpose port called the Port C, which was used to connect two or more stimulators and hence increased the number of stimulation channels. The stimulation sequence and the control strategy were programmed and stored on an exchangeable memory chip (Popovic 2006).

Fig 3-9: The Compex Motion system with 1) The stimulator 2) The keypad with the push buttons 3) The memory cards 4) The EMG electrodes 5) The stimulation electrodes (Popovic et al. 2002)

The use of the Compex Motion as a grasping device for the people with SCI was evaluated in a study involving eleven volunteers. All of the volunteers were complete or incomplete C4-C7. Out of the eleven, nine used FES as a neuroprosthesis. Eight people showed improvement in their grasp function and in performance of their ADL. However, one subject didn't get any benefit from FES (Mangold et al. 2005).

In another study, 21 people with C3-C7 SCI were divided into two groups of twelve and nine members. The larger group received FES using the Compex Motion along with their physiotherapy and occupational therapy while the smaller group didn't receive any FES therapy but received the physiotherapy and occupational therapy. This study concluded that the group with FES did much better than the one that didn't receive (Popovic et al. 2006).

The Compex motion was used by stroke survivors for the restoration of their reach and grasps functions (Miller et al. 2008). In one of the studies, a group of 24 stroke survivors were divided into two groups of fifteen and nine members. The group of fifteen received Functional Electrical Therapy (FET) using the Compex Motion along with the conventional physiotherapy and occupational therapy while the group of nine were the control group who received only conventional physiotherapy and occupational therapy. The

results of this study clearly suggested that the reaching and grasping ability of the group that used FET improved significantly when compared to the one that did not use it (Miller et al. 2008).

This device was marketed by Compex SA, Switzerland, in the year 2001. 100+ devices were manufactured and used across the US, UK, Spain, Switzerland, China, Japan and Canada as a research tool. The company however decided to stop manufacturing this device in the year 2008 citing lack of profit as the reason (Venugopalan et al. 2015).

3.2.10 The Intelligent Functional Electrical Stimulator (IntFES)

The Intelligent Functional Electrical Stimulator (IntFES) was a single channel FES device which delivers stimulation to the target muscles with the help of a multi-pad electrode array (figure 3-10). The electrodes in the multi-pad electrode array were turned ON individually to activate the synergistic muscles and produce a functional movement.

The hardware of the device multiplexed charges from a single pulse train and delivered it to the different conductive pads. This was done using a fast switching system synchronised with the stimulation pulses. Since the number of high-voltage stimulator outputs were reduced to just one, the size, weight and power consumption of the stimulator reduced significantly.

This device was clinically tested on three stroke patients. It was reported during the study that the device was fairly easy to don and doff. Also this device aided in wrist stabilization and the selective activation of the muscles caused the hand to open and close efficiently (Malešević et al. 2012).

Fig 3-10: The IntFES stimulator system with the multi-pad electrode array (Malešević et al. 2012)

3.2.11 Myoelectrically Controlled FES system (MeCFES)

The MeCFES (figure 3-11) is a single channel upper limb FES device that used myoelectric signal from the wrist extensors to control the device. This signal was used either to control wrist extension or thumb flexion. The hardware of this device consisted of an EMG amplifier, a digital signal processing unit and a charge balanced stimulator. This system was called a **homologous stimulator** as it was capable of stimulating even those muscles that were used to record the myoelectric signals. The device operated in two modes: the Wrist extensor Controlled Wrist extensor Stimulation (WCWS) and Wrist extension Controlled Thumb flexor Stimulation (WCTS) (Thorsen et al. 2001).

In the WCWS mode, the stimulation and the recording electrodes were placed on the ECR. These electrodes were placed perpendicular to each other in order to reduce the stimulation artefacts. In the WCTS, the thenar muscles were stimulated to get thumb flexion while the EMG signals were recorded from ECR (Thorsen et al. 2001).

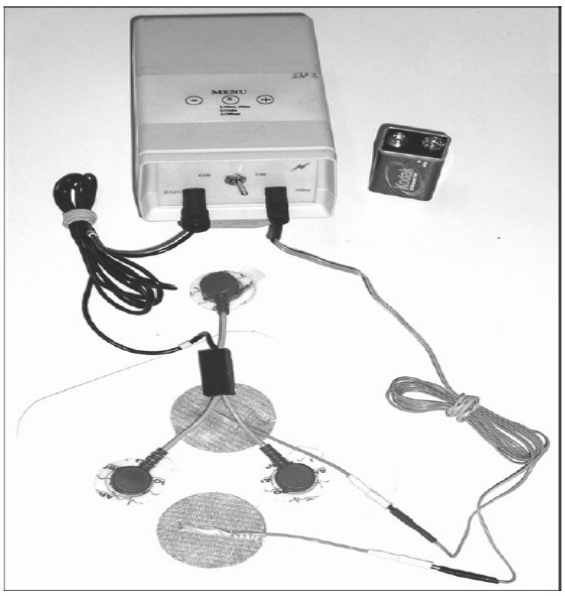


Fig 3-11: The Myoelectrically Controlled Functional Electrical Stimulator (Thorsen et al. 2001)

The MeCFES was clinically tested on eleven stroke survivors. These people were divided into two groups: five people in the MeCFES group and six in the control group. The MeCFES group used the stimulator for eight hours per day for three weeks along with the physiotherapy exercises while the control group received no stimulation. Based on the ARAT scores, it was found that the MeCFES group showed clinically significant improvement in their upper limb function (Thorsen et al. 2013).

This device was also clinically tested on people with C6/C7 SCI and showed positive results. In one of the studies with five C6/C7 SCI people, it was reported that all the five users showed improvement in their ability of grasping common objects such as a bottle, a videocassette and a pen (Thorsen et al. 2006).

In another study, eleven people who had had a stroke were randomly allocated into two groups with five and six members respectively. The first group with five members used FES the MeCFES for eight hours a day for three weeks along with the physiotherapy exercises and the second group with six members did not use the MeCFES but underwent the conventional

physiotherapy. This study revealed that the group that used the MeCFES along with the conventional therapy showed improvement in their ARAT scores when compared to the other group (Thorsen et al. 2013a).

In another clinical study, this device was clinically tested on people with C6/C7 tetraplegia. For this study, the researcher screened around 20 medical records and selected nine volunteers. Out of the nine volunteers, five showed positive response when subjected to electrical stimulation. The hand functions of these five volunteers were assessed both with and without FES by asking them to perform tasks like manipulating a video cassette, drinking from a bottle and writing using a pen. The study concluded that none of the volunteers were able to perform any of these tasks without FES. However all the volunteers were able to perform these tasks successfully with the help of the MeCFES (Thorsen et al. 2006).

This device also underwent a multi-centre clinical trial for assisting the hand functions in people with C5-C7 tetraplegia. In this study, 253 candidates were randomly selected. Out of the 253, 166 met the selection criteria and 107 were contracted and 27 of these volunteers showed positive response to the MeCFES. These 27 volunteers participated in a clinical study which consisted of twelve sessions of using the MeCFES for performing self-selected ADL. At the end of the study, fourteen volunteers found that the MeCFES was useful as a take home device (Thorsen et al. 2013b). This device has not yet been made commercially available and was an open source FES device at the time of writing (Venugopalan et al. 2015).

3.2.12 The MyndMove FES Device

The MyndMove is an eight channel FES device marketed by MyndTech Inc, Canada (figure 3-12). This device has embedded simulation protocols that can help the user with over 30 reach and grasp functions and has an intuitive user interface that allows the therapist to select and deliver a personalised therapy. Each of these protocols provided a specified muscle stimulation

sequence in for performing reaching and grasping tasks such as reaching forwards or sideways, picking up an object and reaching to grasp an object and retrieving it.

The eight channels of this device allowed the stimulation of eight muscle groups in a single protocol. This device also allowed a person with SCI to receive bilateral stimulation during a single protocol. The device was designed in such a way that when a person with SCI chose to use the device bilaterally, they could use both the hand independently for picking and grasping the objects. The MyndMove has a 11.6” touchscreen user interface that allows the user and the therapists to select optimum stimulation protocol (MyndTech 2014).

Fig 3-12: The MyndMove FES Device

The results obtained during the clinical testing of the upper limb FES devices described in this section has revealed that these devices have improved the hand and arm functions on people with tetraplegia and those who have suffered a stroke. The main differences between these devices are the placement of the electrodes (surface, percutaneous or implanted) and the man-machine interface (MMI) used to control the stimulator. The next section describes these MMIs in detail.

3.3 The Man-Machine Interfaces (MMIs) used in the Upper Limb FES devices

Researchers have come up with a number of man-machine interfaces (MMIs) with the help of which, a user can control the FES device. These MMIs are broadly categorised as Mechanical MMIs and Bio-signal based MMIs.

3.3.1 Mechanical MMIs

There are a number of mechanical sensors that have been used as a MMI for upper limb FES devices. Some of them are summarised below:

3.3.1.1 A Push Button

A push button is one of the most commonly used MMI used to generate the control signal. The user is trained to generate the control signal by pressing the button in a specified sequence. The NESS H200 and ETHZ ParaCare have used push buttons as the MMI.

There are a few disadvantages of a push button based upper limb FES device: Either the free arm was used to press the button continuously in order to generate the control signal (Popovic et al. 2000) or the device carried a pre-programmed stimulation sequence and the push button just started it (Snoek et al. 2000). In the former situation, the user was not able to use both the arms independently and in the latter situation, the user did not have any control over how long the stimulation is ON and hence have to finish the given task within the time specified in the stimulator program.

3.3.1.2 The Two Axis Shoulder Position Sensor

The two axis shoulder position sensor (figure 3-13), used in the freehand system, monitored the movement of the shoulder and generated a control

signal accordingly. Ideally, the shoulder sensor monitored the protraction/retraction and the elevation/depression of the contralateral shoulder. The opening and closing of the hand was proportional to the protraction and retraction of the shoulder. The shoulder elevation was used to generate the “LOCK” command which locked the stimulator with the latest settings. The stimulator remained locked until the next command signal was generated.

Fig 3-13: Two Axis Shoulder Position Sensor

This sensor was stuck to the contralateral shoulder using double sided sticky tapes and was connected to the external control unit using fragile wires which made the sensor susceptible to breakdown. The contralateral shoulder was chosen as connecting the sensor to the ipsilateral shoulder would result in false trigger when the user moved the arm for performing the desired function.

3.3.1.3 A Wireless Wearable Joint Angle Sensor as an MMI

The wireless magneto-resistive sensor (figure 3-14) generated the signals proportional to the wrist movement which was in-turn is used to control the FES device. The sensor used in this research work used gigantic magnetoresistive (GMR) sensing techniques for measuring the magnetic field strength and this was worn on the wrist like a wrist watch (Wheeler and Peckham 2009). A disc shaped rare earth fixed magnet was fixed to the back of the hand. The controller was sensitive across a large range of motion because the three sensors responded to different range of magnetic field

strengths. The output from each sensor which was proportional to the movement of the wrist was differentially amplified before sending it to the micro-controller for further processing. After processing, the micro-controller transmitted the signal to the receiver unit which was either a computer used for data acquisition purpose or a FES device (Wheeler and Peckham 2009). This sensor was not cosmetically appealing because of the presence of a magnet at the back of the hand.

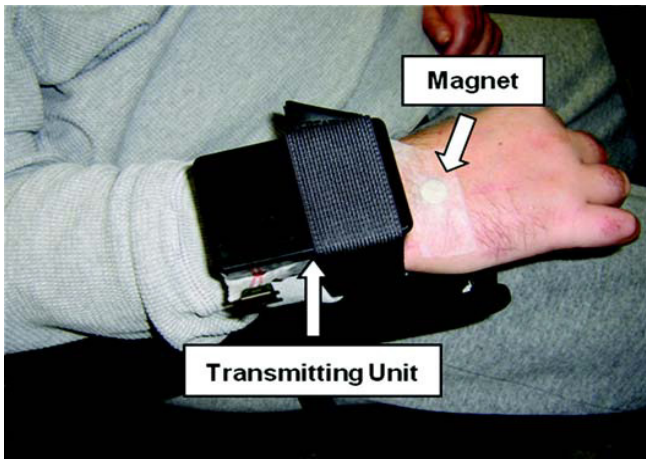


Fig 3-14: Wireless wearable joint angle sensor (Wheeler and Peckham 2009)

3.3.1.4 Accelerometers as a MMI

Accelerometers and gyroscopes can be used to detect the linear and the angular movement of the upper limb which can be used to trigger the FES system. In one of the studies, these sensors were placed on the upper arm and forearm and their responses for various arm movements were studied (Tong et al. 2002). In this study, it was found that the accelerometers were most reliable when placed in the shoulder and the gyroscopes were reliable when placed in the forearm.

In another study, 15 stroke patients were asked to use an accelerometer triggered upper limb FES system. The accelerometer detected the change in the angle from the resting position when the arm tried to reach forward. The

study concluded that it was feasible to use accelerometer as an MMI for upper limb FES device (Mann et al. 2011). Modern day accelerometers and gyroscopes are compact in size and are readily available and can be considered as a potential MMI.

3.3.2 Bio-signal based MMIs

Myoelectric signal (MES) is the most commonly used bio-signal to trigger and control the FES device. Besides MES, Brain Computer Interfaces (BCIs) have also been used. Some of the Bio-signal based MMIs are summarised below:

3.3.2.1 Myoelectric Signal (MES) based MMI

A hand grasp neuroprosthesis for C7 tetraplegic patients used myoelectric signals from the wrist flexors and the extensors to control the device. The myoelectric signals from the flexors and the extensors were recorded from seven volunteers two of which were people with C7 tetraplegia and five were able bodied. These signals were used to generate a customised MES, which was used to control the device. The reliability of the control strategy was evaluated by asking the volunteers to deliberately activate the wrist flexors and extensors and control the opening and closing of a simulated arm. It was reported that each subject was able to achieve 99% of the target states for at least 1 minute. The proficiency with which each of the subject was able to control the opening and closing of the arm for at least 2 minutes was as high as 87% (Knutson et al. 2004).

3.3.2.2 MES from Tibialis Anterior Muscle as a MMI

A recent study explored the possibility of using EMG signals from the muscles supplied by the nerves below the spinal lesion and used this signal as a MMI (Moss et al. 2011a). The muscles involved in this study were

Abductor Hallucis, Extensor Digitorium Brevis, Flexor Digitorium Brevis, Soleus, Tibialis Anterior, Medial Gastrocnemius, Lateral Gastrocnemius and Peroneal Longus which are the muscles of foot and lower leg. A feasibility study with twelve people with SCI showed an EMG activity in at least one of the lower limb muscles. But these signals were not strong enough to be used as a command signal for a FES device. So the subjects underwent a training programme which improved the muscle signal. In this training session, the participants were asked to try and contract a particular muscle till target amplitude was reached. After attending the training session, the EMG signal from the trained muscle was strong enough to be used as a control signal for a FES device (Moss et al. 2011b).

3.3.2.3 Voice signal as a MMI for controlling the FES device

A voice controlled FES system for people with tetraplegia was developed by Roger Nathan and his group (Nathan 1989). In this system, vocal command through a voice recognition system was used to drive the FES system. A 24 channel micro-controller based stimulator was built which generated square wave, compensated double pulses at a constant current. Parameters like the pulse width, current intensity, pulse frequency and delay were controlled with the help of the computer.

This voice operated computerised neuromuscular stimulation system was clinically tried on two people with C4 tetraplegia. The stimulator used a voice recognition system to get the commands from the user. In order to increase the success rate of this system, fourteen command words in Hebrew which were acceptable by the users, were chosen. These fourteen words were divided into two command vocabularies. The first one enables the user to control and operate all the programs in the stimulator like system parameter adjustment, pre-programmed coordinated movements, operation mode for functional moves and physiotherapy routines. The second set of commands were used to specifically control operation mode for functional moves (Nathan & Ohry 1990).

3.3.2.4 BCI as a MMI

Brain Computer Interfaces (BCIs) and Electroencephalography (EEG) signals can also be used as a MMI to control FES devices. Researchers have used Motor Imagery (MI) technique, which is asking the user to imagine the movement of the limb and capturing the change in EEG signal, to instruct the FES device to stimulate the corresponding muscles. The idea behind using this technique was to allow people with high-level tetraplegia use FES and regain some of their upper limb functions. The EEG signals were constantly monitored. When the user generated the MI related to a specific hand movement, a change in the EEG signal occurred, which was then detected and conditioned to control the FES device. This technique was successfully implemented on two subjects, one using surface FES system and the other using implanted FES system (Rupp et al. 2012).

In another study, a hybrid upper limb FES system was developed which used shoulder movements and MI based BCI as its MMI. This system was clinically tested on a person with C4 tetraplegia. This person underwent extensive training sessions before managing to successfully perform some of the activities of daily living there by proving that a MI based BCI can be used as a MMI in the future (Rohm et al. 2013).

Most of the devices described in the literature were commercialised at some point but were withdrawn from the market as the company marketing them cited lack of profit. There is an urgent requirement for an upper limb FES device that will help in the rehabilitation of the people with SCI. This device should be flexible enough to accommodate and improve the hand functions of a wider group of patients. Increasing the number of end users would interest companies in manufacturing and marketing the device. The desired upper limb FES device should have the features necessary to improve the hand function such as:

- Assist the user in performing key grip and palmar grasp movements.

- Allow them to adjust the grip while grasping or releasing the object without the need to turn ON and OFF the device every time.
- Allow the user the flexibility to quickly turn the device ON only when they need the assistance of FES to perform a task.

FES device	Research Group	Manufactured By	Available	Channels	Type	MMI
The NeuroControl® Freehand System	Case Western Reserve University, Cleveland, USA	NeuroControl Corp USA	No	8	Implanted	Two Axis shoulder position sensor
The NESS H200 (the Handmaster)	Ben-Gurion University, Israel	Bioness Inc Israel	Yes	3	Surface	A push button
The Bionic Glove	University of Alberta, Canada	NeuroMotion Inc, Canada	No	4	Surface	LVDT
The FESMate	Sendai FES Group, Japan	NEC, Japan	No	16	Percutaneous	EMG
The Belgrade Grasp System	University of Belgrade, Serbia	Neurodan, Denmark	No	4	Surface	A Push Button
The ETHZ ParaCare	ETH, Zurich, Switzerland	-	-	4	Surface	A push Button, Sliding potentiometer, EMG

The Compex Motion	ETH, Zurich, Switzerland	Compex SA Switzerland	No	4	Surface	EMG
Implanted Stimulator Telemeter	Case Western Reserve University, Cleveland, USA	-	No	12	Implanted	EMG
Intelligent FES (IntFES)	University of Belgrade, Serbia	-	-	1	Surface	Flex Sensors
Myoelectrically controlled FES (MeCFES)	European Project TMR-EUROS2	-	-	1	Surface	EMG
Voice Controlled FES device	Ben-Gurion University, Israel	-	-	24	Surface	Voice Signals
Rehabtronics Wireless Triggered Hand Stimulator	University of Alberta, Canada	Rehabtronics Inc, Canada	Yes	4	Surface	Wireless tooth click detector
The MyndMove FES device	University of Toronto, Canada	MyndTech, Canada	Yes	8	Surface	Computerised User Interface

Table 3-1: Upper limb FES device

3.4 Choice of MMI

The main issues with the MMIs used in the existing upper limb FES devices are:

- A bio-signal based MMI increases the number of electrodes that needs to be placed precisely in order to get the desired performance.
- Although the use of a push button as a MMI makes the device less complicated to use, it limits the flexibility to control the device. Either the user uses the pre-programmed stimulation sequence (Snoek et al. 2000; Popovic et al. 2002a) and tries and gets the best possible response, or the user uses the contralateral hand to change the intensity during the stimulation (Popovic et al. 2002b).
- A MMI such as the two axis shoulder position sensor used in the NeuroControl® Freehand System allows the user more flexibility in controlling the stimulation delivered by the FES device. However this sensor is connected to the main control unit using very delicate wires which are subjected to a lot of wear and tear which causes breakdown of the sensor. Also the sensor is stuck to the contralateral shoulder using a double sided sticky tape. Some of the users have complained of skin irritation caused due to the tape (Taylor et al. 2002).

It is therefore proposed that a MMI using a robust IMU will allow the user the flexibility to control the intensity during the stimulation while avoiding the sensor failure due to possible breakdown. If the direct contact of the IMU with the skin is avoided, then the issue of skin irritation can also be avoided. The possibility of using the shoulder movements which are used in natural reach and grasp such as shoulder elevation, protraction and retraction will be explored to generate the control signals. Since the user would already be using these movements in their daily lives, they will not have to make any conscious effort in generating these control signals while using the device and can learn to generate the required control signals with minimal efforts. It is proposed that the contralateral shoulder is used to generate the control

signals as using ipsilateral shoulder can result in false triggers when the user uses the device to perform an ADL.

3.5 Summary

A summary of all the upper limb FES devices described in this chapter is presented in table 3-1. These devices underwent intenstive clinical testing and most of the studies suggested that FES improved the hand function of a person with SCI. Many of these devices were made commercially available as well but were withdrawn from market due to profit issues for the company marketing them. After a detailed literature review, it is clear that at the time of writing, the NESS H200 was the only commercially available upper limb FES device that has shown clinically significant results with people with SCI. However this device has some limitations as it does not allow flexibility in the placement of the electrodes and the rigid arm splint does not fit everyone. The MyndMove FES device is commercially available but at the time of writing, there were not enough clinical evidence to prove that this device is beneficial to the people with SCI. Hence there is an urgent requirement for an upper limb FES device that will help in improving the upper limb functions of people with SCI.

The NESS H200 has its limitation such as the rigid arm splint does not fit everyone and does not allow the user to use the tenodesis grip (if available). Also this device does not allow the clinician to explore more electrode positions in order to get a better response. Hence there is a requirement for a new upper limb FES device that will help in improving the hand functions of people with SCI. This device should allow them to use any residual hand function to the maximum and provide flexibility to the clinician in choosing the electrode positions that provide the best possible response.

This chapter also discusses the MMIs that have been used in the upper limb FES devices and lists out the advantages and disadvantages of these MMIs. The advantages of using the shoulder movements such as elevation,

protraction and retraction, for generating the control signals are also discussed in this chapter. It concludes by justifying the selection of an IMU as a MMI for this research work. The exploration of various IMUs that are capable of detecting the shoulder movements and the selection of the IMU is discussed in the next chapter.

Chapter 4 Inertial Measurement Sensors for Detecting the Shoulder Movements

4.1 Introduction

An electronic device with accelerometers, gyroscopes and sometimes magnetometers is called an Inertial Measurement Unit (IMU). These sensors can measure the acceleration, the rate of turn and the magnetic field if a magnetometer is present. An IMU was chosen to be explored as a possible shoulder position sensor because if successful:

- An IMU will allow the user the flexibility to turn the device ON and OFF whenever the user wants to.
- An IMU will allow the user the flexibility to modify their grasp when the stimulation is ON. This will allow the user to grasp or release an object without needing to turn the device ON and OFF every single time.
- An IMU can be made wireless or connected using sturdy connectors and strapped across the arm on top of the clothing. This would eliminate the issues of sensor breakdown due to fragile wires and skin irritation due to contact with the sensor.

It should have the following specifications in order to be used as a shoulder position sensor:

- Should be able to detect the shoulder movements such as shoulder elevation, protraction and retraction.
- Should be small and light weight.
- Should be cost effective.
- Should be readily available.

This chapter describes in detail the working principles of the IMU and briefly describes some of the commercially available IMUs that can possibly be used as a MMI for upper limb FES device. Finally, this chapter highlights the sensor selection criteria for this research.

4.2 Accelerometers

An accelerometer is a device that measures physical acceleration experienced by an object. At rest, on the surface of the earth, it will measure an acceleration of 1g in the upward direction, where g = 9.8 m/s^2. This happens because any point in the earth's surface is accelerating upwards relative to the frame of a freely falling object near the surface of the earth.

Commercially available accelerometers can be classified as: mechanical accelerometers, capacitive accelerometers, piezoelectric accelerometers and Hall-effect accelerometers. Out of the four transducers listed, the most commonly used are piezoelectric and capacitive accelerometers.

A mechanical accelerometer can be compared to a spring with a mass attached at one end while the other end is attached to the casting. When whole system accelerates, the outer casting accelerates immediately but the mass lags behind thereby causing the spring to experience a force. According to Newton's second law, this force is directly proportional to the acceleration.

In a piezoelectric accelerometer, a piezoelectric crystal is attached to the mass in the accelerometer. So when the whole system accelerates, the mass induces a force on the crystal thereby generating an electrical signal which will be proportional to the acceleration. In a Hall-effect accelerometer, a Hall generator is mounted on one of the spring which moves in a non-uniform magnetic field. The hall voltage generated by the mechanical displacement of the spring will be proportional to the acceleration if the gradient of the

magnetic field is linear. A capacitive accelerometer uses the property of a parallel plate capacitor where the capacitance varies in accordance to the acceleration. When attached to a circuit, these accelerometers produce a voltage proportional to the change in the acceleration.

The advancement in the MEMS technology has resulted in the production of accelerometers in a small semiconductor MEMS device (figure 4-1). This device contains an electrode with enough mass to move up and down which is attached to a cantilever beam. This beam is rigid enough to hold the electrode in position and at the same time flexible enough to allow it to oscillate. An electrical connection from the electrode and cantilever to the outside of the device is provided so that it can be wired into another circuit. The centre electrode is surrounded by two electrodes in the top and bottom with an air gap in between them (Woodford 2009).

Two conductive electrodes (marked as 6 in figure 4-1) separated by an airgap generate a capacitive effect. When the system accelerates, the force exerted on the central electrode (marked as 1 in figure 4-1) which is supported by tiny cantilever beam (marked as 2 in figure 4-1) causes it to move which in turn causes a change in the capacitance proportional to the acceleration. The central electrode has tiny insulating caps on both the ends (4 and 5 in figure 4-1) in order to protect the MEMS from a short circuit in case it is subjected to a sudden jolt. The parts of the MEMS marked as 6 and 3 in figure 4-1 are the pins of the MEMS that gets connected to the external circuitry.

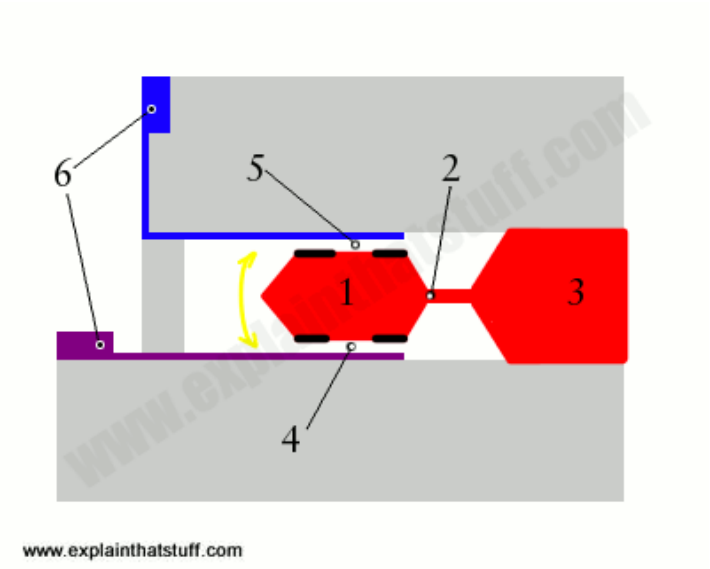


Fig 4-1: A semiconductor MEMS based accelerometer (Woodford 2009)

Commercially available accelerometers are single axis, two axis or tri-axis accelerometers. Most of the IMUs used for the upper limb research have either two axis or tri axis accelerometer. This helps in tracking the motion of the arm in all directions.

4.3 Gyroscopes

A gyroscope is a device that either measures or maintains the orientation of an object relative to a specific reference frame. Inertial navigation systems, robotics, computer input devices and game controllers are some of the applications of the gyroscope based IMUs. The gyroscopes, like the accelerometers, have become smaller and cheaper with the use of MEMS based technologies. MEMS based gyroscopes use Coriolis force to measure the angular velocity. Figure 4-2 shows the working principle of a MEMS based gyroscope.

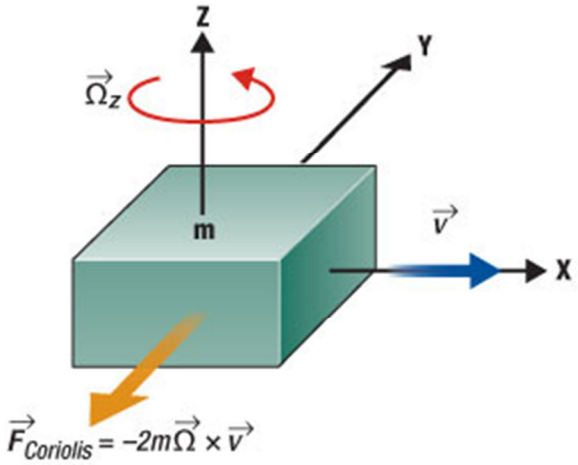


Fig 4-2: Working principle of MEMS based gyroscope (Esfandyari 2010)

If an object is moving with a velocity V→ along the x-axis and an angular velocity of Ω→ is applied along the z-axis then the object experiences Coriolis force F→ in the direction shown in the figure 4-3. A capacitive transducer measures this force (Esfandyari 2010).

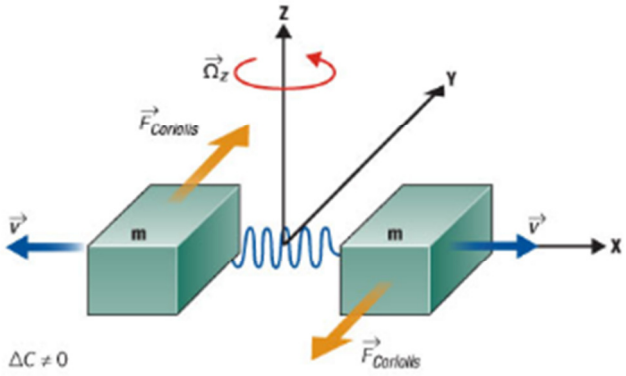


Fig 4-3: Tuning fork configuration in a gyroscope (Esfandyari 2010)

In order to measure the angular velocity, the MEMS based gyroscopes employ a tuning fork configuration. In this configuration, when no angular velocity is applied, two masses oscillate and constantly move in the opposite direction. When angular velocity is applied, the Coriolis force on each mass acts in the opposite direction. This causes change in the capacitance and this change is directly proportional to the angular velocity Ω→. (Esfandyari 2010).

4.4 Magnetometers

The magnetometer was invented by Carl Friedrich Gauss and is used to detect the magnetisation of a ferromagnetic material or the direction of the magnetic field at a point in the space. Magnetometers are widely used to measure the earth's magnetic field and to detect the magnetic anomalies in geophysical surveys. They are also used in the military to detect the presence of submarines. For a shoulder position sensor, a magnetometer is not mandatory.

Magnetometers are classified into two types: Vector Magnetometer and Scalar Magnetometer. The vector magnetometer measures magnetic flux density in a specific direction. Scalar magnetometers can only measure the magnitude of the magnetic flux density. Figure 4-4 shows a miniature MEMS based magnetometer.

Fig 4-4: An example of a MEMS based magnetometer (Electronics 2015)

4.5 Need for the development of an IMU

Accelerometer when used alone provides information about the linear acceleration but does not provide the orientation. The accelerometers are accurate over longer duration of time but are sensitive to the vibrations and external forces exerted on them. This often causes error in the accelerometer readings. A gyroscope is used to calculate the initial orientation and the change in orientation of an object. But gyroscope does not provide information about the position or the velocity with which an object is moving

and hence IMUs were developed which integrated the accelerometers and the gyroscopes in order to get more accurate information about the orientation and the position of an object. Gyroscopes are also subjected to drift errors which are caused due to integration of the angular velocity over time in order to obtain the orientation but they are accurate over short duration of time as the drift accumulates over time.

In an IMU, complementary filters or Kalman filters are often used to compensate for the drift errors. A complementary filter combines the slow moving accelerometer signals and the fast moving signals from the gyroscopes. The accelerometer signals are passed through a low pass filter and the gyroscope signals are passed through a high pass filter and the combined output provides the corrected output. The complementary filter is accurate and properly tuned only when summation of the frequency response of the low pass and the high pass filter is 1 at all the frequencies. These filters are preferred over the Kalman filters because they have fewer equations and are easy to implement as digital filters compared to the Kalman filter.

The MEMS based accelerometers, gyroscopes and magnetometers have made it possible to develop small sized and light weight IMUs which can be used to detect the shoulder movement which in turn can be used to control an upper limb FES device. The commercially available IMUs that can be used to detect the shoulder movement are explained in the next section.

4.6 Commercially Available IMUs

The Xsens MTx has been used as a MMI to detect the position of the arm in the space and control the FES device to stimulate the corresponding upper limb muscles (Tresadern et al. 2006). The Nintendo Wii and Wii motion have been used in stroke rehabilitation (Park 2016). A detailed explanation of these IMUs along with some other possible shoulder position sensors is described in this section.

4.6.1 The Xsens MTx Module

The Xsens MTx (figure 4-5) is a nine axis IMU that, according to the manufacturer, can accurately determine biomechanical movement and can be attached to the upper limb. This unit incorporates two ADXL202E biaxial accelerometers, three ENC-03J single axis gyroscopes and three KMZ51 magneto-resistive sensors. The size of the sensor is 3.8 x 5.3 x 2.1 cm and weight is 30 grams (Xsens 2006). Figure 4-5 shows the axis orientation of the unit.

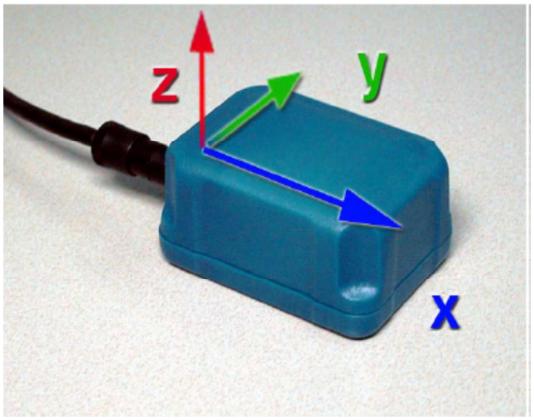


Fig 4-5: Axis orientation of Xsens MTx inertial measurement sensor (Xsens 2006)

The Xsens MTx kit consists of three sensors, the connecting wires and the controller called the Xbus. The Xbus receives the raw data from all the three sensors and processes it to give the orientation of the sensor. The Xsens MTx is a sensor that has been used for biomechanical applications (Song et al. 2012; Gil-Agudo et al. 2013; Banos et al. 2014) and has been previously used to detect the position of the upper limb in space and used this information to trigger an upper limb FES device (Tresadern et al. 2006) and is hence considered the gold standard for biomechanical application. However this sensor is expensive as it cost approx.. £1000 and has to be used along with the Xbus which processes the sensor data and provides the

orientation. This would increase the connectors and the hardware that the user has to deal with. Hence other sensors, capable of detecting the shoulder movements, that is comparatively cost effective and is as efficient as the Xsens MTx in detecting the shoulder movements.

4.6.2 Nintendo Wii and Wii Motion Plus

The Nintendo Wii remote (figure 4-6), released in the year 2006, has a built in infrared camera that captures the motion by tracking the movement of the infrared LEDs. A single tri-axis accelerometer is used to estimate the motion when the data from the camera is lost because of the position of the controller. An integral Bluetooth transmitter is used to transmit the data from the remote.

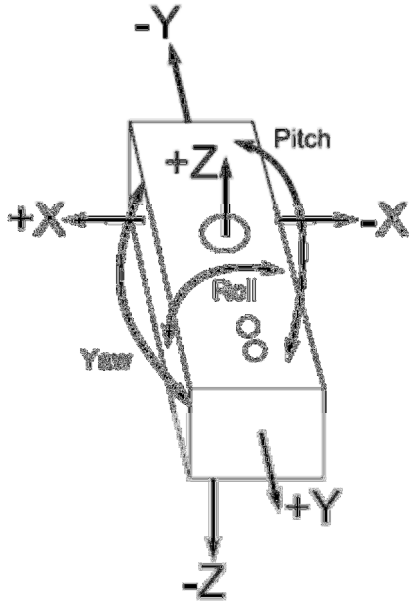


Fig 4-6: A Nintendo Wii Remote (Vargas et al. 2009)

Wii remote does not incorporate a gyroscope hence the device cannot accurately detect the shoulder movements. The dimensions of a Wii remote are 16 x 3.6 x 3.1 cm and would make a very bulky shoulder position sensor.

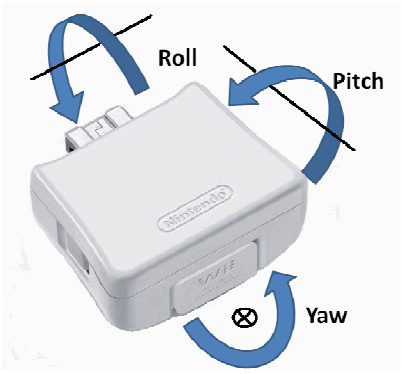


Fig 4-7: Wii MotionPlus (Arduinoprojects4u 2013)

Nintendo released the Wii MotionPlus in the year 2009, which incorporates two dual axis gyroscopes to provide the roll, pitch and yaw data. The Wii MotionPlus comes as an extension that can be attached to the Wii remote. This increases the length of the Wii remote by 4 cm. Again the remote along with the extension is bulky to be used as a shoulder position sensor and hence more sensors were explored.

4.6.3 Sony PlayStation Move

The Sony Playstation Move was released in the year 2010. The hardware consists of a three-axis accelerometer, a two axis gyroscope and a single axis gyroscope and a three axis magnetometer. Figure 4-8 shows a Sony PlayStation Move.

Fig 4-8: Sony PlayStation Move controller

The circular orb at the head of the controller has RGB LEDs which enables the head to glow in any colour. The colour light of the controller head is an active marker that can be tracked by a camera. The accelerometer and the gyroscopes are used to track the overall motion along with the rotation of the controller. The magnetometer helps in aligning the controller's orientation to the earth's magnetic field. The size of this sensor is 20 x 4.7 x 4.7 cm which is similar to the Wii remote.

Although the technical specification of this sensor satisfies all the prerequisites for the shoulder position sensor for this research work, it cannot be used as one because the sensor is bulky therefore it will not be practical to strap it across a person's shoulder.

4.6.4 Flyduino Nanowii and Hextronics Microwii Flight Controller

The flyduino Nanowii flight controller is an Arduino based IMU that has an InvenSense MPU-6050 (figure 4-9), which is a six axis motion tracking MEMS device that combines a three axis accelerometer and a three axis gyroscope. These flight controllers are used to make toy quadcopters. Open source software available at the Arduino forum is used to configure the accelerometers and the gyroscopes and calculate the heading and attitude values required to know the position of the quadcopter. With the help of some additional coding, it is possible to transmit the accelerometer and gyroscope data through the available serial port which can then be received and interpreted by another device. The size of the board is 3.7 cm by 3.7 cm, weighs 4 grams and cost around £35.

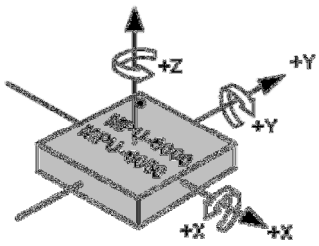
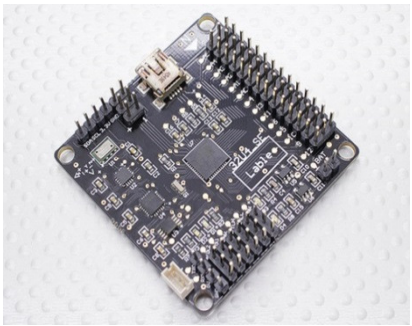


Fig 4-9: Axis orientation of InvenSense MPU-6050 (Invensense 2013)

The Hextronix Microwii board has the same InvenSense MPU 6050 MEMS device. It also has a HMC-5883L magnetometer and a MS5611-01BA03 barometer. The size of this board is 5 x 5 x 1.6 cm and it weighs 14 g. Since the Nanowii is smaller in size compared to the Microwii and both have similar specification, Nanowii is chosen over Microwii. Figure 4-10 shows these two IMU boards.



(a)

(b)

Fig 4-10: (a) Hextronix MicroWii (Duffy 2014) (b) Flyduino MicroWii (SparkFun 2012)

Table 4-1 summarises all the above-mentioned sensors along with their specifications.

Sensor	Size (L x B x H) in cm	Hardware specification	Cost	Weight
Xsens MTx	3.8 x 5.3 x 2.1	Two bi-axial accelerometers, three single axis gyroscope and three magneto-resistive sensors	£1000 (approx.)	30g
Nintendo Wii	14.8 x 3.6 x 3.1	One Tri-axis accelerometer	£20.00 (approx.)	200g
Nintendo Wii MotionPlus	19 x 3.6 x 3.1	One Tri-axis accelerometer, two dual axis gyroscope	£25.00 (approx.)	210g
Sony PlayStation Move	20 x 4.7 x 4.7	A three axis accelerometer, a dual-axis gyroscope, a single axis gyroscope, a three axis magnetometer	£20.00 (approx.)	145g
Hextronix Microwii flight controller	5.0 x 5.0 x 1.6	A three axis accelerometer, a three axis gyroscope, a three axis magnetometer and a barometer	£30.00 (approx.)	14g
Flyduino Nanowii flight controller	3.7 x 3.7 x 1.6	A three axis accelerometer and a three axis gyroscope	£35.00 (appox.)	4g

Table 4-1: Summary of the Inertial Measurement Sensors

4.7 Summary

This chapter summarises some of the commercially available IMUs which could be used to detect the shoulder movement and can be used as an MMI for an upper limb FES device. The IMUs described here are the Xsens MTx, the Nintendo Wii and the Wii MotionPlus, the Sony PlayStation Move, the Flyduino Nanowii and the Hextronix Microwii. The Nintendo Wii does not have a gyroscope which makes it unsuitable for the accurate detection of the shoulder position and hence was rejected as a possible shoulder position sensor. The issue of the gyroscope can be resolved by using the Wii MotionPlus along with the Nintendo Wii.

Comparing the dimensions of the potential sensors summarised in table 5-1 and the requirement of the shoulder position sensor mentioned in section 5-1, only the Xsens MTx, the Hextronix MicroWii and the Flyduino NanoWii are the sensors that are compact enough to be strapped across the shoulder of the user. Since the Hextronix MicroWii and Flyduino NanoWii have similar specifications and the Flyduino NanoWii is comparatively smaller in size, it was chosen over the Hextronix MicroWii. A comparative study between the two sensors is presented in the next chapter.

Chapter 5 Comparison of Xsens MTx and Flyduino Nanowii

5.1 Introduction

This chapter summarises the comparative study between the potential shoulder positions sensor (the Xsens MTx and the Flyduino NanoWii Flight Controller). Here, the Xsens MTx is used as the gold standard as it is a well-established device for measuring biomechanical movements. The protocol for the experiment, the results obtained from the able-bodied volunteers who participated in the study and the selection of the shoulder position sensor for the TetraGrip is described in this chapter.

5.2 Experiment Protocol

Before setting up the experiment, the volunteers were provided with a volunteer information sheet (Appendix C) which described the procedure of the experiment. The volunteer information sheet clearly stated the purpose of the experiment and the procedures. The main objectives of the first experiment are:

- To record the signals from Nanowii and Xsens and analyse the correlation between the two signals.
- To observe if there is a specific pattern in the signals when a specific shoulder movement is performed. The definition of the control signal will be feasible if the signals from the IMU change in a particular manner when shoulder elevation, relaxation, protraction and retraction are performed.

In the second experiment, the volunteers were asked to perform shoulder elevation, relaxation protraction and retraction in a sequence of their choice. The main objectives of this experiment are:

- To check if the signals from the sensors remain correlated even when the user generates the signals in a random sequence.
- To check if it is possible to identify a specific shoulder movement when the user generated the signal in a random sequence.
-

The procedure for both the experiments is the same and is summarised below.

1. The volunteer was asked to relax and be seated comfortably on a chair.
2. The Nanowii sensor was strapped across the upper arm as close to the shoulder as possible. The sensor was strapped such that it was neither lose nor too tight. Adequate precautions were taken to make sure that the sensor remained stable as this reduced the movement artefacts.
3. The Xsens was firmly strapped on top of the Nanowii and the axes of the two IMUs were aligned as closely as possible (figure 5-1).
4. The MT9 software and the C program that recorded the data from the Nanowii were executed in the researcher's computer.
5. The sensors were tapped on the top. This generated a spike in the recorded data. This step was done to mark the beginning of the data.
6. The volunteer was then asked to perform the shoulder elevation, relaxation, protraction, relaxation, retraction and relaxation in the given sequence.
7. Once the volunteer performed all the shoulder movements, the execution of both the software were stopped and the data was saved for further processing.

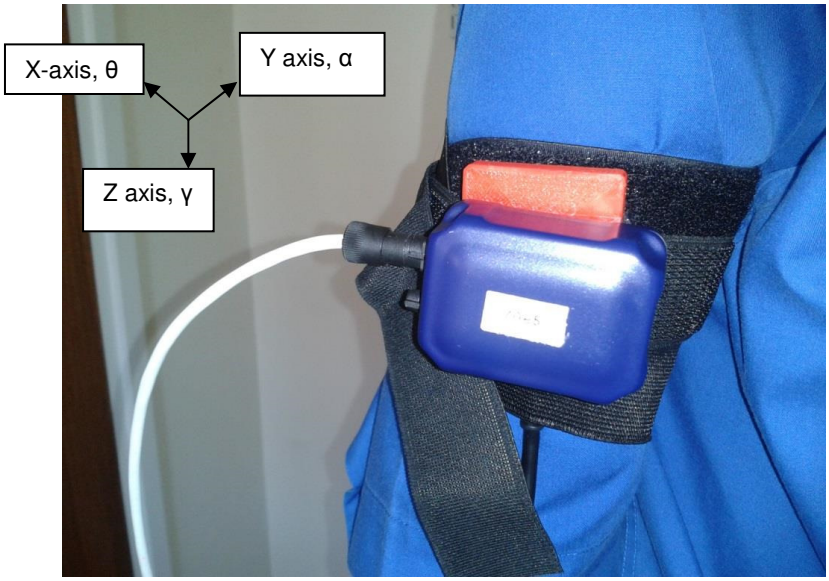


Fig 5-1: Experimental Setup

Five volunteers participated in this experiment and the results of these experiments are summarised in the next section. This study was reviewed for ethical clearance by the Research Ethics Committee, Faculty of Science and Technology, Bournemouth University.

5.3 Results from Experiment 1

In experiment 1, the volunteers were asked to perform three shoulder movements: Shoulder elevation followed by shoulder protraction and shoulder retraction. The graphs from all the six axes of the Nanowii were plotted against the corresponding six axes of the Xsens MT9. Figures 5-2 to 5-7 show the results of volunteer 1. The data obtained were normalised between the minimum and maximum values available in the string of data and the formula used for normalisation is as follows:

$$Data_{norm} = (data_{present} - data_{min})/(data_{max} - data_{min})$$

Equation 5-1: Formula to calculate the normalised values

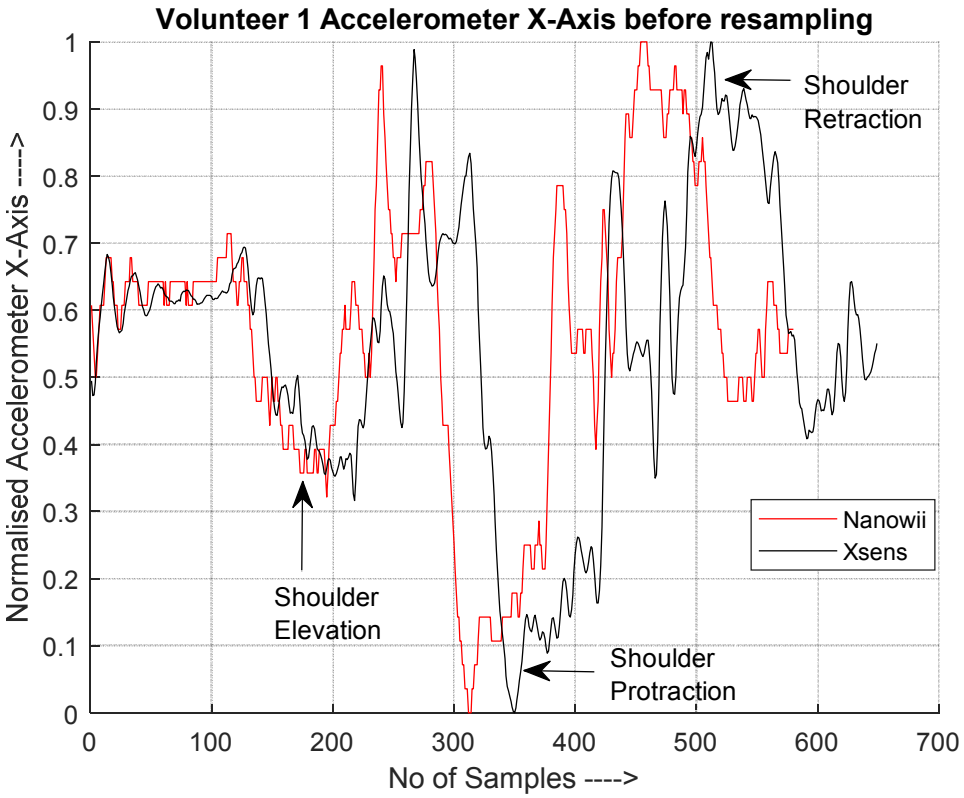


Fig 5-2: Volunteer 1, Experiment 1: Accelerometer X axis signals

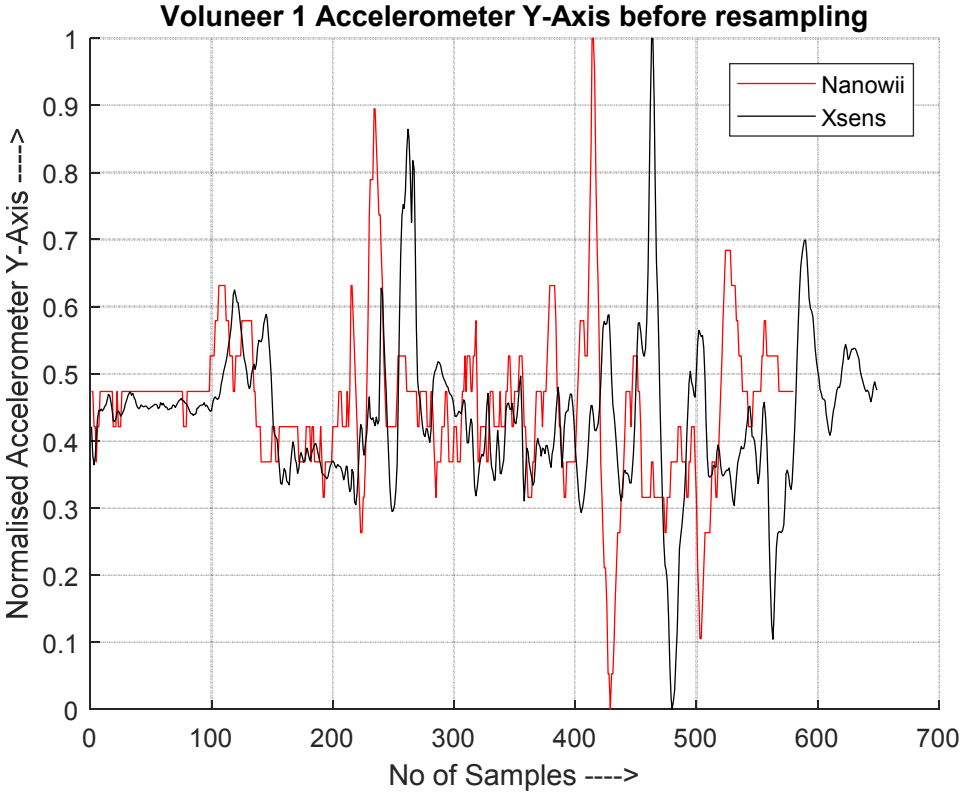


Fig 5-3: Volunteer 1, Experiment 1: Accelerometer Y axis signals

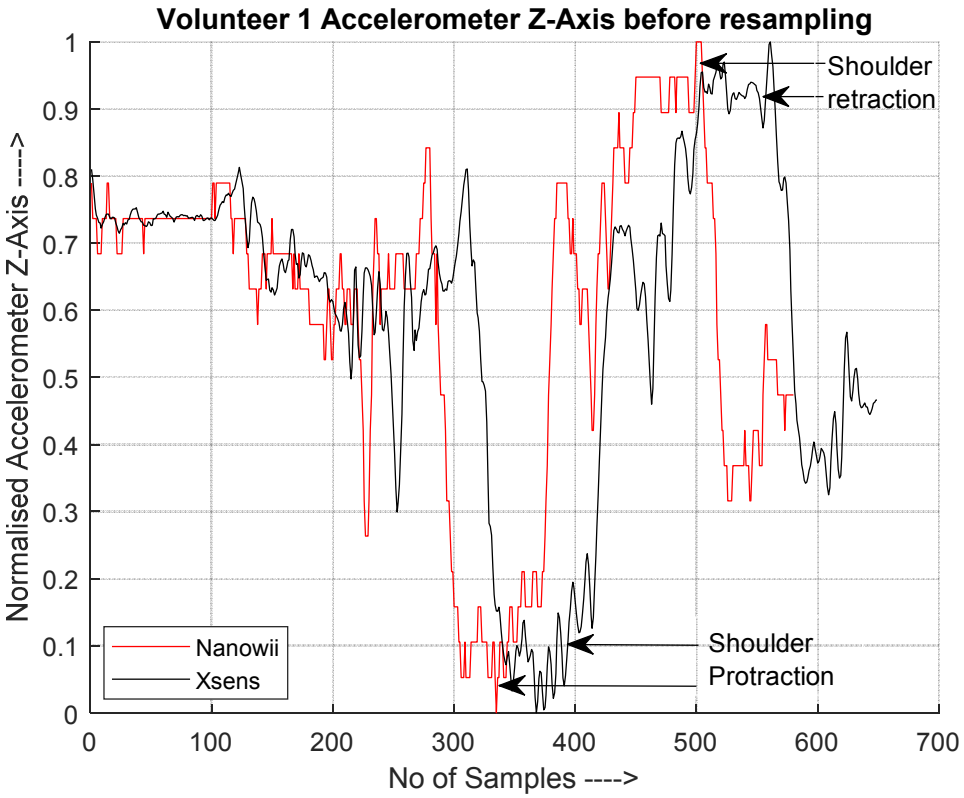


Fig 5-4: Volunteer 1, Experiment 1: Accelerometer Z axis signals

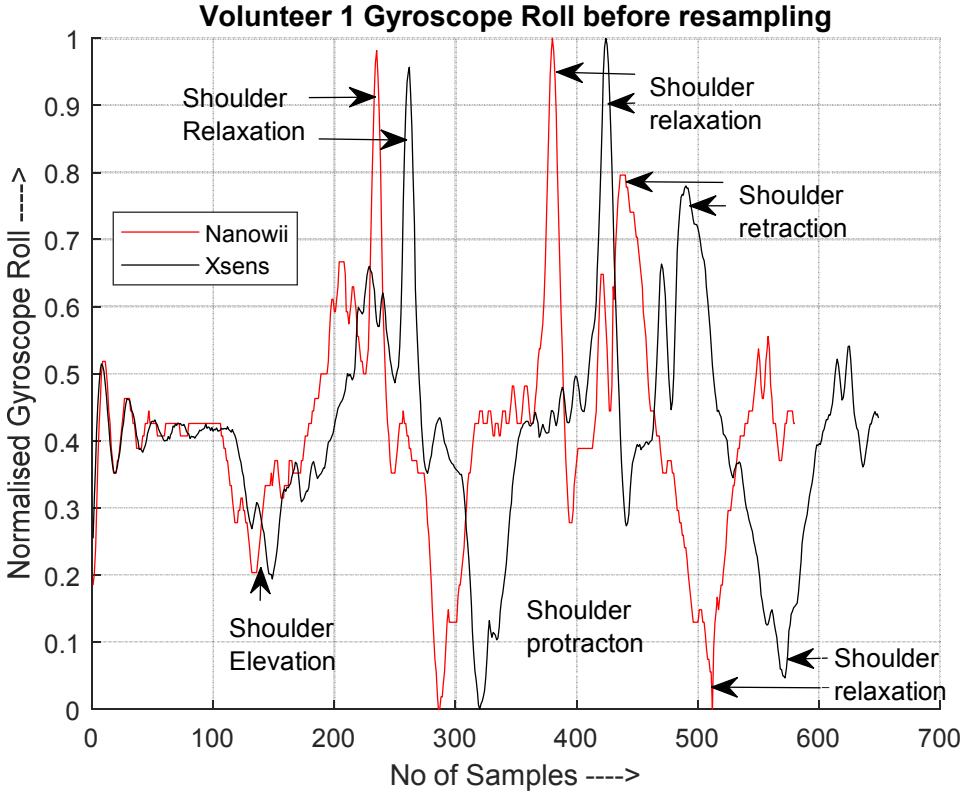


Fig 5-5: Volunteer 1, Experiment 1: Gyroscope Roll signals

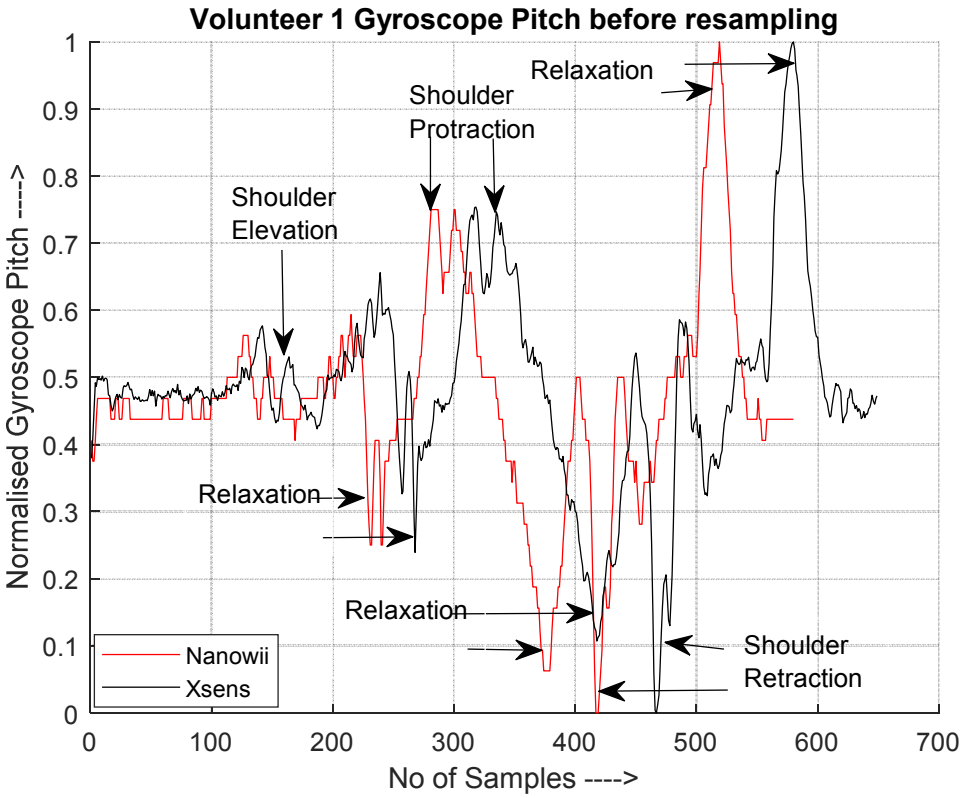


Fig 5-6: Volunteer 1, Experiment 1: Gyroscope Pitch signals

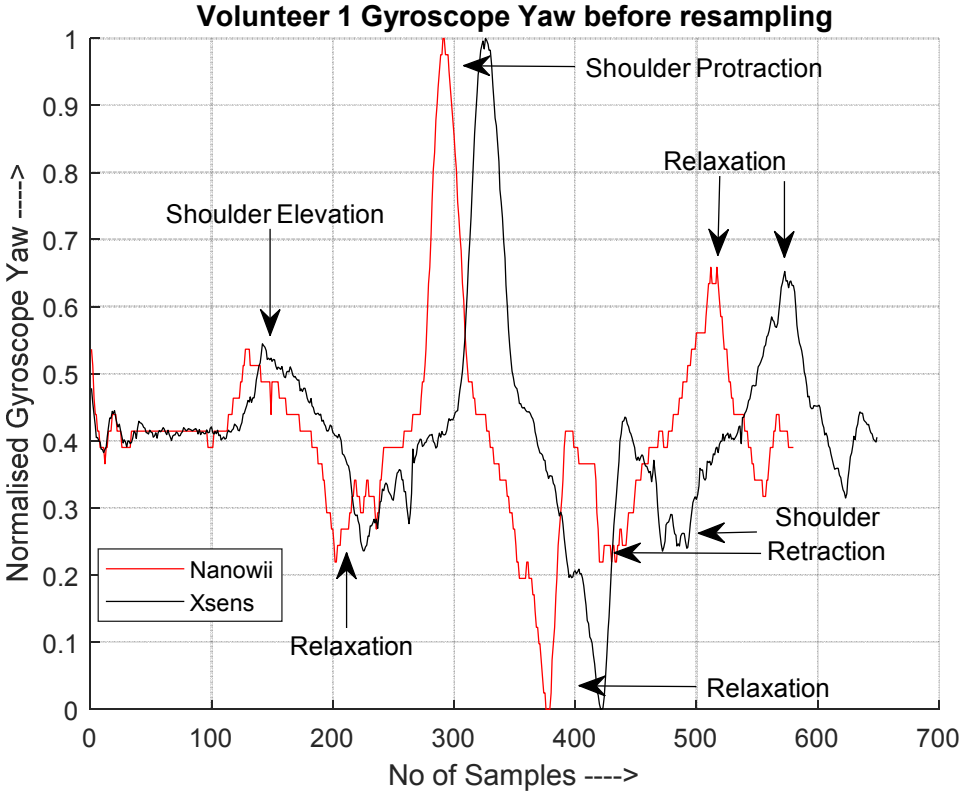


Fig 5-7: Volunteer 1, Experiment 1: Gyroscope Yaw signals

From the graphs, it is very clear that there is a lag between the two signals and this lag is not uniform as the signals start at the same time but the shift between the two signals increase with time. One possible explanation for this lag is the sampling frequency mismatch between the two sensors. The inbuilt sampling frequency for the NanoWii was 1000 Hz and this was downsampled to 100 Hz in order to match the sampling frequency of the Xsens MTx. However this downsampling introduced quantisation errors and the sampling frequency was approximate and not exact. Hence there was a frequency mismatch which introduced the lag.

In order to calculate the correlation, it was important that the two signals started and ended at the same time. The signal from the NanoWii was post processed using MATLAB (R2009b) in an attempt to eliminate the lag. MATLAB has a function 'resample()' which takes a signal X that needs to be resampled as the input argument along with two integer values P and Q and resamples the signal X at P/Q times the original sampling frequency.

The post processed signals obtained from Volunteer 1 are shown in the figures 5-8 to 5-13.

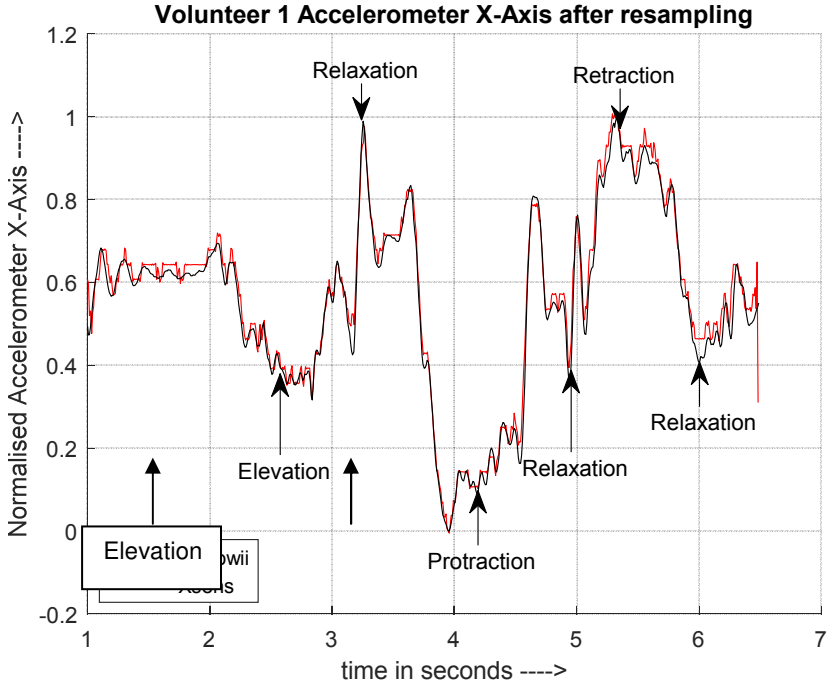


Fig 5-8: Volunteer 1, Experiment 1: Resampled accelerometer X axis signals

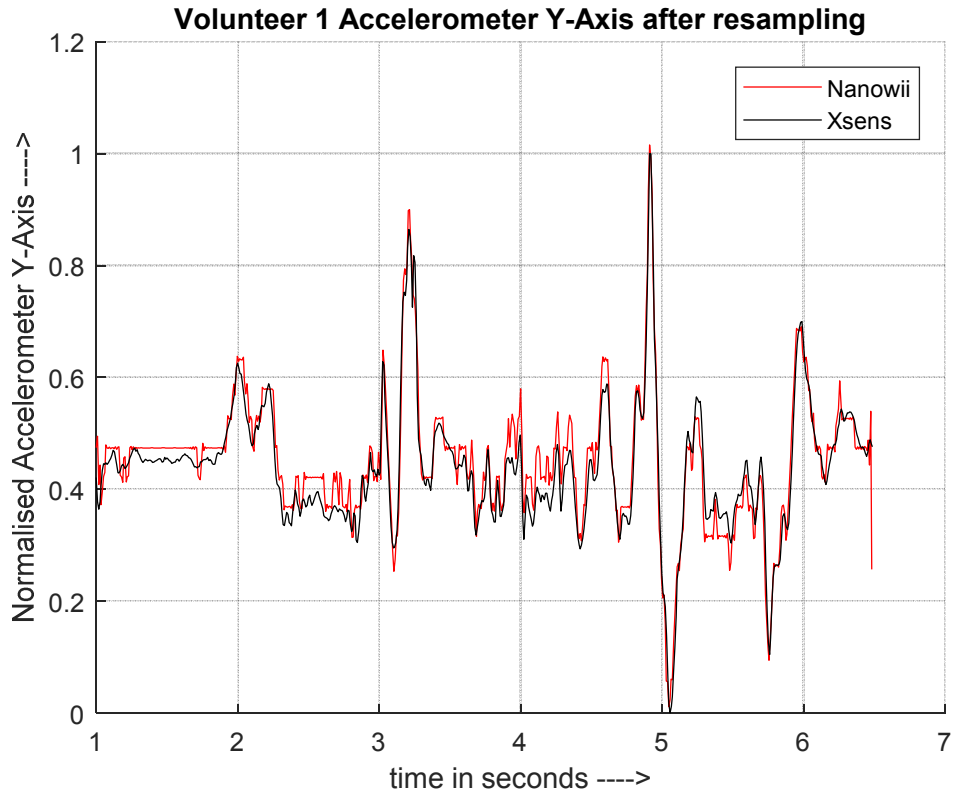


Fig 5-9: Volunteer 1, Experiment 1: Resampled accelerometer Y axis signals

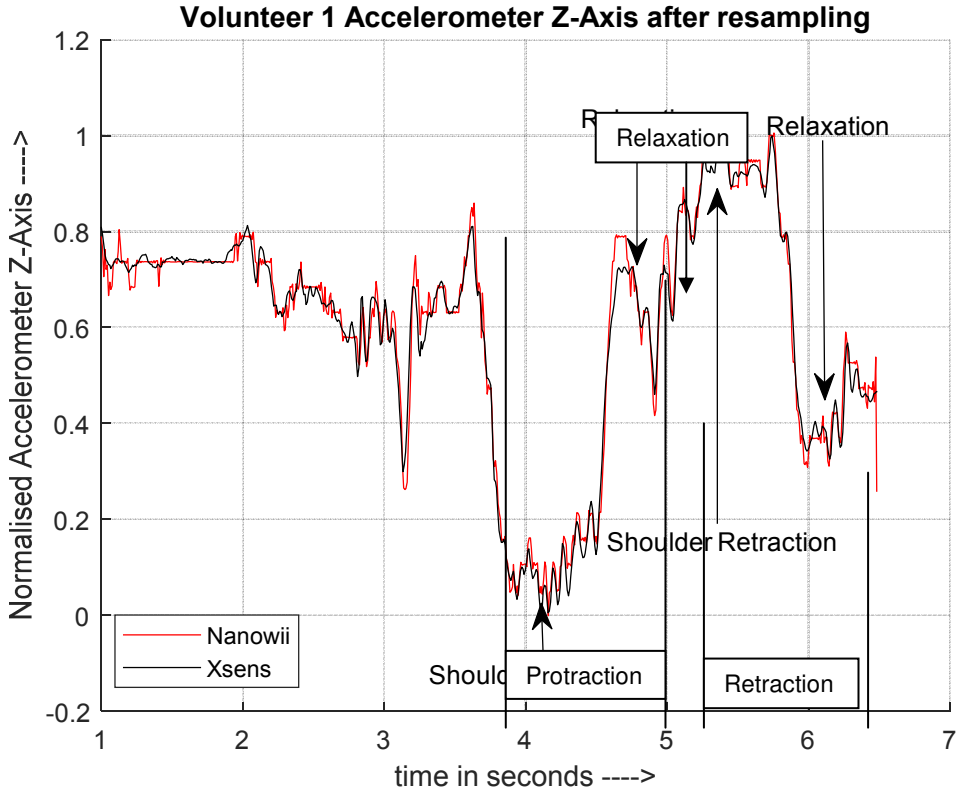


Fig 5-10: Volunteer 1, Experiment 1: Resampled accelerometer Z axis signals

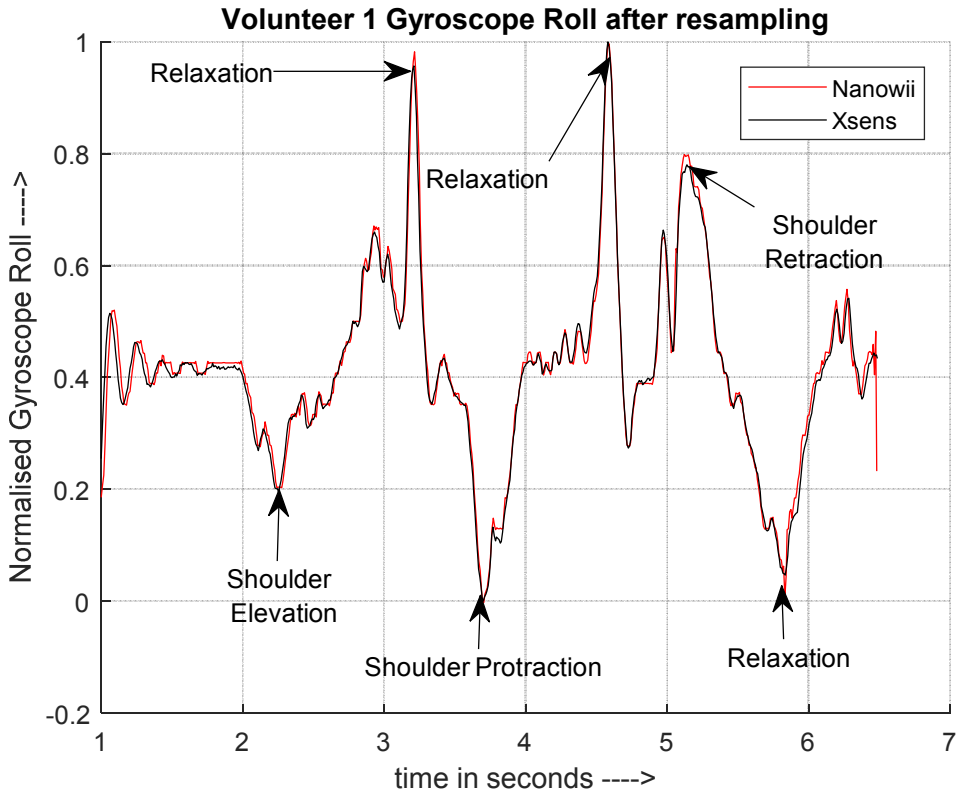


Fig 5-11: Volunteer 1, Experiment 1: Resampled Gyroscope Roll signals

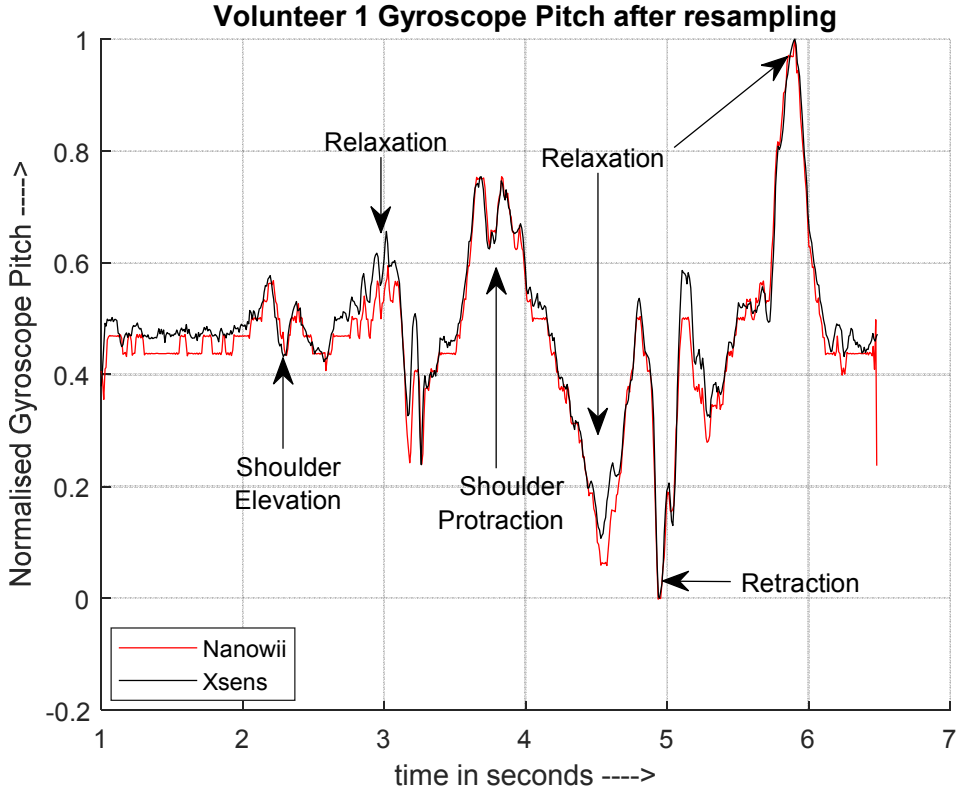


Fig 5-12: Volunteer 1, Experiment 1: Resampled Gyroscope Pitch signals

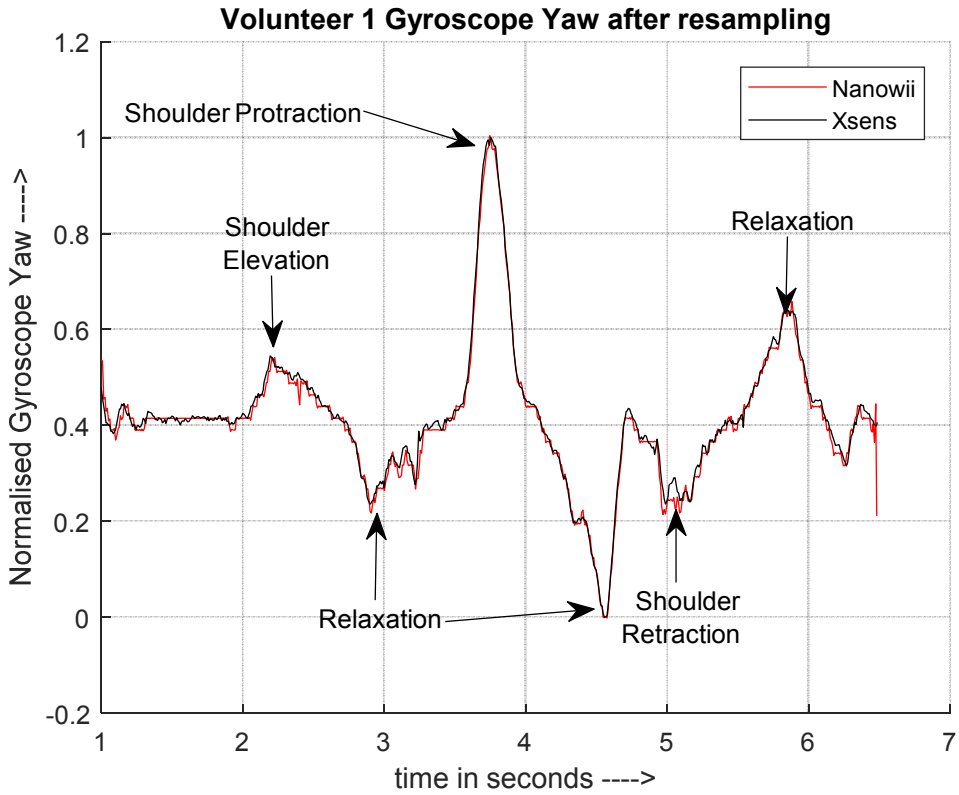


Fig 5-13: Volunteer 1, Experiment 1: Resampled Gyroscope Yaw signals

From the graphs above, it can be concluded that the signals from both the sensors were similar. Also both sensors were rigidly strapped on top of each other which subjected both the sensors to the same movement at the same time. Figures 5-14 to 5-19 summarise the cross-correlation between the two sensors along the R^2 values for each axis for Volunteer 1.

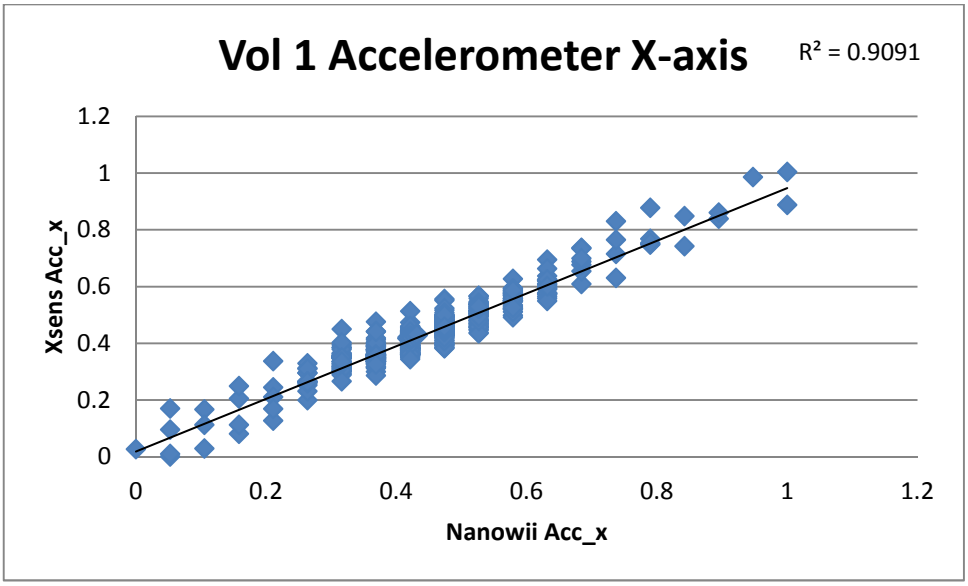


Fig 5-14: Scatter plot of accelerometer x-axis from Nanowii and Xsens

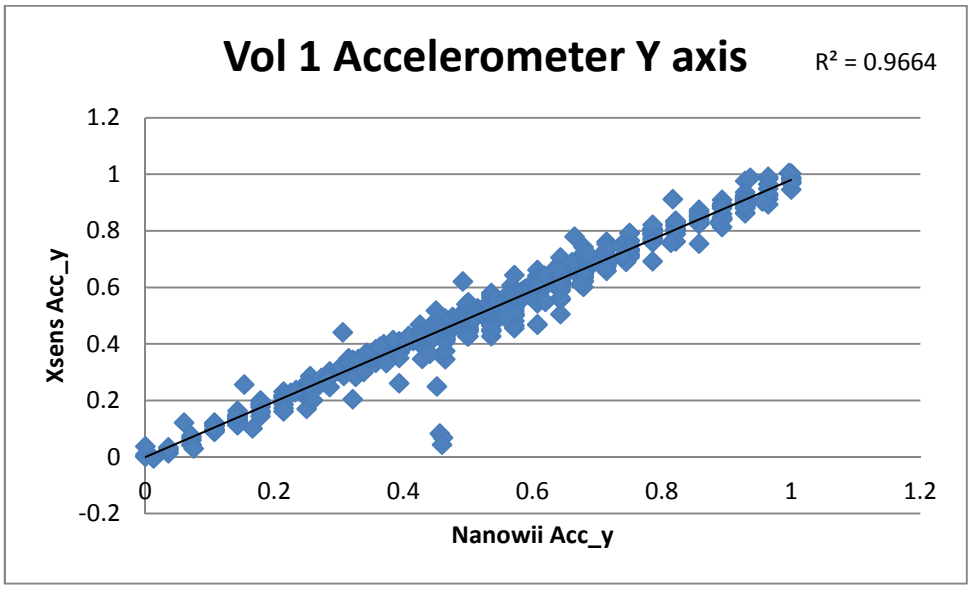


Fig 5-15: Scatter plot of accelerometer y-axis from Nanowii and Xsens

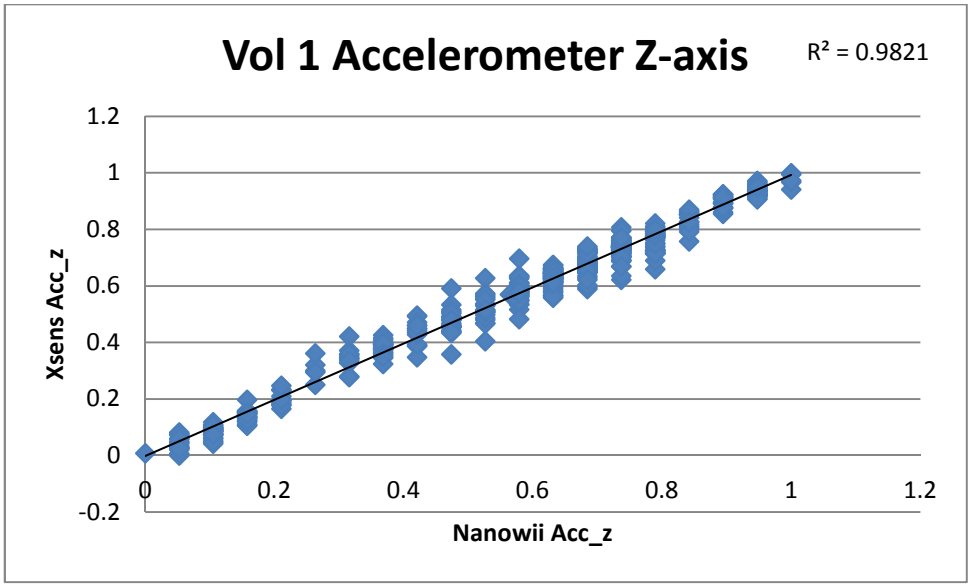


Fig 5-16: Scatter plot of accelerometer z-axis from Nanowii and Xsens

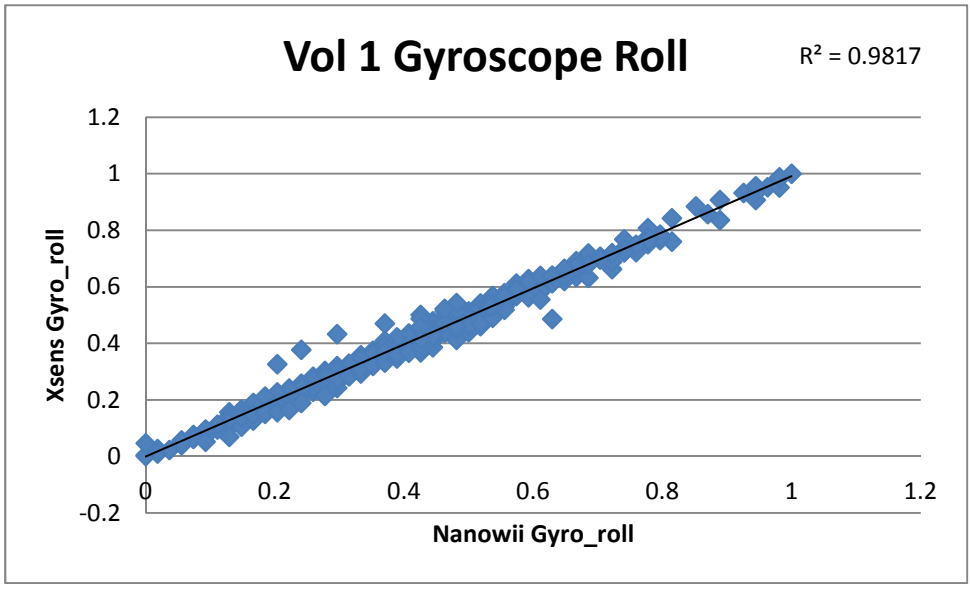


Fig 5-17: Scatter plot of gyroscope roll from Nanowii and Xsens

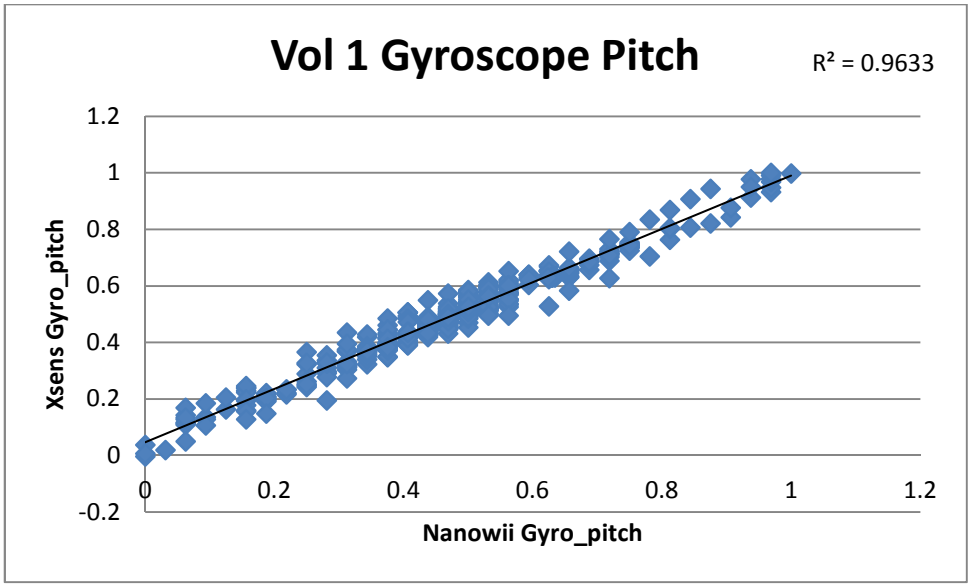


Fig 5-18: Scatter plot of gyroscope pitch from Nanowii and Xsens

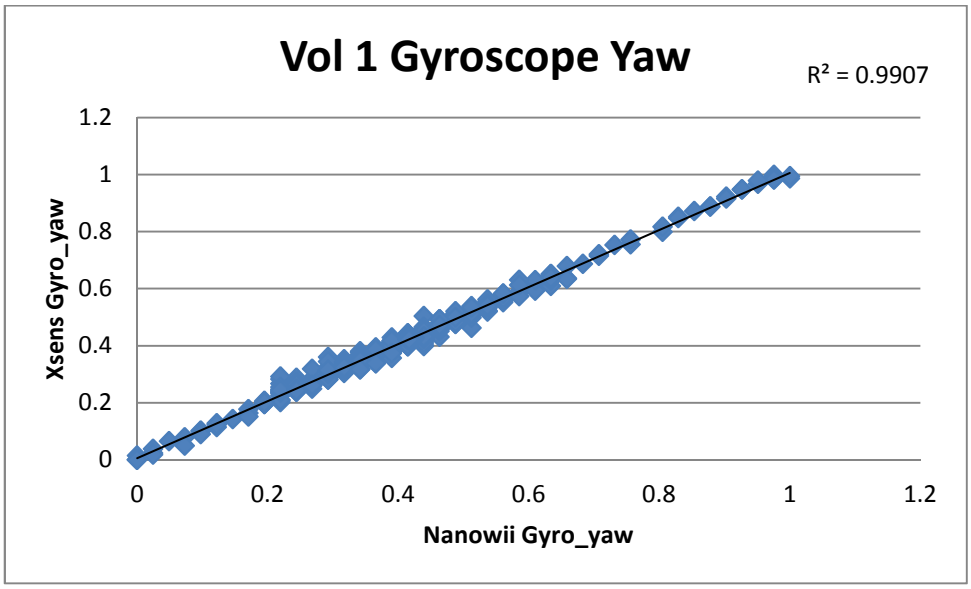


Fig 5-19: Scatter plot of gyroscope yaw from Nanowii and Xsens

The R^2 values in these graphs for all the nine volunteers range between 0.7086 and 0.9907. This shows that the signals from the two sensors are highly correlated. The cross-correlation values from all the volunteers are summarised in table 5-1.

Volunteer no	Acc X-axis	Acc Y-axis	Acc Z-axis	Gyro Roll	Gyro Pitch	Gyro Yaw
1	0.9091	0.9834	0.9821	0.9817	0.9633	0.9907
2	0.8873	0.8101	0.9477	0.8901	0.9555	0.8046
3	0.817	0.8009	0.8631	0.8607	0.7086	0.8306
4	0.9019	0.8776	0.9103	0.9317	0.8213	0.8741
5	0.9396	0.7957	0.9526	0.9752	0.8173	0.9118
6	0.903	0.811	0.8738	0.9237	0.8683	0.9316
7	0.9478	0.8999	0.9592	0.9914	0.9354	0.9766
8	0.9614	0.9652	0.9545	0.981	0.9692	0.9586
9	0.9734	0.9396	0.9808	0.979	0.9045	0.9673

Table 5-1: Cross correlation values of all the 6 axes of NanoWii and Xsens MTx

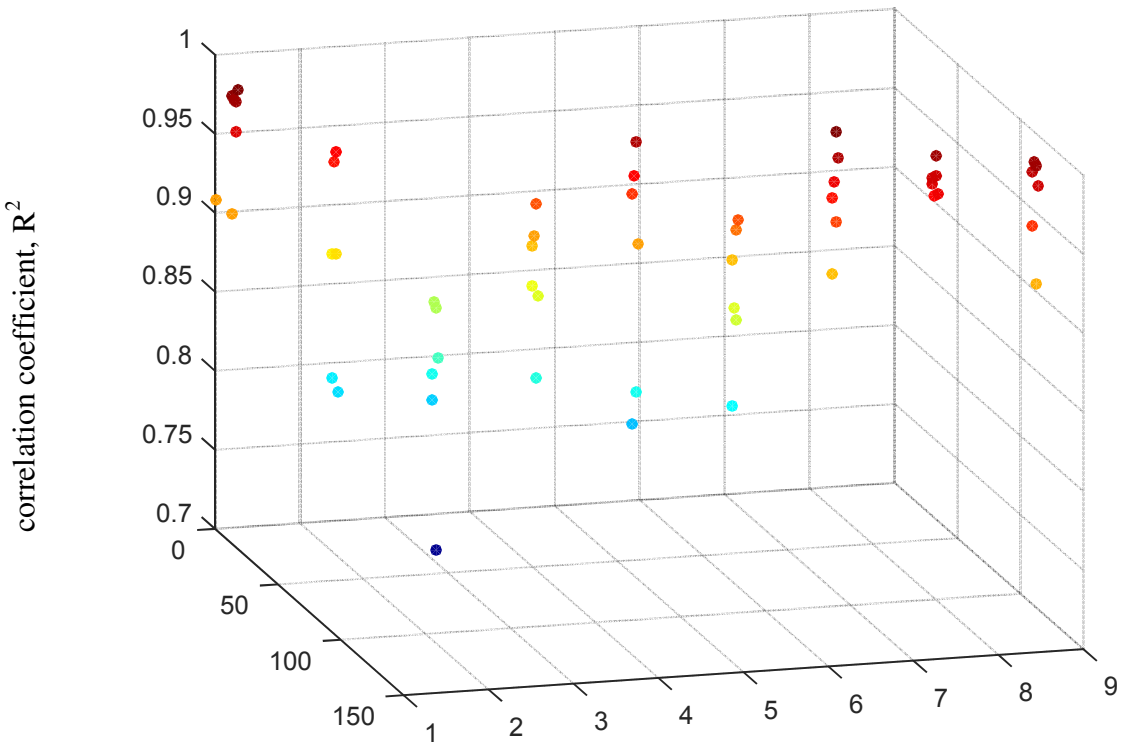


Figure All six axes and volunteer number

Fig 5-20: A 3-D plot of the correlation values in table 5-1

The signals from NanoWii were mapped as a single byte data before transmission. This along with the quantisation error introduced during downampling has affected the correlation values for some volunteer. Also the correction factor (P/Q ratio) for the resample() function in MATLAB was calculated using iterative process for each volunteer. For some volunteers,

the correction factor resulted in better correction of the lag compared to others. This is because each volunteer had different perception of how to perform the shoulder movements and the time interval between each shoulder movement was different for each of them. Hence the lag introduced was different for each volunteer. The graphs from the data obtained from other volunteers are presented in Appendix D. The results obtained from the second experiment is summarised in the next section.

5.4 Results from Experiment 2

In this experiment, the volunteers were asked to perform shoulder elevation, shoulder protraction and shoulder retraction in a sequence of their choice. While in the first experiment, they performed the movements in a specified order, in this experiment, they had the freedom to perform the movements in any order. The volunteers were asked to do the shoulder movements as long as they were comfortable. Figures 5-21 to 5-26 show the results obtained after analysing the data obtained from one volunteer. The results obtained from other volunteers are presented in the Appendix D.

These signals were also resampled with the help of the resample() function in MATLAB. The graphs after resampling are as shown in the figures below.

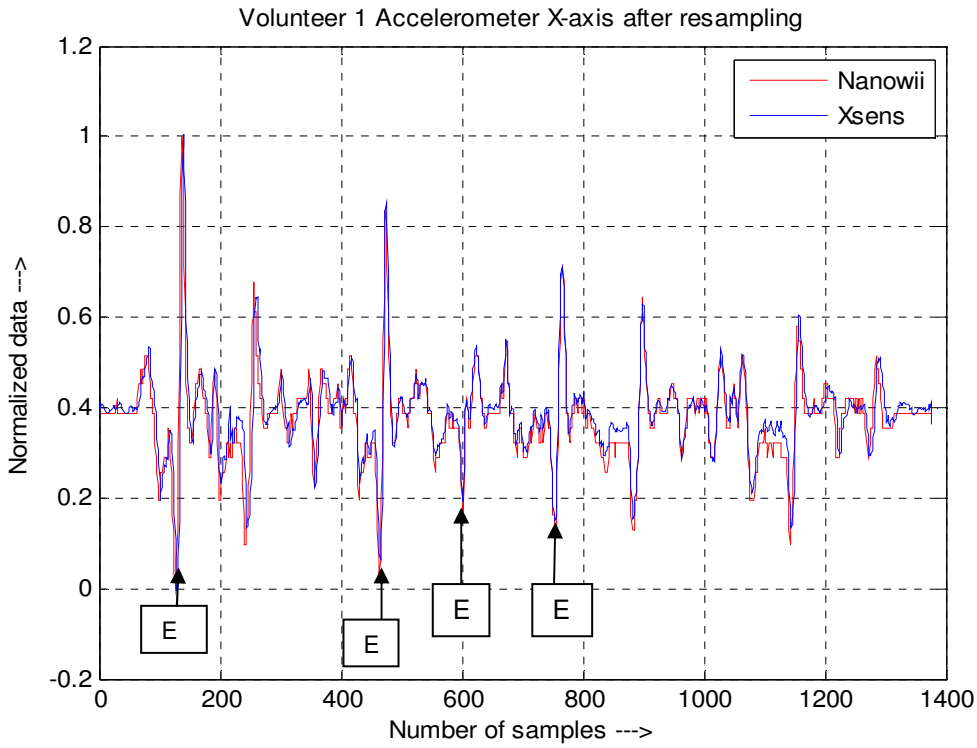


Fig 5-21: Volunteer 1, Experiment 2: Resampled Accelerometer X-axis signals

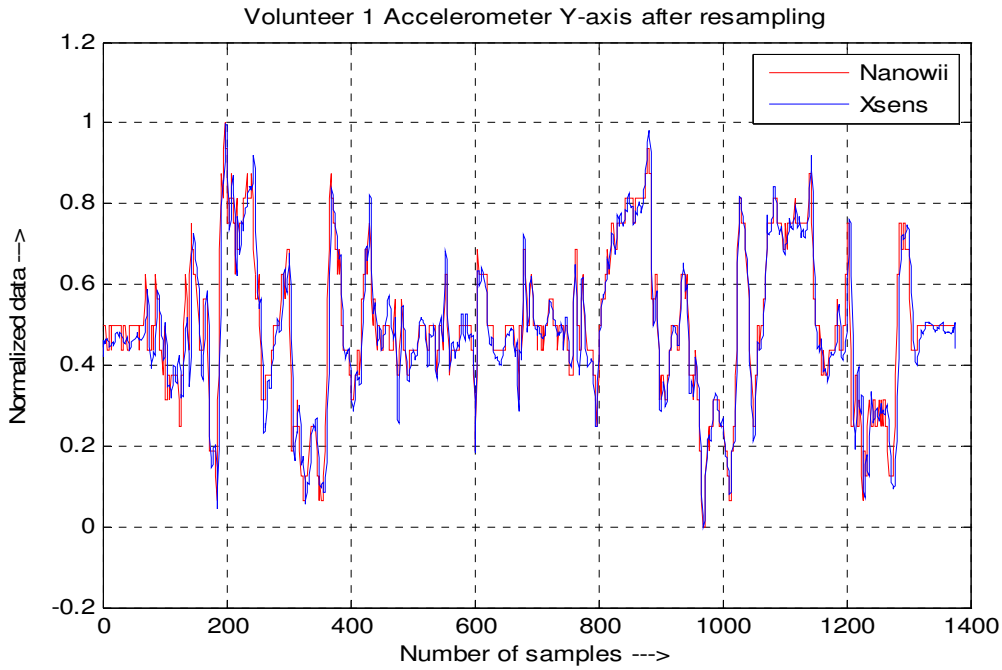


Fig 5-22: Volunteer 1, Experiment 2: Resampled Accelerometer Y-axis signals

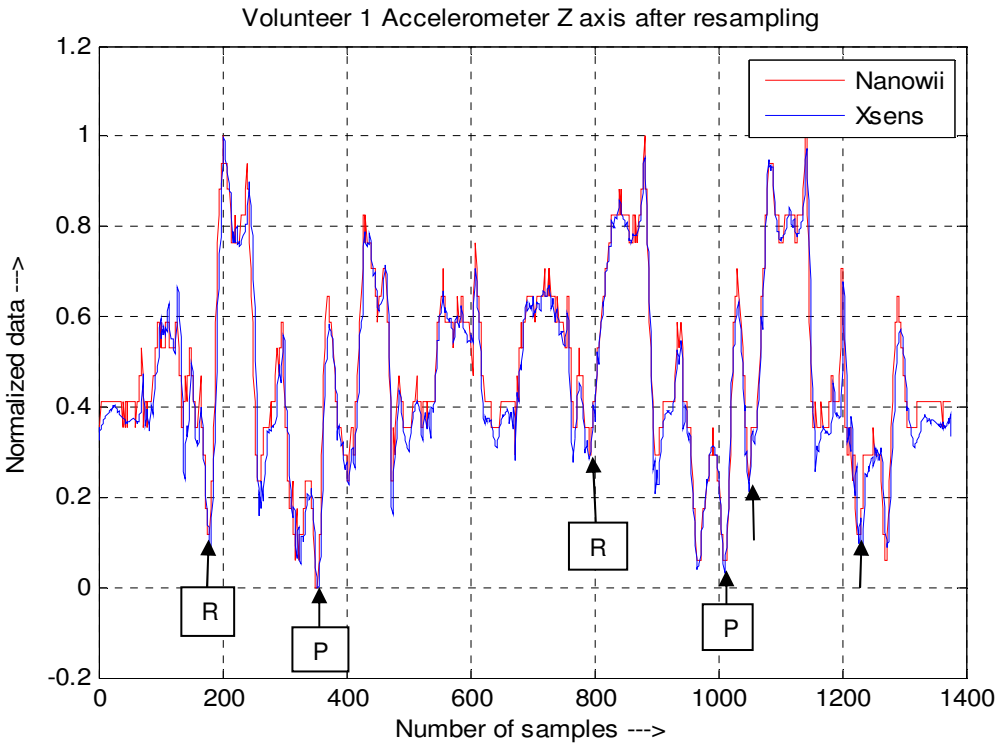


Fig 5-23: Volunteer 1, Experiment 2: Resampled Accelerometer Z-axis signals

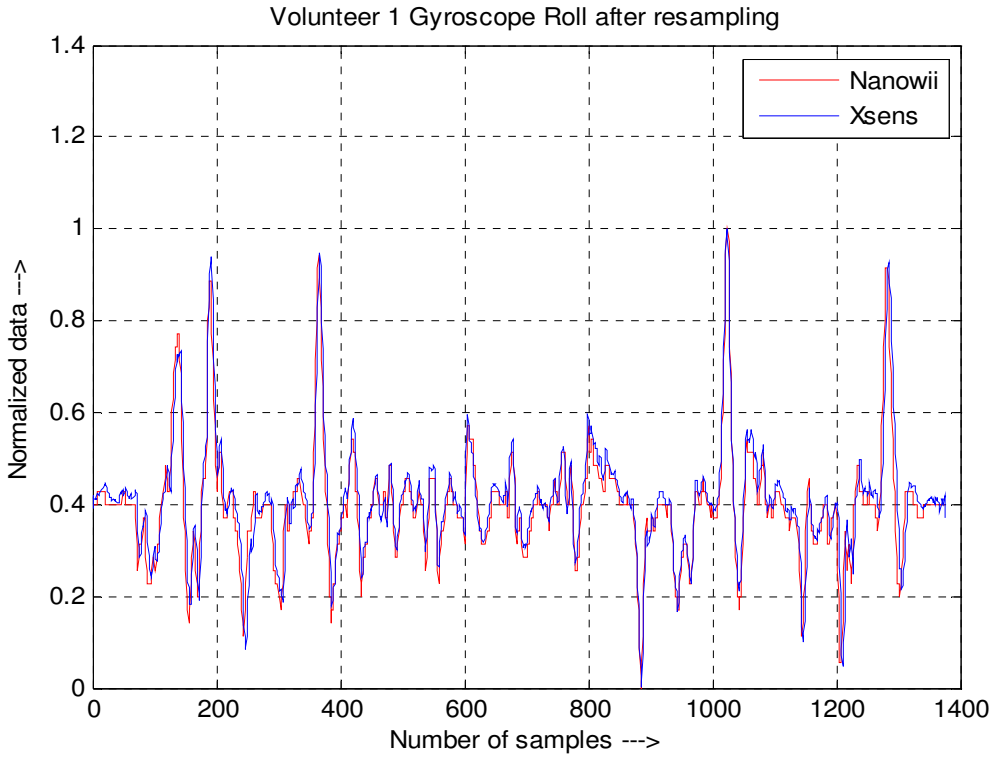


Fig 5-24: Volunteer 1, Experiment 2: Resampled Gyroscope Roll signals

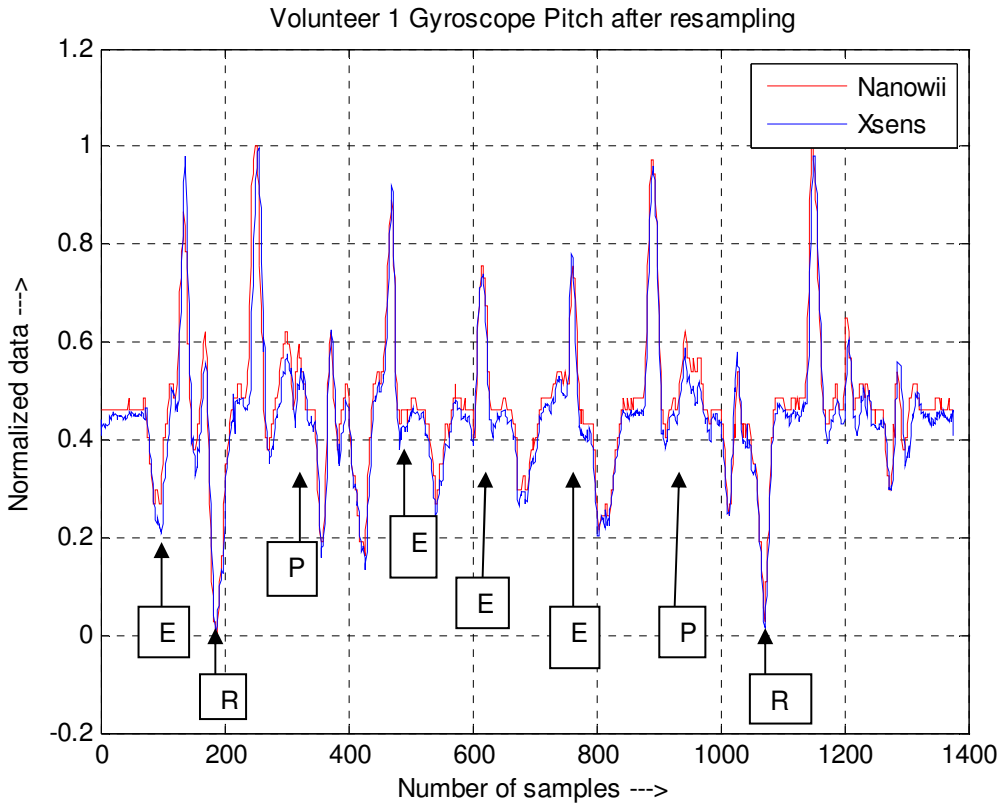


Fig 5-25: Volunteer 1, Experiment 2: Resampled Gyroscope Pitch signals

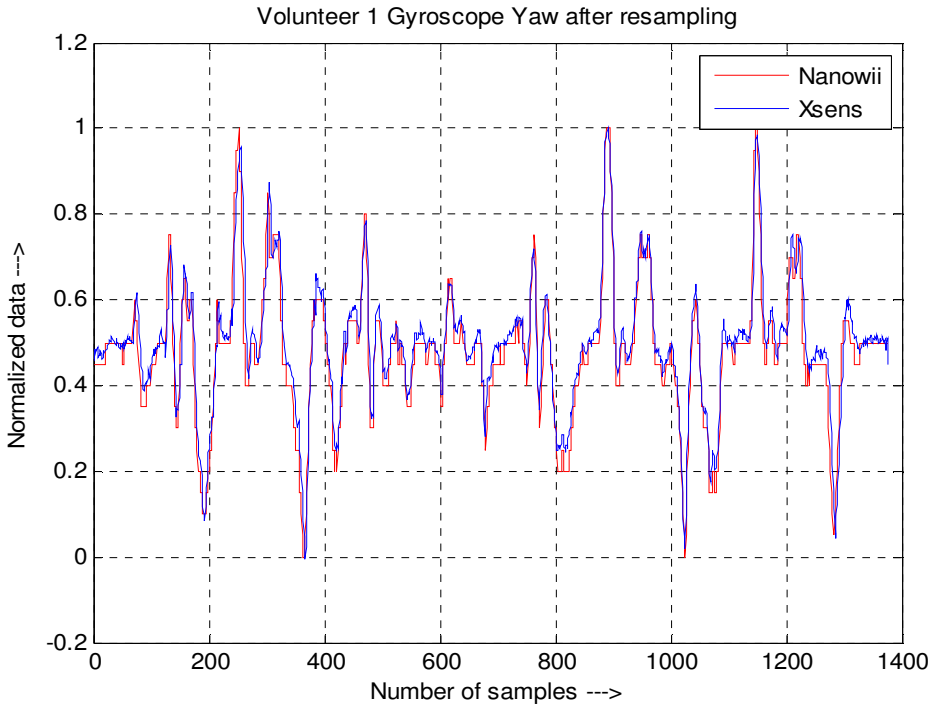


Fig 5-26: Volunteer 1, Experiment 2: Resampled Gyroscope yaw signals

In the above graphs, “**E**” stands for elevation, “**P**” for Protraction and “**R**” for Retraction, From the above graphs, it can be concluded that both the performance of both the sensors were similar even when the shoulder movements were generated in a random sequence. The correlation between the signals ranged between 0.6362 and 0.7267. The correlation between the two signals was slightly low due to quantisation error and the correction factor used to resample the NanoWii signal. By comparing the graphs from experiment 1 and experiment 2, the sequence of movement by the volunteer are elevation, retraction, protraction, elevation, elevation, elevation, retraction, protraction.

After analysing the signals from the IMU, it can be observed that when the sensors are strapped as shown in figure 5-1, the accelerometer x-axis signal generates a clear pattern when the volunteer performed a shoulder elevation and both the accelerometer y-axis and the accelerometer z-axis signal showed clear change when the volunteer performed shoulder protraction and retraction. However the pattern generated by the accelerometer z-axis was more pronounced compared to the accelerometer y-axis and hence was chosen to define the control signal. The gyroscope roll showed clear change in position when the sensor was strapped as shown in figure 5-1.

With the tetraplegic volunteers, if the sensor was strapped as shown in figure 5-1, then the connector wires got tangled with the armrest of the wheelchair. Hence the sensor was mounted such that the Z-axis of the accelerometer and the gyroscope yaw were parallel to the torso of the volunteer. In this position, the gyroscope pitch detected the clear change in position of the sensor compared to the other two gyroscope signal and hence was chosen as the control signal. The patterns recorded from a tetraplegic volunteer are shown in figures 5-27 and 5-28.

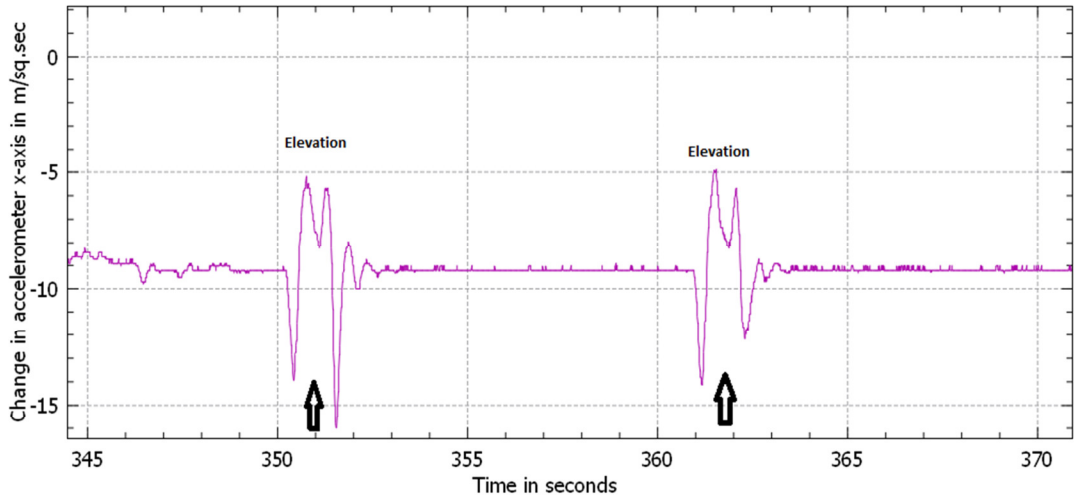


Fig 5-27: Magnified change in accelerometer x-axis signal in m/sec^2 when a shoulder elevation was performed

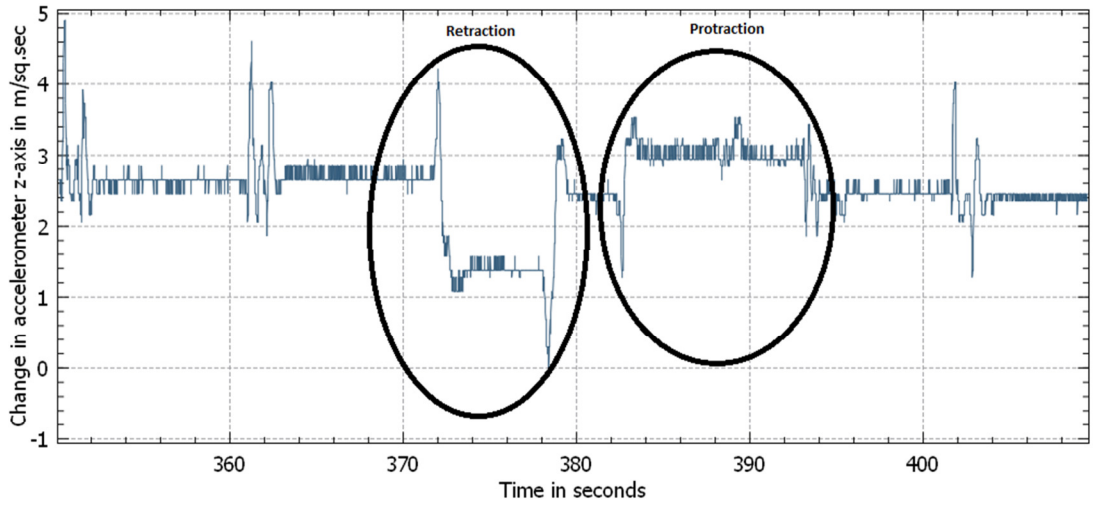


Fig 5-28: Magnified change in accelerometer z-axis signal in m/sec^2 showing the change in signal during shoulder protraction and retraction

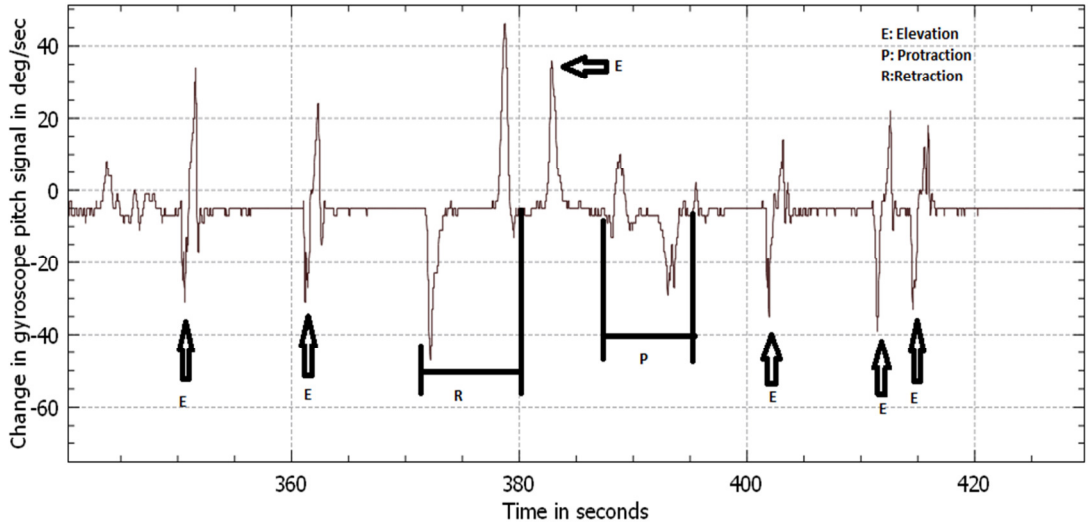


Fig 5-29: Change in Gyroscope Pitch signal in deg/sec showing a significant change when the sensor detected a sudden movement

5.5 Summary

This chapter summarises the results obtained from the two experiments performed in order to analyse the performance of Nanowii. The first experiment asked the volunteers to perform shoulder elevation, protraction and retraction in the given sequence. It then compared the results obtained from the two sensors. The signals from the two sensors were found to be correlated which demonstrates that both the sensors are equally efficient in detecting the shoulder movements.

In the second experiment, the volunteers were asked to perform the shoulder movements in random sequence. From the graphs of experiment 2, shoulder protraction, retraction and elevation can be identified even when the user performs the shoulder movement in a random sequence. These two experiments demonstrates that the Flyduino NanoWii can be used as a MMI for the upper limb FES device and it is possible to define a control signal using the Flyduino NanoWii for controlling an upper limb FES device.

A detailed description of the design of a four channel upper limb FES device called the TetraGrip, that uses the Flyduino NanoWIi as a shoulder position sensor, is provided in the next chapter.

Chapter 6 System design

6.1 Introduction

The system design of a FES device can be broadly divided into two sub-divisions: Software design and Hardware design. The first half of this chapter describes in detail the hardware used to build the TetraGrip four channel FES device. This includes details about the power supply unit that provides supply to all the electronic circuits used in the system, the main controller unit which interprets the control signal and commands the output stages to deliver the pulses according to the stimulation parameters and the output stage that delivers the electrical impulses to the target muscle group. The second half of this chapter provides the detailed description of the software design which includes the details about the modes of operation of the stimulator, the control signal interpretation and the communication between the master controller and the output stages.

6.2 A detailed block diagram of the TetraGrip 4 Channel Stimulator

The hardware of the TetraGrip consists of the following circuits:

- Arduino Mega 2560 as the master controller
- Adafruit powerboost 500mA+ battery charger ciruit
- 3.3 V regulator power supply
- 5V to 3.3V level shifter circuit
- 4 Odstock® Medical Stim Engines
- OML boost circuit for providing the boost voltage to the stim engines

A detailed block diagram of this system is shown in figure 6-1. The Arduino Mega 2560 was the master microcontroller and had the following functions:

- It received the stimulation parameters entered by the clinician using the software interface and wrote these parameters to the corresponding registers of the Stim Engine which delivered the stimulation pulses.
- It received the signals from the Flyduino NanoWill and interpreted the generation of a control signal.
- Based on the control signal generated, it switched ON the corresponding channels in a pre-programmed sequence thereby causing the contraction of muscles.

The output unit consisted of four Odstock® Stim Engines which developed the stimulation envelope based on the entered stimulation parameters. Each channel had preloaded data which defined the pulse width, current, frequency and ON time for each stage of the stimulation envelope. The Odstock® Stim Engines modified their outputs based on the parameters for each stage. The complete stimulation envelope for the key grip and the palmar grasp movements consisted of eight phases and hence eight set of stimulation parameters were preloaded.

The Odstock® Stim Engines and the Arduino Mega 2560 were powered using a 3.8V Lithium ion battery which was charged through an Adafruit powerboost 500mA+ C battery charger using a regular micro USB charger. The whole hardware required three different power supplies. The I/O lines of the Arduino Mega 2560 required 5V supply in order to function properly, the Stim Engines functioned at 3.3V supply and the output section of the Stim Engines required a 12V power supply in order to generate the stimulation output. The Adafruit Powerboost 500+ C circuit generates enough current to power and run all the four Odstock® stim engines but this current is not enough to generate an output of up to 120 mA. The Odstock® Stim engines require 12 V high current power supply to power its output stage. Therefore,

3.3V and 5V regulator ICs were used to ensure regulated power supply to the Arduino Mega 2560 and the Odstock® Stim Engines and an OML boost circuit was used to supply power to the output section of the Odstock® Stim Engines.

The SPI communication lines of the Odstock® Stim Engines were very sensitive to 3.3V signals. The I/O lines of the Arduino Mega 2560 that were used as chip select and enable often caused false triggers especially when the system was reset. The I/O lines of the Arduino Mega 2560 had floating impedance and when the reset button in the board was pressed; it caused the I/O lines to briefly send a 5V signal which was mistaken as a positive signal by the Odstock® Stim Engines which in turn generated an output based on the default parameters.

This false trigger was unacceptable as it caused unnecessary stimulation to the user. Also initially for the EMC testing, the engineers who developed the Odstock® Stim Engines programmed the stimulator to generate an output current of 80 mA. This along with the design flaw of the system posted serious health and safety issue to the user. Hence the engineers reprogrammed the Odstock® Stim Engines to generate an output of 0 mA current as default. The researcher introduced a 5V to 3.3V level shifter with the I/O lines of the Arduino Mega 2560 connected to the 5V input lines of the IC and the corresponding 3.3V output lines were connected to the SPI lines of the Odstock® Stim Engines. These changes to the hardware resolved the false trigger issues and addressed the health and safety risk of the device. The details of the individual circuits used to assemble the TetraGrip are presented in Appendix B. A risk assessment for the device is presented in Appendix E and the ISO 60601 checklist for the TetraGrip is presented in Appendix F. The software design of the device is presented in the next section.

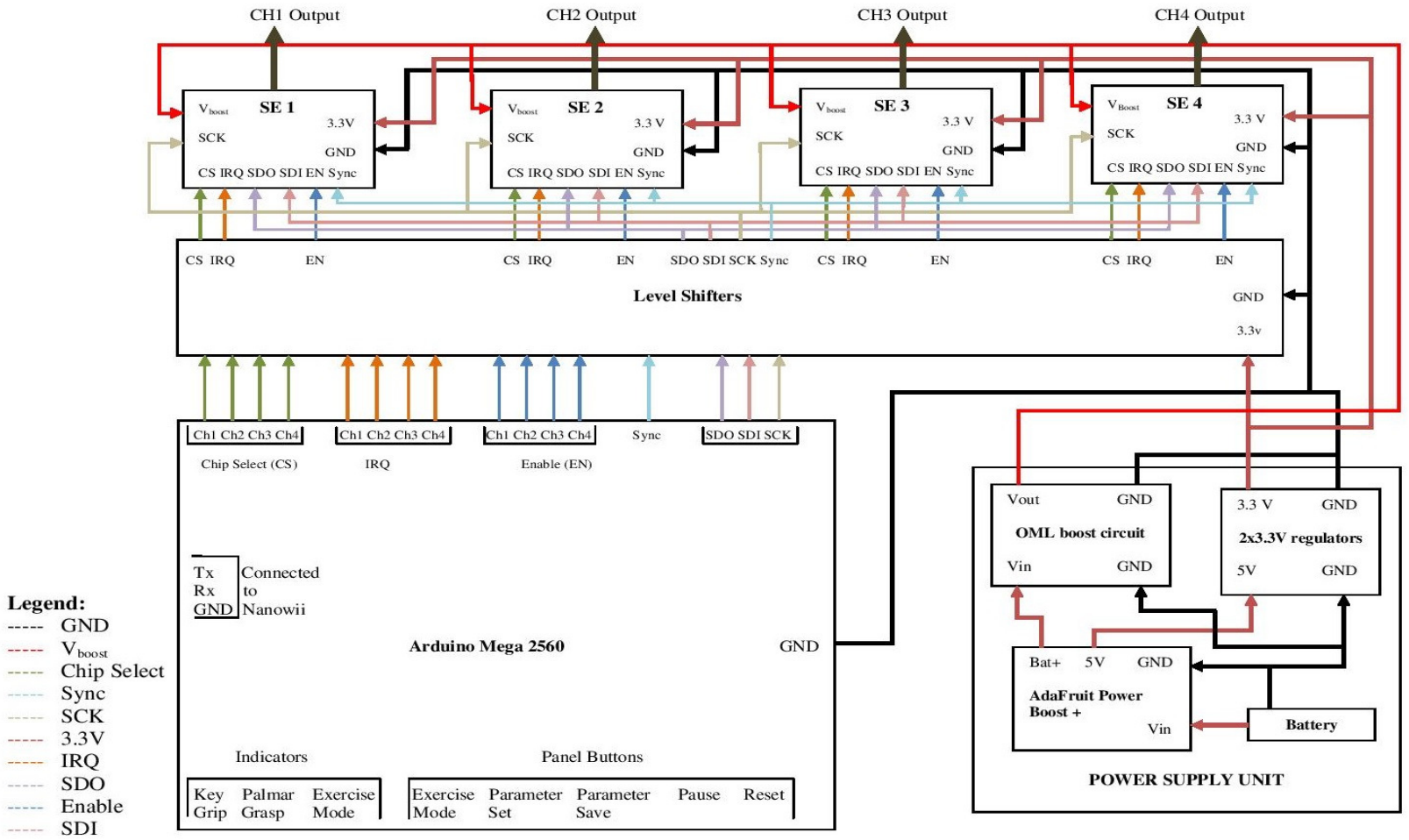


Fig 6-1: A block diagram of the TetraGrip

6.3 Software Design of the TetraGrip

The TetraGrip software can be subdivided into the following parts based on its operation:

- The Stimulation Parameter Setup
- The Control Signal Design
- The Functional and Exercise modes

6.3.1 The Stimulation Parameter Setup

The parameters for the stimulation envelope are: current in mA, pulse width in micro µs, frequency in Hz, ramp times and duration in ms. The current is the minimum value required for getting efficient movement and varies not only from individual to individual but also form one channel to the other. The stim engines can be programmed to generate an output current from 1 mA to 120 mA from 0 to peak. Initially, the TetraGrip software limits the maximum output current to 60 mA from 0 to peak which is same as the maximum output current of a commercially available surface upper limb FES device, the NESS H200(Snoek et al. 2000). But during the clinical trials, it was found out that one of the volunteers with tetraplegia required around 75 mA from 0 to peak current in the finger extensors in order to get good hand opening. Hence the maximum current output was revised to 100 mA from 0 to peak.

The pulse width of the stimulation pulse can be varied from 3µs to 360µs which is the range in most of the commercially available surface FES devices. Initially, the pulse width is set at a default value of 180 µs but the user can modify this value when the system is in a functional mode. A further detailed explanation regarding the change in the pulse width is provided in the section 6.3.2. The frequency of the output waveform can be varied from 20 Hz to 60 Hz (Quandt and Hummel 2014). A common frequency for surface upper limb FES devices in clinical practice is 40 Hz (Quandt and Hummel 2014). The output waveform itself is asymmetric biphasic waveform but the device can be programmed to generate symmetric biphasic

waveform. The time spent by the device in each phase (hand opening, hand closing etc.) is defined by the duration which can be varied from100 ms to 6 s. A slow ramp is preferred for upper limb applications because the opening and closing movement of the hand will not be abrupt and the movements will appear more natural. The default value of the TetraGrip was 1s.

The software of the stim engine was used to calibrate the current in the output unit. The procedure for calibration was provided in the datasheet and the same was referred to perform calibration and ensure that the output was accurate with a tolerance of ±10%. The output waveform was observed in the Picoscope 3405DMSO manufactured by PicoTech. This Picoscope had a band width of 100 MHz and a 256 megasample memory. The sampling rate for recording the singals was 20 Kilo Samples/Second.

For setting up the parameters, the clinician used serial communication software such as the Arduino Serial Monitor, the RealTerm Serial Capture program or the Telegesis Terminal for entering the stimulation parameters. The clinician had to enter the current for all the four channels but had an option of either customising the remaining parameters according to the individual or load the default parameters initially and then modify the required values during the stimulation. During the initial setup, default values for all the parameters were entered by pressing the parameter set button in the front panel and then entering the character 'D' in the serial monitor screen. The default values for all the stimulation parameters were chosen as:

Current: 15 mA peak to peak
Pulse width: 180 µS
Frequency: 40 Hz
Time: 2000 ms

These chosen values were the default parameters used in standard clinical practice and hence were adopted for this research work. The user was then asked to generate the control signal for key grip in order to customise the current for each channel in order to get a good functional response. The

current was set when the stimulation envelope for all the three channels had reached steady phase. Once the stimulator was in steady phase, the current was set by the following procedure:
Initially the character ‘C’ was entered using the computer key board and the characters ‘+’ or ‘-‘ was used to select the appropriate channel.

Next, the character ‘P’ was entered to choose the steady phase for each channel which was known to the clinician.
Once the channel and the phase were selected, the clinician entered ‘i’ followed by ‘+’ and ‘-‘ sign to increment and decrement the current.

The instructions along with the keys for modifying each parameter were displayed in the welcome screen of the serial communication software wnen the device was switched ON. Figure 6-2 is a screen shot of Real Term Communication software with a display of the welcome message once the TetraGrip was switched ON.

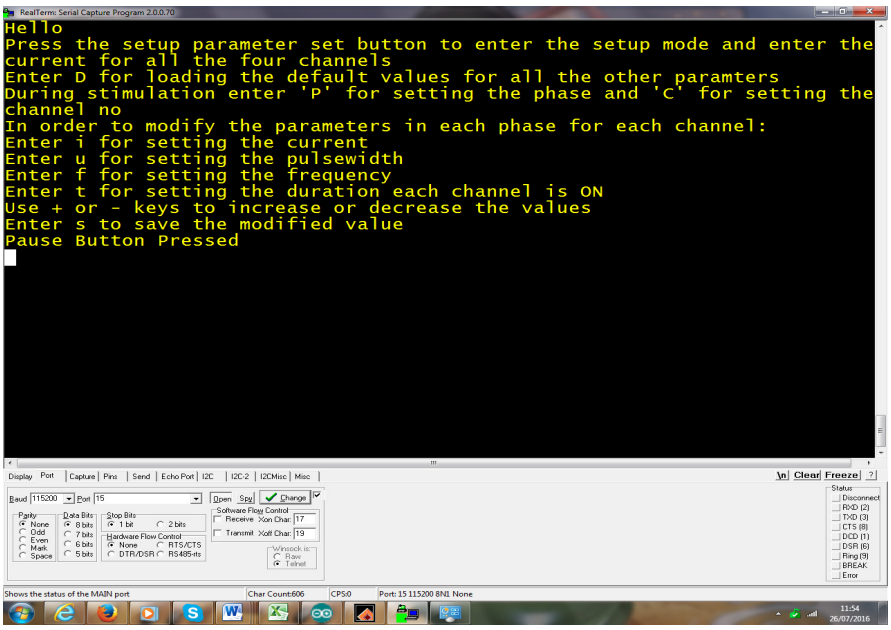


Fig 6-2: A screen shot of The TetraGrip Operation Instructions Displayed on the Serial Communication Interface after Start up

The list of keys for setting up the parameters are:

+ increment the value of the selected parameter

- decrement the value of the selected parameter
P Modify the phase
C Modify the channel
i Modify the current for the selected phase and channel
u Modify the pulse width for the selected phase and channel
f Modify the frequency for the selected phase and channel
t Modify the duration the channel remains ON
s Save the modified parameter
D to load default values for all the channels once the current is entered

Once the parameters for all the phases for each of the channels was set, these parameters were written to the corresponding registers in the stim engine with the help of the SPI communication protocol defined in the data sheet of the Odstock® Stim Engine. Once these parameters were written to the corresponding registers, the system was ready for use. The control signals for manipulating the system are defined in the next section.

6.3.2 The Control Signal Design

The TetraGrip allowed the user to control the operation of the device with the help of the Flyduino NanoWii that was strapped across the contralateral shoulder (shoulder of the arm without the FES) of the user. The device relied on the user's ability to generate the control signals summarised in the table 6-1 for entering the functional modes, modifying the pulse width of the channels controlling the movement of the thumb and for stopping stimulation.

Stimulator State Control Signal	Stimulator Idle	Stimulator Locked	Stimulator Unlocked
Single Shoulder Elevation	Key Grip	Unlocked	Locked
Two shoulder elevations (3 sec apart)	Palmar Grasp	Stop	Alternates between lock and unlock
Shoulder Protraction	NA	NA	Increments the pulse width of Ch3 or Ch4.
Shoulder Retraction	NA	NA	decrements the pulse width of Ch3 or Ch4

Table 6-1: Summary of the Control Signals Used in the TetraGrip

The detailed description of the control signals and the operation of the stimulator when these signals were generated are as follows:

When the stimulator is idle:

1. Single shoulder elevation – Key Grip
2. Two shoulder elevations three seconds apart – Palmar Grasp
3. When the stimulator is in a functional mode (either key grip or palmar grasp):
    a. When the stimulator is locked
        i. One shoulder elevation – Unlock the stimulator
        ii. Two shoulder elevations three seconds apart – Stop Stimulation
    b. When the stimulator is unlocked
        i. Slow shoulder protraction – Increment the pulse width of the channel controlling the thumb
        ii. Slow shoulder retraction – Decrement the pulse width of the channel controlling the thumb
        iii. One shoulder elevation – locks the stimulator and save the modified parameter.

A flowchart with all the control signals is shown in figure 6-3.

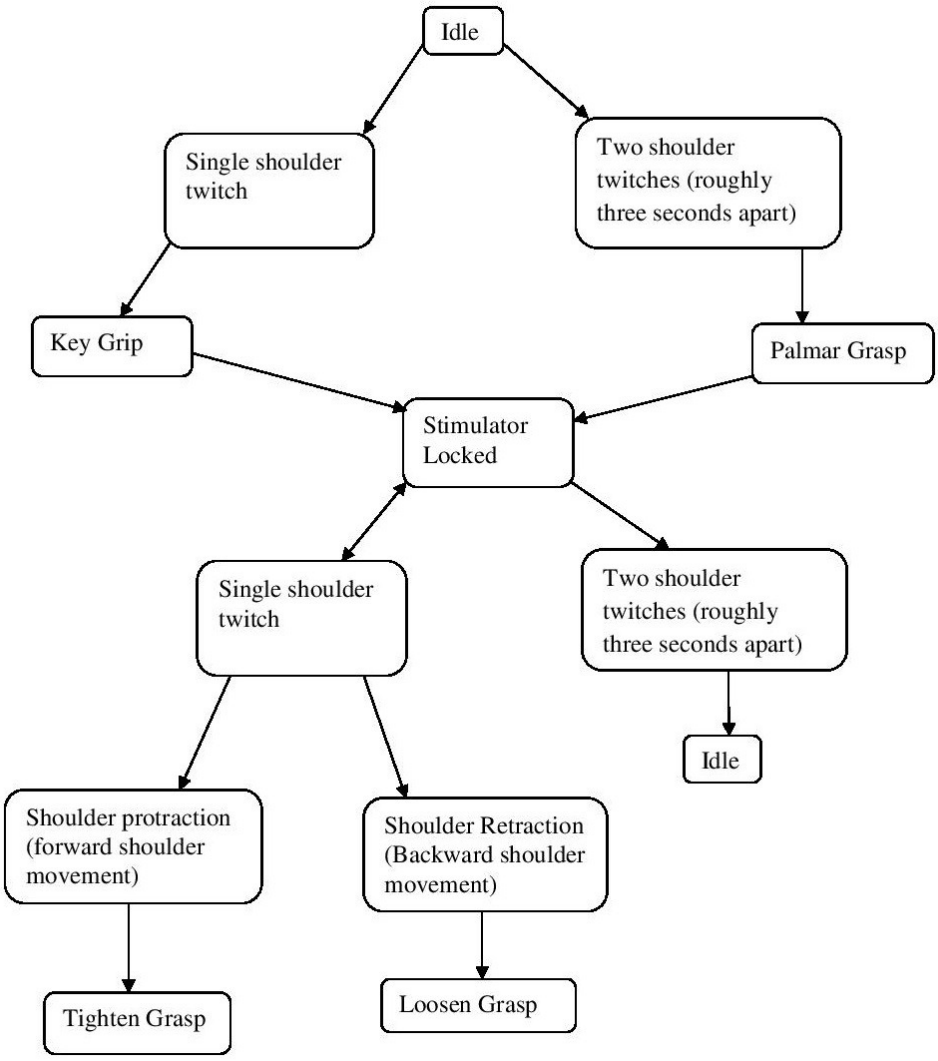


Fig 6-3: Flowchart Describing the Control Signals used to Operate the TetraGrip

The TetraGrip software starts monitoring the change in acceleration in the accelerometer x-axis and the gyroscope pitch data once the stimulation parameters for all the phases when the pause button in the device was released. The device registers a quick shoulder elevation or a shoulder twitch if the values cross a predefined threshold. The threshold values for the accelerometer x-axis, the accelerometer z-axis and the gyroscope pitch data were defined by iterative method. Initially a threshold value was decided based on the movements performed by the researcher. However this value was not suitable for all the able bodied volunteers. The threshold values were modified based on the performance of the volunteers till a value that suited most of the volunteers was finalised.

If a shoulder elevation was registered, the device waited for three seconds to check if the user attempted another shoulder elevation. If only one elevation was registered, then the device entered the key grip mode and if two shoulder elevations were registered, then the device entered the palmar grasp mode. If the device detected more than two twitches, then it resets the count to zero and waited for more attempts.

Once the device was in a functional mode and locked, it continues to monitor the accelerometer x axis and the gyroscope pitch signal to detect either unlock or a stop attempt. If an unlock attempt was detected, the accelerometer z axis signal was monitored for the tightening or loosening the grasp and the accelerometer x-axis signal and the gyroscope pitch signal was monitored to detect a lock signal. If a stop attempt was detected, then the device entered the stop stimulation phase where the stimulation for all the ON channels was turned OFF sequentially. This sequencing is explained in the next section along with the functional and the exercise modes. Figure 6-4 and 6-5 shows the output from the sensor when a volunteer attempted to generate the control signals for entering the Key Grip.

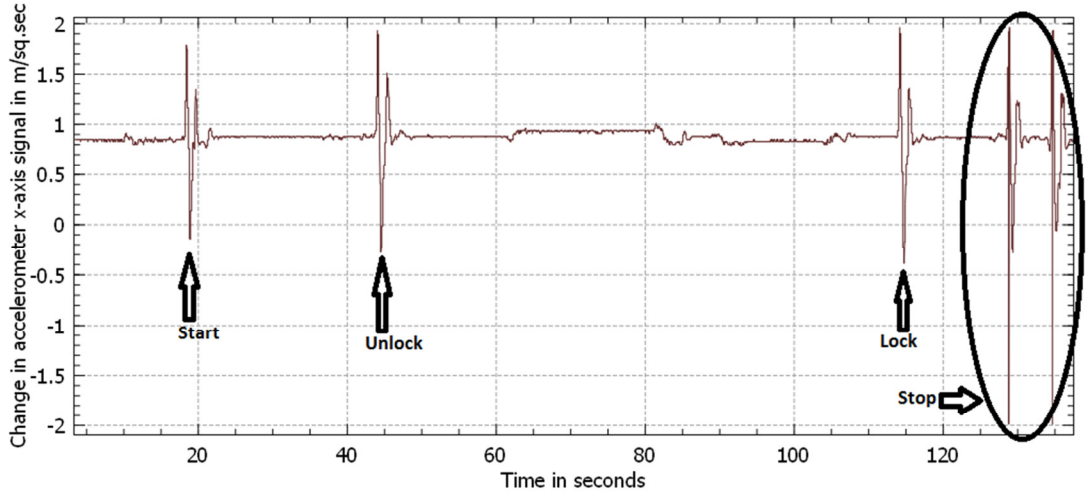


Fig 6-4: Illustration of the shoulder elevation signal recorded for changing the state of the stimulator

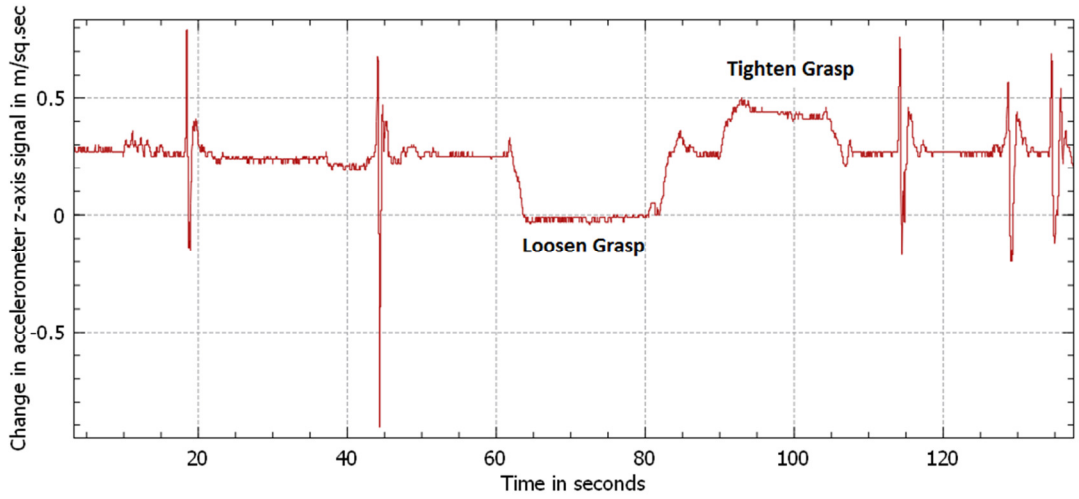


Fig 6-5: Illustration of the control signal for tightening and loosening the grasp

The sensor was strapped across the contralateral shoulder of the user above their clothing. Attempts were made to strap the sensor as tightly as possible. However, the sensor still experienced a small bounce when the user relaxed after performing a shoulder elevation. Due to this bounce a small positive acceleration peak was generated while performing shoulder elevation resulting in the triphasic waveform for the same. A magnified view of a single triphasic waveform is represented in figure 6-6. The DC offset shown in figures 6-4 and 6-5 is the difference between the current and previous value of acceleration detected by the x-axis and the z-axis of the accelerometer.

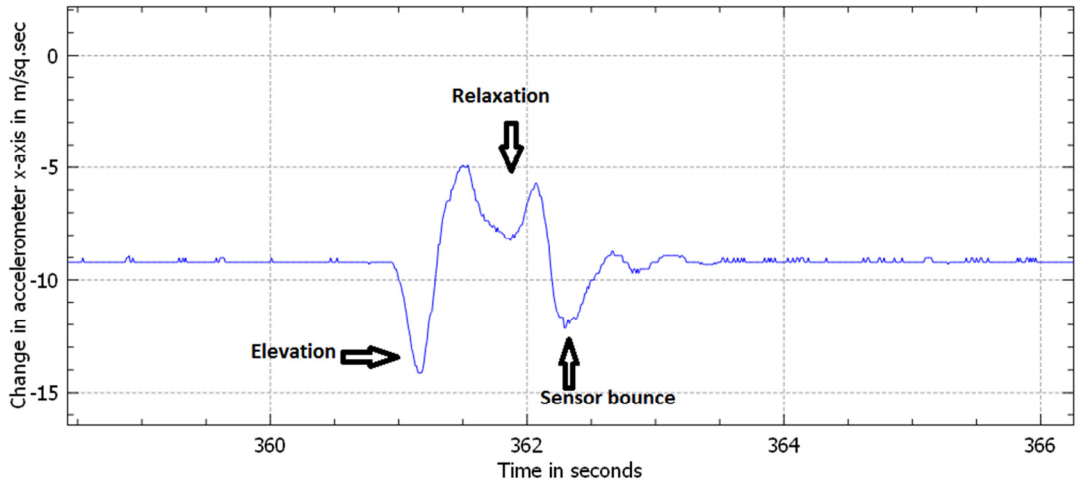


Fig 6-6 Triphasic waveform generated during shoulder elevation and relaxation.

6.3.3 The Functional and Exercise Modes

The two functional modes that help people with tetraplegia perform majority of their ADL are the key grip and the palmar grasp. The key grip mode is used for grasping smaller objects such as a pen or a fork while the palmar grasp movement is used for grasping wider objects such as a can or a cup. In order to achieve the desired hand movement, the corresponding channels of the TetraGrip needs to be switched ON in a particular sequence. These sequences along with the stimulation envelopes for each channel during various stages of the hand movement are summarised in the next section.

6.3.3.1 The Key Grip

The key grip mode closed the hand of the user in a fist and pushed the thumb against the fist (figure 6-7). If the grip was strong enough, then the user could firmly hold a pen and write or hold a fork and eat a meal.

When the system detected the command signal for initiating a key grip, it switched ON the Channel 1 which is connected to the EDC muscle and hence opened the hand and pushed the wrist into extension. Once the stimulation in this channel is ramped up to the desired current and pulse width, the stimulator switched ON the Channel 2 which was connected to the FDS/FDP or the Flexor Incidcis (FI) muscle which caused the fingers to flex. The Channel 4 which was connected to the electrode positioned at the ulnar nerve/ FPL or adductor pollicis muscle was switched ON after Channel 2 reached the steady phase. If both Channels 2 and 4 were switched ON simultaneously, then the thumb got trapped between the fingers and the user was not able to achieve a functional key grip. Throughout the stimulation sequence, the channel connected to the EDC was kept ON because the co-contraction of the flexors and the extensors held the wrist in a neutral position. The pulse width of Channel 1 was however reduced from 180µs to 100µs when other channels were switched ON.

Fig 6-7: The Key Grip

The different states in the key grip mode were: Idle, hand opening, hand closing, key grip, tighten grasp and release object. In the idle state, the system waited for the control signal from the user. Once it detected the control signal for the key grip (one shoulder elevation), the system moved to the next state which was hand opening and remained in this state for a duration specified by the clinician during the setup. The system then switched to the hand closing state which resulted in the flexion of the fingers and once this state timed out, the system moved to the next state which caused the thumb to adduct. The system remained in this state till the user provided the control signal to stop stimulation.

The system allowed the user to manipulate their grasp when the stimulation was ON in a state called Tighten Grasp. This state was entered when the system was unlocked in a functional mode and allowed the user to fine tune their grasp by incrementing or decrementing the pulse width of the channel controlling the thumb (Channel 4). Figures 6-8 – 6-10 explain the sequence of the hand movement, the state diagram and the stimulation envelope for the key grip in detail.

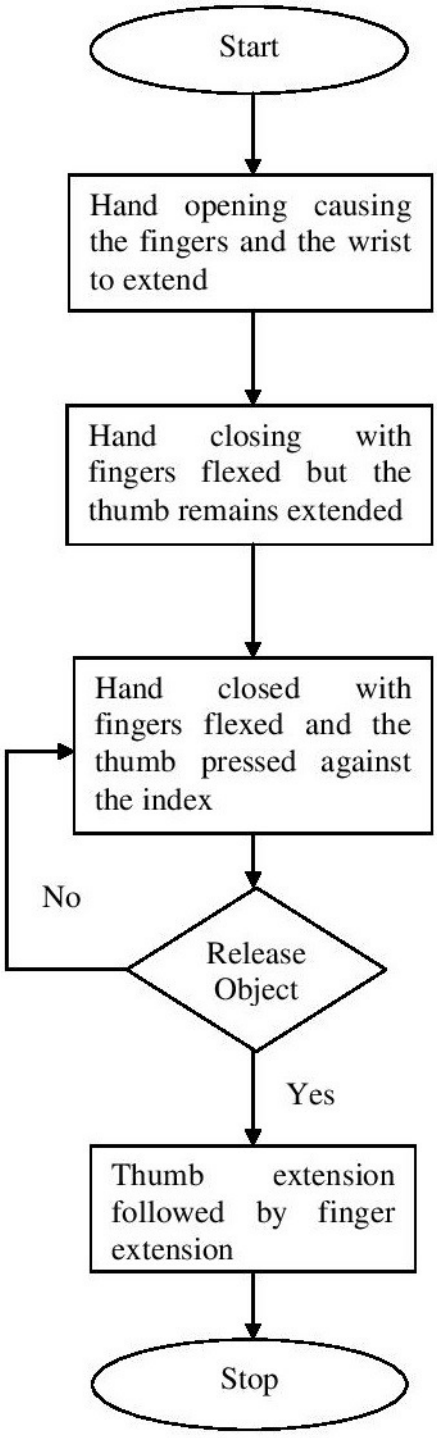


Fig 6-8: Flow chart and hand positions describing the hand movement for achieving a key grip

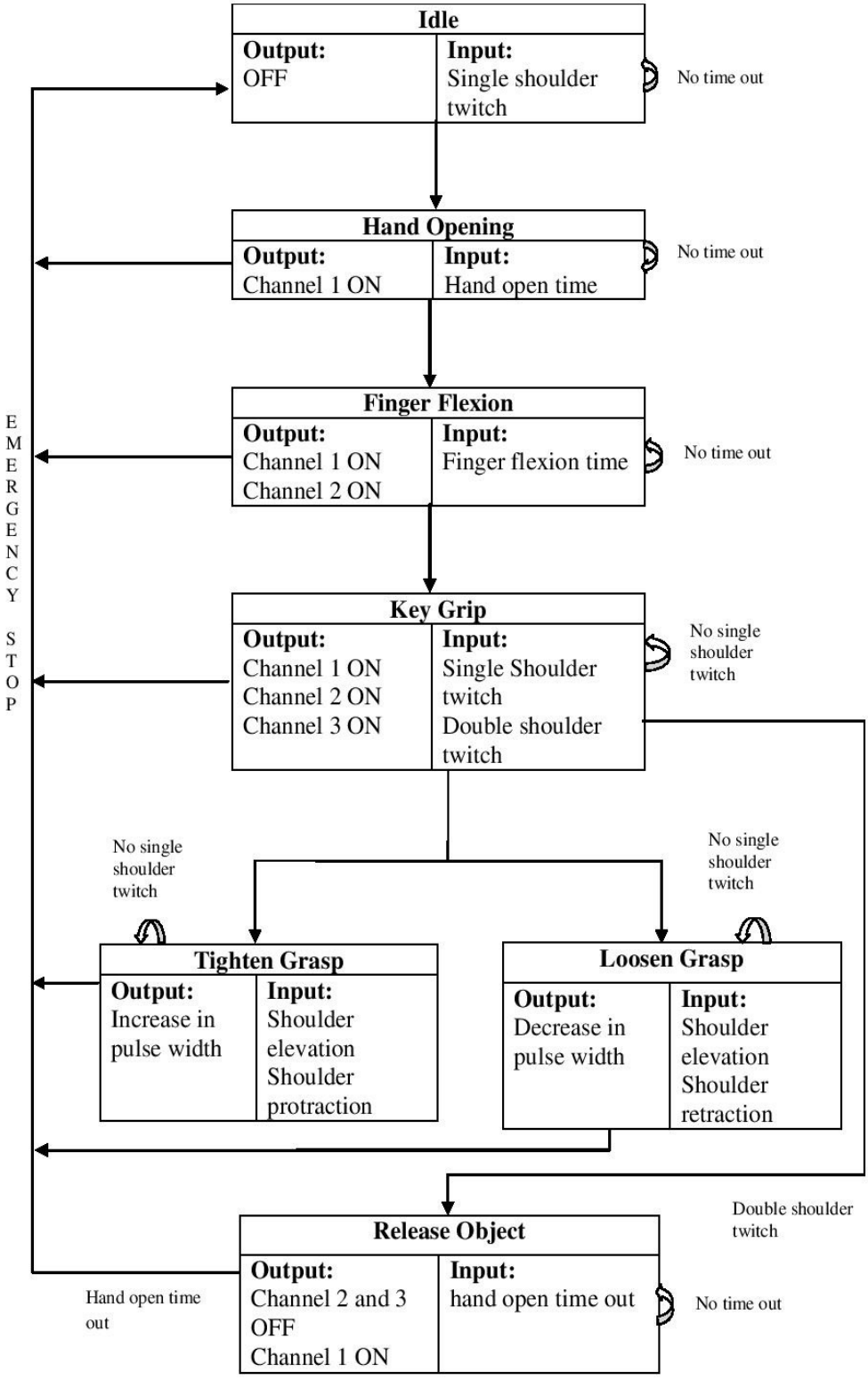


Fig 6-9: State diagram for the Key Grip Movement in the TetraGrip

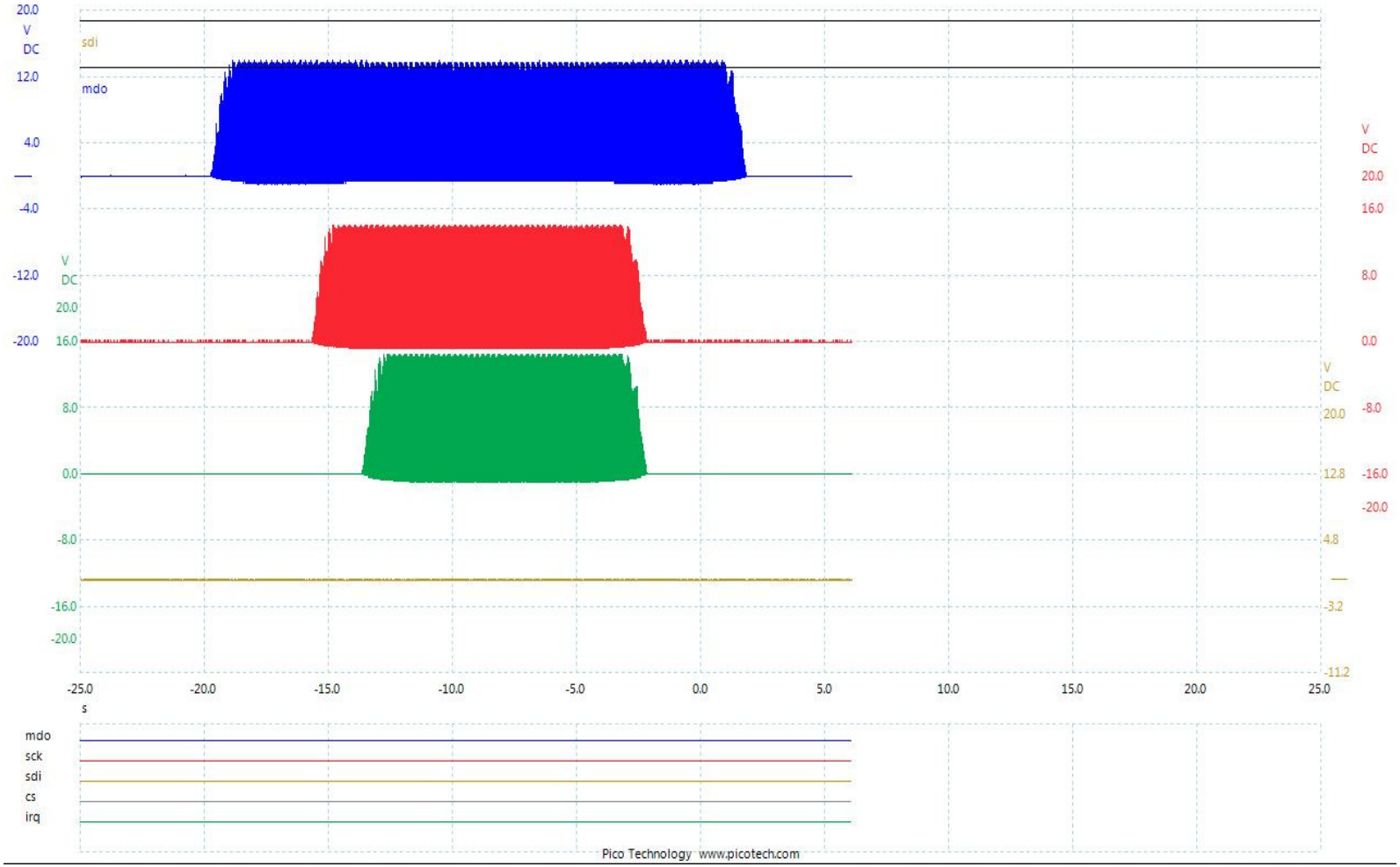


Fig 6-10: Stimulation envelope for the Key Grip: Blue – Channel 1; Red – Channel 2; Green – Channel 4

6.3.3.2 The Palmar Grasp Mode

The palmar grasp mode allowed the user to curl their hand around a wider object such as a cup or a can (figure 6-11). A firm grasp allowed the user to perform activities such as picking up a glass of water and drinking from it or picking up a juice can and drinking from it.

When the system detected the command signal for the palmar grasp, it switched ON the Channel 1 which was connected to the electrodes positioned at the EDC thereby opening the hand. The system then switched ON Channel 3 which causes thumb opposition and allows the user to reach for an object. The system then switched ON Channel 2 which was connected to the FDS/FDP/FI muscle. This caused the fingers to curl around the object to be grasped.

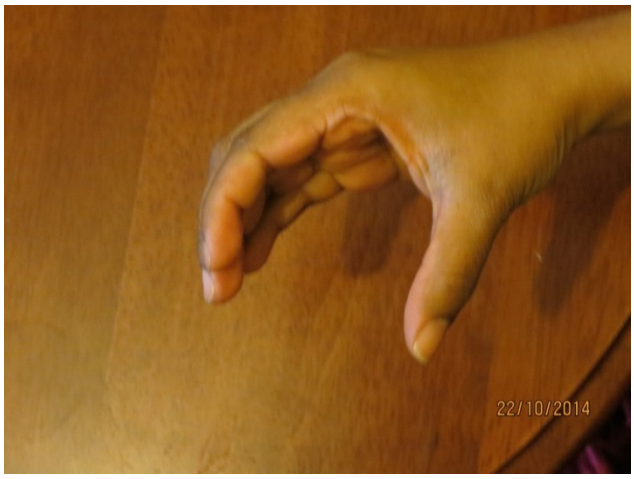


Fig 6-11: The Palmar Grasp

The different states in the Palmar Grasp were: Idle, hand positioning, palmar grasp, tighten grasp and release object. In the idle state, the system waited for the control signal from the user. Once it detected the control signal for the palmar grasp (two shoulder elevations, three seconds apart), the system moved on to the next state which was called hand positioning and remained in this state for a duration specified by the clinician during the setup. During this state, the Channel 1 is switched ON which caused the fingers to extend

and after a specified duration, the system moved on to the thumb opposition state where it switched ON the Channel 3 along with the Channel 1 causing thumb opposition. After this state timed out, the stimulator switched ON the channel 2 which caused the fingers to flex and allowed the user to grasp the object.

The device remained in this state till the user generated the command signal for stop stimulation or if the user hit the emergency stop button. The system also allowed the user to manipulate their grasp by incrementing or decrement the pulse width of the channel controlling the thumb (Channel 3). Figures 6-12 – 6-14 explain the hand sequence during the palmar grasp, the state diagram and the stimulation envelope for the palmar grasp in detail.

The device used to record the signals in figures 6-9 and 6-13 is the PicoScope 3000 series model no 3405DMSO. The X-axis represents time and the y-axis represents voltage. The Y axis represents the voltage output of the waveforms of all the four channels and the values in blue, red, yellow and green represent the Y-axis grid values for channels 1,2,3 and four respectively. The voltages for all the four channels in the figure was ±20V. The signal lines MDO,SDI,SCK,IRQ and CS were the Master Data Out, Slave Data In, Serial Clock, Interrupt Request and Chip select lines used in the SPI communications and were used to debug SPI related issues during the development process. The lines were not used to record any signals when the waveforms in figure 6-10 and 6-14 were recorded because the SPI communication was working reliably.

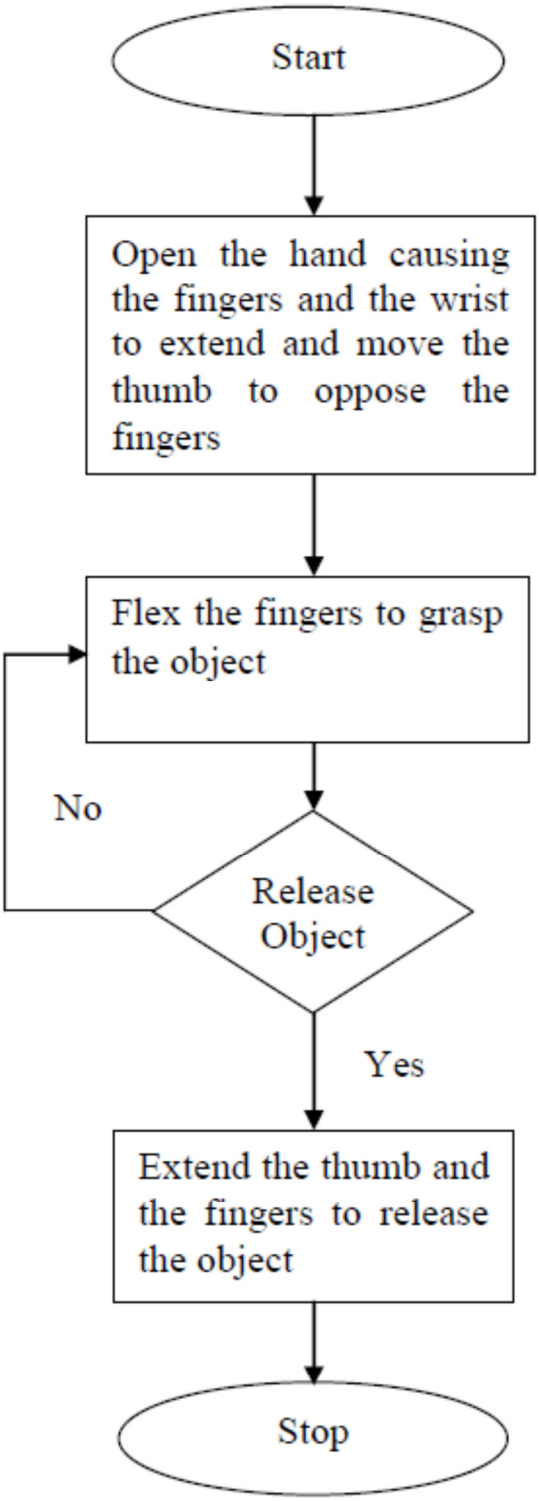


Fig 6-12: Flow chart and hand positions describing the hand movement for achieving a palmar grasp

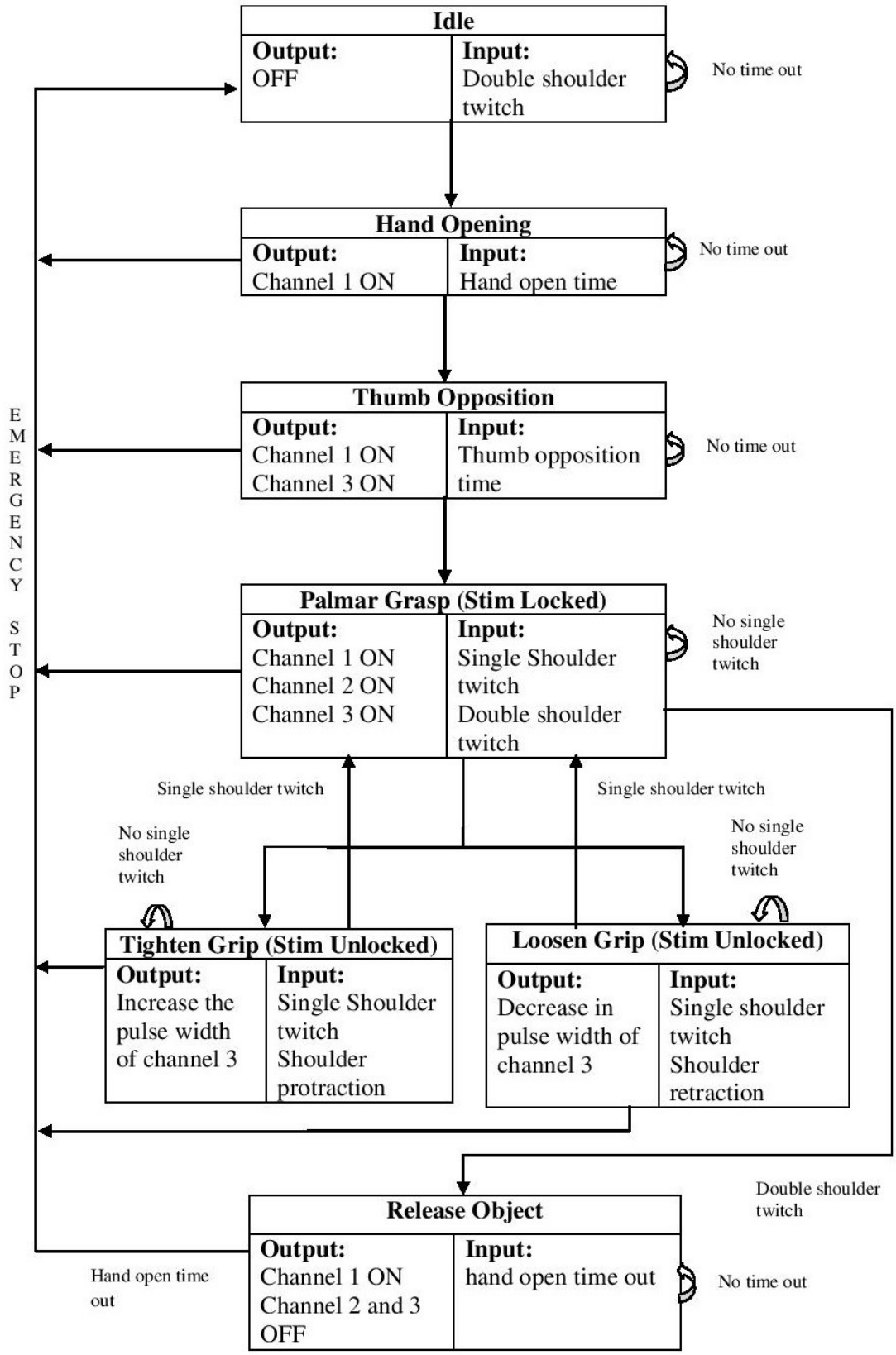


Fig 6-13: State diagram for the Palmar Grasp Movement in the TetraGrip

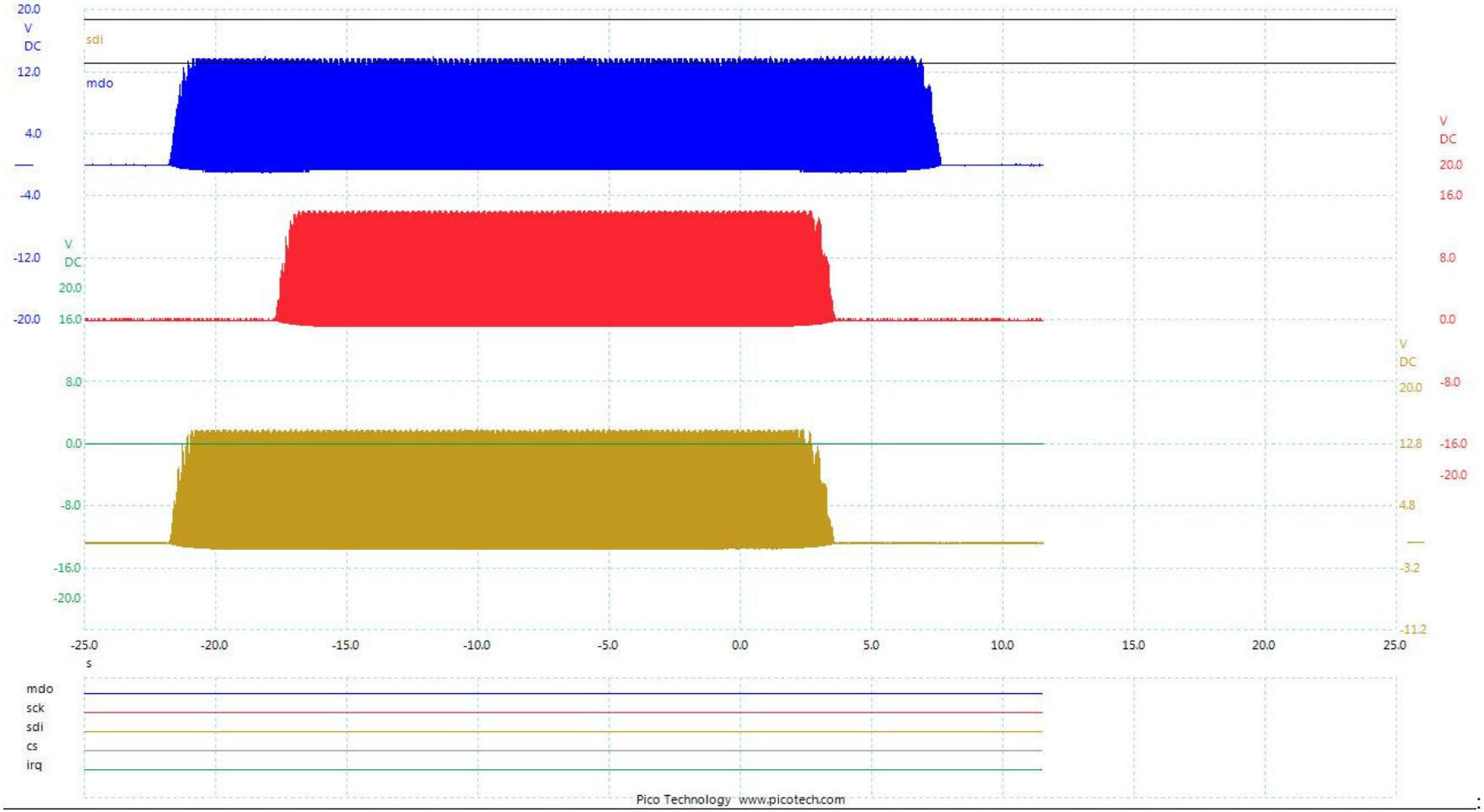


Fig 6-14: Stimulation Envelope for the Palmar Grasp Sequence. Blue – EDC; Red – Finger Flexors; Yellow – Thumb Opposition

6.3.3.3 The Exercise Mode

The TetraGrip was also programmed to operate in exercise mode where the system alternated between the key grip and the palmar grasp movements as explained in the figure 6-15. The stimulation envelope for the exercise mode is presented in figure 6-16. The clinician or the user pressed the exercise mode button once the stimulation parameters were uploaded. Once the button was pressed, the stimulator started the palmar grasp. All the channels ramped up and remained in the steady state for two seconds and then started to ramp down. The whole sequence from initiation to stop stimulation lasted for thirteen seconds. The stimulator allowed the user to rest for eight seconds and then went into key grip mode. The device cycled between the two modes with eight seconds gap till the clinician or the user pressed the parameter set button which resulted in the channels ramping down and stopping stimulation after which the system went into the idle state. Once the system was in the idle state, the user could use the shoulder position sensor to generate the control signals and enter the functional modes.

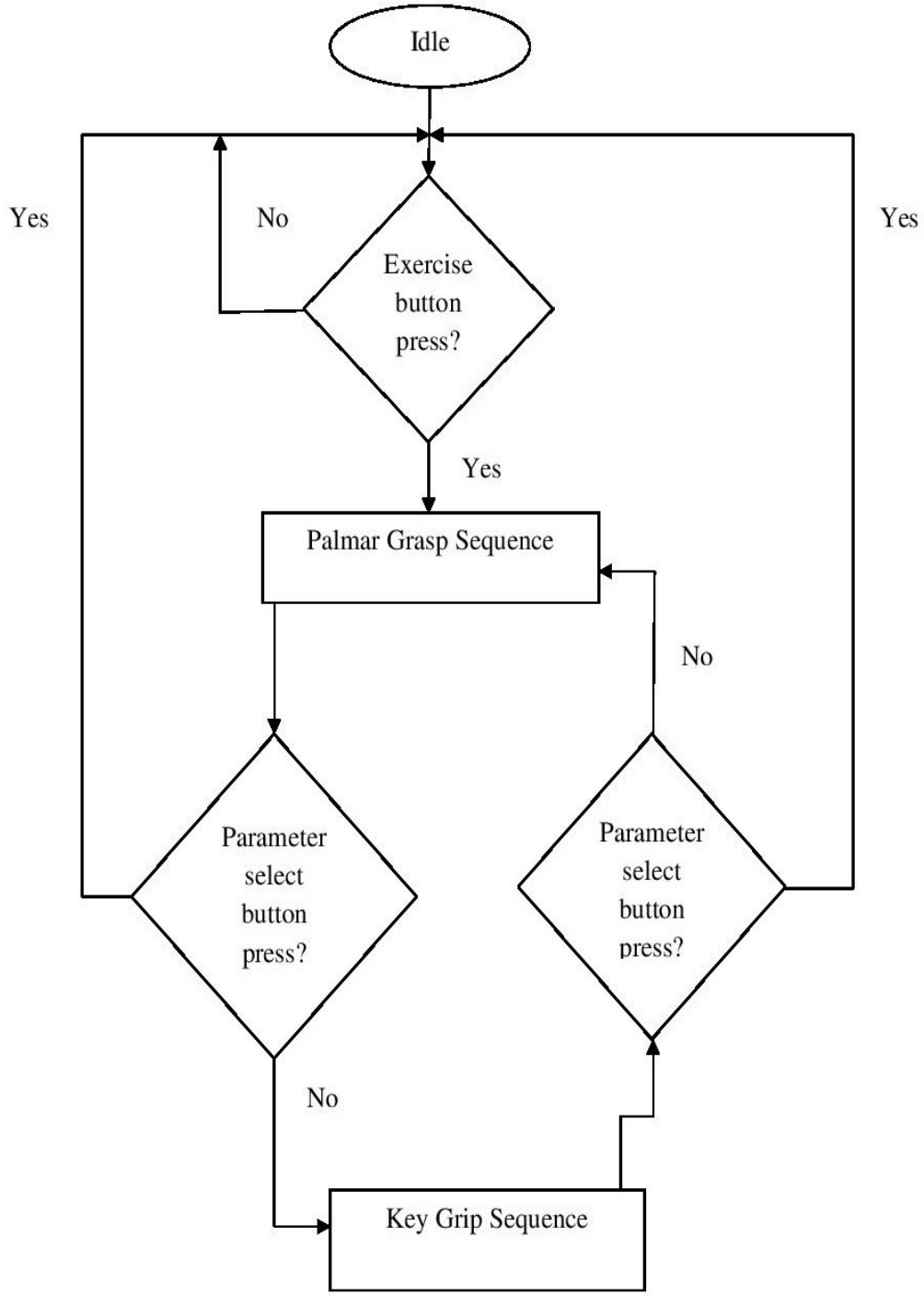


Fig 6-15: Flow chart describing the Exercise Sequence in the TetraGrip

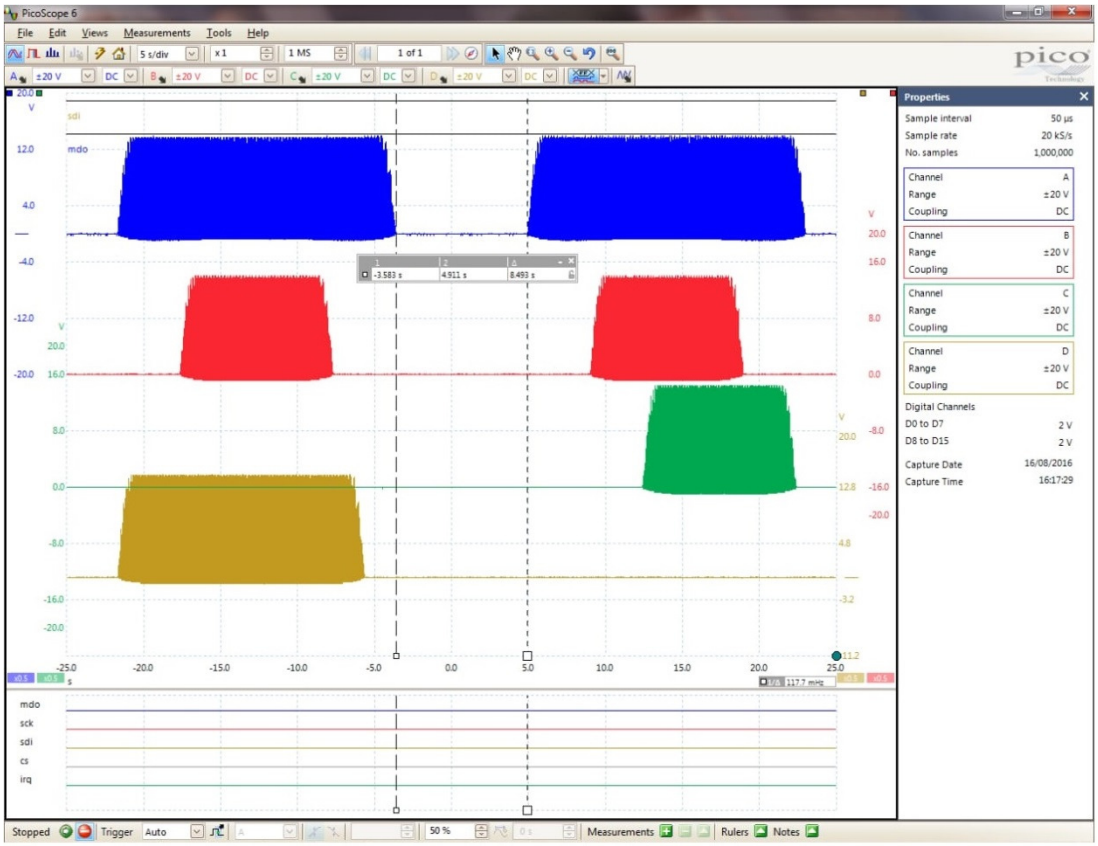


Fig 6-16: Exercise mode of the TetraGrip. Blue: Channel 1 (EDC), Red: Channel 2 (FDS), Yellow: Channel 3 (Thumb Opposition), Green: Channel 4: Thumb Adduction

Once the device was programmed, it was bench tested where the outputs of the device were connected to an oscilloscope and the performance was observed. Once the device performed satisfactorily, it was used in a study involving able-bodied volunteers. The protocol for this study along with the one for the clinical study involving tetraplegic volunteers is presented in the next chapter.

6.4 Summary

This chapter summarises the design of the TetraGrip by providing the details about the various circuits used to assemble the device and the functioning of each of these circuits. The chapter then describes the software of the TetraGrip which is divided into three sections: the stimulation parameter

setup, the control signal design, the functional and exercise modes. The software allows the clinician to enter the stimulation parameters for a particular individual and these parameters are used by the device to develop the stimulation envelope. Another section of the software monitors the signal from the Flyduino NanoWii and detects the generation of a control signal. Based on the control signal, the stimulator generates the stimulation envelope for a particular functional mode by sequentially switching ON the channels. The device performed satisfactorily during the bench test and was used in a study with able bodied volunteers and a clinical study involving tetraplegic volunteers was undertaken. The protocol for these studies is defined in the next chapter.

Chapter 7 Methodology for the Clinical Testing of the Device

7.1 Introduction

A detailed study, divided into two parts, was proposed in order to evaluate the performance of the TetraGrip. In the first part, the performance of the device was analysed when it was tried by able-bodied volunteers. In the second part, the tetraplegic volunteers used the device to perform the tasks specified in the outcome measures and they were awarded scores according to the outcome measures based on their performance. The details of the protocols of both the studies are presented in this chapter.

7.2 Protocol for the Testing of the TetraGrip with the Able-Bodied Volunteers

7.2.1 Aim

To evaluate the repeatability and the reproducibility of the TetraGrip

Fifteen able-bodied volunteers were invited to try the device in order to analyse the repeatability and the reproducibility. Repeatability is defined as the ability of the device on a given day to detect the same control signal when the user produces the same movement and perform the same task. Reproducibility is defined as the ability of the device to perform in a similar manner on two different days when the user uses it to perform the same task. The volunteers were asked to generate the control signals and the number of attempts by the user and the number of times the device detected the control

signals were recorded. The %error between the attempts by the user and the recorded values determined the repeatability of the device. The volunteers were invited for two more rounds of this experiment and the performance of the device was compared to the previous one and the reproducibility of the device was analysed.

7.2.2 The Exclusion Criteria

The volunteers were not included in this research work if:

- They used cardiac pacemaker.
- They were pregnant.
- They had a history of poorly controlled epilepsy.
- There was malignancy around the area of the electrode placement.

7.2.3 The Experiment Protocol

The volunteers were provided with a volunteer information sheet (Appendix C) and on the day of the experiment, they were given time to ask questions and clarify any doubts before testing the device. The working of the device was explained in detail and after which the volunteer signed the consent form. The movements required to generate the control signals were demonstrated and the volunteers were given several practice attempts to generate them. The protocol for the experiment, once the user was comfortable with the generation of the control signal, is summarised below:

- The shoulder position sensor was strapped on the contralateral upper arm as close to the shoulder as possible.
- The motor points of the muscles required for generating functional key grip and palmar grasp movements were identified using Odstock® Microstim FES device.

- Surface electrodes were placed on the motor points identified in the previous step and these electrodes were connected to the stimulator with the help of connectors
- The stimulation parameters for all the four channels were set such that it was enough to generate the desired movement and was comfortable to the user.
- The volunteers were asked to generate the desired control signal and the operation of the stimulator was monitored. They were asked to generate the control signals for the key grip and palmar grasp five times. The control signals for the increment and the decrement of the pulse width was generated as many times as the volunteer wished to.
- The volunteers were asked to come back after a week and the procedure mentioned above was repeated and the performance of the stimulator was observed. The entire experiment was repeated three times on each volunteer.

The stimulator kept a log of the number of times the volunteer initiated the stimulation sequence for the key grip and the palmar grasp movements successfully and the number of attempts by the user was manually counted by the researcher. Analysing the %error was helpful in validating the repeatability and reproducibility of the device using the following formula:

$$\left(Control\ Signal_{attempted} - Control\ Signal_{recoded}\right) * \frac{100}{Contro\ Signal_{attempted}}$$

Equation 7-1: Equation to Calculate the %Error

Also the p value for each control signal was calculated using Wilcoxon Signed Rank Test to see if there was any improvement in the user's ability in generating the control signals as they got used to the device. Once enough data from the able bodied volunteers were collected, the device was clinically tested on people with Tetraplegia. The protocol for this experiment is summarised in the next section.

7.3 The Protocol for the Clinical Testing of the TetraGrip on People with Tetraplegia

7.3.1 Aim

To evaluate the performance of the IMU based upper limb FES device in strengthening the upper limb functions like Key Grip and Palmar Grasp in the people with C5-C7 tetraplegia.

7.3.2 The Recruitment of the Research Volunteers

The volunteers were recruited by advertising in the Newsletter released by INSPIRE, a charitable organisation for people with SCI. A volunteer sheet along with the consent form (Appendix B) was sent to the potential volunteers either by post or through an e-mail. The information sheet provided the details of the experiment and the contact details of the researcher which allowed the volunteers to contact the researcher for asking questions or confirming their participation. The volunteers who agree to participate in the experiment were asked to sign a consent form and were invited for an initial assessment to the National Clinical FES Centre, Salisbury, which was the centre for the clinical trials. The volunteers were also provided an opportunity to ask questions and clarify their doubts before and during the experiments. The volunteers were informed about their right to quit the experiment at any time without giving a reason. Pictures and videos of the experiment were taken if and only if the volunteer agreed do so.

The inclusion and exclusion criteria for the research study is summarised in the next section. These criteria were also clearly stated in the volunteer information sheet.

7.3.3 The Inclusion and the Exclusion Criteria for the People with Tetraplegia

The volunteers will be included in this study if:

- The volunteer had C5, C6 or C7 tetraplegia and responded to electrical stimulation.
- The muscle strength of extensor digitorium communus (EDC), flexor digitorium superficialis (FDS), thumb flexors/extensors and thumb adductors/abductors with electrical stimulation was greater than or equal to 3. The strength was decided based on the medical research council (MRC) scale of muscle strength (table 2-1 in Chapter 2).
- The volunteer was able to understand and comply with the assessment procedures.
- The volunteer was able to give an informed consent.
- The muscle strength of the shoulder muscles was greater than 4 according to the MRC scale.

The volunteers will not be included in this research work if:

- They used cardiac pacemaker.
- They experienced autonomic dysreflexia in response to FES.
- The muscle strength of EDC, FDS, thumb flexors/extensors and thumb adductors/abductors with electrical stimulation was below 3 in the MRC scale of muscle strength.
- They were pregnant.
- They had a history of poorly controlled epilepsy.
- There was malignancy around the area of electrode placement.

7.3.4 Experiment Protocol

After receiving consent from the volunteer, they were assessed as an outpatient and if they were found suitable, the researcher clearly explained the procedure of the experiment and answered the volunteer's questions (if any). This was followed by estimation of the base line values for the outcome

measures. Each volunteer was provided with an Odstock® Microstim stimulator to take home. The electrode placements were explained to the carer and the volunteer was asked to use the device at home for half an hour to an hour every day for 4 weeks. This enabled them in building the required muscle strength. The volunteer then came back once every week for the next 8 weeks and participated in the experiment. For the remaining six days, they used the Microstim for an hour at home. The total duration of the study was 12 weeks.

When the volunteer came back to the clinic after the initial assessment, the researcher explained and demonstrated the movements to generate the control signals and clearly explained what happens when a particular control signal is generated. After the demonstration, the device set-up was completed in the following steps:

- The shoulder position sensor was strapped on the contralateral upper arm as close to the shoulder as possible.
- The motor points for EDC, FDS, Median Nerve and the Ulnar Nerve were identified using Odstock® Microstim stimulator.
- Surface electrodes were placed on the motor points identified in the previous step and these electrodes were connected to the stimulator with the help of connectors.
- The stimulation parameters for all the channels were set so that the stimulation was enough to generate the desired movement and was comfortable to the user.

After setting up the device, the volunteer was asked to generate the control signals for key grip and palmar grasp so that they got used to the control signals and the electrical stimulation. Once the user was confident of using the device, the researchers used the following outcome measures to validate the study.

7.3.5 Outcome Measures

The GRT, the box and block test and the grip test will be used to validate the experiments. The details of these outcome measures are provided below:

7.3.5.1 The Grasp Release Test

The Grasp Release Test (GRT) was formulated by the Cleveland FES group to measure the changes in hand function while using FES. The test consists of six tasks: three requires the use of palmar grasp and three uses key grip.

The tasks in GRT are:

- Picking up wooden pegs and dropping them in a box (figure 7-1)

Fig 7-1: The Pegs task in the GRT

- Lifting a 250g weight and dropping it in a box (figure 7-2)

Fig 7-2: The weights task in the GRT

- Gripping and pushing a plunger down. This device simulates the act of stabbing with a fork and is calibrated to the standard baked potato (figure 7-3)

Fig 7-3: Set up for the Fork task in the GRT

- Picking up wooden cubes and dropping them in a box (figure 7-4)

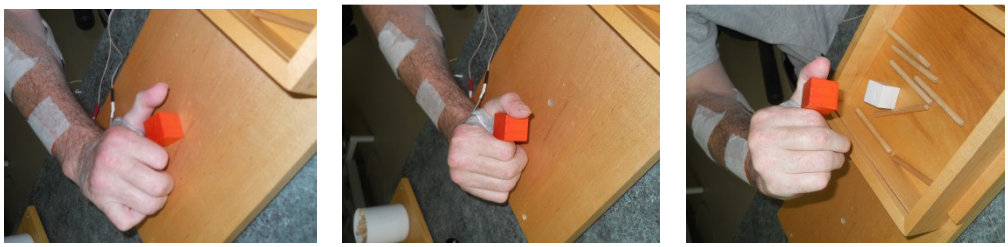


Fig 7-4: The block task in the GRT

- Lifting a plastic cylinder that is similar to a juice can and placing it in a box (figure 7-5)

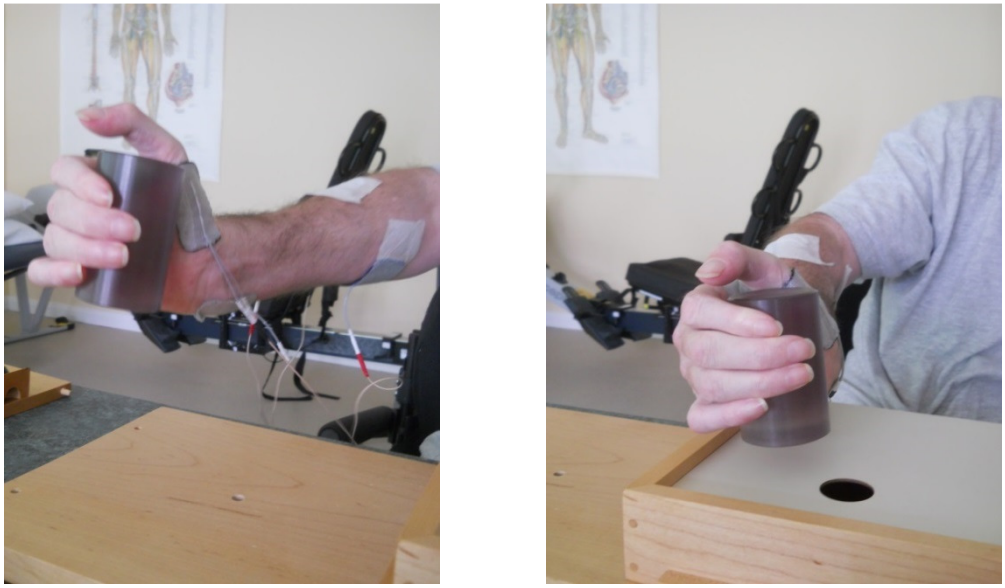


Fig 7-5: The task with the Cans in GRT

- Lifting a video tape and placing it on a box (figure 7-6)

Fig 7-6: Video tape task in the GRT

The number of times the volunteer is able to repeat the tasks with and without FES in 30s is recorded.

7.3.5.2 The Grip Test

The grip strength was measured using a modified pinch meter (figure7-7) which provided information about the improvement in the grip (if any). The pinch meter used for this study was the Modified Jamar Pinch Meter. Extension levers were attached to the device in order to improve its sensitivity. When the user pressed the hand grip, the device provided the mass at the edge of the lever in kilograms. This mass when multiplied with the acceleration due to gravity, provided the force exerted in Newtons. The attachment of the levers however introduced a multiplication factor of three. This was calculated by placing a standard one kilogram weight on the levers and noting the reading on the pinch meter. The dial in the centre was used for zero correction.

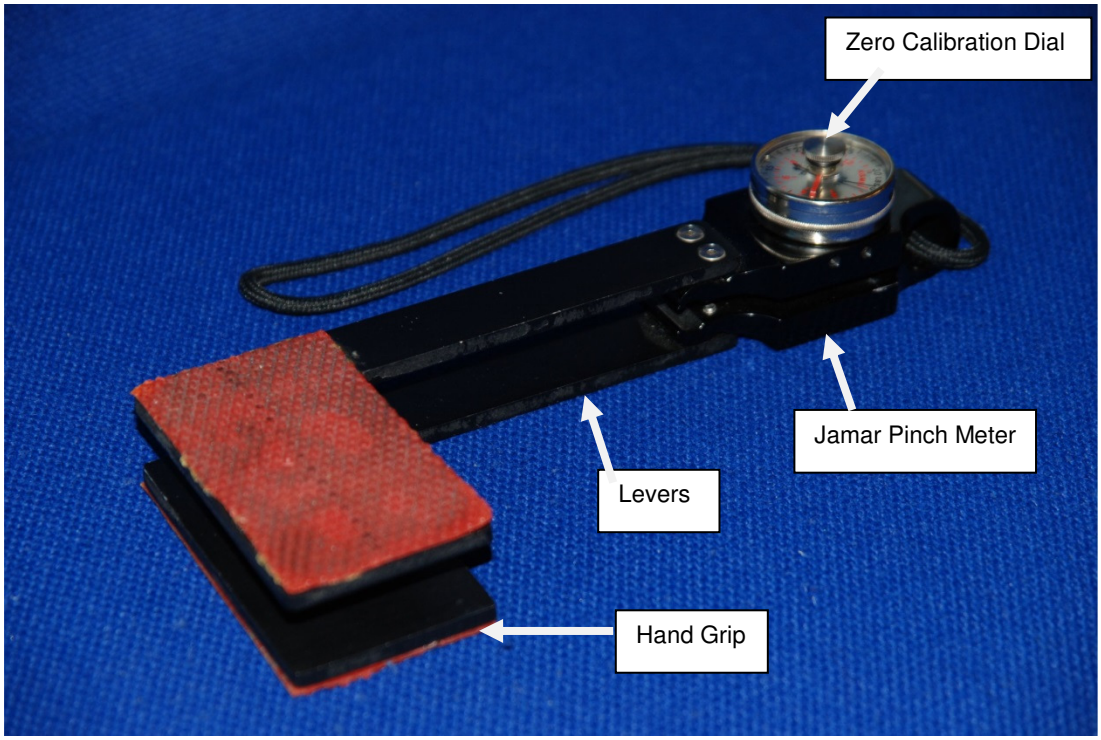


Fig 7-7: The Modified Jamar Pinch Meter

This outcome measure gave a clear idea about the volunteer's ability to perform key grip and palmar grasp and also grip an object on their own. The volunteer performed this test both with and without FES. The readings with FES were used to identify if FES improved the volunteer's ability to grasp an object better when compared to their grasp without the use of FES. The reading without FES were used to idenfity any possible training effect. A volunteer performing palmar grasp grip strength is demonstrated in figure 7-8.

Fig 7-8: The grip strength test using modified pinch meter

7.3.5.3 The Box and Block Test

The box and block test (figure 7-8) required the volunteer to pick up blocks and transport it over a barrier to the other side of the box. Firstly, the task was repeated without the use of FES. The volunteer is allowed a 15 seconds trial period to get used to the test and then they are asked to repeat the test for a minute. After the test the number of blocks transported. Box and block test was performed without the use of FES. The user was asked to exercise using FES during the week and performed the test once in a week and the scores were assessed on a weekly basis. This outcome measure provided information about the improvement in the user's ability in performing activities without the use of FES.

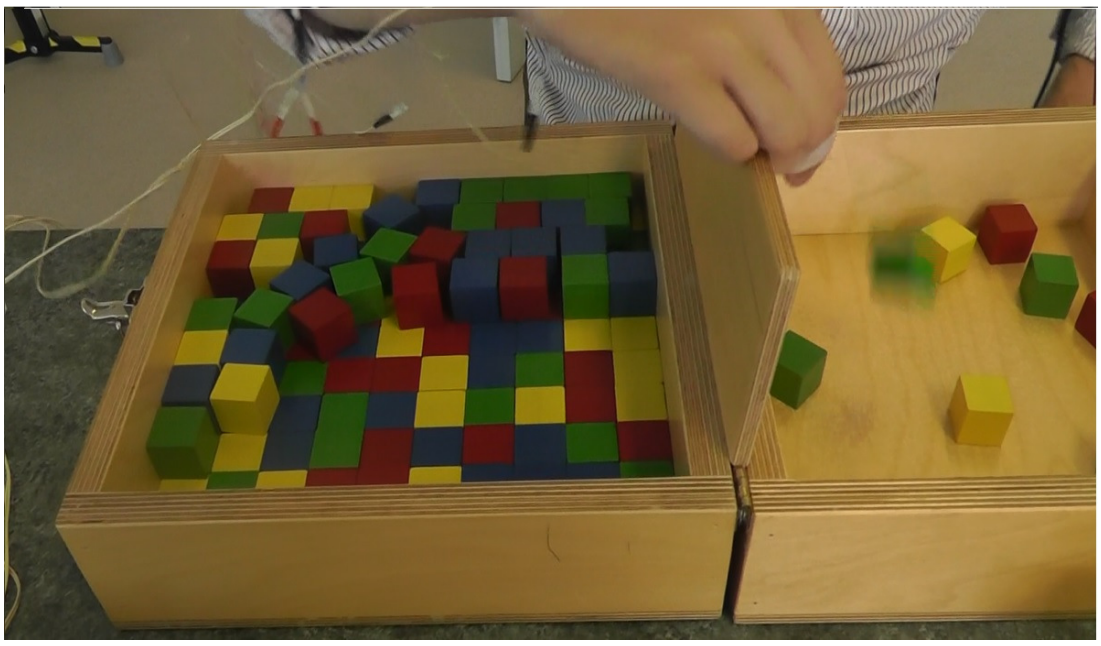


Fig 7-9: Box and Block Test

The time duration for this experiment will be approximately 90 seconds. The normal range for both the right and left hand for people between the age group of 20-45, which is the range of age of both the tetraplegic volunteers who participated in the clinical study, is approximately 80 blocks in 90 seconds. The volunteers will be asked to come once in a week to the clinic and the experiment described above will be repeated and their GRT, box and block test and grip strength scores will be recorded. The travel costs for up to 100 mile round trip will be paid to the volunteer.

7.3.6 Ethical Considerations

The risks associated with the electrical stimulation in this experiment are no greater than when FES is applied in the clinics. The main risk associated with this experiment will be mild discomfort caused due to the electrical stimulation and skin irritation caused due to the electrodes. If the participant experiences any adverse reaction, the stimulation will be stopped immediately and they will be excluded from the study. The protocol for the experiment along with the ethical clearance is provided in Appendix B.

7.4 Summary

The protocol for the clinical study to validate the TetraGrip is summarised in this chapter. The procedure for the recruitment of the volunteers and the purpose of each of the experiments is explained in detail. Firstly, the device will be tried by the able bodied volunteers in order to assess the repeatability and the reproducibility. If the performance of the device is satisfactory, then people with tetraplegia will be invited to the National Clinical FES Centre in Salisbury to try the device. A series of outcome measures like the grip strength test, the box and block test and the GRT will be used to assess the user's performance over eight weeks' time.

The results obtained from both the studies are summarised in the next two chapters.

Chapter 8 Results from the able-bodied volunteers

8.1 Introduction

The TetraGrip was clinically tested on able bodied volunteers in order to evaluate the repeatability and the reproducibility of the device. Repeatability measures the device's ability to give the same output for the same conditions without changing the test setup. Reproducibility measures the ability to get the same output when the test condition is recreated on three different days (**Day 1**, **Day 2** and **Day 3**). Fourteen able bodied volunteers participated in this study.

Once the functioning of the device was satisfactory, people with tetraplegia were invited for a clinical study. The duration of the study was twelve weeks and the main objectives were:

- To test if a person with C5-C7 tetraplegia can use the device to perform the specified tasks.
- To test if the repeated use of FES improves the person's ability to grip and grasp objects.

Ten tetraplegic volunteers were invited to participate in this study and two agreed to participate for the whole study. Both the volunteers (referred as Volunteer 1 and Volunteer 2 in this chapter) were male aged between 20-50 years and were C6 complete.

The results from the fourteen able-bodied volunteers and the two tetraplegic volunteers are summarised in next sections of this chapter.

8.2 Testing of the TetraGrip on Able-Bodied Volunteers

Fourteen able bodied volunteers participated on **Day 1** of the study. On **Day 2** and **Day 3**, nine volunteers participated and six were not able to participate because of their work commitments. Out of the nine able bodied volunteers, the first two volunteers to try the device provided valuable feedbacks to improve the device. Based on their feedbacks, the device underwent a lot of changes before the others tried it. Hence the results from these two volunteers are presented as a pilot study and the results from the others are used to establish the repeatability and the reproducibility of the device. The able-bodied volunteers will be addressed as **ABV followed by their volunteer no** in an attempt to anonymise their identity.

8.2.1 Pilot Study Results with ABV1 and ABV2

ABV1 and ABV2 were the first two able bodied volunteers to test the TetraGrip. For AVB1, the setup of the TetraGrip was successful with functional key grip and palmar grasp. But the shoulder position sensor did not work very well for him as there were numerous occasions of false triggers. He had to try hard to generate the control signal and repeated attempts to generate the same proved both tiring and frustrating for him. Also the control signals for tightening and loosening the grasp did not work for him as he found moving his shoulder in a slow and controlled manner for reaching the threshold very difficult.

For AVB2, the setup of the device was successful as it produced functional key grip and palmar grasp but again there were numerous occasions of false triggers and he struggled to control the device using the shoulder position sensor. He was not able to protract and retract his shoulder in a slow and controlled manner and hence the control signals for the tightening and loosening of the grasp did not work for him either.

The **Day 1** results for volunteers ABV1 and ABV2 are presented in tables 8-1 and 8-2 and the same results are represented as graphs in figures 8-1 and 8-2.

	Start	Lock	Unlock	Tighten Grasp	Loosen Grasp	Stop
AVB1 (p = 0.1)	29	35	5	-	-	62.5
AVB2 (p = 0.6)	28.6	54.5	76.6	-	-	54.5

Table 8-1: Average %Error for Key Grip for ABV1 and ABV2 before the modification of the threshold values

	Start	Lock	Unlock	Tighten Grasp	Loosen Grasp	Stop
AVB1 (p = 0.4)	64.2	43.8	68	-	-	73.6
AVB2 (p = 0.1)	64.2	63.3	59.3	-	-	54.5

Table 8-2: Average %Error for Palmar Grasp for ABV1 and ABV2 before the modification of the threshold values

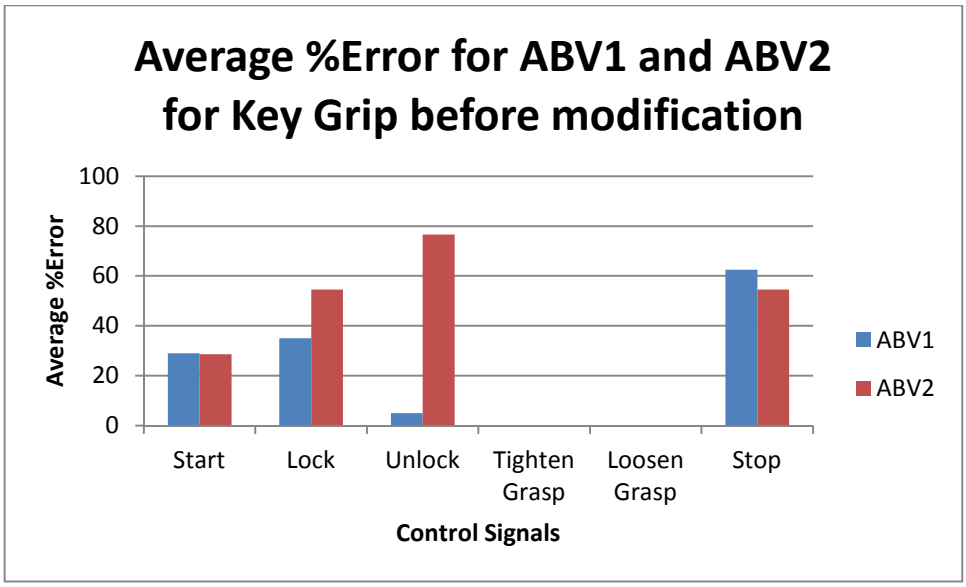


Fig 8-1: Graphical Representation of Table 8-1

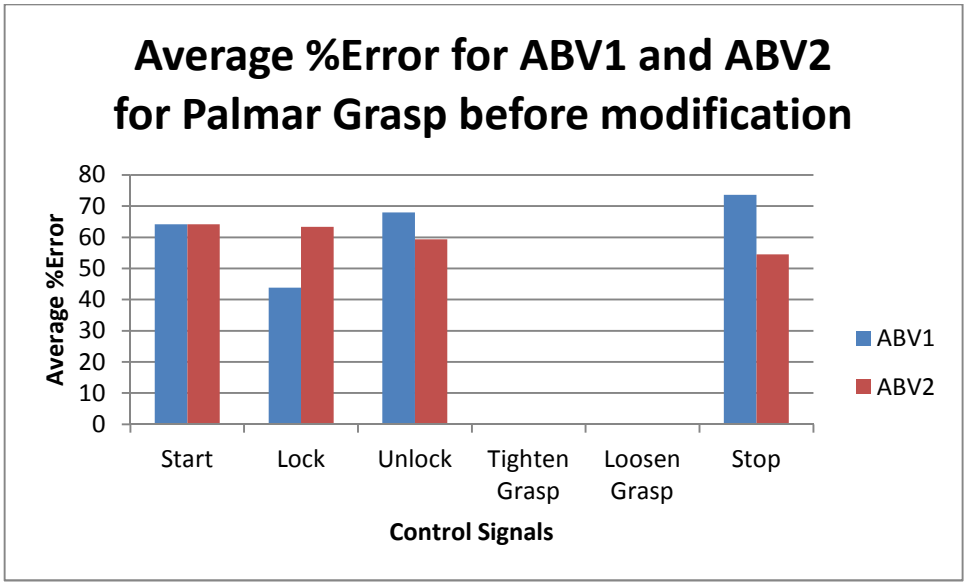


Fig 8-2: Graphical Representation of Table 8-2

After analysing the data from the tables 8-1 and 8-2 and the figures 8-1 and 8-2, it can be concluded that both the volunteers found it difficult to generate the control signals as the %error for key grip and palmar grasp ranged between 28.8% - 76.6% and 0 – 73.3% respectively. The Wilcoxon Signed Rank Test revealed that the p values for the result obtained for key grip ranged between 0.1 and 0.4 and those for palmar grasp ranged between 0.1 and 0.6. The main reason for these %error and p values was the threshold set for the control signals.

Since both the volunteers found the sensor too sensitive and it was detecting shoulder de-bounce as a lock/unlock signal, the threshold values for all the control signals were changed. Initially, the shoulder elevation was detected only when the change in acceleration in the acceleration X-axis was 10 deg/sec or more and the change in gyroscope pitch was 50 deg/sec or more. This setting worked when the researcher bench tested this device but didn't work well for ABV1 and ABV2. When the threshold values were revised, then the change in acceleration in acceleration X axis was 3 m/sec^2 or more and the change in the gyroscope pitch was 20 deg/sec. This reduced the effort the volunteer had to put in order to generate the control signal using shoulder elevation.

The change in acceleration for the acceleration Z axis was increased from 0.25 to 0.5 m/sec^2. This ensured that the volunteer did not have to move their shoulder in an extremely slow and controlled manner. If the threshold was increased more than 0.5 m/sec^2, then the fast shoulder protraction was mistaken as a shoulder elevation which resulted in false triggers. ABV2 was invited again on the same day to try the device and he was able to generate the control signals more efficiently. ABV1 was not able to come back for another study immediately because of his work commitments. He was able to participate for the **Day 2** and **Day 3** studies. The results obtained from ABV2 before and after the modification on **Day 1** are documented in table and a graphical representation of the same is provided in figures 8-3 and 8-4.

	Start	**Lock**	**Unlock**	**Tighten Grasp**	**Loosen Grasp**	**Stop**
Before (*p* = 0.6)	28.6	54.5	76.6	0	0	54.5
After (*p* = 1)	0	0	0	0	0	0

Table 8-3: Key grip average %error for ABV2 before and after modification

	Start	**Lock**	**Unlock**	**Tighten Grasp**	**Loosen Grasp**	**Stop**
Before (*p* = 0.1)	64.2	63.3	59.3	0	0	54.5
After (*p*=0.4)	0	14.3	16	0	0	0

Table 8-4: Palmar grasp average %error for ABV2 before and after modification

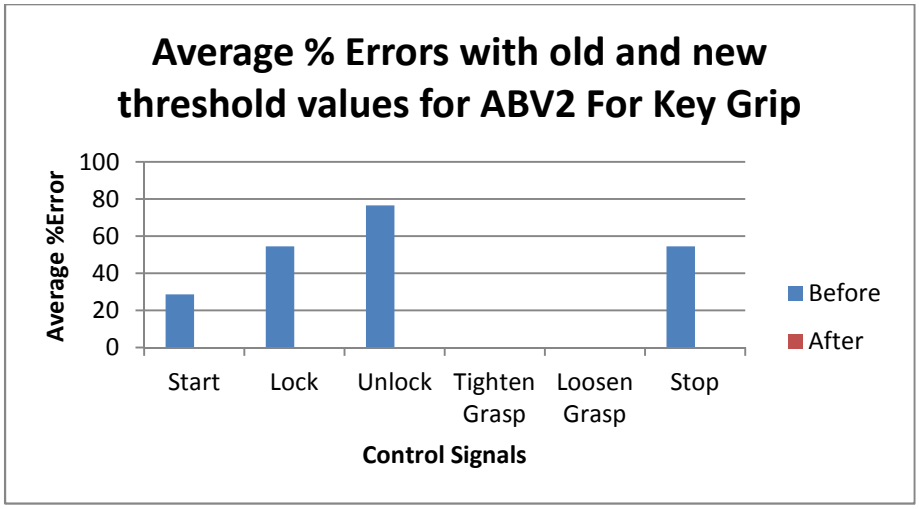


Fig 8-3: Graphical representation of the average %error for key grip for ABV2

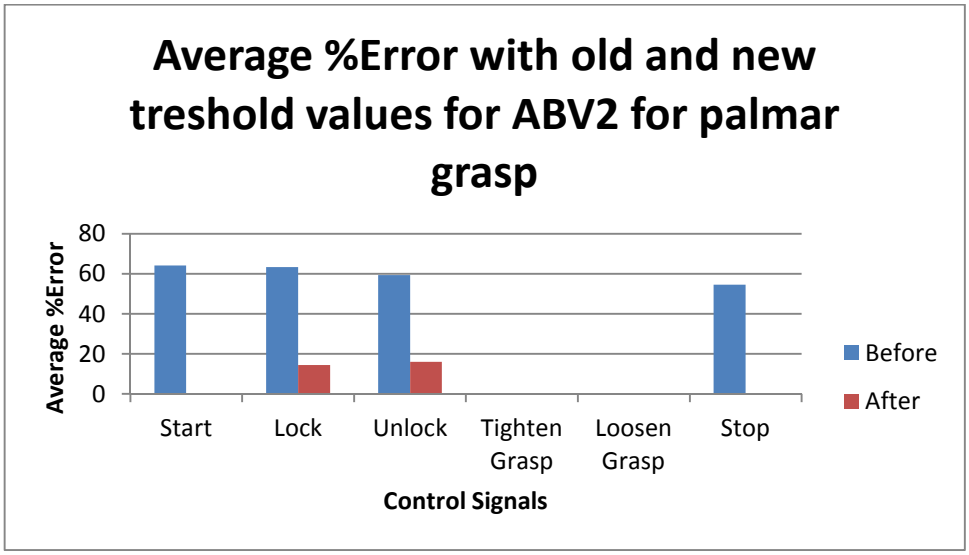


Fig 8-4: Graphical representation of the average %error for palmar grasp for ABV2

From the data in tables 8-3 and 8-4 and the graphs 8-3 and 8-4, ABV2 was much efficient in controlling the device with the new threshold values. The average %error with the new threshold values for the control signals for key grip was 0% and for palmar grasp it ranged from 0-16% compared to 28.6 – 76.6% and 54.5% – 64.2% for key grip and palmar grasp respectively with the old threshold values. The p value calculated using Wilcoxon signed rank test for the results obtained from ABV2 improved from 0.6 to 1 for key grip and 0.1 to 0.4 for palmar grasp

Both ABV1 and ABV2 also suggested implementing a feedback system that would indicate the successful generation of the control signals and indicate the state of the stimulator. Also both the volunteers could not generate the control signals for the tightening and loosening the grasp, that section of the software was reprogrammed as there were bugs in that section of the software and the feedback system was implemented. There were three LEDs available in the front panel: blue, green and orange. After reprogramming, the blue LED lit up when the system was in Key Grip and locked. If an unlock signal was detected, then both the blue and orange LED started blinking. When the tighten grasp signal was detected, the brightness of the orange LED increased accordingly. The orange LED was brightest when the channel controlling the thumb reached a pulse width of 360 µs. The brightness of the orange LED gradually faded when the control signal for loosening the grasp was generated.

The average %error for ABV1 and ABV2 for Day 1, Day 2 and Day 3 for key grip and palmar grasp is presented in tables 8-5 and 8-6 and the graphical representation of the same is presented in figures 8-5 and 8-6.

	Start	**Lock**	**Unlock**	**Tighten Grasp**	**Loosen Grasp**	**Stop**
Day 1	28.8	44.75	40.8	0	0	58.5
Day 2	8	24.5	16.5	62.5	20	14.3
Day 3	8	7.15	32.5	32.5	0	16

Table 8-5: Key Grip Average %Error for the results obtained on Day 1, Day 2 and Day 3 for ABV2 and ABV3

	Start	**Lock**	**Unlock**	**Tighten Grasp**	**Loosen Grasp**	**Stop**
Day 1	64.2	53.55	63.65	0	0	61.8
Day 2	0	36	20	32.7	26.8	8
Day 3	0	14.5	22.75	71.4	7.5	0

Table 8-6: Palmar Grasp average %error for ABV2 and ABV3 for the results obtained on Day 1, Day 2 and Day 3

The p values for both the volunteers for all the three days are summarised in table 8-7.

	Key Grip			Palmar Grasp		
	Day 1	**Day 2**	**Day 3**	**Day 1**	**Day 2**	**Day 3**
ABV1	0.1	0.3	0.06	0.4	0.3	0.3
ABV2	0.4	0.6	0.8	1	1	1

Table 8-7: The *p* values for the results obtained on Day 1, Day 2 and Day 3 for ABV1 and ABV2

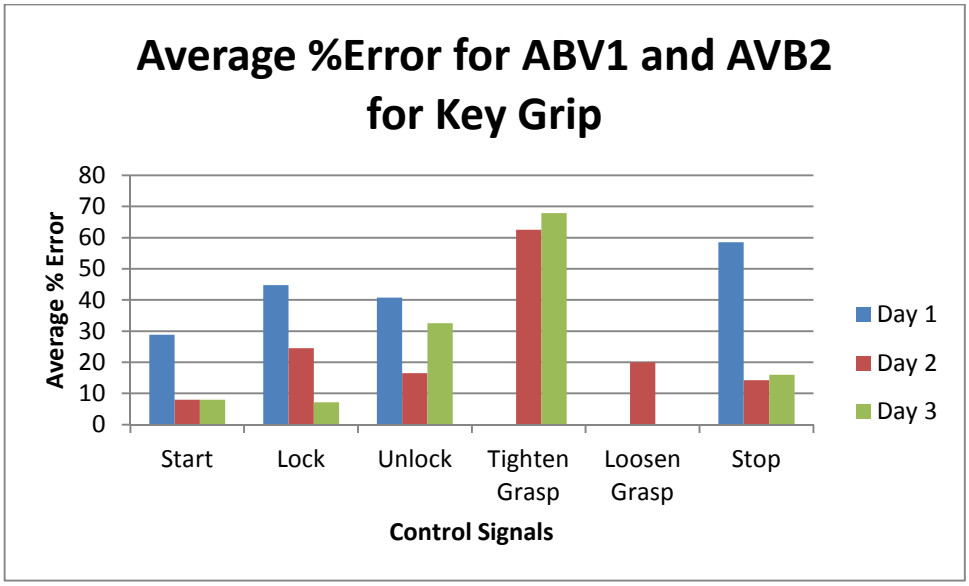


Fig 8-5: Graphical representation of table 8-5

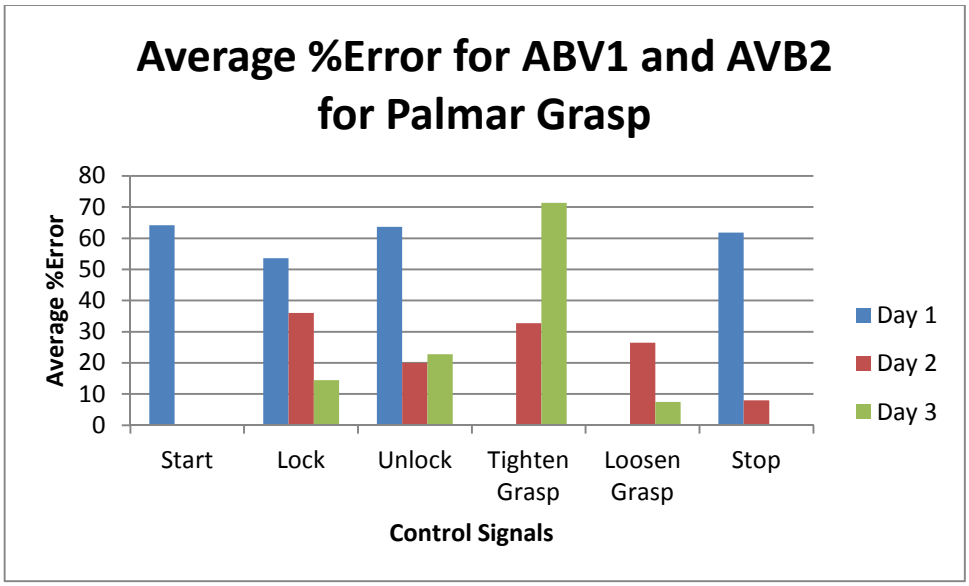


Fig 8-6: Graphical representation of table 8-6

The performance of both the volunteers improved on **Day 2** and **Day 3** when compared to **Day 1**. However ABV1 faced problems while generating the control signal for tighten grasp because he found moving the shoulder forwards slowly and in controlled manner very challenging. ABV1 failed to register even a single increment and decrement signal on **Day 3** which is the reason for the decrease in the p values on **Day 3** for this volunteer. There was a steady improvement in the p values for the key grip results from ABV2 which indicated improvement in his ability to generate the key grip control signals and a p value of 1 for the palmar grasp indicated that ABV2 was able to generate all the control signals for the palmar grasp efficiently. The results obtained from other volunteers after implementing the changes done in this pilot study is summarised in the next section.

8.2.2 The results obtained from other able bodied volunteers

Out of the fourteen volunteers who participated on **Day 1**, the results from ABV1 and ABV2 were included in the pilot study described in the previous section. From the remaining twelve volunteers, the setup for one volunteer was not successful and she could not participate in the rest of the study due to her work commitments and four volunteers did not participate on **Day 2** and **Day 3**. The results obtained from the remaining seven volunteers who participated on all three days of the experiment are presented in the tables 8-8 and 8-9.

	Start	**Lock**	**Unlock**	**Tighten Grasp**	**Loosen Grasp**	**Stop**
Day 1	2.482	23.55	20.35	8.821	16.04	9.0
***p* values**	1	0.2	0.8	1	1	0.23
Day 2	4.571	29.48	35.7	13.4	16.95	11.21
***p* values**	0.37	0.06	0.06	0.2	0.1	0.6
Day 3	2.28	7.31	3.21	1.42	10.92	2.28
***p* values**	1	0.6	1	1	0.4	1

Table 8-8: Average % Error and *p* values for Key Grip for the rest of the able bodied volunteers

	Start	Lock	Unlock	Tighten Grasp	Loosen Grasp	Stop
Day 1	9.928	24.21	19.42	15.28	20.17	7.65
***p* values**	0.17	0.5	0.13	0.3	0.1	1
Day 2	6.28	27.6	20.65	15.21	9.64	13.52
***p* value**	1	0.1	0.1	0.18	0.18	0.17
Day 3	4.57	5.15	15.14	2.14	7.14	6.37
***p* value**	0.4	1	0.1	1	1	0.4

Table 8-9: Average % Error and *p* values for Palmar Grasp for the rest of the able bodied volunteers

A graphical representation of the results obtained from the rest of the able bodied volunteers is presented in figures 8-7 and 8-8.

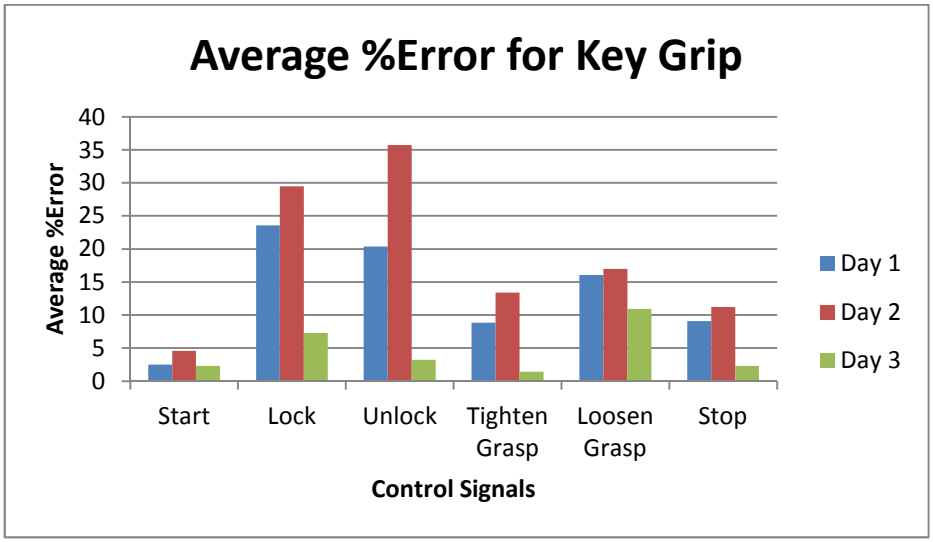


Fig 8-7: Graphical representation of table 8-8

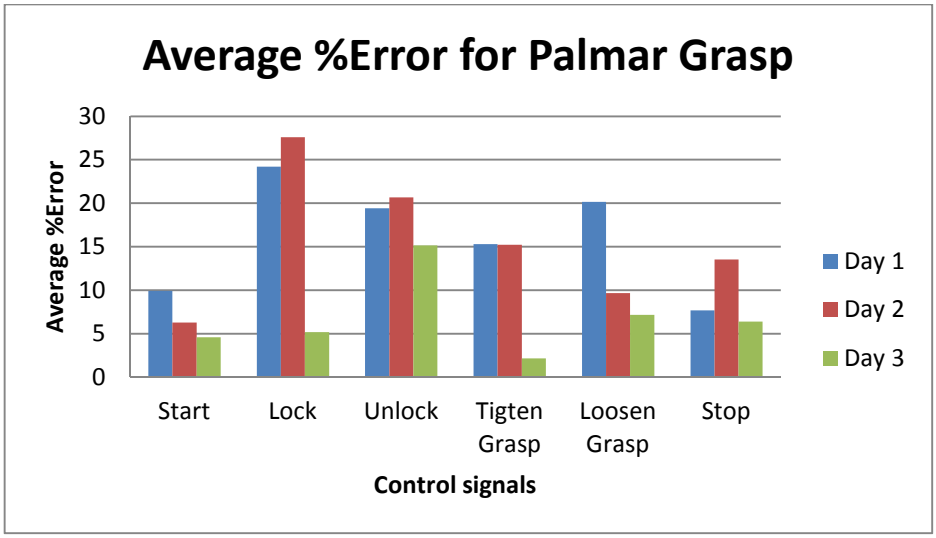


Fig 8-8: Graphical representation of table 8-9

From the graphs in figures 8-7 and 8-8, the average % errors for key grip and palmar grasp improved from 2.482% – 23.55% on **Day 1** to 2.28% – 10.92% on **Day 3** and 9.928% – 24.21% on **Day 1** to 4.57% - 15.14% on **Day 3** respectively. There was improvement in the p values as well for most of the controls signals which indicated that the volunteers got better when they got more opportunities to generate the control signals.

The % errors for all the control signals for both key grip and palmar grasp was higher and the p values were lower on **Day 2** compared to **Day 1** and **Day 3** mainly because of the high %errors and low p values for volunteers ABV3 and ABV5. There was a significant gap between the time when ABV3 did his **Day 1** and **Day 2** experiment but the gap between **Day 2** and **Day 3** was approximately one week and hence ABV3 was able to generate the control signals more efficiently on **Day 3**. When ABV5 performed the **Day 2** experiment, there were few occasions of shoulder de-bounce because his elbow was hitting the armrest of the chair he was sitting upon when he was generating the control signals for Lock and Unlock and this resulted in a high %error.

From the experiment with able bodied volunteers, it was observed that the volunteers were able to generate the required control signals with good efficiency once they had enough opportunity to try the device which indicates

a learning effect. The FES setup was successful on most of the volunteers and the possible combination electrode positions for successful setup were identified. Identification of the electrodes positions in this experiment helped in better setting up during the clinical case studies with Tetraplegic volunteers. The device was working reliably without any major breakdown issues and was ready to be used by people with tetraplegia. The results obtained during the clinical testing on two volunteers with tetraplegia is summarised in the next section.

8.3 Clinical Testing of the TetraGrip on People with Tetraplegia

The results from the clinical study of the two tetraplegic volunteers are presented as two case studies in the subsequent sections because both the volunteers were very different and came across different challenges while using the device.

8.4 Results from the Clinical Study for Volunteer 1

The results obtained during the clinical study with Volunteer 1 are divided into the following sections: The initial assessment, week by week progress and the results from the outcome measures which are presented in the next few sections.

8.4.1 Initial Assessment

Volunteer 1 was a male in his mid-forties and acquired his injuries due to a paddle pool accident. He was clinically diagnosed as C6 ASIA complete and was right handed both pre and post injury. He was neurologically stable and didn't have any history of diabetes, skin breakdowns or epilepsy. He didn't use a pacemaker but he did have a history of autonomic dysreflexia. The volunteer had not used FES before, his previous episodes of autonomic dysreflexia were not triggered by the use of FES and therefore he was included in the study. Since he was aware of the symptoms for autonomic

dysreflexia, he was asked to stop the use of FES immediately if he encounters any symptoms with FES.

He used a hybrid wheelchair for moving from one place to another and was able to move independently at home but needed help occasionally while moving in the community. He held a pen between his index and middle finger for writing and used his knuckles to type and used a touch-screen phone. He used adopted cutleries for eating and held his drinks with both hands.

When the upper extremity muscles for the Volunteer 1 were assessed, it was found out that he had really strong biceps, Br, pronators, supinators and wrist extensors but had weak triceps, very weak wrist flexors and no strength in the finger muscles. He had pins and needles like sensation in his fingers and palms and this sensation was less towards his ring and little fingers compared to the other three fingers.

8.4.1.1 Response to the Electrical Stimulation

Volunteer 1 had good voluntary wrist extension and good range of movements in his shoulders but showed very weak response to stimulation at EDC and the median nerve. There was no response to stimulation at FPL but the response to stimulation was very good at the ulnar nerve and FDS. Hence the electrodes were placed at the following positions:

- Hand opening: EDC
- Finger Flexion: FDS
- Thumb opposition for palmar grasp: Opponnens Pollicis as the median nerve stimulation was not very effective
- Thumb Adduction for key grip: Ulnar Nerve.

The common indifferent electrode for the finger extensors was placed at the forearm and the electrode at FDS was used as the indifferent electrode for the two thumb electrodes. The volunteer used Odstock® Microstim with one channel connected to the finger extensors. The second channel was

connected to the finger flexors and the ulnar nerve for strengthening the key grip. Once he exercised these muscles for a specified duration, the connector at the unlar nerve electrode was connected to the electrode placed at Opponens Pollicis to enable him to exercise the palmar grasp muscles for the specified duration and strengthen his palmar grasp. Figure 8-9 shows the position of the electrodes for functional key grip and palmar grasp for Volunteer 1.

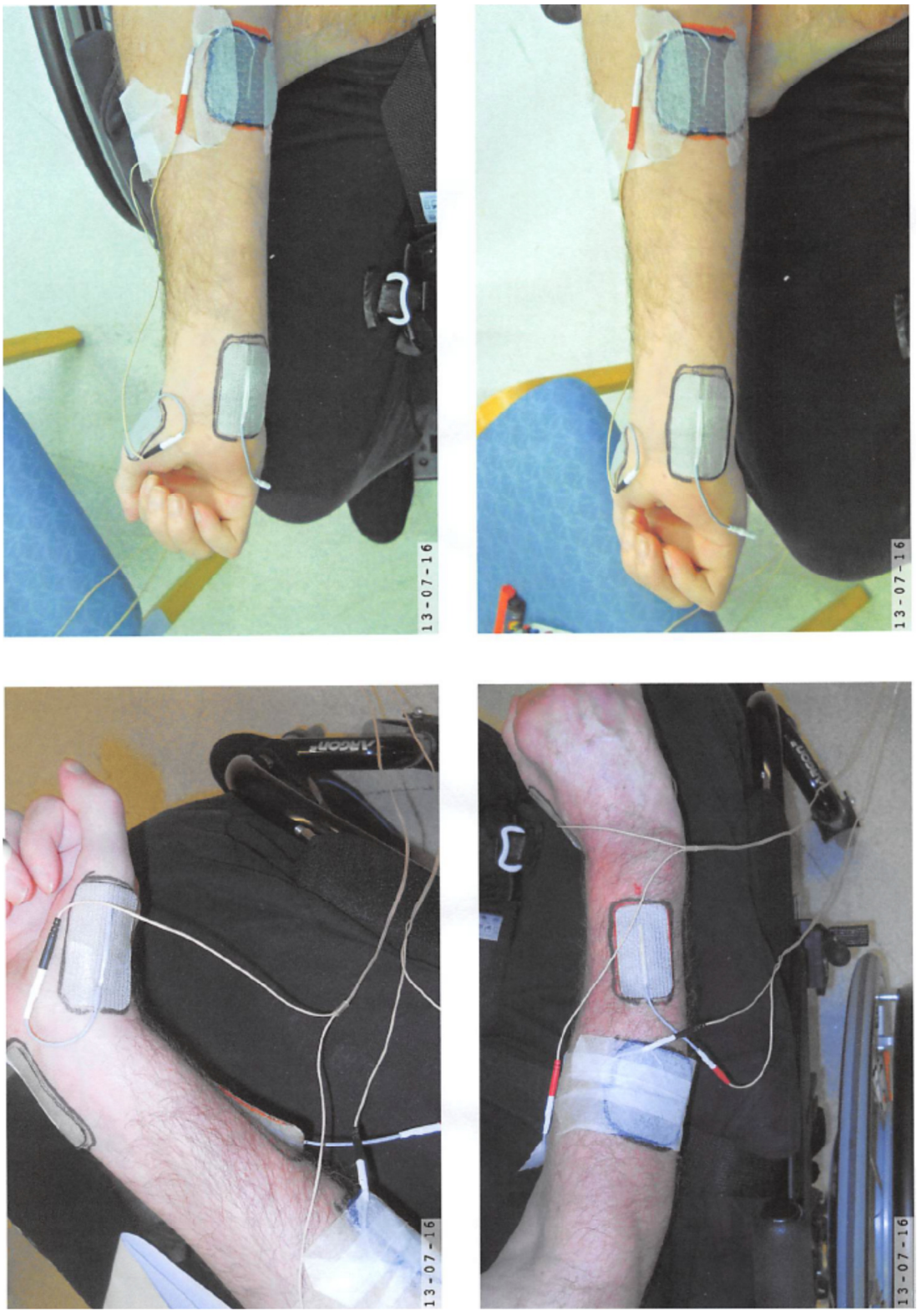


Fig 8-9: The electrode position set up for Volunteer 1

8.4.2 Week By Week Assessment

After exercising the targeted muscle for four weeks, Volunteer 1 came back to the clinic to use the TetraGrip and to perform the tasks specified in the outcome measures. The scores for the outcome measures that required the volunteer to perform the tasks without FES (box and block and grip strength test) were available. However Volunteer 1 could not perform the tasks that required FES as there was not much functional movement available in the thumb and finger extensors after setting up the TetraGrip. At the end of the clinic session, he was advised to continue the exercises suggested to him during the initial assessment.

On Week 2, there was some improvement in the finger extensors but it was still not enough to allow him to perform any functional task. Hence the scores for the box and block test and grip strength test were recorded and then the researchers concentrated on exercising the muscles rather than setting up the TetraGrip. A new sequence of exercise for the key grip was suggested, where the active electrode was placed at the AdP and the common electrode was placed at the ulnar nerve. Both the electrodes had an effect on the thumb adduction which made the key grip very strong. Also the stimulation of the ulnar nerve straightened the fingers which if done regularly would loosen the fingers and aid in the hand opening. Figure 8-10 shows the new electrode positions. The circled area in the top and the bottom images are the reference electrode at the ulnar nerve and the active electrode at AdP respectively.

Week 3 again resulted in exercising the muscles as the fingers were still quite spastic and the volunteer forgot to do the new set of exercises. The set up the TetraGrip was again not successful as the key grip achieved was not strong enough to allow the volunteer to perform any functional tasks. The set up itself was not very straightforward. Channel 1 was connected to the finger extensor active and common indifferent electrode as shown in figure 8-9 (bottom right photo). The active electrodes for the key grip and the palmar grasp were placed at the adductor pollicis and opponens pollicis respectively

and the electrode at the FDS was used as the common indifferent electrode. With this electrode placement, the pre-programmed stimulation envelope for the palmar grasp caused the thumb to get trapped between the fingers. Hence the stimulation envelope was modified to suit the volunteer. This modification is discussed in detail in the next chapter.

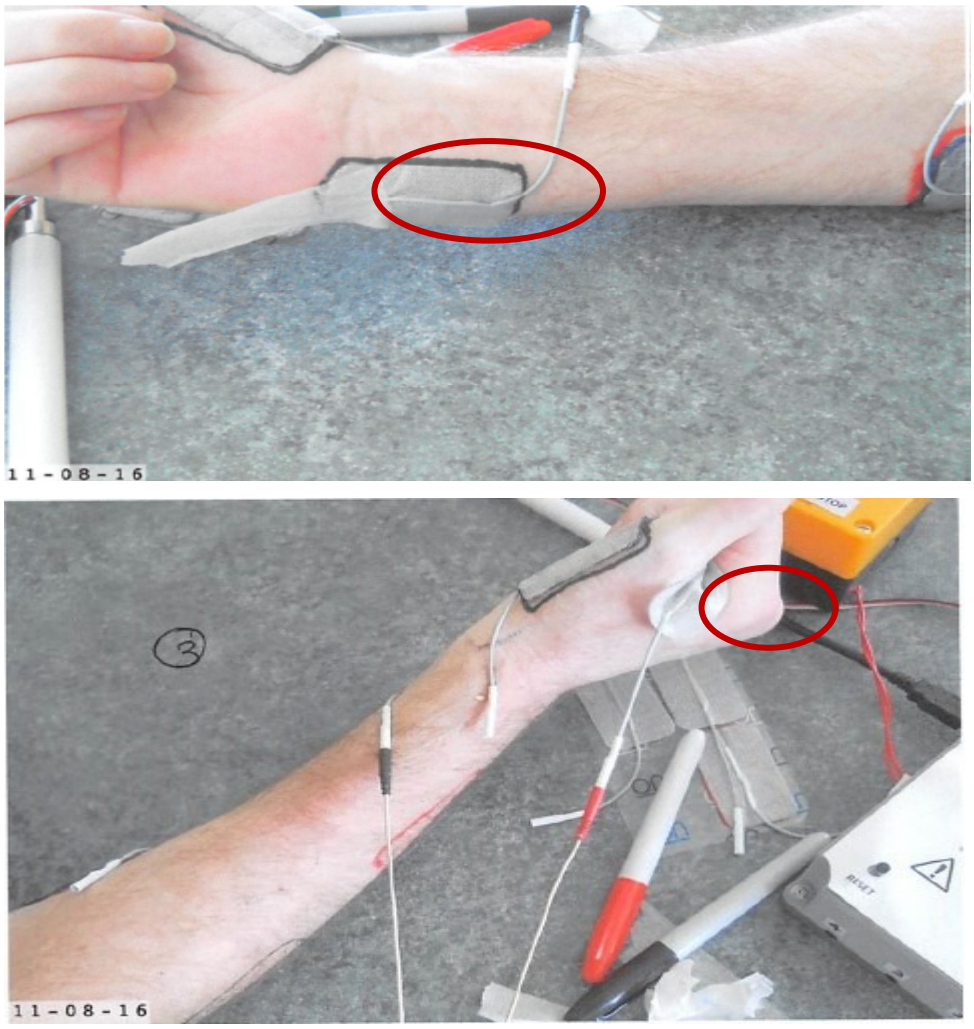


Fig 8-10: New electrode position for stronger key grip for Volunteer 1

Week 4 resulted in the successful setting up of the TetraGrip. The settings for the TetraGrip were:

- Current: Channel 1: 77mA; Channel 3: 48mA; Channel 4: 75mA
- Pulsewidth: 180 µs for all the four channels
- Frequency: 40 Hz
- Type of waveform: Asymmetric Biphasic

The electrode positions that worked the best for this volunteer were standard EDC position for the finger extensors (figure 8-9, bottom right), the active at opponens pollicis and common at FDS for the palmar grasp and active at adductor pollicis and common at ulnar nerve for the key grip (figure 8-10). Channel 2 was left unconnected. The grip strength with FES when compared to without FES for the key grip and the palmar grasp went up from 1.46N to 6.73N and 0.21N to 4.09N respectively.

On Week 5, the TetraGrip setup was successful but the current was altered. The new current settings were: Channel 1: 75mA; Channel 3: 40mA; Channel 4: 75mA. Other settings were the same as the previous week. The volunteer had very strong key grip and palmar grasp which allowed him to attempt the tasks specified in the GRT for the first time. He was able to perform almost all the specified tasks and the scores for the GRT were recorded for the first time. The scores for the grip strength test with and without FES and the box and block test were also documented.

On Week 6, the settings for the TetraGrip were same as the previous week. The volunteer was tired during the clinical study which was due to an extensive gym session in the morning. Because of fatigue, the volunteer was restless and occasionally leaned over to one side of the wheelchair which caused few incidences of false trigger. During the setup, it took some time to find the optimum electrode position for the finger extensors but eventually resulted in good hand opening while doing the experiment. The scores for all the outcome measures were recorded but the fact that the volunteer was tired while performing the tasks affected the scores.

On Week 7, the settings for the TetraGrip remained same. There were few occasions of false trigger which got rectified when the sensor was strapped correctly. The FES setup was successful and the volunteer had a very strong key grip and palmar grasp. He was able to perform all the tasks specified in the GRT except lifting the 250g weight.

On Week 8, the volunteer found the settings at the AdP very strong so it had to be modified. The new current settings were: Channel 1: 75mA; Channel 3: 40 mA; Channel 4: 65mA. Once the setup was completed, he was able to perform all the tasks specified in the outcome measures efficiently. Since this was the last week of the study, the volunteer successfully attempted to hold a fork and eat lunch with the help of the TetraGrip which showed his ability to use the device to perform one of the ADLs. He wished to continue using FES even after the completion of the study.

8.4.3 Results from the Outcome Measures

The outcome measures used to validate this clinical study are: the box and block test, the grip strength test and the grasp release test. These outcome measures are discussed in detail in section 7.3.6 in Chapter 7. The results for volunteer 1 are summarised in the next sections.

8.4.3.1 The Box and Block Test

The results for the box and block test for Volunteer 1 are summarised in table 8-10 and a graphical representation of the same is presented in figure 8-11.

	Week1	Week2	Week3	Week4	Week5	Week6	Week7	Week8
Right Hand	9	10	16	16	18	20	14	16
Left Hand	23	23	25	25	22	26	26	29

Table 8-10: Box and Block scores for the right (dominant) hand and the left (non-dominant) hand for Volunteer 1

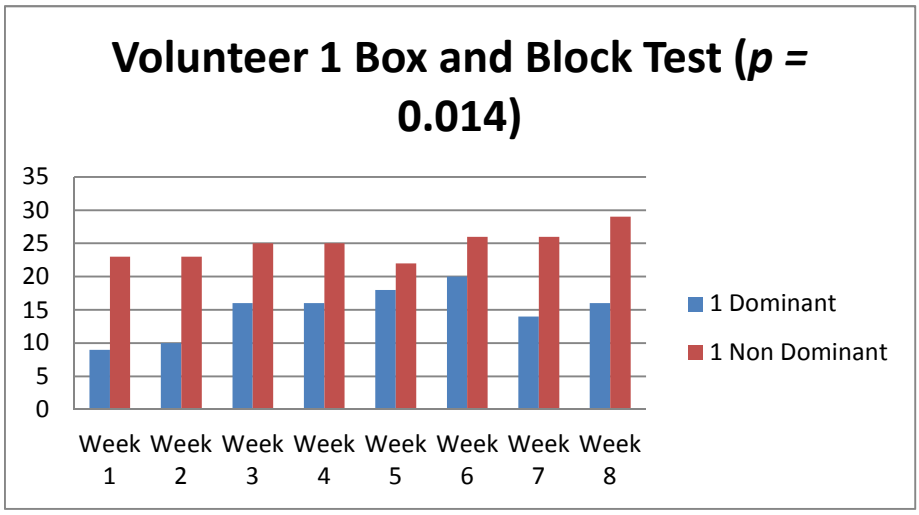


Fig 8-11: Box and Block Test Results for Volunteer 1. Normal range is approximately 80 blocks for left hand and 83 blocks for right hand.

The scores for the dominant hand and the non-dominant hand varied from 9 to 20 and 23 to 29 respectively. The Wilcoxon signed rank test revealed a p value of 0.014 which suggested a statistically significant improvement in the user's ability to perform the test. The non-dominant (left) hand was functionally better than the dominant (right) hand as the fingers were comparatively less spastic. This enabled him to pick up the blocks more efficiently and hence the scores for this hand were higher. However, FES for this hand was not considered because the volunteer had a cancerous tumour removed from the forearm exactly on the spot where the electrode for the finger extensors would have to be placed. The volunteer had been clear of any malignancy for more than two years and was hence considered for this study. On the other hand, the scores of the dominant hand improved during the course of the study. Regular use of FES enabled the volunteer to open his hand better. The scores dipped slightly towards the end of the study because the volunteer was actively engaging in other activities such as archery and gym which made him tired during the sessions.

8.4.3.2 The Grip Strength Test

The results for the grip strength test for both the hands are summarised in tables 8-11 and 8-12. A graphical representation of the same is provided in figure 8-12 and 8-13. The right hand (dominant) received FES and the left hand (non-dominant) did not receive any FES therapy.

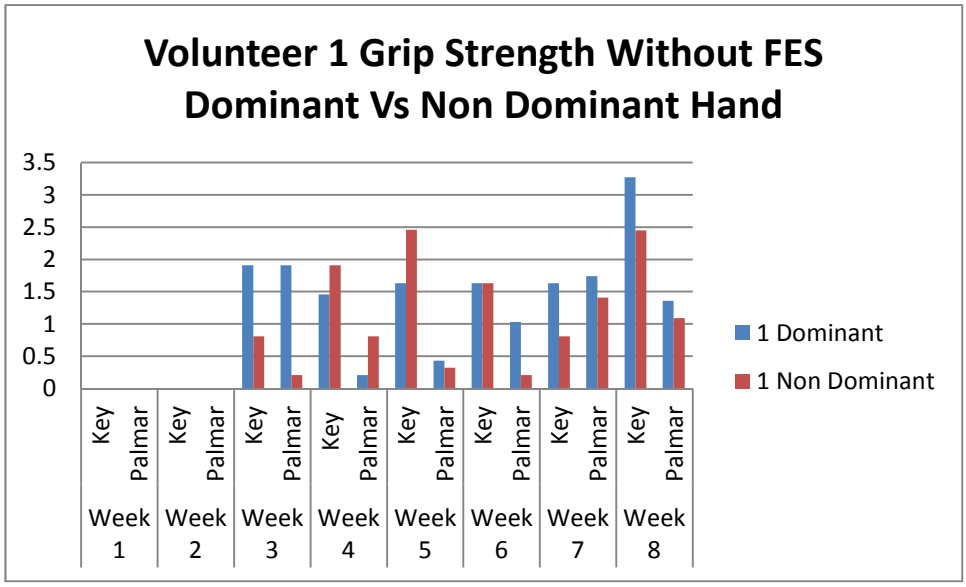


Fig 8-12: The Grip Strength without FES for the dominant (right) and the non-dominant (left) hand for Volunteer 1

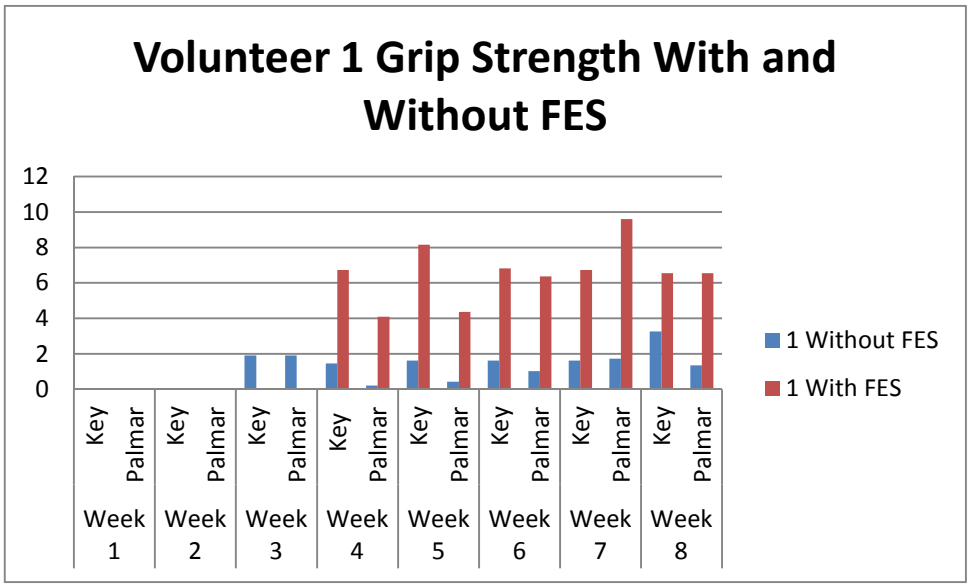


Fig 8-13: Grip Strength Without and With FES for the dominant hand of Volunteer 1

	Week1		Week2		Week3		Week4		Week5		Week6		Week7		Week8	
	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar
Right	0	0	0	0	1.91	1.91	1.46	0.21	1.63	0.43	1.63	1.03	1.63	1.74	3.27	1.36
Left	0	0	0	0	0.81	0.21	1.91	0.81	2.46	0.32	1.63	0.21	0.81	1.41	2.45	1.09

Table 8-11: Grip Strength in Newtons without FES for both the dominant (right) and the non-dominant (left) hand for Volunteer 1

	Week1		Week2		Week3		Week4		Week5		Week6		Week7		Week8	
	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar
No FES	0	0	0	0	1.91	1.91	1.46	0.21	1.63	0.43	1.63	1.03	1.63	1.74	3.27	1.36
With FES							6.73	4.09	8.16	4.36	6.82	6.37	6.73	9.59	6.54	6.54

Table 8-12: Grip Strength in Newtons both with and without FES for the dominant (right) hand for Volunteer 1

The grip strength for Volunteer 1 was recorded from the week 3 of the clinic sessions because the modified pinch meter available at the clinic was not functioning properly on week 1 and 2. Initially the volunteer was not able to generate any force on the modified pinch meter but as the study progressed, his grip showed slight improvement. However the duration of the study was very short to see any significant changes in the grip strength without FES.

The Grip Strength for the dominant and non-dominant and for key grip ranged between 0 – 3.27N and 0 – 2.46N and that for palmar grasp ranged between 0 – 1.91N and 0 – 1.41N respectively. The p value for key grip was 0.6 and that for palmar grasp was 0.3 which was not statistically significant. A comparison of the grip strength with and without FES for the dominant hand showed that the grip with FES for both the key grip and the palmar grasp for Volunteer 1 was much stronger with FES than without FES. The ranges for the grip strength with and without FES were 0 - 3.27N and 6.54 – 8.19N respectively for key grip and 0 – 1.91N and 4.09 – 9.59N respectively for palmar grasp. The p values were 0.059 for the results from the key grip and palmar grasp which suggests improvement in the volunteer's ability to perform key grip but it was still not statistically significant.

8.4.3.3 The Grasp Release Test (GRT)

The GRT consist of six tasks, three that requires the user to use key grip for the completion and three that requires palmar grasp. Details of these tasks are explained in section 7.5.3.1 of Chapter 7.

Volunteer 1 attempted the tasks specified on GRT from Week 5 onwards because the first four weeks were spent on strengthening the muscles and finding the optimum electrode positions for the TetraGrip. All the six tasks were performed both with and without FES and the cumulative results for the hand receiving the FES therapy are presented in table 8-13 and figure 8-14.

	Week1	Week2	Week3	Week4	Week5	Week6	Week7	Week8
FES	-	-	-	-	20	25	30	36
No FES	-	-	-	-	41	28	38	41
p value					0.4	1	0.5	0.6

Table 8-13: The cumulative GRT score for the hand receiving FES for Volunteer 1

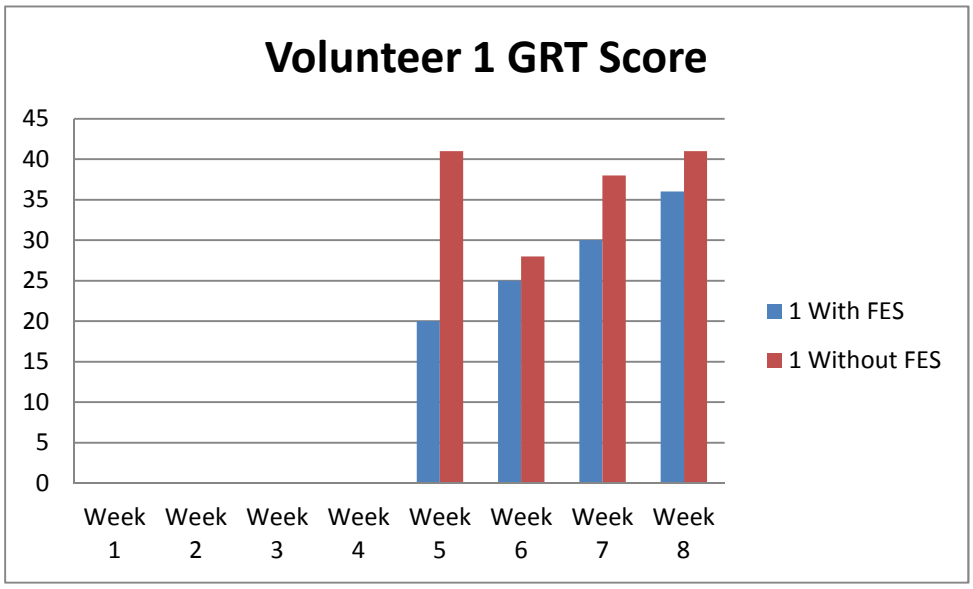


Fig 8-14: Comparison of the cumulative GRT score with and without FES for Volunteer 1

The cumulative scores indicate that Volunteer 1 performed better without FES on all the four occasions. The p values ranged between 0.4 and 1 which was not statistically significant. However, if we analyse his ability to perform each task separately, he was able to perform tasks like pegs, cans and blocks very well without FES but for tasks like using the fork, lifting the video tape and the 250g weight, he required FES. Most of his attempts to do the later set of tasks resulted in failures when he attempted them without FES. A detailed breakup of the GRT scores for Volunteer 1 is provided in table 8-14. Based on the data available in table 8-14, it is clear that the volunteer was able to perform some tasks better without FES but could perform some tasks (fork and the weights) only with the help of FES.

Tasks	Week1		Week2		Week3		Week4		Week5		Week6		Week7		Week8	
	FES	No FES	FES	No FES	FES	No FES	FES	No FES	FES	No FES	FES	No FES	FES	No FES	FES	No FES
Pegs									5	15	6	16	8	15	9	20
Weight									2	0	2	0	0	0	2	0
Fork									1	0	0	0	3	0	0	0
Blocks									4	14	11	5	6	11	11	10
Cans									5	10	4	3	5	8	10	8
Video Tapes									3	2	2	3	8	4	4	3

Table 8-14: Number of successful attempts by Volunteer 1 while performing the GRT tasks both with and without FES

8.5 The Results from the Clinical Study for Volunteer 2

The clinical study results for Volunteer 2 is also divided into the following sections: Initial assessment, week by week assessment and the results obtained from the outcome measures, which are summarised in the next few sections.

8.5.1 Initial Assessment

Volunteer 2 was a male in his mid-twenties and acquired his injuries as a result of a mountain bike accident. He was diagnosed as C6 ASIA complete, was right handed both pre and post injury and was neurologically stable at the time of the study. He had no complaints diabetes, uncontrolled epilepsy or allergy and did not use pacemakers. However he did have a history of autonomic dysreflexia, but it was not FES induced as the volunteer had not used FES before. He was aware of the symptoms and was advised to discontinue the use of FES immediately if he experiences any symptoms of autonomic dysreflexia and inform the researchers about the same.

He uses a hybrid wheelchair for locomotion and was fully independent while moving around at home and could move around with minimum assistance in community. He uses normal fork and spoon for eating food and uses normal cup or glass for his drinks. He uses specialised pen for writing and uses his knuckles for typing in a touch-screen device.

The assessment of the upper limb muscles for Volunteer 2 revealed that he had really strong biceps, Br, and supinators on both hands but the triceps and pronators were absent. His wrist extensors were strong in the right and weak in the left. All other muscles in the forearm and the upper arm received a score of 0 in the MRC scale. Since his dominant had was right and the wrist extensors in the right hand were stronger than the left (score of 4 vs 2 in a MRC scale) and the shoulders of both the hand had good range of movement, the right hand was chosen for FES and the sensor will be

strapped across the left shoulder. He had good sensations in his thumb and index finger but not much in other fingers.

8.5.1.1 Response to FES

Volunteer 2 showed good response to stimulation at EDC, FDS, and ulnar nerve. However the response to stimulation was better at Opponnens Pollicis when compared to Median Nerve. He also showed good response to FPL. Hence the electrode positions were:

- Hand opening: EDC
- Hand closing: FDS
- Thumb adduction/flexion: FPL
- Thumb Opposition: Opponnens pollicis
- Reference Electrodes: for EDC and FDS an electrode was placed just able the elbow and for the thumb electrodes, the reference electrodes were placed on back of the wrist.

Figure 8-15 shows the placement of the electrodes for Volunteer 2. For exercise purpose, the electrodes at the ulnar nerve and the Opponnens Pollicis were used as the active electrodes for the key grip and the palmar grasp movements and the electrode at FDS was used as the reference electrode. Volunteer 2 was provided with an Odstock® MicroStim and spare electrodes and was asked to exercise the muscles for key grip and palmar grasp for 15 minutes to start with and increased it to half an hour a day once he got used to the sensation and the exercises. He did these exercises for four weeks and then came back to the clinic for the eight week study.

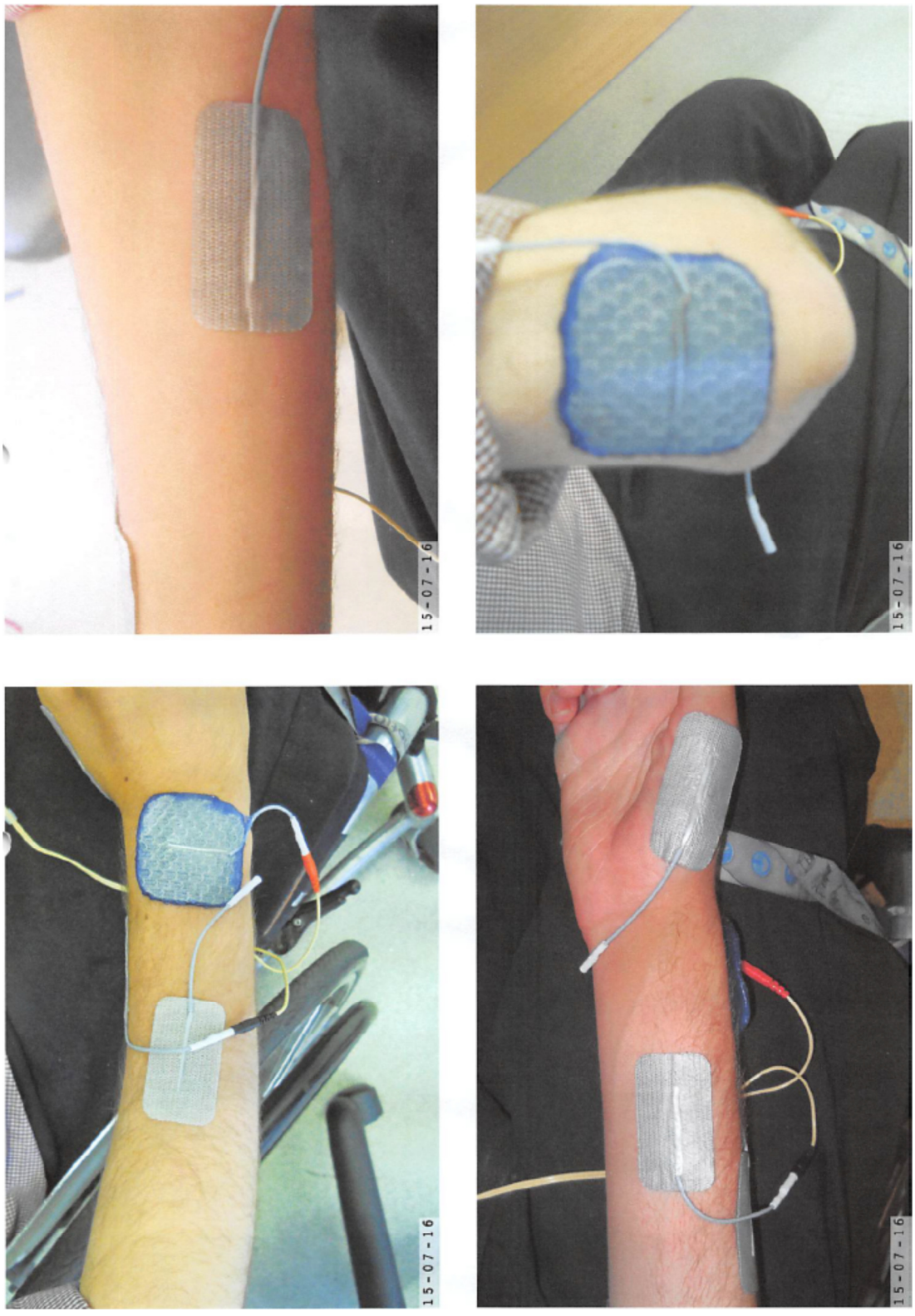


Fig 8-15: Electrode positions for Volunteer 2

8.5.2 Week by Week Assessment

On Week 1, the volunteer attempted both the box and block test and the grip strength test and the scores for the same were recorded. He did not report any changes after the use of FES for four weeks. The electrode position for thumb adduction/flexion was changed from FPL to AdP which resulted in stronger key grip. The setup of the TetraGrip was successful and the volunteer was able to use the shoulder position sensor efficiently for changing the states of the stimulator. However he was not able to use shoulder protraction/retraction for tightening and loosening the grasp. So instead of moving the shoulder forwards and backwards, the volunteer was asked to move his arm backwards for tightening the grasp and forwards for loosening the grasp. This change of movement worked well for the volunteer.

On Week 2, there was slight improvement on the grip when the FES was ON. The volunteer attempted some of the tasks specified in the GRT without FES but the grasp was not strong enough as the researchers were able to pull the object out of the volunteer's hand. However, with FES, the grasp was much stronger and the researchers were not able to pull the object from the volunteer's hands. The researcher couldn't record the scores for GRT because of time constraint this week. The settings for the TetraGrip were:

- Current: Channel 1: 25mA; Channel 2: 27mA; Channel 3: 43mA and Channel 4: 41mA.
- Pulsewidth: 180 µs for all the four channels
- Type of waveform: Asymmetric Biphasic
- Frequency: 40 Hz

Week 3 resulted in the successful setting up of the TetraGrip and successful recording of the scores for all the outcome measures. The current for all the four channels were modified and other parameters were the same. The new currents were: Channel 1: 27mA; Channel 2: 17 mA; Channel 3: 49 mA; Channel 4: 50 mA. The volunteer was able to perform all of the tasks specified in the GRT except the video tapes and the 250g weights. The

researcher had to tape the index and the middle finger of the volunteer together because the index finger was not flexing enough with the electrode at FDS. A different electrode position at Flexor Indicis was tried but the stimulation was not comfortable for the volunteer.

Week 4 resulted in the successful setting up of the TetraGrip and successful recording of the scores for all the outcome measures. Again the current was altered this week. The new settings were: Channel 1: 27mA; Channel 2: 24 mA; Channel 3: 49 mA; Channel 4: 56 mA. The volunteer was able to perform all the tasks specified in the GRT except the video tapes and the weights. The volunteer also used the device to hold a pen and doodle which he couldn't do without FES.

On Week 5, the TetraGrip settings remained same as the previous week and the scores for all the outcome measures were recorded. There was improvement in the grip strength with FES and the GRT scores improved when compared to the previous week.

On Week 6, the settings remained same and the volunteer was able to perform all the tasks in the GRT including lifting of the 250g weight and the video tapes. He was also able to hold an ordinary pen using FES and write. When he doesn't use FES, he uses a special pen to write. The scores for both the grip strength and the GRT improved when compared to the previous week but the box and block scores remained close to the previous scores.

On Week 7, the TetraGrip was setup with the same settings as the previous week and both the key grip and the palmar grasp were much stronger. Because of a strong key grip, the volunteer was able to hold a pen and write much clearly than he previously did. The scores for both GRT and the grip strength improved when compared to last week but the box and block scores remained close to the last week's value. The volunteer was also able to hold the video tape in the air against gravity which he couldn't do without FES.

Week 8 was the last day of the clinical study and the device was set up with the same settings. Again the key grip and the palmar grasp with FES were really strong. This week, for the first time, the GRT score with FES was higher than that without FES. This was because of the strong key grip and palmar grasp which allowed the user to perform the tasks like using the fork and weights much more efficiently than previous weeks. The volunteer held a fork using the TetraGrip and ate his lunch. He said he could use a normal fork even without FES but he couldn't hold a pen and write on a piece of paper without FES. He expressed his wish to continue the use of FES especially for strengthening his key grip which would help him in tasks like writing and soldering.

8.5.3 Results from the Outcome Measures

The results from the outcome measures for Volunteer 2 are summarised in the next few sections.

8.5.3.1 The Box and Block Test

The scores for the box and block test for Volunteer 2 are summarised in table 8-15 and a graphical representation of the same is presented in figure 8-16.

	Week1	Week2	Week3	Week4	Week5	Week6	Week7	Week8
Right hand	25	28	32	31	33	31	30	27
Left hand	16	18	20	23	19	21	22	26

Table 8-15: Box and Block Scores for the dominant (right) and the non-dominant (left) hand for Volunteer 2. Normal range is approximately 80 blocks for left hand and 83 blocks for right hand.

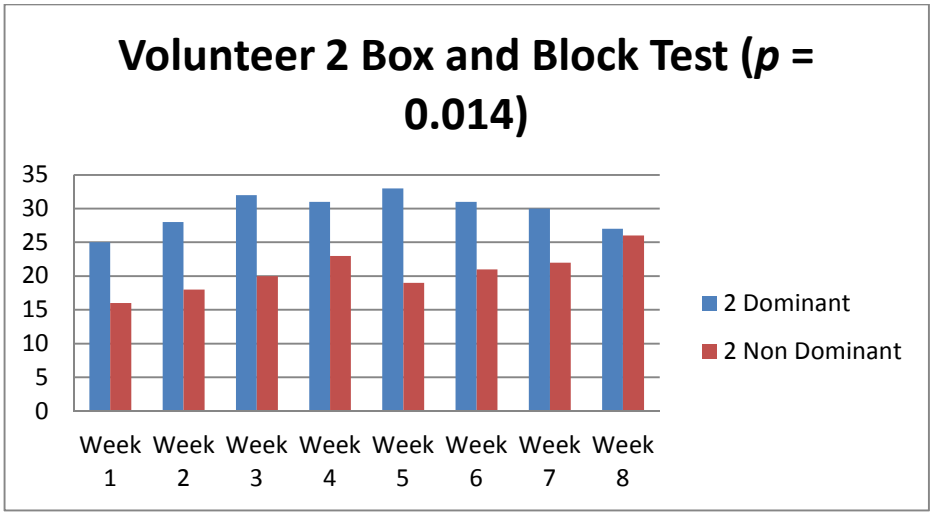


Fig 8-16: Graphical representation of the box and block scores of Volunteer 2

The scores for the dominant and the non-dominant hand ranged from 25-33 and 16-26 respectively. The p value for the results obtained during the box and block test was 0.014 which indicated a statistically significant result. The dominant hand was much better than the non-dominant hand while performing this test. It is because the tenodesis grip of the dominant hand was superior to the non-dominant hand. However the scores plateaued during the study possibly because the volunteer was already using the tenodesis grip to his best possible ability. Use of FES over the eight weeks did not have any influence on the box and block scores.

8.5.3.2 The Grip Strength Test

The scores for the grip strength without FES for both the hands and with and without FES for the dominant hand for Volunteer 2 is presented in tables 8-16 and 8-17 and graphical representation is provided in figures 8-17 and 8-18. The right hand (dominant) received FES and the left hand (non-dominant) did not receive any FES therapy.

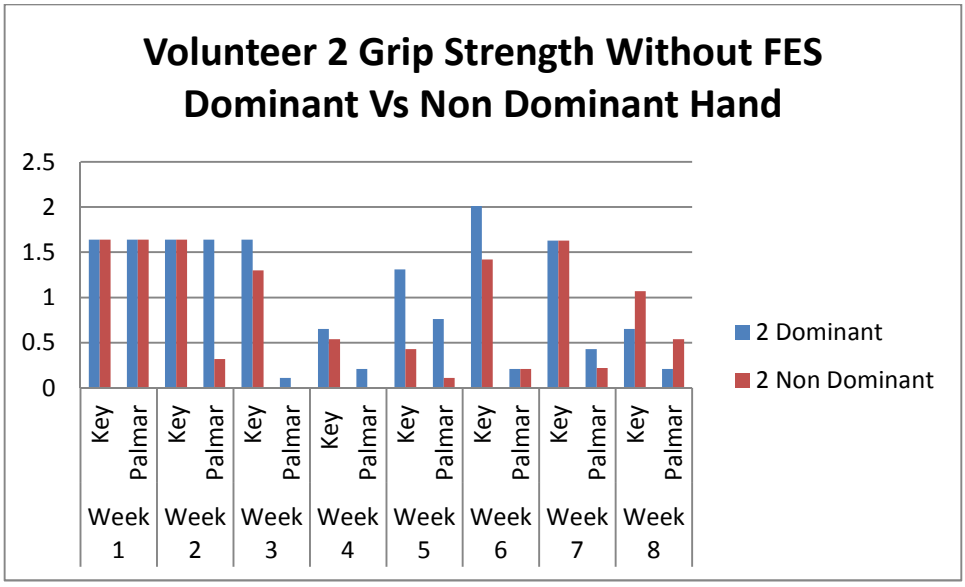


Fig 8-17: The grip strength score for the dominant (right) and the non-dominant (left) hand for Volunteer 2

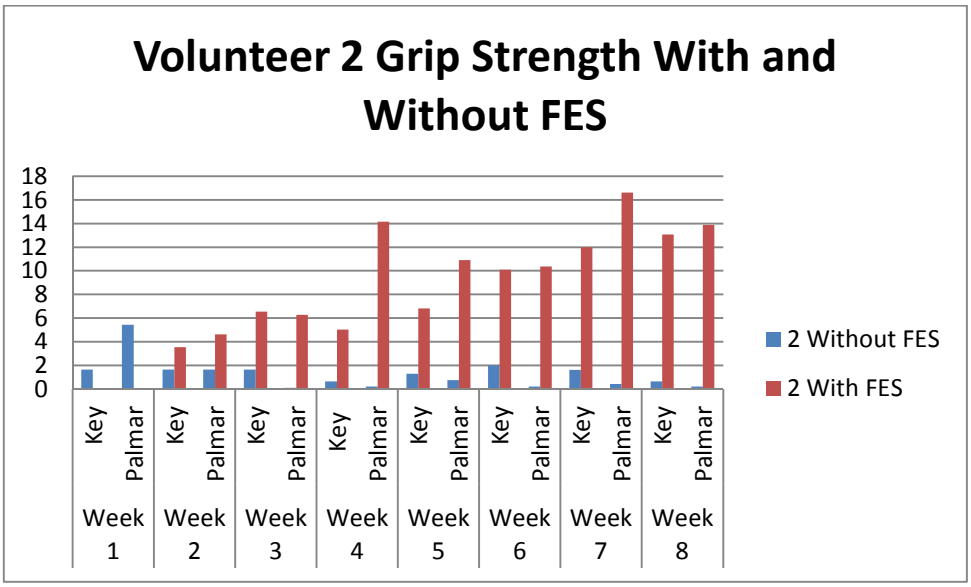


Fig 8-18: Grip strength scores with and without FES for the dominant (right) hand for Volunteer 2

	Week1		Week2		Week3		Week4		Week5		Week6		Week7		Week8	
	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar
Right	1.64	1.64	1.64	1.64	1.64	0.11	0.65	0.21	1.63	0.43	1.63	1.03	1.63	1.74	3.27	1.36
Left	1.64	1.64	1.64	0.32	1.3	0	0.54	0	0.43	0.11	1.42	0.21	1.63	0.22	1.07	0.54

Table 8-16: The Grip Strength in Newtons for the dominant and the non-dominant hand without FES for Volunteer 2

	Week1		Week2		Week3		Week4		Week5		Week6		Week7		Week8	
	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar	Key	Palmar
No FES	1.64	1.64	1.64	1.64	1.64	0.11	0.65	0.21	1.63	0.43	1.63	1.03	1.63	1.74	3.27	1.36
With FES	-	-	3.54	4.63	6.54	6.27	5.02	14.16	6.81	10.9	10.08	10.35	11.99	16.62	13.08	13.89

Table 8-17: The Grip Strength in Newtons for the dominant hand with and without FES for Volunteer 2

The grip strength was recorded using a modified pinch meter. The grip strength without FES while using key grip showed some improvement as the study progressed. The range of the grip strength was 0.65 – 3.27N for the key grip and 0.11 - 1.74N for palmar grasp. The grip strength remained almost constant for the first seven weeks but it improved on week 8. The volunteer also reported about his grip being stronger than the previous weeks. The p values obtained from the results from the dominant and non-dominant and without FES were 0.3 and 0.21 for key grip and palmar grasp respectively which did not show any statistically significant result.

The grip strength with FES varied from 3.54 – 13.08N for key grip and 4.63 – 16.62N for palmar grasp. The grip strength for both the key grip and palmar grasp were superior when compared to the grip strength without FES. The grip with FES got better as the weeks progressed. The p values for the results obtained with and without FES were 0.021 for key grip and 0.03 for palmar grasp which indicated a statistically significant result and showed that the grip was superior with FES when compared to the grip without FES.

8.5.3.3 The Grasp Release Test (GRT)

The scores for the GRT for Volunteer 2 are summarised in the table 8-18 and a graphical representation of the same is presented in figure 8-19.

	Week1	Week2	Week3	Week4	Week5	Week6	Week7	Week8
FES	-	-	31	39	45	55	65	75
No FES	-	-	40	47	51	67	73	73
p value			0.6	1	0.9	0.5	0.9	0.8

Table 8-18: The cumulative GRT score for Volunteer 2

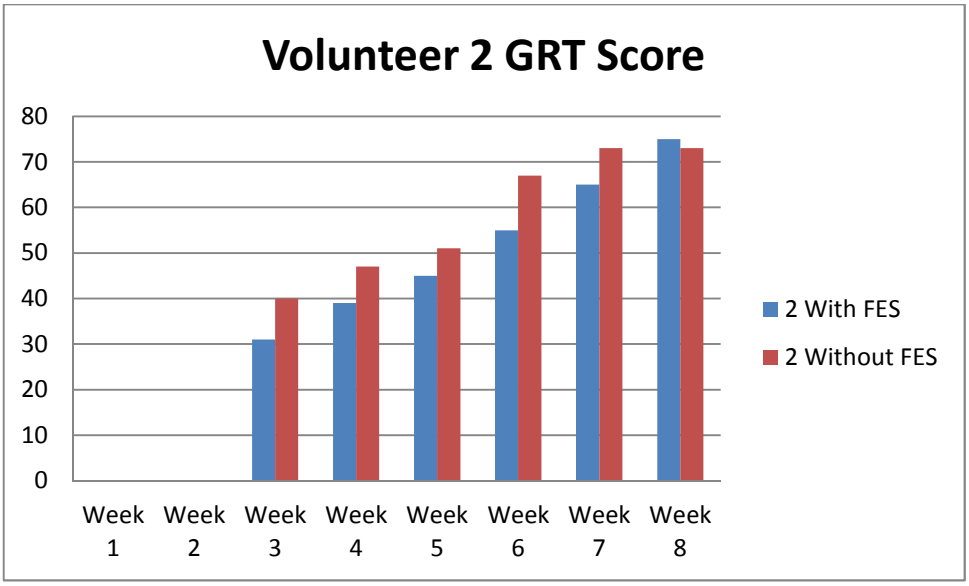


Fig 8-19: Graph representing the cumulative GRT score for Volunteer 2

The p values for the scores obtained during GRT ranged between 0.5 and 1 which indicated that the result is not statistically significant. Similar to Volunteer 1, the GRT scores without FES for Volunteer 2 were higher for most part of the study when compared to the scores with FES. This was because Volunteer 2 was much better in performing tasks like pegs, blocks and cans without FES than with FES. But he could not perform tasks like fork, weights and video tapes without FES initially.

However as the study progressed, he was able to lift the video tapes even without FES. But FES allowed him to hold the video tapes in the air against the gravity which he couldn't do without FES. His ability to lift the 250g weight and use the fork using FES improved tremendously as the study progressed but he couldn't perform these tasks without FES. A detailed breakup of the GRT scores for Volunteer 2 is provided in table 9-18. The scores in table 8-19 indicate the volunteer's ability to perform tasks such as weights, video tapes and fork very well with the help of the TetraGrip.

Tasks	Week1		Week2		Week3		Week4		Week5		Week6		Week7		Week8	
	FES	No FES	FES	No FES	FES	No FES	FES	No FES	FES	No FES	FES	No FES	FES	No FES	FES	No FES
Pegs					12	14	12	17	14	20	13	20	12	23	13	22
Weight					4	0	2	0	8	0	8	0	8	0	13	0
Fork					0	0	0	0	3	0	5	0	9	0	14	0
Blocks					8	11	11	14	7	14	12	20	13	21	15	22
Cans					7	15	9	4	8	13	10	18	13	20	11	23
Video Tapes					0	0	5	2	5	4	7	9	10	9	9	6

Table 8-19: Number of successful attempts by Volunteer 2 while performing the GRT tasks both with and without FES

8.6 Summary

This chapter summarises the results obtained during the clinical testing of the TetraGrip with fourteen able bodied volunteers and two tetraplegic volunteers. Out of the fourteen able bodied volunteers; nine participated in all the three days of the study. The results obtained from volunteers ABV2 and ABV3 were used for a pilot study to identify the necessary changes that needed to be done in order to improve the performance of the device. After analysing the results obtained, it was found out that the user's ability to use the device efficiently improved, thereby indicating a learning effect. At the end of this study, the device was working reliably without any major issues.

In the next part of the study, the device was used for a clinical study with two tetraplegic volunteers. Neither of the volunteers had received FES therapy before, both were neurologically stable and didn't have any complaints except for autonomic dysreflexia. The volunteers took home an Odstock® Microstim after their initial assessment for four weeks in order to strengthen the muscles for key grip and palmar grasp. For the remaining eight weeks they came once in a week to the clinic and exercised with the Odstock® Microstim for the rest of the days.

In the clinic, the progress of both the volunteers was assessed using three outcome measures: the grip strength test, the box and block test and the GRT. Volunteer 1 showed some improvement in his box and block test scores but for Volunteer 2, the scores plateaued as he was already using his tenodesis grip to his best possible ability. The grip strength with and without FES improved for both the volunteers over the course of study and the GRT scores with FES improved as the study progressed. The GRT scores without FES was higher for both the volunteers because the volunteers were able to perform some of the specified tasks very well without FES compared to with FES. However they required FES for lifting weights and holding a fork.

A detailed discussion about the results obtained and the modifications done to the device in order to improve its performance are discussed in the next chapter.

Chapter 9 Discussion

9.1 Introduction

This chapter discusses the progress of this thesis and highlights the key outcomes of this research work. The chapter begins by revisiting the research question and then discusses the aims that were achieved along with the evidence. A detailed discussion about the outcome of this research work is also presented in this chapter.

9.2 Revisiting the Research Aim

The research aim stated in Chapter 1 is as follows:

To explore the possibility of developing a multi-channel upper limb FES device controlled using a man-machine interface that can be used by people with C5/C6 tetraplegia for improving their hand function and to study the user's ability to control the device efficiently in order to perform the required task.

The main objectives of this research work in order to answer research aim were:

- **Objective 1:** To explore different sensors in order to provide a reliable input for the user to control the device.

- **Objective 2:** To develop a control system which uses the input from the sensor and allows the user to operate the device without undue conscious effort.

- **Objective 3:** To develop a multichannel upper limb FES device that can stimulate the corresponding muscles for key grip and palmar grasp movements with the help of the defined control signals.

- **Objective 4:** To study the performance of the device and the shoulder position sensor when used by a person with C5/C6 tetraplegia and to evaluate the performance of the device in improving their upper limb functions.

Some of the key observations made throughout this research work are discussed in the next section.

9.2.1 Objective 1: To explore different sensors in order to provide a reliable input for the user to control the device.

The desired characteristics of a MMI for an upper limb FES device were as follows: It should allow the user to easily control the FES device, easy to don and doff, lightweight and compact and cost-effective. The MMIs used for controlling the upper limb FES devices are described in section 3.3 of Chapter 3. The choice of using shoulder movements to control the FES device, the limitations of the commonly used MMIs, such as push buttons or bio-signal based MMIs, and the resulting selection of an IMU for controlling the TetraGrip, is discussed in section 3.4 of Chapter 3. Shoulder movement such as elevation, protraction and retraction were considered as the potential control signal because they replicated the natural shoulder movements in reaching and grasping tasks. Since a person with tetraplegia uses these movements regularly either as a part of an exercise program or in order to perform ADL, it did not take them excessive conscious effort to generate these control signals. An IMU capable of detecting the shoulder movements in two planes was chosen as a potential shoulder position sensor because it allowed the user the freedom to turn the device ON or OFF, select the grip

type according to their requirement or modify the grip strength in order to improve their ability to perform an ADL.

In order to choose the right shoulder position sensor, a number of IMUs, capable of detecting the shoulder movements, were explored and one of the potential sensors was the Xsens MTx. The Xsens MTx is one of the most widely used sensors for detecting hand and shoulder movement in biomechanics (Song et al. 2012; Gil-Agudo et al. 2013; Banos et al. 2014; Bergmann et al. 2014) and is hence considered the gold standard for IMUs for biomechanical applications. Also it has previously been used for detecting the movement of the upper limb in space and has triggered an upper limb FES device (Tresadern et al. 2006). A detailed literature about the explored sensors is provided in Chapter 5 of this thesis.

A major disadvantage of the Xsens MTx is that it costs approx. £1000 and would have to be used along with the Xbus and other related accessories which would increase the number of connectors and the hardware. Hence a more compact and cost-effective sensor was explored and the Flyduino NanoWii Flight Controller which costs approx. £35, was chosen as another potential choice of sensor as it had specifications similar to the Xsens MTx sensors. However this sensor is used for developing toy quad copters and has not been used for biomedical applications previously. Hence a study was performed to compare the two sensors to explore if the Flyduino NanoWii Flight Controller can detect shoulder movements as well as the Xsens MTx.

The protocol for this study is defined in Chapter 4 and the results are summarised in Chapter 5. It was observed during this study that both the sensors were equally efficient in detecting the shoulder movements. Also both the sensors produced distinct signals for each of the shoulder movements. Therefore the Flyduino NanoWii FC was chosen as the shoulder position sensor for this research work because it was comparatively compact and cost-effective.

9.2.2 Objective 2: To develop a control system which uses the input from the sensor and allows the user to operate the device without undue conscious effort.

Since the Objective 1 was achieved, control signals based on shoulder elevation, protraction and retraction were developed for controlling an upper limb FES device. The control signal developed was based on threshold detection and the optimum threshold value that was effective on majority of the volunteers was determined by an iterative process. These defined control signals were effective as they allowed the user to turn ON and OFF the stimulation, select the grip type and vary the grip force. The results obtained when the volunteers with tetraplegia attempted the tasks specified in the GRT (summarised in the sections 8.4.3.3 and 8.5.3.3 of Chapter 8) support this claim. The defining of the control signal is discussed in Chapter 6 of this thesis.

However there were issues of false triggers when the able-bodied volunteers used the device. Some of the false triggers due to the shortcomings of the control signals are summarised below:

- False trigger due to the quick movement of the shoulder either while recovering after generating the control signal or when the elbow hit the armrest
- False trigger when the tetraplegic volunteer leaned on the armrest of their wheelchair
- False trigger when the volunteer adjusted their position in the wheelchair.

The main reason for the false trigger due to the quick movement of the shoulder was the use of the threshold detection technique for registering the control signal. It took several trial attempts to find the best possible combination of threshold values that worked for majority of the volunteers. This reduced the number of false triggers but did not eliminate them

completely as some volunteers encountered them even when the sensor was working perfectly well for others. Most of the false triggers occurred when the volunteers attempted the control signal to tighten or loosen the grasp. One possible reason for these false triggers was the volunteer's inability to produce slow and sustained movements which could be due to tight shoulder muscles.

The issue of false trigger when the volunteer leaned on the armrest of their wheelchair was another shortcoming of using only threshold detection for defining the control signals. In order to prevent the false triggers when the tetraplegic volunteers readjusted their position in the wheelchair, they were asked to inform the researcher when they did that and the researcher would press the pause button in the stimulator which would pause the system and hence would prevent false trigger. This was the technique used to avoid the false trigger. However it was not a solution for the problem. If the sensor automatically realigned when the system was in the idle state or realigned after a specific interval of time, then the system would register the control signal irrespective of the volunteer's position.

A more sophisticated control signal that uses the orientation of the sensor and looks for a specific pattern in the signals for defining the control signal would resolve these false trigger issues. Although the control signal used in this research work depended on threshold values, specific signals corresponding to a specific shoulder movements was identified as shown in figures 5-27, 5-28 and 5-29 in section 5.4 of Chapter 5. This information can be used to develop and train a pattern recognition system that can monitor all the channels of the IMU and trigger the FES device when the user generates the controls signal. This system can also be programmed and trained to identify the orientation of the sensor which will be helpful in eliminating the false trigger issues when the user changes his/her position in the wheelchair. Due to time constraint, it was not possible to implement such a complicated control signal as these false trigger issues were identified only during the study involving the able-bodied volunteers.

Another possible solution for this problem can be use of two sensors and considering the relative position between the two. One sensor can be placed on the torso of the body and the other in the same position as the shoulder position sensor. If the user changes his/her seating position in the wheelchair, the change in the orientation will be detected by both the sensors and the effect of false trigger due to change in orientation will be minimal. Since the two sensors will not be identical, additional precautions can be taken while developing the software to ensure that any difference in detecting the change in orientation. This will ensure that the control system triggers the FES system accurately. A facility to customise the control signal will make the device even more user friendly. The threshold values used in this research work was the same for all the users. The volunteers were trained to use the device and some them found it difficult to generate the control signal while others used the device with great ease, If the software measures the range of movement of the shoulder for each user and customises the threshold values, then this information along with the control signals described above would improve the performance of the device.

9.2.3 Objective 3: To develop a multichannel upper limb FES device that can stimulate the corresponding muscles for key grip and palmar grasp movements with the help of the defined control signals.

The two main hand movements that enable a person with tetraplegia to perform majority of their ADL are the key grip and the palmar grasp movement (Kilgore et al. 2008; Ragnarsson 2008). In order to achieve a functional key grip and a palmar grasp, the TetraGrip was programmed to deliver impulses in a specified sequence. This programmed sequence worked well as it allowed the users to perform various functional tasks summarised in Chapter 8. However there were some design flaws which resulted in false triggers such as:

- False trigger when the user generated the control signal before the stimulation terminated from the previous cycle.

- False trigger due to the wear and tear of the connectors
- False trigger due to the length of the electrode leads

When the device was first used by the able bodied volunteers, it was not programmed to provide any feedback to the user about the state of the stimulator while stimulating. The volunteer had to rely on the sensation of the stimulation to judge the state of the stimulator. Once they generated the control signal for stopping the stimulation, the volunteers had to concentrate on the sensation of the electrical stimulation and predict when the stimulation stopped completely. Often this prompted the user to generate the next control signal before the stimulation stopped completely thereby resulting in false triggers.

This issue was resolved when the device was reprogrammed to provide visual feedback using three different coloured LEDs. These LEDs provided indications when they successfully generated the control signal and when the system switched states. However auditory feedback would have been helpful as it would not require the users to constantly look at the front panel of the device in order to confirm the successful generation of the control signals. The user can make their judgement about the state of the device based on the signals from the sounder and generate the control signals accordingly. However including an auditory feedback required hardware modifications which were out of the scope of this research work.

The connector connecting the serial communication lines of the shoulder position sensor to the stimulator was subjected to a lot of wear and tear especially when the volunteers made repeated attempts to generate the control signal. The holes in the plastic connectors would expand with regular use and caused loose connection. As a result, the device was unsuccessful in registering the control signal even though the user was using the right shoulder movement, thereby resulting in a false trigger. In order to resolve this issue, the wires had to be replaced regularly. During the clinical study with the tetraplegia volunteers and the study involving the able bodied

volunteers, this connector wire was replaced four times. A more permanent solution for this problem would be either the use of more sturdy connectors or make the shoulder position sensor wireless. If the shoulder position sensor is made wireless, the designer should take appropriate precautions not to make the device bulky and should optimise the power consumption.

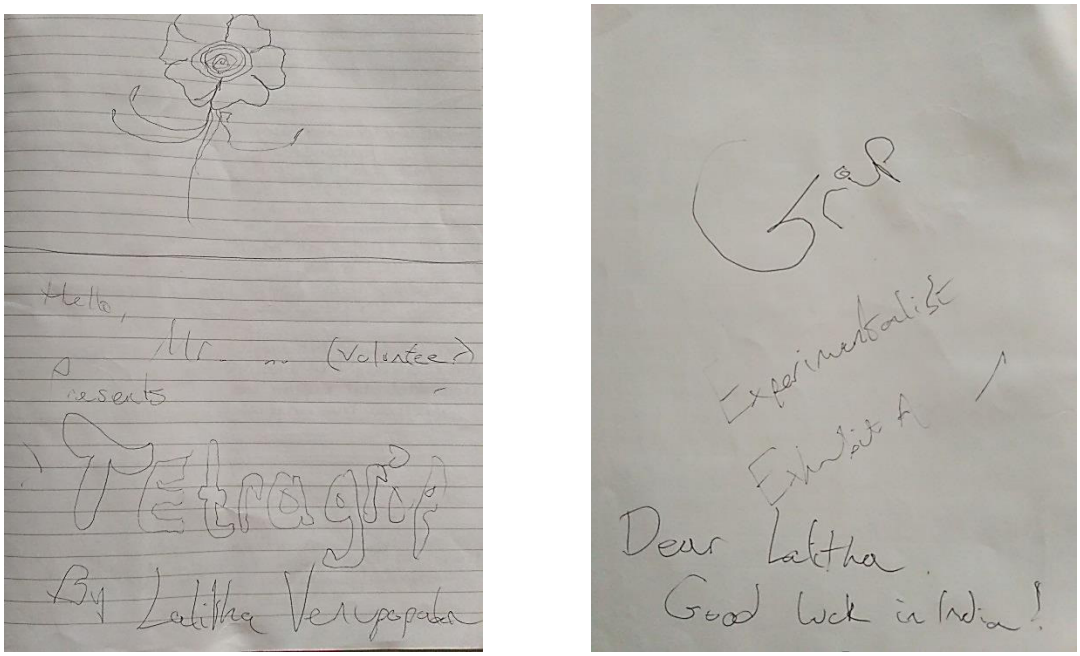
Another issue identified during the clinical study was the length of electrode leads. The device rested in a table next to the user and standard electrode leads were used to connect the stimulator to the electrodes. The length of these leads was not optimal and often got tangled with the armrest of the user's wheelchair. Any sudden movement by the user caused these leads to unplug which affected the performance of the device. Therefore the extra length of the electrode leads was taped to the volunteer's skin or garment. However this does not offer permanent solution to the problem. Use of an electrode garment such as the one developed by the researchers in the University of Southampton, could offer a more possible solution to this problem (Yang 2016).

During the clinical study, the researchers noted the parameters in the volunteer's clinic notes and entered the stimulation parameters each time the volunteer came to the clinic. This was done with the help of a computer and worked well since the number of volunteers was less. However if this device has to be used for a larger clinical study, then it would be beneficial to incorporate a digital display and a built in memory. This will enable the clinician to set the stimulation parameters quickly and allow the clinician to save the current settings thereby reducing the setting up time. Also, the TetraGrip was developed by assembling various circuit boards and connecting them with the help of wires and connectors. This would create electromagnetic compatibility (EMC) issues and would not qualify as a take home device under the current ISO 60601 standards. Hence the design of the device needs to be remodified and a more extensive testing of the ISO 60601 standards is required.

9.2.4 Objective 4: To study the performance of the device and the shoulder position sensor when used by a person with C5/C6 tetraplegia and to evaluate the performance of the device in improving their upper limb functions.

In order to evaluate the performance of the tetraplegic volunteers, a twelve week long clinical study was undertaken and their performance was monitored by evaluating the results obtained. The results obtained during the study for both the volunteers are presented as two case studies in the sections 8.4 and 8.5 of Chapter 8. Both the volunteers had to switch between the key grip and the palmar grasp for performing the tasks specified in the GRT and they had to continuously use the control signals for tightening and loosening the grasp for holding and releasing the object. Both the volunteers were able to successfully perform the tasks specified in GRT multiple number of times (scores are presented in tables 8-12 and 8-13 for Volunteer 1 and 8-17 and 8-18 for Volunteer 2). Also both were able to perform an ADL of their choice on Week 8 of the study as illustrated in figures 9-3, 9-4 (a) and 9-4 (b). Volunteer 1 was able to use the TetraGrip to hold an ordinary fork and eat his lunch. On a daily basis he uses modified cutlery to eat his food. Volunteer 2 was able to firmly hold an ordinary ball-point pen and write with the help of the TetraGrip. Under normal circumstances, he uses a special pen to write.

Fig 9-1: Volunteer 1 using the TetraGrip for having his lunch



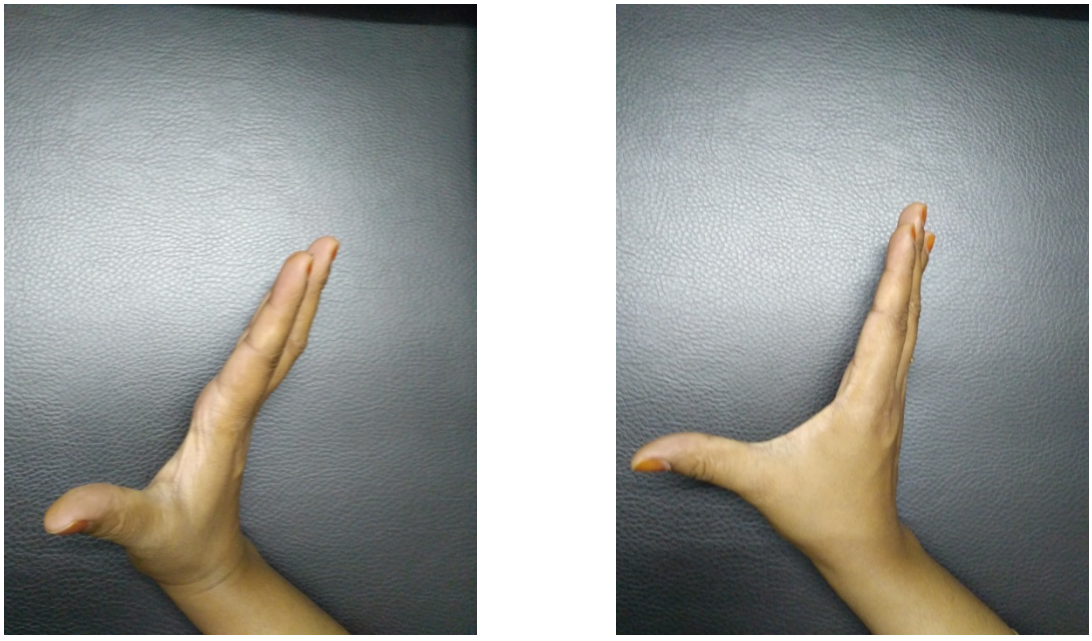
(a) **(b)**

Fig 9-2: Volunteer 2 using the TetraGrip for holding a pen and writing. (a) was written at the 3rd week and (b) was written at the 8th week in the clinic which was darker than previous week and indicates a stronger grip

The palmar grasp stimulation envelope had to be modified during the clinical study in order to improve the hand position and to make it more functional. The modifications done to the stimulation envelope and the outcome of the modification are discussed in the next section.

9.2.4.1 The Palmar Grasp Stimulation Envelope Modification

The palmar grasp stimulation envelope was programmed to stimulate the group of muscles in the following sequence: Hand open followed by the closing of the fingers followed by the opposition of the thumb. However this sequence resulted in Volunteer 2 reaching for the object with an extremely open hand and Volunteer 1 facing the issue of the thumb getting trapped between the fingers. Volunteer 1 faced this problem because the indifferent electrode for Channel 3 (connected to Opponens Pollicis) was placed at the FDP.



(a) **(b)**

Fig 9-3: Hand positions during palmar grasp: (a) before modification and (b) after modification of the stimulation envelope

In order to accommodate both the volunteers' needs, the stimulation envelope was modified such that Channel 3 was switched ON along with Channel 1 which resulted in the simultaneous stimulation of the Opponens Pollicis and the EDC. The indifferent electrode for Channel 3 was still placed at the FDP. However when the Channel 3 was ON, the pulse width of the stimulation envelope of Channel 1 was 180 µs which resulted in a stronger finger extension compared to flexion. This allowed the fingers to be extended and the thumb to move into opposition which was the desired hand position for grasping an object. Figures 10-5 (a) and 10-5 (b) illustrate the position of the hand before and after the modification of the stimulation envelope respectively.

Overall, both the volunteers showed improvement in their ability in performing the tasks specified in the outcome measures and their ability to perform an ADL of their choice. The observations made during the clinical study and a comparison of these observations with the studies published in the literature is presented in the next section.

9.2.4.2 Observations from the clinical study

The results obtained during the clinical study were analysed using the Wilcoxon signed rank test and it was observed that the p value for the results obtained during the GRT with Volunteer 1 ranged between 0.3 and 1 and the p value for Volunteer 2 ranged between 0.5 and 1. This indicates no significant difference in the person's ability to perform task with and without FES. The main reason for such a high p value is because both the volunteers were able to perform lighter tasks such as the pegs, the blocks and the cans with great ease without the use of FES. However the volunteers were not able to perform the tasks that required a lot of strength such as the weights and the fork without the use of FES but were successfully able to perform these tasks with the help of the TetraGrip.

Analysing Volunteer 1's results (summarised in section 8.4 of Chapter 8) indicate some improvement in the volunteer's ability in performing the tasks specified in the GRT. He showed improvements while performing all the tasks but the results obtained were not consistent enough to indicate the possibility of a training effect. The protocol for the clinical study was for twelve weeks with four weeks for training the muscle and eight weeks for obtaining the results. However, four weeks of training proved insufficient for Volunteer 1 and he needed extra three weeks of training before the TetraGrip was successfully set up on him. If the protocol was designed such that the training period was kept flexible and the results from the outcome measures were obtained for a fixed duration once the device setup was successful, then more meaningful results can be obtained..

Conversely, analysing Volunteer 2's results did indicate a possible training effect. The detailed GRT scores summarised in table 8-18 in the section 8.5.3.3 of Chapter 8 show a steady improvement in his ability to perform the tasks specified in GRT. The volunteer's ability in performing tasks such as the weights and the fork using the TetraGrip improved significantly on Week 7 and Week 8 of the study. He was not able to perform these tasks without FES. But he showed steady improvement in his ability to perform the other

tasks specified in the GRT both with and without FES indicating the possibility of a training effect. A more detailed clinical study is required to predict the possibility of a training effect in Volunteer 1 and would provide more evidence to justify the possible training effect in Volunteer 2.

A comparison of the results obtained using the TetraGrip with the NeuroControl® Freehand System and the NESS H200 (two FDA approved upper limb FES devices) is discussed in the next section.

9.2.4.2.1 The TetraGrip vs The NeuroControl® Freehand System

Analysing the results in this study indicated that the improvement was not statistically significant whereas those obtained during the study with the NeuroControl® Freehand System showed a statistically significant difference between the results obtained with and without FES (Taylor et al. 2002). However the study with the NeuroControl® Freehand System was for one year and the one with the TetraGrip was for 12 weeks, out of which four weeks were used for strengthening the muscles which could be one possible reason for such a large difference in the p values.

In the clinical study performed by Taylor et al involving nine people with C5/C6 tetraplegia, it was observed that the subjects with C6 tetraplegia were able to perform the tasks involving the light objects efficiently without the device but required the NeuroControl® Freehand System for performing the tasks involving the heavy objects or the tasks that required them to use more force (Taylor et al. 2002). The observations made during the clinical study with the TetraGrip concur with this result.

When the grip strength results were compared with the results obtained using the NeuroControl® Freehand System, it was observed that the mean grasp strength for key grip and palmar grasp was lower than the NeuroControl® Freehand System users (6.6N compared to 11.2 N) (Taylor et al. 2002). However, the individual p values for the results obtained from Volunteer 1 did

not quite obtain statistical significance (p= 0.059) whereas that for Volunteer 2 was statistically significant (p=0.03). This indicates that both the volunteers possessed stronger grasps when they used the TetraGrip. This comparison provides evidence that the TetraGrip can provide assistance to people with C6 tetraplegia in performing the tasks that requires lifting heavy objects.

The results from these two clinical studies indicate that the NeuroControl® Freehand System was better than the TetraGrip. It was more extensively tested and there were statistically significant results to support the use of this device for upper limb rehabilitation. However the NeuroControl® Freehand system is an implanted device and a similar system would increase the cost and duration of rehabilitation because of the surgeries associated with it. The TetraGrip however is a surface device which can be quickly set up on a person who is suitable for electrical stimulation and does not and any surgery for setting up. This makes the device cost effective and easy to use compared to the NeuroControl® Freehand System.

9.2.4.2.2 The TetraGrip vs the NESS H200

A fair comparison of the results obtained using the TetraGrip and the NESS H200 was not possible. At the time of writing there was no study in the literature with the NESS H200 that evaluated tetraplegic volunteers using outcome measures. The literature survey yielded just one published study where ten tetraplegic volunteers used the NESS H200 for performing tasks similar to ADL such as opening a bottle, cutting meat and writing. It is mentioned in this study that three volunteers rejected the NESS H200 because they found the arm splint to be too tight (Snoek et al. 2000) which was not an issue with the TetraGrip. However the advantage of using the arm splint was the reduced donning and doffing time which would be an issue with the TetraGrip as there are six electrodes that need to be placed precisely in order to obtain a functional key grip and palmar grasp movements.

The TetraGrip was used by Volunteer 2 for writing using an ordinary pen which compares with the NESS H200 being used by two volunteers for writing. However whether the volunteers used a modified pen or an ordinary pen is not mentioned in the study. Hence it was not possible to compare the two devices but the NESS H200 is definitely superior to the TetraGrip as far as the donning and doffing of the device is concerned. However the TetraGrip allows the user to change their grasp strength according to their requirement while the stimulation is ON which is not possible using the NESS H200 as it is a push button operated system.

Another advantage of using the TetraGrip is that the volunteer can switch ON the TetraGrip only when they are performing the tasks that they can perform only with the help of FES. The use of the shoulder position sensor provides them the independence to choose when they want to use the device which is not possible when a person with tetraplegia uses a push button based system. If the issue of placing individual electrodes is addressed, then a clinical study to compare the two devices would provide more definitive information about the performance of these two devices.

The clinical study yielded some useful information about the TetraGrip and the volunteer's ability to rehabilitate using this device. The volunteers who participated in this clinical study possessed good voluntary wrist extension and hence the device could be used as it is. However for a user with no or not so strong wrist extension, it would be beneficial to use an orthotic wrist splint just to provide additional stability to the wrist and improve their hand function. This wrist splint would be beneficial especially to someone who is C5 complete or C5 incomplete with the wrist extensor muscle strength of less than 3 in the MRC scale. Making the use of this wrist splint mandatory would limit the number of users and hence this has to be an additional orthosis that would get used only when required.

9.3 Research Contribution

The TetraGrip is a four channel upper limb FES device that was programmed to perform the key grip and palmar grasp movements like most of the other upper limb FES devices summarised in the literature survey presented in chapter 3. However there were a few things that were done differently in the TetraGrip which worked efficiently during the clinical study.

Firstly, the device was programmed such that the electrical stimulation for the finger extensors was ON throughout the stimulation envelope although the strength of the stimulation was reduced to 100 µs when the other channels were switched ON and was increased to 180 µs when the stimulation for other channels were switched OFF. The co-contraction of the finger flexor and finger extensor muscles stabilised the wrist which in turn made the key grip and palmar grasp resemble the natural hand movements and were comfortable for the user.

Both the tetraplegic volunteers had good voluntary wrist control and hence the need for the co-contraction was questionable. In order to justify the need for this, the device was reprogrammed such that Channel 1 (EDC) was completely switched OFF when other channels were switched ON and the volunteers were asked to try the device with this stimulation envelope. It was observed that without any stimulation to the finger extensors, the wrist was pulled into maximum flexion during the key grip and the palmar grasp. The volunteers were not able to resist the flexion with their voluntary wrist extension. Both the volunteers agreed that the stimulation envelope with the co-contraction was better than the one without the co-contraction. At the time of writing, this method of stabilising the wrist while stimulating had not been listed in the literature and hence adds novelty to this research work.

One of the main drawbacks of using a surface multichannel upper limb FES device is the need for precise placement of a number of electrodes. This issue was addressed in this research work by reducing the number of indifferent electrodes from four to two which has not been done previously

(not listed in the literature). Channel 1 and Channel 2 had one common indifferent electrode and Channel 3 and Channel 4 had one common indifferent electrode and the total number of electrodes used for setting up the device was six. The device was also set up with just one indifferent electrode but this setup was ruled out because the sensation at the indifferent electrode when all the three channels were switched ON was uncomfortable.

The use of IMU for controlling an FES device has been previously explored but a fully functional FES device controlled using an IMU that has been clinically tested has not been listed in the literature at the time of writing and hence adds novelty to this research work.

9.4 Summary

This chapter discussed the key aspects of this research work. It started by revisiting the research question and justifying the research work done in an attempt to answer all the research questions. A comparison of the TetraGrip and the NeuroControl® Freehand System and the NESS H200 is also presented here. The chapter then discussed the modifications done to the system in order to address the issues identified during the study involving the able bodied and the tetraplegic volunteers. The chapter concludes by discussing the novelty of this research work. The conclusion and suggested future works is presented in the next chapter.

Chapter 10 Conclusion and Future Work

10.1 Conclusion

This thesis explores the possibility of developing an upper limb FES device that can be used by people with C5/C6 tetraplegia for improving their hand and arm functions. The literature survey in Chapter 3 identified the need for another upper limb FES device which subsequently led to the statement of the following research aim:

To explore the possibility of developing a multi-channel upper limb FES device controlled using a man-machine interface that can be used by people with C5/C6 tetraplegia for improving their hand function and to study the user's ability to control the device efficiently in order to perform the required task.

The following were the objectives of this research work (summarised in section 1.5 of Chapter 1 and 9.2.1 – 9.2.4 of Chapter 9) in order to answer the research question:

10.1.1 Objective 1: To explore different sensors in order to provide a reliable input for the user to control the device.

Shoulder movements were chosen as the method for controlling the upper limb FES device as they replicate the natural reach and grasp movements and hence the user was not required to put conscious effort in generating the control signals and operating the device. IMUs were explored as a possible shoulder position sensor and the ones capable of detecting the shoulder movements were explored. In the end, the Flyduino NanoWii Flight Controller

was chosen as the shoulder position sensor because this device efficiently detected the shoulder movements, was compact and light weight so that it could be strapped across the shoulder of the user and was cost effective.

10.1.2 To develop a control system which uses the input from the sensor and allows the user to operate the device without undue conscious effort.

The signals used to control the operation of the devices were: shoulder elevation, protraction and retraction. The shoulder elevation signal was used to select a grip type and to LOCK and UNLOCK the device when it had entered a particular function. The shoulder protraction and retraction signal was used to modify the grip strength when the stimulator was UNLOCKED. Accelerometer x-axis signal was used to determine a shoulder elevation and accelerometer z-axis signal was used to determine the shoulder protraction and retraction. The gyroscope pitch signal was used to confirm the generation of a control signal.

10.1.3 Objective 3: To develop a multichannel upper limb FES device that can stimulate the corresponding muscles for key grip and palmar grasp movements with the help of the defined control signals.

A four channel upper limb FES device (the TetraGrip) was developed and programmed to generate two functional hand movements, the key grip and the palmar grasp movements, and an exercise mode that alternated between the palmar grasp and the key grip modes. The repeatability and the reproducibility of the device was tested on fourteen able bodied volunteers who used the device to generate the functional hand movements on three different days and the results were analysed. At the end of this study, the device was working reliably without any major issues.

10.1.4 Objective 4: To study the performance of the device and the shoulder position sensor when used by a person with C5/C6 tetraplegia and to evaluate the performance of the device in improving their upper limb functions.

Two volunteers with tetraplegia participated in a twelve week long clinical study and were asked to perform the tasks specified in the outcome measures with and without the use of the TetraGrip. Both the volunteers showed improvement in their ability to perform the specified task and were able to perform an ADL of their choice on the last day of the clinical study. This indicated a possible training effect for both the volunteers, however a longer study is required to explore stronger evidence for the training effect.

Both the volunteers who participated in this clinical study were C6 ASIA A complete and the results from this study indicated that the device worked well for them. A larger clinical study is required in order to evaluate if the TetraGrip will be helpful in improving the hand functions of people with different levels of tetraplegia.

10.2 Future Work

The TetraGrip underwent a number of changes during the clinical study in an attempt to improve its performance. If a similar device is developed in the future, some suggested solution for the issues identified during this research work are summarised in next sections

10.2.1 Improving the control signal

The main issue with the shoulder position sensor was the false triggers. These issues are discussed in section 9.2.2 of Chapter 9. The main reason for these false triggers was the use of only the threshold detection technique for defining the control signal. In order to make the control signal more reliable, a more sophisticated method is required for defining the control

signal. One important desired feature while defining the control signal is to realign or calibrate the sensor before it detects a shoulder position. This would eliminate the false triggers when a tetraplegic volunteer leans on the armrest of their wheelchair.

Few suggested ways of calibration are:

- Programing the software to reset the sensor to zero when it detects significant change in the gyroscope signal using an adaptive algorithm can be one possible solution to resolve this issue. The algorithm should be designed such that it resets the base position to the current position if it detects a tilt greater than a threshold value which can be evaluated using iterative process.
- Using relative shoulder movements instead of absolute shoulder movement can be another potential solution. If the software is defined such that it detects the change in shoulder movement with respect to the current shoulder position then it would eliminate the abovementioned false trigger
- A pattern recognition based system for defining the control signal can also be considered. The signals from the IMU can be fed to a pattern recognition system which can look at a combination of patterns from different axes and interpret the user's command to the FES device.
- A reference IMU can be placed on the torso the body and the relative change between the reference sensor and the shoulder position sensor can also be used to define the control signal.

10.2.2 Improving the Stimulator

The next generation TetraGrip would benefit with an inbuilt sounder for auditory feedback and a display along with a built in memory for the clinician to enter the stimulation parameters and save the settings for the user. These features will also help in the design of a take home device.

Customised electrode garments will eliminate the need for precise placement of the six electrodes used in this study and would make the device more user friendly.

The shoulder position sensor can be connected to the stimulator either using a sturdy connector or by making the sensor wireless. Modern day Bluetooth devices which are available in very small sizes with optimised power consumption can be explored for this purpose.

A programmable stimulator similar to the recently developed FESS-UP stimulator by the Odstock Medical and the University of Salford can be used to develop the next generation TetraGrip. This stimulator has undergone intensive testing for EMC, is compatible with the ISO 60601 standards and is capable of being CE marked. This stimulator can also be reprogrammed to perform the functions of the TetraGrip.

10.2.3 Improving the Clinical Study

The protocol for the clinical study can be modified in order to obtain more useful results. The TetraGrip was designed to be applicable for a wide range of people with tetraplegia and hence volunteers with different levels of tetraplegia should be recruited in order to evaluate the feasibility of this device. It would require obtaining an NHS ethics as this would enable the researchers to approach and recruit volunteers from different spinal units across the country. This multicentre clinical study will be possible if the device is portable and CE marked.

The duration of the study can be made flexible if possible. The clinical study can be designed such that all the volunteers get equal attempts with the outcome measures. Their exercise period with the FES device should be kept variable in order to strengthen the desired muscles. This is because the volunteers deal with different level of impairment and some require more exercise to build the required muscle strength. Hence if the exercise period is

kept flexible and the data obtained during the clinical study from the volunteers would be analysable, though each volunteer would finish the study at a different time. This would make results more conclusive and would help in deciding if further investigation would be beneficial.

A randomised control trial similar to Kapadia et al, can also help in establishing the difference between the volunteers who just receive OT and those who receive FES therapy along with the OT. It would also be beneficial to include outcome measures such as Functional Independence Measure (FIM) and Spinal Cord Independence Measure (SCIM) which would provide more information about the usability of the device in improving the independence of the user when they use the device (Kapadia et al. 2013).

Another outcome measure to include in the study would be the two-point discrimination as this would provide information on whether there is any restoration of sensation due to the prolonged use of FES. In the study by Taylor et al, it was reported that some of the C6 volunteers who used the NeuroControl® Freehand System, showed improvement in the sensation in the hand with FES and some of the areas with sensations did not have any before the use of the device (Taylor et al. 2002). Hence it would be helpful to analyse and verify if there is a similar effect when a surface system is used.

The result obtained in this study suggests that it is possible to use an IMU to control an FES orthosis for people with tetraplegia and to improve their hand function. However further development is required to make the TetraGrip usable at home on a daily basis and some of the suggested changes in the future work section of this chapter will be helpful in achieving this.

References

Alexander&TurnerStudio, 2015. *Human Anatomy Chart Pictures of the Human Body* [online]. Available from: http://humananatomychart.us/category/bone/page/9/ [Accessed 26/07/2017].

Apparelyzed Spinal Cord Injury Peer Support, 2014. *Spinal Cord Injury Statistics* [online]. Available from: http://www.apparelyzed.com/statistics.html [Accessed 14/10/2016].

Arduinoprojects4u, 2013. *Gyro & Accelerometers* [online]. Available from: http://arduino-projects4u.com/wii-motion-plus/ [Accessed 25/01/2017].

Bajd, T. and Munih, M., 2010. Basic functional electrical stimulation (FES) of extremities: an engineer's view. *Technology and health care: official journal of the European Society for Engineering and Medicine*, 18, 361-369.

Banos, O., Toth, M. A., Damas, M., Pomares, H. and Rojas, I., 2014. Dealing with the Effects of Sensor Displacement in Wearable Activity Recognition. *Sensors (Basel, Switzerland)*, 14 (6), 9995-10023.

Benton, L. A., Baker, L. L., Bowman, B. R. and Waters, R. L., 1993. Functional Electrical Stimulation -- A Practical Clinical Guide.

Bergmann, J. H. M., Langdon, P. M., Mayagoitia, R. E. and Howard, N., 2014. Exploring the Use of Sensors to Measure Behavioral Interactions: An Experimental Evaluation of Using Hand Trajectories. *PLoS One*, 9 (2), e88080.

Bioness, 2013. *NESS H200 Wireless* [online]. Bioness. Available from: http://www.bioness.com/Documents/H200Consumer/H200_Wireless_Brochure_Update.pdf [Accessed 13/12/2016].

Broderick, B., Breen, P. and Ólaighin, G., 2008. Electronic stimulators for surface neural prosthesis. *Journal of Automatic Control*, 18, 25-33.

Buckett, J. R., Peckham, P. H., Thrope, G. B., Braswell, S. D. and Keith, M. W., 1988. A flexible, portable system for neuromuscular stimulation in the paralyzed upper extremity. *IEEE Transactions on Biomedical Engineering*, 35, 897-904.

Buick, A., Kowalczewski, J., Carson, R. and Prochazka, A., 2015. Tele-Supervised FES-Assisted Exercise for Hemiplegic Upper Limb. *IEEE Trans Neural Syst Rehabil Eng*, 11, 11.

Duffy, O., 2014. *F330 Quadcopter* [online]. Available from: http://owenduffy.net/rc/aircraft/F330-03/index.htm [Accessed 25/01/2017].

Dunn, J. A., Sinnott, K. A., Rothwell, A. G., Mohammed, K. D. and Simcock, J. W., 2016. Tendon Transfer Surgery for People With Tetraplegia: An Overview. *Arch Phys Med Rehabil*, 97 (6 Suppl), S75-80.

Electronics, S., 2015. *LIS3MDL three axis magnetometer* [online]. Available from: http://www.st.com/content/ccc/resource/technical/document/datasheet/54/2a/85/76/e3/97/42/18/DM00075867.pdf/files/DM00075867.pdf/jcr:content/translations/en.DM00075867.pdf [Accessed 25/01/2016].

Esfandyari, J., De Nuccio, R. , Xu, G., 2010. *Introduction to MEMS gyroscopes* [online]. ST Mcroelectronics. Available from: http://electroiq.com/blog/2010/11/introduction-to-mems-gyroscopes/ [Accessed 25/01/2017].

Feix, T., Romero, J., Schmiedmayer, H. B., Dollar, A. M. and Kragic, D., 2016. The GRASP Taxonomy of Human Grasp Types. *IEEE Transactions on Human-Machine Systems*, 46 (1), 66-77.

Gater, D. R., Dolbow, D., Tsui, B. and Gorgey, A. S., 2011. Functional electrical stimulation therapies after spinal cord injury. *NeuroRehabilitation*, 28, 231-248.

Gil-Agudo, Á., de los Reyes-Guzmán, A., Dimbwadyo-Terrer, I., Peñasco-Martín, B., Bernal-Sahún, A., López-Monteagudo, P., del Ama-Espinosa, A. and Pons, J. L., 2013. A novel motion tracking system for evaluation of functional rehabilitation of the upper limbs. *Neural Regeneration Research*, 8 (19), 1773-1782.

Huxley, A. F. and Niedergerke, R., 1954. Structural Changes in Muscle During Contraction: Interference Microscopy of Living Muscle Fibres. *Nature*, 173, 971.

Huxley, H. and Hanson, J., 1954. Changes in the Cross-Striations of Muscle during Contraction and Stretch and their Structural Interpretation. *Nature*, 173, 973.

Invensense, 2013. *MPU-6000 and MPU-6050 Product Specification* [online]. Available from: https://www.invensense.com/wp-content/uploads/2015/02/MPU-6000-Datasheet1.pdf [Accessed 25/01/2017].

Kapadia, N., Zivanovic, V. and Popovic, M. R., 2013. Restoring Voluntary Grasping Function in Individuals with Incomplete Chronic Spinal Cord Injury: Pilot Study. *Topics in Spinal Cord Injury Rehabilitation*, 19, 279-287.

Kidport, 1998. *Motor Nerves or Motor Neurons* [online]. Available from: http://www.kidport.com/reflib/science/HumanBody/NervousSystem/MotorNeuron.htm [Accessed 16/11/2016].

Kilgore, K. L., Hoyen, H. A., Bryden, A. M., Hart, R. L., Keith, M. W. and Peckham, P. H., 2008. An implanted upper-extremity neuroprosthesis using myoelectric control. *The Journal of hand surgery*, 33, 539-550.

Kirshblum, S. C., Burns, S. P., Biering-Sorensen, F., Donovan, W., Graves, D. E., Jha, A., Johansen, M., Jones, L., Krassioukov, A., Mulcahey, M. J., Schmidt-Read, M. and Waring, W., 2011. International standards for neurological classification of spinal cord injury (Revised 2011). *The Journal of Spinal Cord Medicine*, 34 (6), 535-546.

Knutson, J. S., Chae, J., Hart, R. L., Michael, W., Hoyen, H. A., Harley, M. Y., Otr, L., Hisel, T. Z., Bryden, A. M., Kilgore, K. L. and Peckham, P. H., 2013. NIH Public Access. 49, 1505-1516.

Knutson, J. S., Hoyen, H. a., Kilgore, K. L. and Peckham, P. H., 2004. Simulated neuroprosthesis state activation and hand-position control

using myoelectric signals from wrist muscles. *Journal of rehabilitation research and development*, 41, 461-472.
Kowalczewski, J., Chong, S. L., Galea, M. and Prochazka, A., 2011. In-home tele-rehabilitation improves tetraplegic hand function. *Neurorehabil Neural Repair*, 25 (5), 412-422.
Lynch, C. L. and Popovic, M. R., 2008. Functional Electrical Stimulation. *IEEE Control Systems*, 28 (2), 40-50.
Malešević, N. M., Popović Maneski, L. Z., Ilić, V., Jorgovanović, N., Bijelić, G., Keller, T. and Popović, D. B., 2012. A multi-pad electrode based functional electrical stimulation system for restoration of grasp. *Journal of neuroengineering and rehabilitation*, 9, 66.
Mangold, S., Keller, T., Curt, a. and Dietz, V., 2005. Transcutaneous functional electrical stimulation for grasping in subjects with cervical spinal cord injury. *Spinal cord*, 43, 1-13.
Mann, G., Taylor, P. and Lane, R., 2011. Accelerometer-triggered electrical stimulation for reach and grasp in chronic stroke patients: a pilot study. *Neurorehabilitation and neural repair*, 25, 774-780.
Memberg, W. D., Polasek, K. H., Hart, R. L., Bryden, A. M., Kilgore, K. L., Nemunaitis, G. A., Hoyen, H. A., Keith, M. W. and Kirsch, R. F., 2014a. Implanted neuroprosthesis for restoring arm and hand function in people with high level tetraplegia. *Arch Phys Med Rehabil*, 95 (6), 1201-1211 e1201.
Memberg, W. D., Polasek, K. H., Hart, R. L., Bryden, A. M., Kilgore, K. L., Nemunaitis, G. A., Hoyen, H. A., Keith, M. W. and Kirsch, R. F., 2014b. An Implanted Neuroprosthesis for Restoring Arm and Hand Function in People with High Level Tetraplegia. *Archives of physical medicine and rehabilitation*.
Miller, R., Popovic, M., Thrasher, A. and Verrier, M., 2008. Functional electrical stimulation therapy improves grasping in chronic cervical spinal cord injury: Two case studies. *Journal of Automatic Control*, 18, 53-61.
Moss, C. W., Kilgore, K. L. and Peckham, P. H., 2011a. A novel command signal for motor neuroprosthetic control. *Neurorehabilitation and neural repair*, 25, 847-854.
Moss, C. W., Kilgore, K. L. and Peckham, P. H., 2011b. Training to improve volitional muscle activity in clinically paralyzed muscles for neuroprosthesis control. *Conf Proc IEEE Eng Med Biol Soc*, 2011, 5794-5797.
Mulcahey, M. J., Betz, R. R., Kozin, S. H., Smith, B. T., Hutchinson, D. and Lutz, C., 2004. Implantation of the Freehand System® during initial rehabilitation using minimally invasive techniques. *Spinal Cord*, 42, 146-155.
MyndTech, 2014. *MyndTec Improving Movements, Improving Lives* [online]. Available from: http://www.myndtec.com/myndmove [Accessed 10/12/2016].
Nas, K., Yazmalar, L., Sah, V., Aydin, A. and Ones, K., 2015. Rehabilitation of spinal cord injuries. *World J Orthop*, 6 (1), 8-16.
Nathan, R. H., 1989. An FNS-based system for generating upper limb function in the C4 quadriplegic. *Medical and Biological Engineering and Computing*, 27, 549-556.

Nathan, R. H. and Ohry, A., 1990. Upper limb functions regained in quadriplegia: a hybrid computerized neuromuscular stimulation system. *Arch Phys Med Rehabil*, 71 (6), 415-421.
OpenStax, 2013. *Anatomy and Physiology*. OpenStax.
Park, J. H., 2016. The effects of game-based virtual reality movement therapy plus mental practice on upper extremity function in chronic stroke patients with hemiparesis: a randomized controlled trial. *J Phys Ther Sci*, 28 (3), 811-815.
Popovic, D. and Popovic, M., 1998. Tuning of a nonanalytical hierarchical control system for reaching with FES. *IEEE Trans Biomed Eng*, 45 (2), 203-212.
Popović, D., Stojanović, A., Pjanović, A., Radosavljević, S., Popović, M., Jović, S. and Vulović, D., 1999. Clinical evaluation of the bionic glove. *Archives of Physical Medicine and Rehabilitation*, 80, 299-304.
Popovic, Mirjana B., Popovic, Dejan B., Sinkjær, T., Stefanovic, A. and Schwirtlich, L., 2002a. Restitution of Reaching and Grasping Promoted by Functional Electrical Therapy. *Artificial Organs*, 26, 271-275.
Popovic, M. R., 2006. Transcutaneous electrical stimulation technology for functional electrical therapy applications. *Conference proceedings: ... Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE Engineering in Medicine and Biology Society. Conference*, 1, 2142-2145.
Popovic, M. R., Keller, T., Pappas, I. P. I., Dietz, V. and Morari, M., 2000. ETHZ-ParaCare Grasping and Walking Neuroprostheses.
Popovic, M. R., Popovic, D. B. and Keller, T., 2002b. Neuroprostheses for grasping. *Neurological research*, 24, 443-452.
Popovic, M. R., Thrasher, T. a., Adams, M. E., Takes, V., Zivanovic, V. and Tonack, M. I., 2006. Functional electrical therapy: retraining grasping in spinal cord injury. *Spinal cord*, 44, 143-151.
Prochazka, A., Gauthier, M., Wieler, M. and Kenwell, Z., 1997. The bionic glove: an electrical stimulator garment that provides controlled grasp and hand opening in quadriplegia. *Archives of physical medicine and rehabilitation*, 78, 608-614.
Quandt, F. and Hummel, F. C., 2014. The influence of functional electrical stimulation on hand motor recovery in stroke patients: a review. *Experimental & Translational Stroke Medicine*, 6 (1), 1-7.
Ragnarsson, K. T., 2008. Functional electrical stimulation after spinal cord injury: current use, therapeutic effects and future directions. *Spinal cord*, 46, 255-274.
Rohm, M., Schneiders, M., Müller, C., Kreilinger, A., Kaiser, V., Müller-Putz, G. R. and Rupp, R., 2013. Hybrid brain-computer interfaces and hybrid neuroprostheses for restoration of upper limb functions in individuals with high-level spinal cord injury. *Artificial intelligence in medicine*, 59, 133-142.
Rupp, R., Kreilinger, A., Rohm, M., Kaiser, V. and Muller-Putz, G. R., 2012. Development of a non-invasive, multifunctional grasp neuroprosthesis and its evaluation in an individual with a high spinal cord injury. *Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, EMBS*, 1835-1838.

Savić, G., 2003. ABC of Spinal Cord Injury. *Spinal Cord*, 41, 57-57.
Segil, J. L. and Weir, R. F. f., 2015. Novel postural control algorithm for control of multifunctional myoelectric prosthetic hands. *Journal of Rehabilitation Research and Development*, 52 (4), 449-466.
Shimada, Y., Sato, K., Kagaya, H., Konishi, N., Miyamoto, S. and Matsunaga, T., 1996. Clinical use of percutaneous intramuscular electrodes for functional electrical stimulation. *Archives of physical medicine and rehabilitation*, 77, 1014-1018.
Snoek, G. J., IJzerman, M. J., in `t Groen, F. a. C. G., Stoffers, T. S. and Zilvold, G., 2000. Use of the NESS Handmaster to restore handfunction in tetraplegia: clinical experiences in ten patients. *Spinal Cord*, 38, 244.
Song, Z., Guo, S., Xiao, N., Gao, B. and Shi, L., 2012. Implementation of Human-Machine Synchronization Control for Active Rehabilitation Using an Inertia Sensor. *Sensors (Basel, Switzerland)*, 12 (12), 16046-16059.
SparkFun, 2012. *Nanowii FC Manual* [online]. Available from: http://flyduino.net/documents/NanoWii_manual.pdf [Accessed 25/01/2017].
Swain, I., 1992. Conditioning of Skeletal Muscle by Long Term Functional Stimulation-Implication for the development of Practical Systems in Spinal Cord Dysfuntion. *In:* L., I., ed. *Spinal Cord Dysfunction: Functional Stimulation.* Oxford Medical Publications, 360.
Taylor, P., Esnouf, J. and Hobby, J., 2002. The functional impact of the Freehand System on tetraplegic hand function. Clinical Results. *Spinal cord*, 40, 560-566.
Thorsen, R., Cortesi, M., Jonsdottir, J., Carpinella, I., Morelli, D., Casiraghi, A., Puglia, M., Diverio, M. and Ferrarin, M., 2013a. Myoelectrically driven functional electrical stimulation may increase motor recovery of upper limb in poststroke subjects: a randomized controlled pilot study. *J Rehabil Res Dev*, 50.
Thorsen, R., Dalla Costa, D., Chiaramonte, S., Binda, L., Beghi, E., Redaelli, T., Occhi, E. and Ferrarin, M., 2013b. A noninvasive neuroprosthesis augments hand grasp force in individuals with cervical spinal cord injury: the functional and therapeutic effects. *ScientificWorldJournal*, 30 (836959).
Thorsen, R., Spadone, R. and Ferrarin, M., 2001. A pilot study of myoelectrically controlled FES of upper extremity. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*, 9, 161-168.
Thorsen, R. A., Occhi, E., Boccardi, S. and Ferrarin, M., 2006. Functional electrical stimulation reinforced tenodesis effect controlled by myoelectric activity from wrist extensors. *Journal of Rehabilitation Research and Development*, 43, 247-256.
Tong, K. Y., Mak, A. F. T. and Ip, W. Y., 2002. Control for FES hand grasp systems using accelerometers and gyroscopes, *Engineering in Medicine and Biology, 2002. 24th Annual Conference and the Annual Fall Meeting of the Biomedical Engineering Society EMBS/BMES Conference, 2002. Proceedings of the Second Joint* (Vol. 3, pp. 2379-2381 vol.2373).

Tresadern, P., Thies, S., Kenney, L., Howard, D. and Goulermas, J. Y., 2006. Artificial neural network prediction using accelerometers to control upper limb FES during reaching and grasping following stroke. *Conf Proc IEEE Eng Med Biol Soc*, 1, 2916-2919.

Triolo, R., Nathan, R., Handa, Y., Keith, M., Betz, R. R., Carroll, S. and Kantor, C., 1996. Challenges to clinical deployment of upper limb neuroprostheses. *J Rehabil Res Dev*, 33 (2), 111-122.

Vargas, H., Preza, E. and Velazquez, R., 2009. A Combined Wiimote-Camera Tracking System for Small Aerial Vehicles, *2009 Electronics, Robotics and Automotive Mechanics Conference (CERMA)* (pp. 226-231).

Venugopalan, L., Taylor, P. N., Cobb, J. E. and Swain, I. D., 2015. Upper limb functional electrical stimulation devices and their man-machine interfaces. *J Med Eng Technol*, 39 (8), 471-479.

Waterbury, C., 2007. *The Secret to Motor Unit Recruitment* [online]. TNation. Available from: https://www.t-nation.com/training/secret-to-motor-unit-recruitment [Accessed 01/02/2018].

Wheeler, C. a. and Peckham, P. H., 2009. Wireless wearable controller for upper-limb neuroprosthesis. *Journal of rehabilitation research and development*, 46, 243-256.

Woodford, C., 2009. *Accelerometers* [online]. Available from: http://www.explainthatstuff.com/accelerometers.html [Accessed 25/01/2017].

Xsens, 2006. Available from: http://wiki.icub.org/images/8/82/XsensMtx.pdf [Accessed 25/01/2017].

Yang, K., 2016. Low-cost personalised intrumented clothing with integrated FES electrodes for upper limb rehabilitation. University of Southampton: MRC.

Appendix A

List of Publications

Journal Publication:

Venugopalan, L., Taylor, P. N., Cobb, J. E. and Swain, I. D., 2015. Upper limb functional electrical stimulation devices and their man-machine interfaces. *J Med Eng Technol*, 39 (8), 471-479.

Conference Presentation:

Venugopalan, L., Cobb, J., Swain, I., Taylor, P., 2016. TetraGrip: A four channel FES device for improving the hand functions for people with C5/C6 tetraplegia. Engineering the Upper Limb. 12 – 13 December 2016, London.

Conference Posters:

Venugopalan, L., Cobb, J., Swain, I., Taylor, P., 2015. An Inertial Measurement Unit Based Shoulder Position Sensor for Upper Limb FES Device. 5th Conference of the International Functional Electrical Stimulation Society. 8-9 May 2015 Sheffield.

Venugopalan, L., Cobb, J., Swain, I., Taylor, P., 2015. Man-Machine Interfaces for Upper Limb FES Devices. Bournemouth University School of Design Computing and Engineering Poster Presentation Competition, May 2015.

The abstracts and posters for all of the above are also included here.

JOURNAL OF
Medical
Engineering
&Technology

http://informahealthcare.com/jmt
ISSN: 0309-1902 (print), 1464-522X (electronic)

J Med Eng Technol, 2015; 39(8): 471–479
 DOI: 10.3109/03091902.2015.1102344

Taylor & Francis
Taylor & Francis Group

REVIEW ARTICLE

Upper limb functional electrical stimulation devices and their man–machine interfaces

L. Venugopalan*[1,2], P. N. Taylor[1], J. E. Cobb[2], and I. D. Swain[1,2]

[1]*The National Clinical FES Centre, Salisbury District Hospital, Salisbury, Wiltshire, UK and* [2]*The Faculty of Science and Technology, Bournemouth University, Poole, Dorset, UK*

Abstract

Functional Electrical Stimulation (FES) is a technique that uses electricity to activate the nerves of a muscle that is paralysed due to hemiplegia, multiple sclerosis, Parkinson's disease or spinal cord injury (SCI). FES has been widely used to restore upper limb functions in people with hemiplegia and C5–C7 tetraplegia and has improved their ability to perform their activities of daily living (ADL). At the time of writing, a detailed literature review of the existing upper limb FES devices and their man–machine interfaces (MMI) showed that only the NESS H200 was commercially available. However, the rigid arm splint doesn't fit everyone and prevents the use of a tenodesis grip. Hence, a robust and versatile upper limb FES device that can be used by a wider group of people is required.

Keywords

Functional electrical stimulation, Hemiplegia, Tetraplegia, Activities of daily living, Man–machine interfaces

History

Received 1 April 2015
Revised 3 September 2015
Accepted 22 September 2015

Man-Machine Interfaces for Upper Limb FES Devices

Lalitha Venugopalan[1,2], lvenugopalan@bournemouth.ac.uk
Supervisors: Prof. Ian Swain[1,2], Dr. Jon Cobb[1], Dr. Paul Taylor[2]
1. The Faculty of Science and Technology, Bournemouth University, UK
2. The National Clinical FES Centre, Salisbury District Hospital, Salisbury, UK

Background:

Upper limb Functional Electrical Stimulation (FES) devices are used mainly by Stroke patients or Spinal Cord Injury (SCI) patients to increase their muscle strength and to restore functions of the upper limb [6]. Stimulation is delivered to the nerve supplying the muscles using electrodes which can either be implanted (The NeuroControl Freehand System) or placed on the surface (The NESS H200, The Bionic Glove, The Belgrade Reach and Grasp System and the ETHZ ParaCare) [1][4].

Principle and working:

When stimulating current is applied, an electric field is established between the active and the common electrodes which in turn generates the required action potential. This action potential propagates along the nerve and hence causes muscle contraction by generating a muscle action potential.

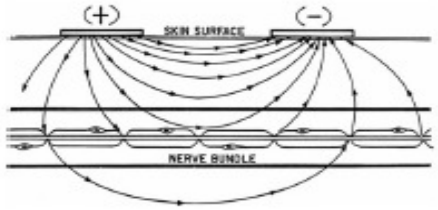


Fig 1: Principle of FES [2]

Man-Machine Interface (MMI):

The user can give commands to the FES device and operate it according to their requirements using the Man-Machine Interface. These can either be mechanical sensors or biosignals.

Mechanical Sensors as MMI:

A Push button has been the most common MMI for the upper limb FES devices. Some of the other popular MMIs are:

1. Sliding potentiometer (Figure 2) used as one of the sensors in the ETHZ ParaCare System. The strength of the finger flexion is proportional to the amount of wrist extension [4].

Fig 2: Sliding Potentiometer

2. Linear Variable Differential Transformer (LVDT) (Figure 3) used in The Bionic Glove which determines the wrist position. The stimulation of the finger flexors is proportional to the wrist position [3].

Fig 3: LVDT

3. Hall Effect based Shoulder Position Sensor used in the NeuroControl Freehand System (Figure 4). Shoulder protraction/retraction is used to control the grasp force and a quick shoulder elevation locks the stimulator. Same signal is used to unlock the stimulator [1].

Fig 4: Shoulder Position Sensor

Biosignals as MMI:

Some researchers have explored the possibility of using a Brain Computer Interface (BCI) to give commands to the FES device and hence have used EEG signals as the MMI.

Researchers have used EMG signals from a number of muscles as the MMI some of which are: wrist extensors to generate powered tenodesis [5], neck muscles to control a 12 channel implanted FES device [8], Tibialis Anterior in complete C4 patients to control 24 channel implanted system [9].

Possible Future MMIs:

The availability of compact accelerometers and gyroscopes has made it possible to use these as potential future MMIs for upper limb FES devices. The Xsens 3D motion tracking device is an inertial measurement sensor (IMU) which has been used to determine the position of the arm in the space in stroke patients [7].

But this module is very expensive. So part of the author's PhD is to explore the possibility of using less expensive IMUs, like the Hextronix MicroWII Flight Controller board as a potential MMI for upper limb FES. After strapping the board to the user's shoulder, the pre-defined shoulder movements will generate the command signal to control the stimulator.

Fig 5: Hextronix Microwii Flight Controller board

Acknowledgement:

This work is funded by Inspire, a charitable organization dedicated to people with spinal cord injuries and Bournemouth University.

References:

[1] J. R. Duckett, P. H. Peckham, G. B. Thrope, S. D. Braswell, and M. W. Keith, "A flexible, portable system for neuromuscular stimulation in the paralyzed upper extremity," *IEEE Trans. Biomed. Eng.*, vol. 35, no. 11, pp. 897–904, 1988.
[2] L. A. Benton, L. L. Baker, B. R. Bowman, and R. L. Waters, *Functional Electrical Stimulation – A Practical Clinical Guide*, 2nd edition. Rehabilitation Engineering Center, CA.
[3] A. Prochazka, M. Gauthier, M. Wieler, and Z. Kenwell, "The bionic glove: an electrical stimulator garment that provides controlled grasp and hand opening in quadriplegia," *Arch. Phys. Med. Rehabil.*, vol. 78, no. 6, pp. 608–614, Jun. 1997.
[4] M. R. Popovic, T. Keller, I. P. I. Pappas, V. Dietz, and M. Morari, "ETHZ-ParaCare Grasping and Walking Neuroprostheses," 2000.
[5] R. Thorsen, R. Spadone, and M. Ferrarin, "A pilot study of myoelectrically controlled FES of upper extremity," *IEEE Trans. Neural Syst. Rehabil. Eng.*, vol. 9, no. 2, pp. 161–168, 2001.
[6] P. Taylor, J. Esnouf, and J. Hobby, "The functional impact of the Freehand System on tetraplegic hand function. Clinical Results," *Spinal Cord*, vol. 40, no. 11, pp. 560–566, Nov. 2002.
[7] P. Treadwell, S. Trilas, L. Kenney, D. Howard, and J. Y. Goulermas, "Artificial Neural Network Prediction Using Accelerometers to Control Upper Limb FES During Reaching and Grasping Following Stroke," in *28th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 2006. EMBS '06*, 2006, pp. 2916–2919.
[8] K. L. Kilgore, H. A. Hoyen, A. M. Bryden, R. L. Hart, M. W. Keith, and P. H. Peckham, "An implanted upper-extremity neuroprosthesis using myoelectric control," *J. Hand Surg.*, vol. 33, no. 4, pp. 539–550, Apr. 2008.
[9] C. W. Moss, K. L. Kilgore, and P. H. Peckham, "A novel command signal for motor neuroprosthetic control," *Neurorehabil. Neural Repair*, vol. 25, no. 9, pp. 847–854, Dec. 2011.

An Inertial Measurement Unit Based Shoulder Position Sensor for Upper Limb FES Device

Venugopalan L[1,2], Swain I.D[1,2], Cobb J.E[1], Taylor P.N[2]

[1]The Faculty of Science and Technology, Bournemouth University

[2] The National Clinical FES Centre, Salisbury District Hospital, Salisbury, Wiltshire, SP2 8BJ

Introduction

Every year, nearly 1200 people in the UK are paralysed due to of spinal cord injuries (SCIs) and there are nearly 40,000 people living with the effects of SCI, 30% of whom are diagnosed as having incomplete tetraplegia, which is a paralytic condition that results in loss of function of all the four limbs in a human being[1]. Functional electrical stimulation (FES) has helped people with C5-C7 tetraplegia regain some of their upper limb functions and efficiently perform their activities of daily living[2]. People with C5-C7 tetraplegia have some redundant shoulder movement which can be used to control an upper limb FES device.

Inertial Measurement Units (IMUs) is an electronic device with accelerometers, gyroscopes and sometimes magnetometers, which provide information like speed of movement and orientation of the body. IMUs like the Xsens MTx have been used to detect the position of the arm in the space[3]. But the Xsens module is quite expensive and slightly bulky.

The aim of this study is to explore the possibilities of using a compact and cost effective commercially available IMU as a shoulder position sensor to control an upper limb FES device.

Commercially Available IMUs

Some of the commercially available IMUs that can be used as a shoulder position sensor are summarized below

Sensor	Size (L x B x H) in cm	Hardware specification	Cost	Weight
Xsens MTx	3.8 x 5.3 x 2.1	Two bi-axial accelerometers, three single axis gyroscope and three magneto-resistive sensors	€1000 (approx.)	30g
Nintendo Wii	14.8 x 3.6 x 3.1	One Tri-axis accelerometer	£20.00 (approx.)	200g
Nintendo Wii plus Wii MotionPlus	19 x 3.6 x 3.1	One Tri-axis accelerometer, two dual axis gyroscope	£25.00 (approx.)	210g
Sony PlayStation Move	20 x 4.7 x 4.7	A three axis accelerometer, a dual-axis gyroscope, a single axis gyroscope, a three axis magnetometer	£20.00 (approx.)	145g
Hextronic Microwii flight controller	5.0 x 5.0 x 1.6	A three axis accelerometer, a three axis gyroscope, a three axis magnetometer and a barometer	$35.00 (approx.)	14g
Flyduino Nanowii flight controller	2.7 x 2.7 x 1.6	A three axis accelerometer and a three axis gyroscope	€40.00 (approx.)	4g

Table 1: Summary of IMUs that can be used as a shoulder position sensor

The main specifications of a shoulder position sensor are: ability to detect shoulder position and should be compact. From the sensors listed in table 1, the two possible sensors for sensing shoulder position are Xsens MTx and Flyduino Nanowii flight controller (FC).

Methodology

An experiment was conducted in order to compare the performance of the Flyduino Nanowii FC and the Xsens MTx as a shoulder position sensor. The Xsens module is also considered as the gold standards for the IMUs for biomechanical applications. The Flyduino Nanowii FC and the Xsens MTx are shown in figures 1 and 2.

Fig 1: Flyduino Nanowii FC

Fig 2: Xsens MTx Sensor

So in the comparison study, if the Flyduino Nanowii FC correlates well with the Xsens MTx, then it can be used as a shoulder position sensor as it satisfies all the specifications. The protocol for the experiment is summarized below:

1. The volunteer was asked to relax and be seated comfortably in a chair.
2. The Nanowii sensor was strapped on the upper arm as close to the shoulder as possible making sure that the sensor remained stable and didn't get affected by motion artefacts.
3. The Xsens MTx sensor was firmly strapped on top of the Nanowii and it was ensured that the axes were aligned as closely as possible (fig 5-1).
4. The MT9 software and the C program that recorded the data from the Nanowii were executed.
5. Both the sensors were tapped on the top. This generated a spike in the output signal which was used as a starting point during post processing.
6. The volunteers were asked to perform shoulder elevation, protraction and retraction in the given sequence.
7. The execution of both the software were terminated and the data was saved.

Fig 3: Experimental Setup

Figure 3 shows the experimental setup. In the second experiment, the volunteers did the shoulder movements in random sequence. The results obtained from these experiments are discussed in the next section.

Results and Discussion

The data from the Nanowii was mapped as a one byte data and serially read by a C program. And the data from the Xsens was in Euler form. So in order to make a fair comparison, the data from both the sensors were normalized and then compared. Also the data from the Nanowii was down sampled so that the number of samples from both the sensors were roughly the same. Figure 4(A),(B) and (C) show the accelerometer x, y and the z axis data.

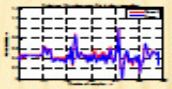


Fig 5(A): Accelerometer X-Axis

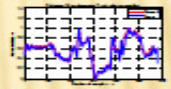


Fig 5(B): Accelerometer Y-axis

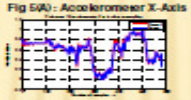


Fig 5(C): Accelerometer Z-axis

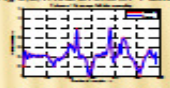


Fig 5(D): Gyroscope Roll

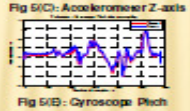


Fig 5(E): Gyroscope Pitch

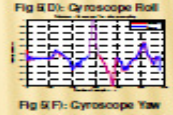


Fig 5(F): Gyroscope Yaw

The cross correlation values calculated from the data obtained from nine healthy volunteers is summarized in table 2. Figures 6(A)-(F) show the post processed graphs from one of the volunteers who performed the shoulder movements in a random sequence multiple times. From the graphs, it is possible to identify the shoulder movements performed by the volunteer.

Volunteer no	Acc X-axis	Acc Y-axis	Acc Z-axis	Gyro Roll	Gyro Pitch	Gyro Yaw
1	0.9091	0.9504	0.9521	0.9517	0.9533	0.9907
2	0.9573	0.9101	0.9477	0.9901	0.9555	0.9046
3	0.917	0.9009	0.9631	0.9607	0.7066	0.9306
4	0.9019	0.9776	0.9103	0.9317	0.9213	0.9741
5	0.9396	0.7957	0.9526	0.9752	0.9173	0.9118
6	0.903	0.911	0.9738	0.9237	0.9583	0.9316
7	0.9478	0.8999	0.9592	0.9914	0.9354	0.9756
8	0.9614	0.9652	0.9545	0.981	0.9692	0.9586
9	0.9734	0.9396	0.9608	0.979	0.9045	0.9673

Table 2: Cross correlation values of the data from Nanowii and Xsens

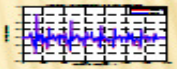


Fig 6(A): Accelerometer X-Axis

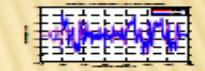


Fig 6(B): Accelerometer Y-axis

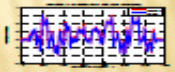


Fig 6(C): Accelerometer Z-axis

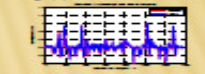


Fig 6(D): Gyroscope Roll

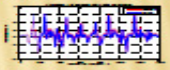


Fig 6(E): Gyroscope Pitch

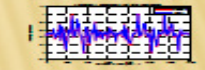


Fig 6(F): Gyroscope Yaw

By comparing the graphs in figures 5(A)-(F) and 6(A)-(F), the sequence of movements performed by this volunteer is shoulder elevation, protraction retraction, protraction, protraction, elevation, protraction, retraction protraction and retraction.

Conclusions and Future Work

After analysing the data obtained from the nine volunteers who participated in the experiment, it can be concluded that the Flyduino Nanowii FC is capable of detecting the shoulder movement. Since it is cheaper and compact compared to the Xsens MTx sensor, it can be used as a shoulder position sensor. In future, an upper limb FES device with this IMU as its shoulder position sensor will be designed and will be clinically tried on people with tetraplegia.

References

1. Spinal Cord Injury: Quadriplegia and Tetraplegia [online]. Apparalyzed, a spinal cord injury peer support. Available from: http://www.apparalyzed.com/quadriplegia-quadriplegic.html [accessed on 24th October 2014].

2. Popovic MR, Popovic DB, Keller T. Neuroprostheses for grasping. Neurological research. 2002;24(5):443–452.

3. Trosadern P, Thias S, Kannoy L, Howard D, Goulermas JY. Artificial Neural Network Prediction Using Accelerometers to Control Upper Limb FES During Reaching and Grasping Following Stroke. In: ; 2006. p. 2916–2919.

Acknowledgement

This research is funded by the INSPIRE foundation, a charitable institution for people with SCI and Bournemouth University.

Abstract

Engineering the Upper Limb, 12 – 13 December 2016, London

TetraGrip: A four channel FES device for improving the hand functions for people with C5/C6 tetraplegia.

Venugopalan L, Cobb, J.E, Taylor, P.N, Swain, I.D

lvenugopalan@bournemouth.ac.uk

Background:

Functional Electrical Stimulation (FES) has helped people with C5/C6 tetraplegia in regaining some of their upper limb functions. At the time of writing, only the NESS H200 was commercially available which uses a rigid arm splint to hold the electrodes in position. This arm splint comes in one size and does not fit everyone and hence limits its usability.

The TetraGrip:

It is a four channel surface FES device controlled using an Inertial Measurement Unit (IMU). The control signal and the stimulation envelope for the functional modes are explained in tables 1 and 2.

	Stimulator Idle	Stimulator Locked	Stimulator Unlocked
Single Shoulder Shrug	Key Grip	Unlocked	Locked
Two shoulder shrugs (roughly 3 sec apart)	Palmar Grasp	Stop	Alternates between lock and unlock
Shoulder Protraction	NA	NA	Increments the pulse width of Ch3 or Ch4.
Shoulder Retraction	NA	NA	decrements the pulse width of Ch3 or Ch4

Table 1: Control signals used in the TetraGrip (Ch: channel)

	Grasp the object			Release the object	
Key	Hand Open Ch 1: ON Ch 2: OFF Ch 3: OFF	Hand Close Ch 1: ON Ch 2: ON Ch 3: OFF Ch 4: OFF	Thumb Adduction Ch 1: ON Ch 2: ON Ch 3: OFF Ch 4: ON	Hand Open Ch 1: ON Ch 2: OFF Ch 3: OFF Ch 4: OFF	System Idle Ch 1: OFF Ch 2: OFF Ch 3: OFF Ch 4: OFF

	Ch 4: OFF				
Palmar	Hand Open Ch 1: ON Ch 2: OFF Ch 3: OFF Ch 4: OFF	Thumb Adduction Ch 1: ON Ch 2: OFF Ch 3: ON Ch 4: OFF	Hand Close Ch 1: ON Ch 2: ON Ch 3: ON Ch 4: OFF	Hand Open Ch 1: ON Ch 2: OFF Ch 3: OFF Ch 4: OFF	System Idle Ch 1: OFF Ch 2: OFF Ch 3: OFF Ch 4: OFF

Table 2: Stimulation sequence for the key grip and palmar grasp modes in the TetraGrip (Ch: Channel)

Results and Discussion:

Experiment 1:

Participants: 13, nine of whom came back to do the same experiment on two different days as well.

Method: Volunteer attempted five key grip and palmar grasp start and stop. Other control signals were attempted as many times as they wanted.

Result: Error between the attempted and recorded values decreased after the researcher made few changes to the system based on the feedbacks from the volunteers and after the volunteer got used to the control signals.

Experiment 2:

Participants: Two C6 complete Tetraplegic

Outcome measures used: Grip Strength test, Box and Block test and the Grasp Release Test (GRT).

Results: Significant improvement in the grip strength with FES when compared to without FES. Box and Block score improved for both the volunteers over a period of time and GRT scores showed improvement in some of the tasks.

Conclusion:

Evidences from the two experiments show that the TetraGrip can be used to improve the hand functions of people with C6 complete tetraplegia. However there is not enough evidence to conclude that the device can be efficiently used by people C5 complete/incomplete or C6 incomplete tetraplegia as well and this requires further investigation with a larger clinical study.

Appendix B

Electronics Used In the TetraGrip

Arduino Mega 2560

The Arduino Mega 2560 (Figure 1) is an ATMega2560 microcontroller based open source programmable prototyping platform. It has 54 digital input/output (I/O) pins, 14 of which can be used as pulse width modulation (PWM) pins, 16 analogue inputs, 4 Universal Asynchronous Synchronous Transmission (UART) hardware serial ports (Serial 0, 1, 2 and 3), a Universal Serial Bus (USB) jack for connecting the Arduino to the computer, a power jack to connect an external 5V power supply, In Circuit Serial Programing (ICSP) header with the pins for Inter Integrated Circuit (I2C) communication and a reset button that causes hardware reset.

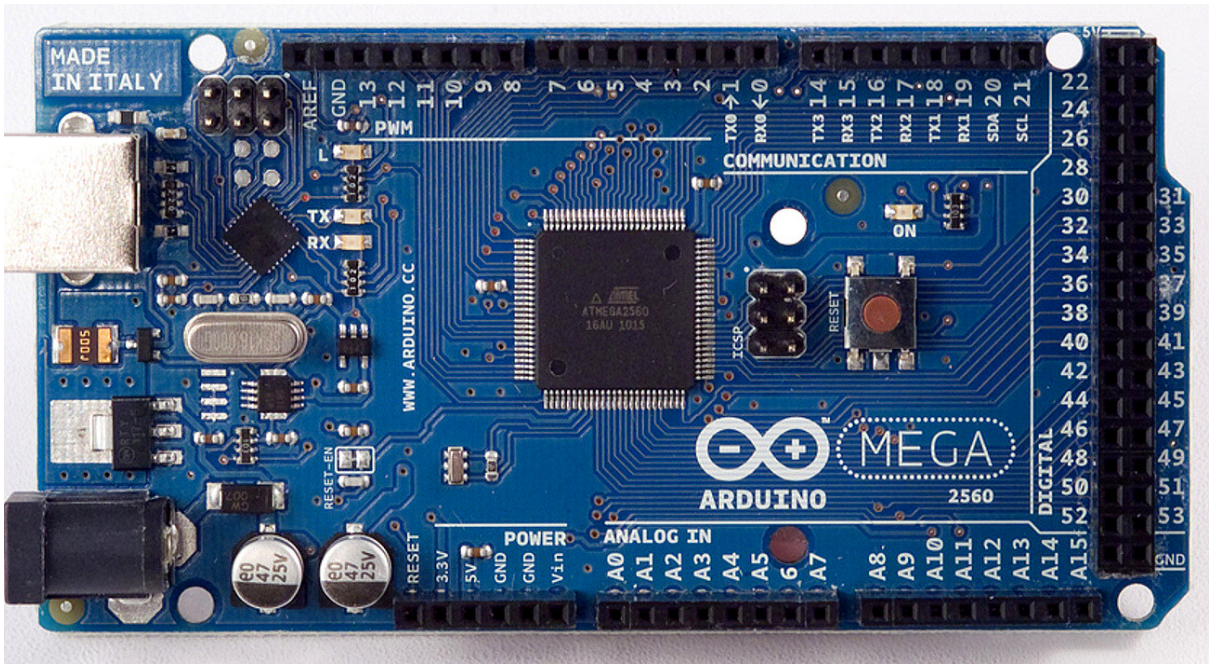


Fig 1: Arduino Mega 2560

The operating voltage of the Arduino Mega 2560 is 5V. The recommended input voltage is 7-12 V but the lower and the upper limits of the input voltages are 6-20V. The DC current per I/O pin is 40 mA and the DC current for the 3.3V power supply pin is 50mA. The power pins are the 5V, 3.3V, V_{in} and

ground (GND). The V_{in} pin is the input voltage to the Arduino Mega 2560 when an external power supply is used.

The available flash memory is 128 KB out of which 4 KB is used by the bootloader. The Static Random Access Memory (SRAM) is 8 KB and the Electrically Erasable Programmable Read Only Memory (EEPROM) is 4 KB. The Arduino software library has a built in EEPROM library that can be used to read and write the data. In order to use the built in library, the header file <EEPROM.h> needs to be included in the program. This device runs at 16MHz clock frequency.

The Arduino Mega I/O pins

The 54 digital I/O pins available in Arduino Mega can be set as input or output pins using the function pinMode(). The data can be read from an input pin using the function digitalRead() command and the data can be written to an I/O pin using the function digitalWrite(). The examples below explain the use of these functions for setting the status the pin 7 which is programmed to monitor the status of one of the buttons in the front panel of the TetraGrip and pin 37 which is the chip select pin for Channel 1.

```
const int setup_parameter_set = 7;          // 7 is the pin no 7 of the Arduino Mega and //setup_parameter_set is the name assigned to //the pin
pinMode(setup_parameter_set, INPUT); // sets pin 7 as an input pin
digitalRead(setup_parameter_set);                  //Reads the status of the pin (HIGH or LOW)

const int EDC_SELECT = 37;                  // 37 is the pin no 37 of the Arduino Mega and
                                                   // EDC_SELECT is the name assigned to the pin
pinMode(EDC_SELEC, OUTPUT);                  // Sets EDC_SELECT as an output pin
digitalWrite(EDC_SELECT, LOW);                  // Sets the status of EDC_SELECT as LOW
```

digitalWrite(EDC_SELECT, HIGH); // Sets the status of EDC_SELECT as HIGH

Some of the I/O pins have specialised functions which are stated below.

UART hardware serial ports: The four UARTs in the Arduino Mega are described below. Serial: Pin 0 is the Receive (Rx) and pin 1 is the transmit (Tx). Serial 1: Pin 19 is the Rx and pin 18 is the Tx. Serial 2: Pin 17 is the Rx and pin 16 is the Tx. Serial 3: Pin 15 is the Rx and pin 14 is the Tx. In order to use the inbuilt serial communication library, a header file called “Serial.h” needs to be included in the program.

External Interrupts: Pins 2, 3, 18, 19, 20 and 21 are the interrupt 0; interrupt 1; interrupt 5; interrupt 4; interrupt 3; interrupt 2 respectively. These interrupt pins can be used to generate interrupts on a rising or falling edge of a square wave, a logic low signal or a change in the value.

Pulse Width Modulation (PWM) pins: Pins 2-13 and 44-46 can be used to provide 8 bit PWM signal.

Serial Peripheral Interface (SPI) pins: Pin 50 is the Master In Slave Out (MISO), pin 51 is the Master Out Slave In (MOSI), pin 52 is the Serial Clock and pin 53 is the slave select pin. These pins are used for the SPI communication either between two Arduino devices or between Arduino Mega and other SPI compatible devices.

The 16 analog pins have 10 bit resolution and by default they measure from ground to 5V but it is possible to change the upper range by using the potential at the Analog Reference (AREF) pin and the analogReference() function.

Adafruit Power Boost C 500 mA+

The Adafruit Power Boost C 500 mA+ (Figure 2) is a power supply with a built in battery charging circuit. This circuit is a DC/DC boost converter module that can be powered using 3.7V Lithium (Li) ion or Lithium Polymer (LiPo) battery which is in turn converted into a 5V DC supply. This power supply unit has a charger circuit that is powered through the microUSB jack. This circuit recharges the 3.7V Li ion or LiPo battery at a maximum rate of 500 mA. The circuit comes with two light emitting diodes (LEDs) which monitor the charge rate. The orange LED indicates that the battery is being charged and the green LED indicates that the charging is complete. The circuit can charge and boost simultaneously as long as the circuit draws current less than 300 mA continuously from the 5V supply pin.

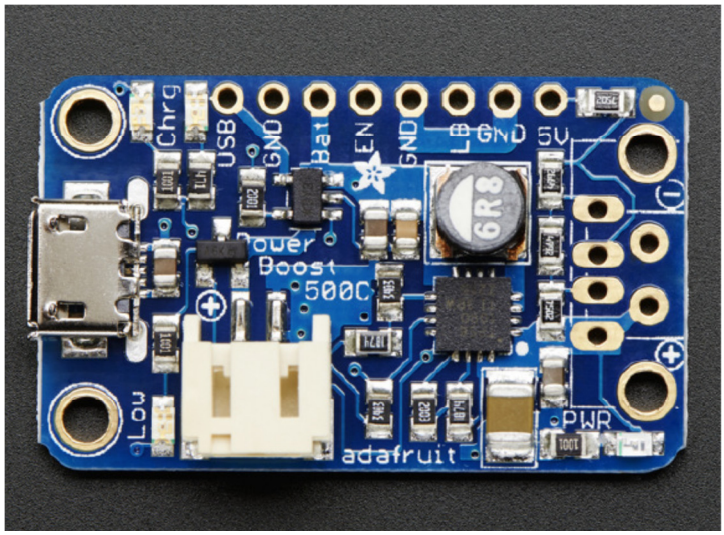


Fig 2: Adafruit PowerBoost C 500 mA+

Odstock Medical Stim Engine

The Odstock® Stim Engine (Figure 3) is a single channel programmable device which can be programmed to function as a FES device and two or more Odstock® Stim Engines can be used to design a multichannel FES device. If a number of stim engines are used, then a master micro controller is used to monitor and control the operations of all the stim engines.

For the stim engine to generate the desired stimulation envelop, the stimulation parameters for all the phases in the stimulation envelop needs to be written to the corresponding registers. The main stim engine registers used for programming the stimulation envelope of the TetraGrip are the General Registers, Command Registers and the Per Phase Stimulation Parameter Registers. Most of the registers in the stim engines are read/write registers and each register has a register number and number of bytes which are mentioned in the data sheet.

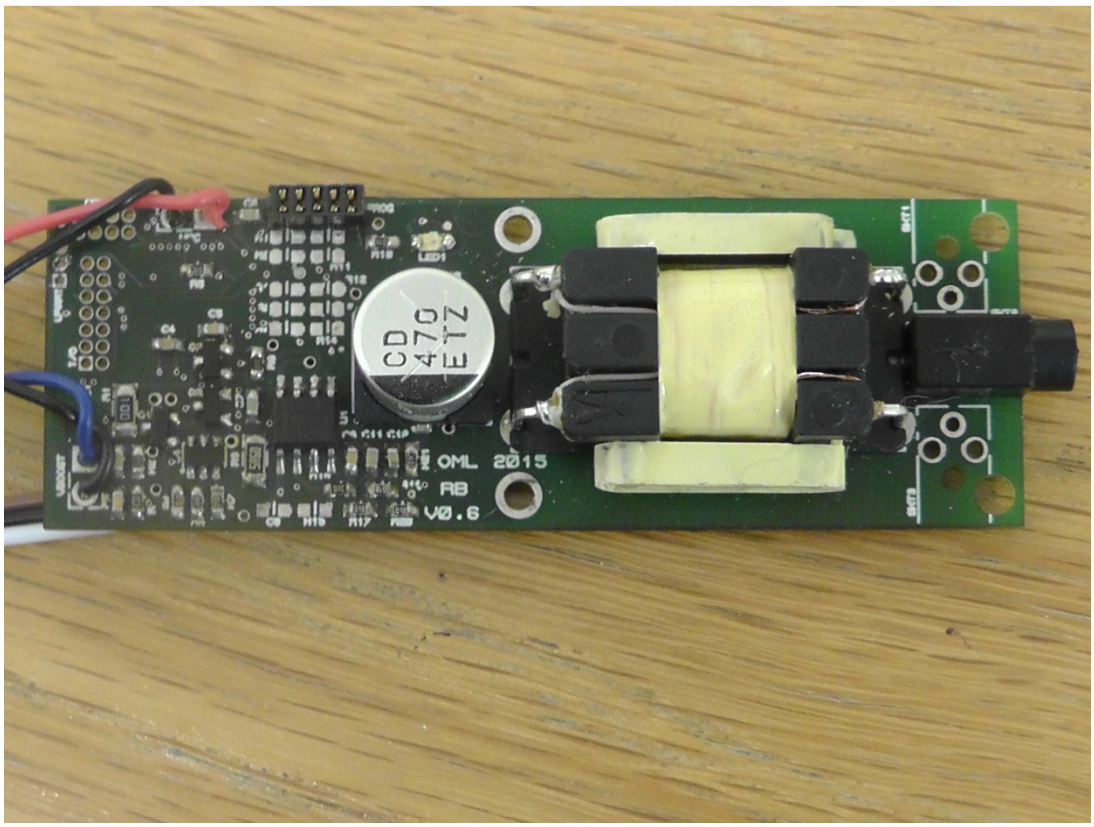


Fig 3: Odstock® Stim Engine

The stim engines use the SPI communication protocol for reading and writing the data. In this communication protocol, the stim engines echo a data back when they receive a data from another device. If the received data is the first data, then the stim engines echo back '0' which is the dummy byte else the echoed data is the previously received data.

The SPI communication using the Stim Engines has the following signal lines: the Slave data out (SDO) or the MISO, the Slave data in (SDI) or the

MOSI, the chip select ($\overline{CS}$) or the slave select ($\overline{SS}$) line, the Comm Request or the Interrupt Request (IRQ) and the Serial Clock (SCK) line. The functions of the SDO, the SDI and the SCK lines are same as the ones in Arduino Mega. The IRQ line is a hardware handshake line which when low indicates that the Stim Engines are ready to receive an SPI message and when the IRQ line is high, it indicates that the Stim Engines are processing the received data and are not ready to receive any message. The $\overline{SS}$ line is used to select a particular stim engine. A particular Stim Engine is selected when its $\overline{SS}$ line goes low. In a multichannel system, selecting two or more Stim Engines can cause a conflict and the data may not get written to the proper Stim Engine. Hence once the data is written to a particular Stim Engine, it should be deselected by pulling the $\overline{SS}$ line high. Before delivering a stimulation pulse, the stimulation parameters for all the phases of the stimulation envelop should be written to the per phase registers. The per phase registers used in the TetraGrip are as follows:

Register 48 – Phase Pointer: This register is used to specify the phase number. The values written in the subsequent per phase registers correspond to the phase number specified by the value in the Phase Pointer register.

Register 50 – Ramp Parameter: This register specifies the parameter on which the stimulation ramps. The stimulator can ramp on pulse width, current or frequency. The TetraGrip stimulator ramps on pulse width. The values written to this register are: 0 to ramp on pulse width, 1 to ramp on current and 2 to ramp on frequency.

Register 51 – Waveform: This register allows the programmer to choose the type of output waveform. This can be done by writing either 0 or 1 to the bits 0,1 and 2. If the value in bit 0 is 1 then the stimulator generates symmetric waveform and if the value is 0, then it generates asymmetric waveform. Similarly the bit 1 takes 0 for generating a positive waveform and 1 for

generating a negative waveform and the bit 2 takes 0 for standard biphasic waveform and 1 for generating true biphasic waveform. The value written to this register while programming the TetraGrip is 0x00, which indicates the waveform generated is asymmetric, positive and biphasic in nature.

Register 52 – Target pulse width: This register is used to specify the target pulse width for a particular phase in the stim engine. The first 12 bits of this 16 bit register is used to hold the pulse width value. The bits 12 to 15 are used to determine if the stim engine considers the value in the target pulse width register or takes an external pulse width value specified in the instantaneous pulse width register (Register 16). In order to take the value specified in the target pulse width register, the values in bits 15 to 12 should be 0. On the other hand, in order to use the value in the instantaneous pulse width register, 0X1000 is written to the target pulse width register which sets bit 12 to 1 and the rest of the bits are 0. This allows the stim engine to use an external value.

Register 54 – Target Current: This register helps in specifying the target current for each phase. The unit of this register is in10µA and hence takes values between 0 and 12000. The TetraGrip however does not require current as high as 120 mA hence the device is programmed in such a way that it does not exceed 60 mA.

Register 56 – Target Frequency: This register takes a value from 0 to 1000 Hz. However the TetraGrip does not require very high frequencies and is hence programmed to operate between 20 and 60 Hz.

Register 58 – Duration: This register defines the length of each phase. This register takes a value from 1 to 6000 and the units are in milliseconds. This register can also be used to program the stimulator in no timeout mode by writing 0xFFFF to this register. This causes the stimulator to remain in the same phase till a transition to the next phase is forced.

Register 64 – Go to Phase on Duration/Target: This register specified the phase the stim engine will enter once it times out or reaches the target pulse width.

Besides the per phase stimulation registers, the other registers used for programming the stim engines are as follows:

Register 12 – Command/Status Register: This register is used to issue commands or get the status of the stim engines. A list of values for commands and status is provided in the data sheet. The TetraGrip uses the Command/Status register to enable the sync line by writing 0x0E to this register.

Register 15 – Phase Number: This register is used to force a phase transition to the phase number specified by the value in this register. It takes values from 0-255. This register is used to force a phase transition in order to get the stim engine out of the no time out phase or to get into the functional modes when the device detects the specific control signal.

Register 16 – Instantaneous Pulse Width Register: This register is used to set the external pulse width value. When the target pulse width register is set to use the external pulse width value, then the stim engines take the value in the instantaneous pulse width register and generate the stimulation envelope accordingly.

Regulator Circuit (3.3 V)

The stim engines operate on 3.3V power supply. The Arduino Mega 2560 has a 3.3V power pin but the maximum current drawn by this pin is 50 mA which is not enough to drive the four stim engines. Hence a separate 3.3V power supply with adequate current capacity is required for the proper operation of the device. The regulator circuit in the TetraGrip (Figure 4) consists of the LM 1117T 3.3 IC which is a 3.3V regulator IC manufactured by the Texas Instruments. These three pin regulator ICs can tolerate up to

15V as input with a dropout voltage of 1.2V. The output voltage is a regulated 3.3V with 800 mA current.

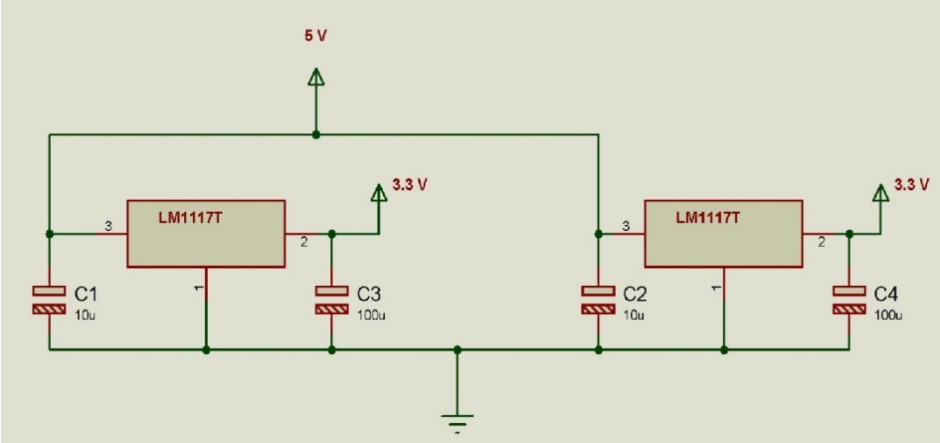


Fig 4: 3.3V Regulator Circuit Used in the TetraGrip

Figure 4 shows the circuit diagram of the 3.3V regulated power supply used in the TetraGrip. The regulator circuit consists of two of LM1117T3.3 ICs, each powering two of the stim engines, so that sufficient current is available to drive all the stim engines. The circuit receives 5 V input supply from the Adafruit Power Boost C 500 mA+ circuit and regulates it down to 3.3V. An input capacitor of 10 µF is connected between the input pin of the IC and the ground which filters out high frequency signals. An output capacitance of 100 µF is connected between the output pin and the ground in order to improve the response of the power supply.

OML Boost Circuit

and this can be achieved with the help of the OML boost circuit (Figure 5). The power received from the battery gets stored in the two input capacitors (C207 and C208). The circuit uses a MAX17112 IC (Figure 6) which is a switching IC from maxim-ic.com. This IC connects and disconnects its LX pin to the ground at 1 MHz frequency. When the LX pin is grounded, current builds up and the energy is stored in the inductor L201. When the LX pins are disconnected, the current through the inductor L201 continuous to flow through the diode (D203), thereby transferring the energy from L201 to the output capacitors C214 and C215. The output voltage is higher than the input voltage because current through the inductor does not change direction

quickly. When LX is grounded, D203 gets reverse biased and hence stops the current flowing back from the output capacitors.

Resistors R213, R214 and variable resistor RV201 provide feedback to the regulator which adjusts the duty cycle of the LX switch so that the average current in the inductor is enough to keep the output at the desired voltage. The boost circuit is set to deliver 12V to power the output stages in the stim engines.

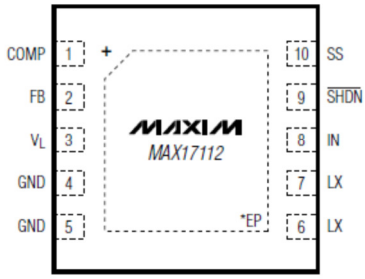


Fig 5: Pin Diagram of MAX17112 Step Up DC to DC Converter IC

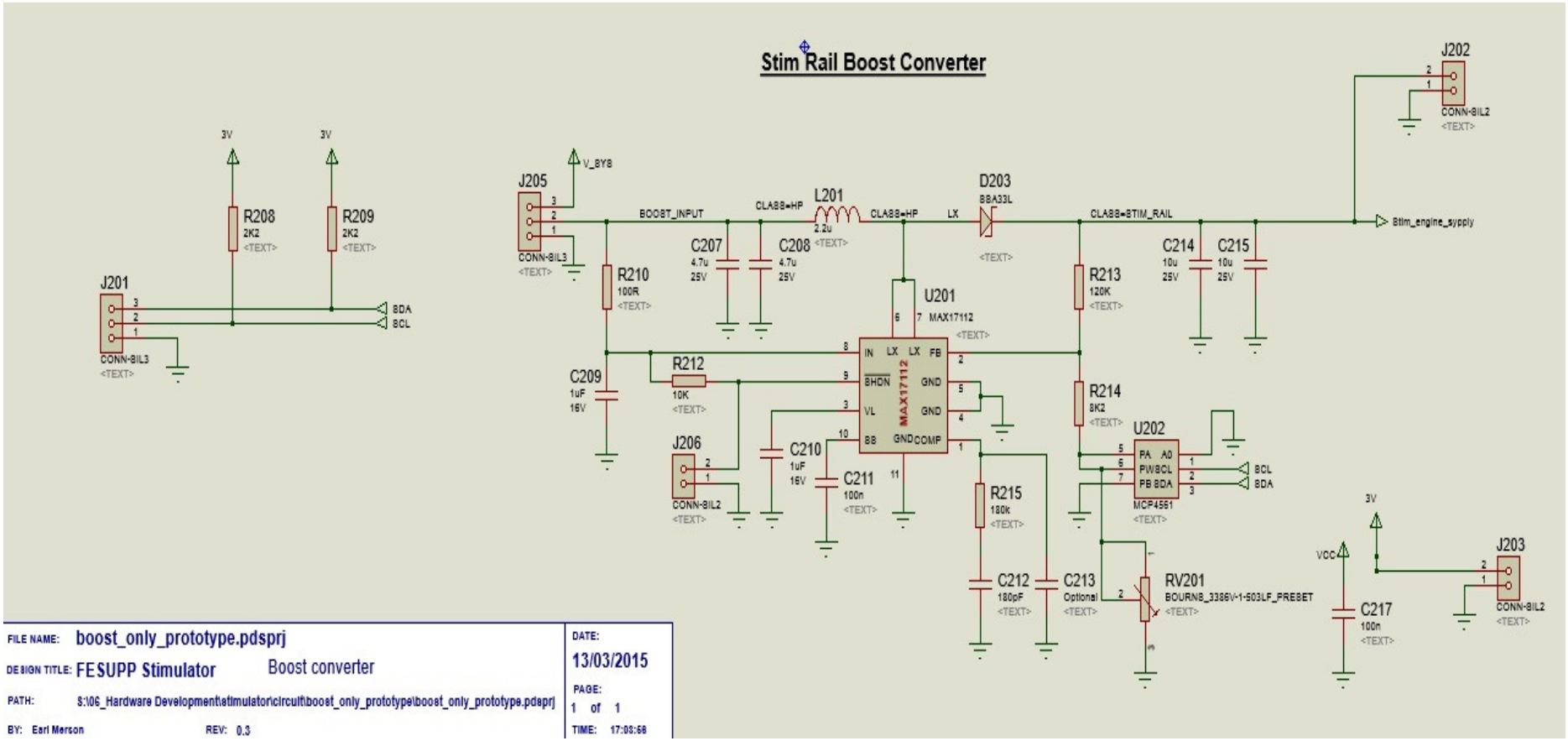


Fig 6: OML Boost Circuit Diagram

Level Shifters

Some of the I/O lines in the Arduino are programmed to act as the $\overline{CS}$, $\overline{pause}$ Error! Bookmark not defined./enable, trigger and sync enable lines for the stim engines. These I/O lines are held at 5V when they are logically high but the corresponding pins in the stim engines are sensitive to 3.3V. So when connected directly, the stim engines start to power up through the Arduino I/O pins connected to them if these pins are held high or when the Arduino is reset which imposes a risk of delivering undesired electrical stimulation to the user.

In order to avoid this undesired power up of the stim engines, the I/O pins of the Arduino is connected to the input of a 5V to 3.3V level shifter and the output of the level shifter is connected to the corresponding pins of the stim engines. The level shifter used for this purpose is SN74LVC245A manufactured by the Texas Instruments (Figure 7).

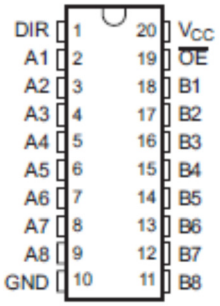


Fig 7: Pin diagram of SN74LVC245A

The DIR pin ensures the direction of communication. The device transmits data from bus A to bus B if the DIR pin is HIGH (or connected to Vcc). The output enable ($\overline{OE}$) is connected to ground in order to ensure efficient data transmission.

Figure 8 describes the level shifter circuit diagram used in the TetraGrip. The $\overline{pause}$ /enable lines, the chip select ($\overline{CS}$) lines, the trigger lines and the sync line from the Arduino are connected the bus A of two SN74LVC245A

ICs. A 1 kΩ pull-down resistor is connected between the bus A and the ground to prevent false trigger from floating voltages. The pins of the bus B are connected to the corresponding pins in the stim engine.

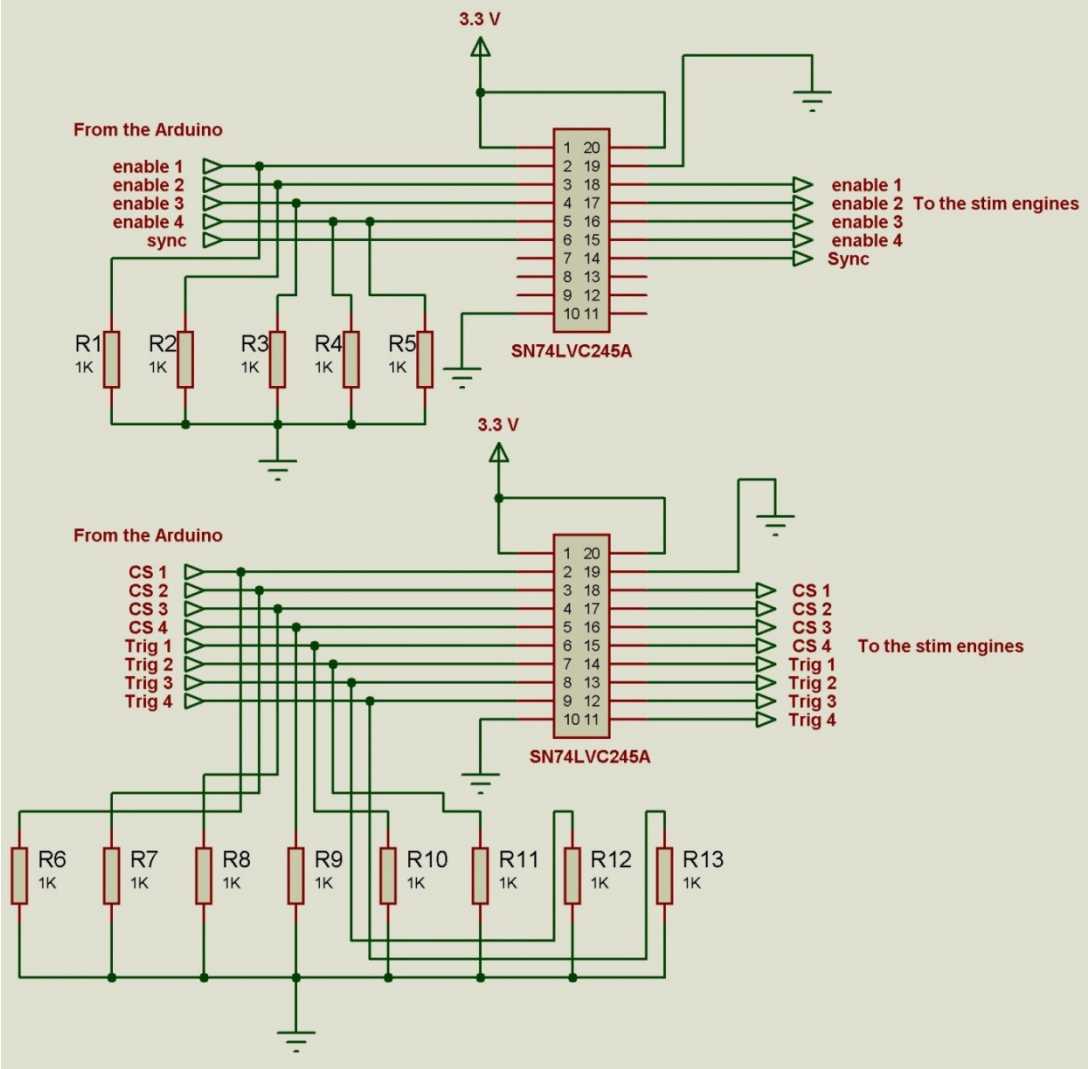


Fig 8: The Level Shifter Circuit Used in the TetraGrip

Communication with the Stim Engines

The TetraGrip software writes the data to the stim engines in a specific sequence with the help of serial communication software, mentioned in the previous section. Since the stimulation envelope has multiple phases, the stimulation parameters for each of these phases have to be written to the stim engines before delivering the stimulation.

For generating a proper stimulation envelope, the correct data needs to be written to the appropriate register. To ensure this, the stim engine SPI protocol accepts the message in the following sequence: a single byte register address, a single byte specifying the number of bytes that will be written/read, the data to be written, a two byte checksum and a dummy byte. The register address can be used to specify whether the data is being written to or read from a particular register by setting the value of the most significant bit (MSB) to either 1 or 0 respectively. For example, in order to read the data from register 15, the Phase Number Register, 0x0F (B00001111) is written as the register address. On the other hand, in order to write the data to the register 15, 0x8F (B10001111) is written as the register address. The data sheet specifies the number of bytes and the range for all the registers. Hence the sequence of the data transmitted from the Master to the respective stim engines is [Register Address, Length, Data, Checksum, Dummy byte].

The checksum used here is the 16 bit Fletcher checksum which uses the data in the message to calculate the two 8 bit check sum values. The advantage of using the Fletcher Checksum over other checksum methods is that it eliminates the single bit errors and takes less processing time to calculate the check sum values. The following example explains the calculation of the fletcher checksum.

Let sum1 and sum2 be the two variables holding the two 8-bit check values and initialised to 0, message be the array variable holding the data to be transmitted, message_length be the length of the message and i the variable that iterates from 0 to message_length-1. Then the two check values are calculated as

sum1 = (sum1 + message[i]) % 255
sum2 = (sum2 + sum1) % 255

Instead of appending the checksum bytes calculated from the above equation directly into the transmission data stream, two new values are calculated from the checksum bytes and transmitted along with the data so

that the checksum for the stream of received data is 0 for the correctly transmitted data. These two new values can be calculated using the following equation

check1 = 255 – ((sum1 + sum2) % 255)
check2 = 255 – ((sum1 + check1) % 255)

These two values are then appended to the data to be transmitted.

In order to load the parameters for the stimulation envelope, the software first selects the phase number and the stim engine to which the data needs to be written. It then sets the ramp parameter which allows the stimulator to ramp on pulse width, frequency or current. Once the ramp parameter is set, the type of waveform is specified. The stimulator is programmed to ramp on the pulse width and deliver asymmetric biphasic waveform in order to simplify the setup but can be modified to ramp on current or frequency and deliver symmetric biphasic waveform. Following the ramp and waveform, it then sets the target pulse width, target current, target frequency and the duration for each phase. Once these parameters are specified, the data for the goto phase on duration/target register is written which allows the stim engine to go the phase number mentioned in the register when it times out or reaches the target. This process repeats for all the phases in the stimulation envelope for all the four channels.

Appendix C

Ethics and Volunteer Information Sheets

This Appendix includes the ethics approvals and the volunteer information sheets used to obtain the results for this research work.

Ethics approval for the study to validate the shoulder postion sensor

Research Ethics Checklist

Status	Approved
Date Approved	10/10/2013

Researcher Details

Name	Lalitha Venugopalan
School	Design Engineering and Computing
Status	Postgraduate Research (PhD, MPhil, DProf, DEng)
Course / Research Centre	Creative Technology Research Centre
Do you intend to apply for external funding to support this research project?	No
Please list any persons or institutions that you will be conducting joint research with, both internal to BU as well as external collaborators.	National Clinical FES Center, Salisbury District Hospital

Project Details

Title	Restoration of hand and arm function to people with tetraplegia as a result of damage to the spinal cord in the neck through the use of Functional Electrical Stimulation
Proposed Start Date	22/04/2013
Proposed End Date	21/04/2016
Supervisor	Ian Swain

Summary (including detail on background methodology, sample, outcomes, etc.)

Background:Functional electrical stimulator is a device used to deliver electrical pulses to the nerve of a muscle affected by stroke or spinal cord injury. Theraputic exercises, dropped foot correction, grip and grasp function, control of micturation, control of breathing in high level tetraplegic patients are some of the applications of FES system.Upper limb FES systems are broadly classified as Implantable, Surface stimulation and percutaneous devices based on the placement of electrodes. NeuroControl Freehand System, Handmaster/NESS H200, Bionic Glove, ETHZ-Paracare and Belgrade Grasp System have shown significant clinical results for upper limb. After the success of the above-mentioned devices, a lot of work has been done to improve the device and make it more user friendly. The use of modern electronics have resulted in more portable and compact devices. A variety of control strategy has been explored to make the user more intependent. Using patients own EMG signal has been worked out as one of the options. Integrating Artificial Neural Networks and Pattern Recognition systems along with EMG has kept the doors for research wide open. Lately researchers have stepped into the world of gyroscopres and accelerometers in an attempt to find a better control strategy.Researchers have also explored the various possible solution to make the donning and doffing of the device more comfortable for the patient. Creating an electrode patch or designing a velcro band with electrrodes fixed in it has been some of the work done in this field. Aim:This research work aims to address the following issues:1. To work out a control strategy that would benefit a wide range of patients. Instead of relying on wrist extension as a possible controls strategy, use of some of the modern day sensors like accelerometers and inertial measurement sensors as a possible control strategy will be explored. This will ensure that people without good wrist extension will also benefit from this device.2. The device should be user and clinician friendly. The user should be able to use this device with minimum assistance. Adjustment of parameters should be straight-forward and less complicated. This will save a lot of time for both the patients and the clinicians.3. The device should adapt according to the movement produced.4. Donning and doffing of the device should be easy and quick.Methodology:Firstly a stimulator will be designed to generate a stimulation sequence which will make the thumb flex or adduct according to the movement of wrist. If the wrist goes more and more into extension, the pulse sequence will drive the thumb towards adduction. This will help the subject achieve a movement called lateral pinch which will aid in activities like holding a fork, key or even a piece of paper. When the wrist starts flexing, then the thumb should start flexing and the flexor digitorium superficialis muscle should be stimulated. This will bring the fingers and thumb towards eachother thereby enabling the subject to grip wider objects like a glass or a bottle.Second part of the work will be to integrate a shoulder sensor with the stimulator which will be used to turn it ON or OFF. A specific movement will be assigned for a specific task. A third movement will be used to lock the stimulator in the ON position. This will be a safety feature to ensure that the stimulator doesn't turn itself ON by any spurious movement. The user will be trained to generate the trigger signal. This will enable the user to control the device according to their will. The shoulder movement combined with the wrist position will decide the activity. IMUs and Flex-sensors will be explored as the possible sensor for this purpose. The third part will be to try and build a cuff for electrode arrangement which will aid in donning and doffing of the electrodes thereby making the device more user friendly. Options like neoprene gloves/sleeve or Velcro cuffs will be considered and the a possible design to make the electrodes easily wearable will be worked out. Also a concept called current steering will be explored to see if it can eliminate the need for precise placement of the electrodes.The device will be tested on human volunteers and its performance will be analysed. Firstly the device will be tested on healthy volunteers and experts in FES system from the National Clinical FES Centre in Salisbury NHS hospital. This will help in analysing the performance of the device better. Then the device will be tested on people with incomplete tetraplegia.

External Ethics Review

Does your research require external review through the NHS National Research Ethics Service (NRES) or through another external Ethics Committee?	Yes

Please ensure that the researcher obtains external ethical approval before commencing research.

Researcher Statement

JOURNALISM / BROADCAST RESEARCHERS: I confirm that I have consulted and understand the Research Ethics Supplementary Guide: For Reference by Researchers Undertaking Journalism and Media Production Projects (available on the Research Ethics page)	Yes

Volunteer Information Sheet for the Study to Validate the Shoulder Position Sensor

TetraGrip: Surface upperlimb FES system for C5/C6 tetraplegic patients

National Clinical FES Center
Laing Building
Salisbury District Hospital
Salisbury, Wiltshire, SP2 8BJ

Telephone: 01722 439566
Email: lvenugopalan@bournemouth.ac.uk

VOLUNTEER INFORMATION SHEET
September 2014

You are being invited to participate in a research study related to **Upper Limb Functional Electrical Stimulation (FES)**. As an existing FES user, your inputs as a volunteer will be extremely helpful in the progress of this research work. But before you decide to volunteer, please spare a few minutes to go through this piece of document which has all the necessary information about the research work and the experiment. Take your time to make the decision on whether or not you want to participate in this experiment. If you have any further questions, please feel free to ask.

Project Title: Restoration of hand and arm function to people with tetraplegia as a result of injury to the spinal cord in the neck through the use of Functional Electrical Stimulation (FES).

About the project:

The purpose of this study, shortly known as **TetraGrip**, will use surface stimulation to restore grip and grasp functions in C5/C6 incomplete tetraplegic patients. The main objectives of this project are

1) **Explore the possibility of using modern day sensors like the Inertial Measurement Units (IMU) as a possible option for triggering the FES device**. In earlier devices, a variety of signals like voice, electromyograph (signals from muscles) or push buttons were used to deliver the command to the stimulator. So the first objective of this project is to use IMUs and see if this is good enough to deliver the required commands to the stimulator. The sensor used in this project has been successfully used as the control unit for model helicoptors. The same board is customized for sensing the shoulder movement and see if it can generate signals good enough to trigger the FES device.

2) **To help the user perform Key Grip and Palmar Prehension to grip and grasp objects better.** Key grip is a hand movement which helps the person hold smaller objects like a key, or hold a pen a write or hold a fork and have dinner. Palmar prehension is the hand movement which helps the person grasp larger objects like a glass of water or a cup or tea. These two hand movements are sufficient to perform almost all the Activities of Daily Living (ADL).

3) **To minimize the donning and doffing time.** The third objective of this research is to try and minimize as much as possible, the amount of time required to put on the device (donn) and take if off (doff).

Funding for the Research: This research is a PhD studentship funded partly by The Bournemouth University and partly by Inspire, a charitable organization dedicated for Spinal Cord Injury people. More information about Inspire is available at www.inspire-foundation.org.uk

Results of the Experiments: Any clinically significant result from the experiment will be published in research articles. It is assured that patient confidentiality will be kept in mind while publishing the results.

Research Ethics Clearance:

This study has been reviewed for ethical issues by The Research Ethics Committee, School of Design, Engineering and Computing, Bournemouth University.

Further Information:

For any further information or queries, please feel to contact any one of us:

Ms. Lalitha Venugopalan: PhD Student
Prof. Ian Swain: Consultant Clinical Scientist and Professor of Clinical Engineering, Bournemouth University
Dr. Paul Taylor: Consultant Clinical Scientist.

All of us are based in The National Clinical FES Centre, Salisbury District Hospital, Salisbury, Wiltshire, SP2 8BJ.

Thank you for reading this information sheet.

Bournemouth University

CONSENT FORM

Project Title: Restoration of hand and arm function to people with tetraplegia as a result of injury to the spinal cord in the neck through the use of Functional Electrical Stimulation (FES).

Please initial each box if you agree:

1) I confirm that I have read and understood the volunteer information sheet dated March 2014 for the above-mentioned study and have had the opportunity to ask questions.

2) I understand that my participation is voluntary and I am free to walk away from the experiment any time, without giving any reason, without my medical care or legal rights affected.

3) I understand that at the end of the study data collected from me will be stored at the National Clinical FES Centre, Salisbury District Hospital in line with the institutional guidelines for good clinical practice in research and in line with the policies for postgraduate research.

4) I am/am not participating in another study at this time (delete the appropriate option)

5) I agree that my arm will be photographed to record the position of the sensor and electrodes.

6) I agree for the photos to be used for publications, teaching or scientific conferences

7) I agree to take part in the above study

_____	_____	_____
Name of the patient	Signature	Date
_____	_____	_____
Name of the Researcher	Signature	Date

One copy to the patient and one for the research team.

Volunteer Information Sheet for Able Bodied Volunteers for testing the TetraGrip

TetraGrip: Surface upper limb FES system for C5/C6 tetraplegic patients

Bournemouth University

National Clinical FES Centre
Salisbury, Wiltshire, SP2 8BJ

Telephone: 01722 439566
Email: lvenugopalan@bournemouth.ac.uk

ABLE BODIED VOLUNTER INFORMATION SHEET
February 2015

You are being invited to participate in a research study related to **Upper Limb Functional Electrical Stimulation (FES)**. This research study is a part of the doctoral study of Ms. Lalitha Venugopalan who is pursuing her PhD with Bournemouth University. Before you decide to volunteer, please spare a few minutes to go through this information sheet which has all the necessary information about the research work and the experiment. Take your time to make the decision on whether or not you want to participate in this experiment. If you have any further questions, please feel free to ask.

Project Title

Restoration of hand and arm function to people with tetraplegia as a result of injury to the spinal cord in the neck through the use of Functional Electrical Stimulation (FES).

What is the purpose of this study?

The FES device developed for this project is called TetraGrip. The main purpose of this study is to check the repeatability and reproducibility of TetraGrip. This study will check if the device generates the stimulation impulses in the required sequence for generating key grip (fig 1) and palmar grasp (fig 2) movements when an appropriate control signal is generated using the motion sensor strapped across the opposite shoulder of the volunteer. Also, the performance of the device will be evaluated when the same user uses the device on a different day. If the performance of the device is found to be consistent, then people with tetraplegia will be invited to try the device.

Fig 1: Key Grip

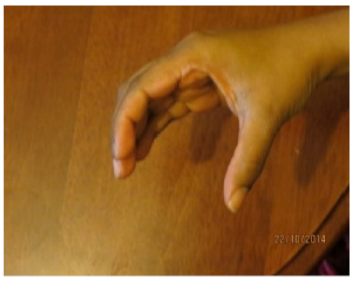


Fig 2: Palmar Grasp

About the Experiment

The protocol for this experiment is as follows:

1. The shoulder position sensor will be strapped on the opposite upper arm as close to the shoulder as possible.
2. The stimulation sites for the muscles that open and close the fingers will be identified using an Odstock® Microstim FES device.
3. Surface electrodes will be placed on the motor points identified in the previous step and these electrodes will be connected to the stimulator with the help of connectors.
4. The stimulator parameters for all 4 channels will be set up so that the stimulation is comfortable and sufficient to generate the desired movement.
5. The volunteers will be asked to generate the desired control signal and the operation of the stimulator will be monitored. They will be asked to generate the control signals for the key grip and palmar grasp five times and the functioning of the stimulator will be monitored.
6. Some of the volunteers will be asked to come back after two days and the procedure described above will be repeated. The performance of the stimulator will be observed and documented. The entire experiment will be repeated three times on these volunteer. This will provide sufficient data to establish the repeatability and reproducibility of the device.

Why have I been invited?

You have been invited to participate in this study because your feedback and responses during the experiment are extremely important to decide the effectiveness of the device. If you agree to participate in the study, you will be one of the ten volunteers taking part.

Do I have to take part?

It is totally up to you. After reading about the project and the experiment, if you are not interested, you can choose not to participate in this research experiment. Also if you have volunteered and half way through the experiment you feel uncomfortable with the proceedings, then you can inform the researcher and stop the experiment at that point.

Expenses and Payments:

If you agree to participate, the researcher will be more than happy to pay the travel costs for up to 100 miles round trip. Light refreshments and tea/coffee will be provided to the volunteers.

What are the possible risks and disadvantages of taking part in this study?

Though the risks involved in this experiment are minimal, electrical stimulation can be uncomfortable and may cause autonomic dysreflexia. Autonomic dysreflexia is a reaction of the body to overstimulation. It is characterized by a sudden increase in blood pressure, throbbing headaches, profuse sweating, hot flushes or anxiety. If the volunteer experiences any of the above mentioned symptoms while using FES, the experiment will be terminated there and then. FES is not recommended for people with a cardiac pacemaker or poorly controlled epilepsy. Also use of FES is avoided during pregnancy or possible pregnancy and if there is malignancy around the area of electrode placement.

What are the possible benefits of taking part in this study?

There are no direct benefits to the volunteer as this is just part of a bigger research study. But if this technique works, then there is the possibility of development of an FES device with this sensor in it which will be beneficial to all upper limb FES users.

What if something goes wrong?

Though the risks involved in this experiment are minimal, if something goes wrong, then there are no compensations arranged. If you are harmed because of someone's negligence, then you may have grounds for legal action but you will have to bear the expenses. Irrespective of this, if you wish to complain, you can contact:

Professor Matt Bentley FLS FSB
Deputy Dean (Research and Professional Practice) and Professor of Marine Biology
Faculty of Science and Technology, C227 Christchurch House
Bournemouth University, Talbot Campus, Poole BH12 5BB
mbentley@bournemouth.ac.uk
Tel: +44 (0)1202 962203

Information Confidentiality

All the information received from the volunteer will be kept confidential. The identity of the volunteer will not be revealed to anyone. Each one will be supplied with a unique code number and this code number will be used to refer to the data obtained from the experiment. The data from this study will be used for the production of the researcher's PhD thesis and related publications and will be stored in a secure password protected location for five years. After five years, the data will be destroyed safely.

Funding for the Research

This research is the subject of the Ralph Crossley Award jointly funded by Bournemouth University and Inspire, a charitable trust for people with spinal cord injuries. More information about Inspire is available at www.inspire-foundation.org.uk

Results of the Experiments

Any clinically significant result from the experiment will be published in research articles. The photos and videos taken during the experiment will be used for publication and conference presentation. It is assured that patient confidentiality will be kept in mind while publishing the results.

Research Ethics Clearance

This study has been reviewed for ethical issues by The Research Ethics Committee, The Faculty of Science and Technology, Bournemouth University.

Further Information

For any further information or queries, please feel free to contact any one of us:
Ms. Lalitha Venugopalan: PhD Student, Bournemouth University. Ph. No: 01722 439566
Prof. Ian Swain: Consultant Clinical Scientist and Professor of Clinical Engineering, Bournemouth University. Ph. No: 01722 429117
Dr. Paul Taylor: Consultant Clinical Scientist.
All of us are based in The National Clinical FES Centre, Salisbury, Wiltshire, SP2 8BJ. Ph. No: 01722 429119
Thank you for reading this information sheet.

Bournemouth University

CONSENT FORM

Project Title: Restoration of hand and arm function to people with tetraplegia as a result of injury to the spinal cord in the neck through the use of Functional Electrical Stimulation (FES).

Please initial/tick each box if you agree:

1) I confirm that I have read and understood the participant information sheet dated…… for the above-mentioned study and have had the opportunity to ask questions. ☐

2) I understand that my participation is voluntary and I am free to leave the project any time, without giving any reason and this will not affect my medical care or legal rights. ☐

3) I understand that at the end of the study data collected from me will be used for the production of the researcher's PhD thesis and related publications and will be stored in a secure password protected location for 5 years ☐

4) I am/am not participating in another study at this time (delete the appropriate option) ☐

5) I agree that my arm will be photographed to record the position of the sensor and electrodes. Also, I agree to allow the researcher to take a video of my arm while I perform the experiment. ☐

6) I agree for the photos and videos to be used for publications, teaching or scientific conferences ☐

7) I agree to take part in the above study ☐

_____	_____	_____
Name of the participant	Signature	Date
_____	_____	_____
Name of the Researcher	Signature	Date

One copy to the patient and one for the research team.

Volunteer Information Sheet for People with Tetraplegia

National Clinical FES Centre
Salisbury, Wiltshire, SP2 8BJ
Telephone: 01722 439566
Email: lvenugopalan@bournemouth.ac.uk

TETRAPLEGIC VOLUNTEER INFORMATION SHEET

February 2015

You are being invited to participate in a research study related to **Upper Limb Functional Electrical Stimulation (FES)**. This research study is a part of the doctoral study of Ms. Lalitha Venugopalan who is pursuing her PhD with Bournemouth University. But before you decide to volunteer, please spare a few minutes to go through this information sheet which has all the necessary information about the research work and the experiment. Take your time to make the decision on whether or not you want to participate in this experiment. If you have any further questions, please feel free to ask.

Project Title

Restoration of hand and arm function to people with tetraplegia as a result of injury to the spinal cord in the neck through the use of Functional Electrical Stimulation (FES).

What is the purpose of this study?

The device developed for this study is called the TetraGrip. The main purpose of this study is to use the TetraGrip to deliver electrical stimulation to the muscles of the upper limb and check if this improves the upper limb grip and grasp functions in people with C5-C7 tetraplegia. The volunteer will use the motion sensor strapped across the opposite shoulder to control the key

grip (Figure 1) and palmar grasp (Figure 2). The key grip movement is used to grip narrow objects like a fork, a pen or a pencil and the palmar grasp movement is used to grasp wider objects like a cup, a mug or a bottle. The ability of the volunteer to perform some simple tasks like picking up wooden cubes and dropping them elsewhere will be evaluated during the experiment.

Fig 1: Key Grip

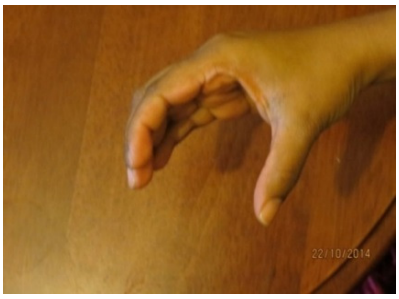


Fig 2: Palmar Grasp

About the Experiment

After receiving consent from you, you will be assessed as an outpatient and if found suitable, the researchers will explain the procedure of the experiment and address any questions you may have. During the initial assessment, you will be asked to perform simple tasks like picking up blocks and placing it elsewhere. This will help the researchers assess your ability before using FES.

After the initial assessment, you will be provided with an Odstock® Microstim stimulator to take home. The electrode placements will be explained to you and your carer and you will be asked to use the device at home for half an hour to an hour every day for 4 weeks. This will build up the required muscle strength. You will then come back once every week for the next 8 weeks and participate in the experiment. The remaining days, you will be using the Microstim for an hour at home. The total duration of the study is 12 weeks.

When you come back to clinic after the initial assessment, the researchers will demonstrate how to use the control device and clearly explain what

happens when a particular control signal is generated. Once this is done, the device set-up will be completed in the following steps:

1. The shoulder position sensor will be strapped on the contralateral upper arm as close to the shoulder as possible
2. The stimulation sites for the muscles that open and close the fingers will be identified using Odstock® Microstim stimulator
3. Surface electrodes will be placed on the motor points identified in the previous step and these electrodes will be connected to the stimulator with the help of connectors
4. The stimulator current for all 4 channel will be set so that the stimulation is comfortable but sufficient generate the desired movement
5. The volunteer will be asked perform shoulder elevation, protraction and retraction and the maximum values will be recorded

After setting up the device, you will be asked to generate the control signals for key grip (used for grasping small objects like a pen, a fork or a key) and palmar grasp (used to grasp larger objects like a cup or a telephone receiver). Once the user is confident of using the device, your hand functions will be assessed using relevant tests like the grip test, the grasp release test (GRT) and box and block tests. The GRT is us a series of hand tasks tests designed to evaluate the hand function of people with tetraplegia.The duration of the experiment will be about 90 minutes.

If the results of this experiment indicate that use of this device has improved the upper arm function of the user, then the two volunteers will be able to take the device home and use it for performing their activities of daily living. After using the device for two months, the volunteers will have to return the device. This study will be evaluated using a questionnaire similar to the one used to validate the NeuroControl® Freehand System.

Why have I been invited?

You have been invited to participate in this study because you have C5, C6 or C7 tetraplegia and have expressed interest in this study. If you agree to participate in the study, you will be one of the five volunteers taking part in this study.

Do I have to take part?

It is totally up to you. After reading about the project and the experiment, if you feel uninterested, then you can choose not to participate in this research experiment. Also if you have volunteered and half way through the experiment if you feel uncomfortable with the proceedings, then you can inform the researcher and stop the experiment at that point.

Expenses and Payments:

If you agree to participate, the researcher will be more than happy to pay the travel costs for up to 100 miles round trip. Light refreshments and tea/coffee will be provided to the volunteers and their carers.

What are the possible risks and disadvantages of taking part in this study?

Though the risks involved with this experiment are minimal, electrical stimulation can be uncomfortable and may cause autonomic dysreflexia. Autonomic dysreflexia is a reaction of the body to overstimulation. It is characterised by sudden increase in blood pressure, throbbing headaches, profuse sweating, hot flushes or anxiety. If the volunteer experiences any of the above mentioned symptoms while using FES, the experiment will be terminated there and then. FES is not recommended for people with cardiac pacemaker, poorly controlled epilepsy. Also use of FES is avoided during pregnancy or possible pregnancy and if there is malignancy around the area of electrode placement.

What are the possible benefits of taking part in this study?

There are direct benefits to the volunteer as this is just part of a bigger research study. But if this technique works, then there is a possibility of development of an FES device with this sensor in it which will be beneficial to all the upper limb FES users.

What if something goes wrong?

Though the risks involved in this experiment are minimal, if something goes wrong, then there are no compensations arranged. If you are harmed because of someone's negligence, then you may have grounds for legal action but you will have to bear the expenses. Irrespective of this, if you wish to complain, you can contact:

Professor Matt Bentley FLS FSB
Deputy Dean (Research and Professional Practice) and Professor of Marine Biology
Faculty of Science and Technology, C227 Christchurch House
Bournemouth University, Talbot Campus, Poole BH12 5BB
mbentley@bournemouth.ac.uk
Tel: +44 (0)1202 962203

Information Confidentiality

All the information received from the volunteer will be kept confidential. The identity of the volunteer will not be revealed to anyone. Each one will be supplied with a unique code number and this code number will be used to refer to the data obtained from the experiment. The data from this study will be used for the production of the researcher's PhD thesis and related publications and will be stored in a secure password protected location for 5 years.

Funding for the Research

This research is the subject of Ralph Crossley Award jointly funded by Bournemouth University and Inspire, a charitable trust for people with spinal cord injuries. More information about Inspire is available at www.inspire-foundation.org.uk

Results of the Experiments

Any clinically significant result from the experiment will be published in research articles. The photos and videos take during the experiment will be used for publication and conference presentation. It is assured that patient confidentiality will be kept in mind while publishing the results.

Research Ethics Clearance

This study has been reviewed for ethical issues by The Research Ethics Committee, The Faculty of Science and Technology, Bournemouth University.

Further Information

For any further information or queries, please feel to contact any one of us:

Ms. Lalitha Venugopalan: PhD Student, Bournemouth University. Ph. No: 01722 439566

Prof. Ian Swain: Consultant Clinical Scientist and Professor of Clinical Engineering, Bournemouth University. Ph. No: 01722 429117

Dr. Paul Taylor: Consultant Clinical Scientist.

All of us are based in The National Clinical FES Centre, Salisbury, Wiltshire, SP2 8BJ. Ph. No: 01722 429119

Thank you for reading this information sheet.

Bournemouth University

CONSENT FORM

Project Title: Restoration of hand and arm function to people with tetraplegia as a result of injury to the spinal cord in the neck through the use of Functional Electrical Stimulation (FES).

Please initial/tick each box if you agree:

1) I confirm that I have read and understood the volunteer information sheet dated…… for the above-mentioned study and have had the opportunity to ask questions. ☐

2) I understand that my participation is voluntary and I am free to leave the project any time, without giving any reason and this will not affect my medical care or legal rights. ☐

3) I understand that at the end of the study data collected from me will be used for the production of the researcher's PhD thesis and related publications and will be stored in a secure password protected location for 5 years ☐

4) I am/am not participating in another study at this time (delete the appropriate option) ☐

5) I agree that my arm will be photographed to record the position of the sensor and electrodes. Also, I agree to allow the researcher to take video of my arm while I perform the experiment ☐

6) I agree for the photos and videos to be used for publications, teaching or scientific conferences ☐

7) I agree to take part in the above study ☐

_____	_____	_____
Name of the patient	Signature	Date
_____	_____	_____
Name of the Researcher	Signature	Date

One copy to the patient, one for the research team and one for the medical notes.

Appendix D

Results from Experiment 1 for validating the sensor

The results obtained after analysing the data from 4 volunteers are presented below.

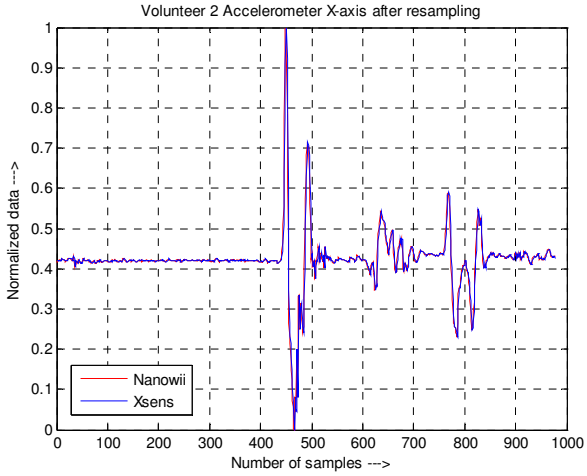


Fig 1: Volunteer 2, Experiment 1: Accelerometer X-axis signal after resampling

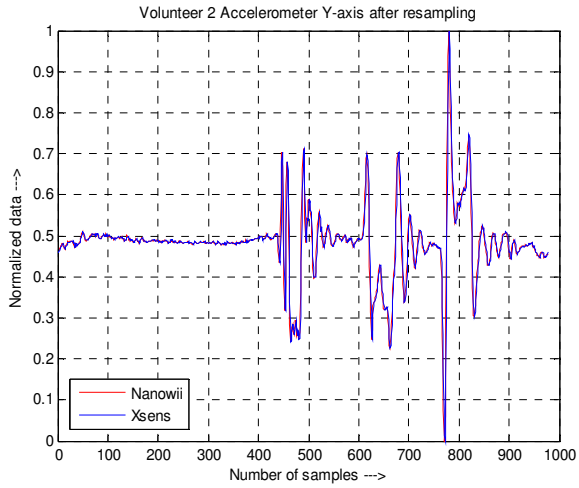


Fig 2: Volunteer 2, Experiment 1: Accelerometer Y-axis signal after resampling

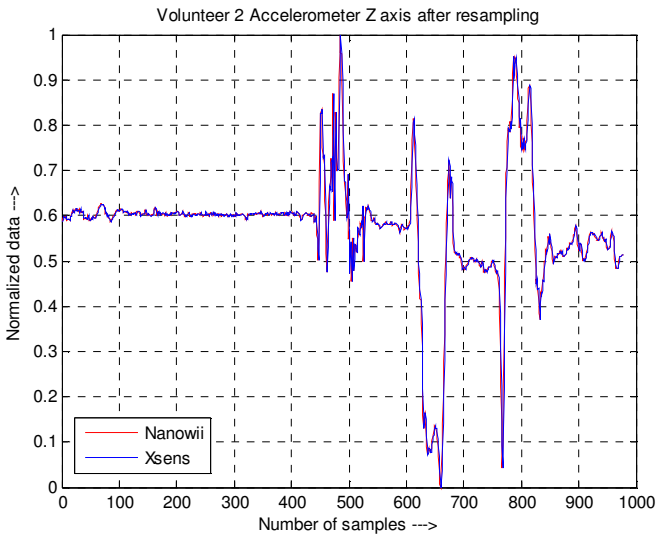


Fig 3: Volunteer 2, Experiment 1: Accelerometer Z-axis signal after resampling

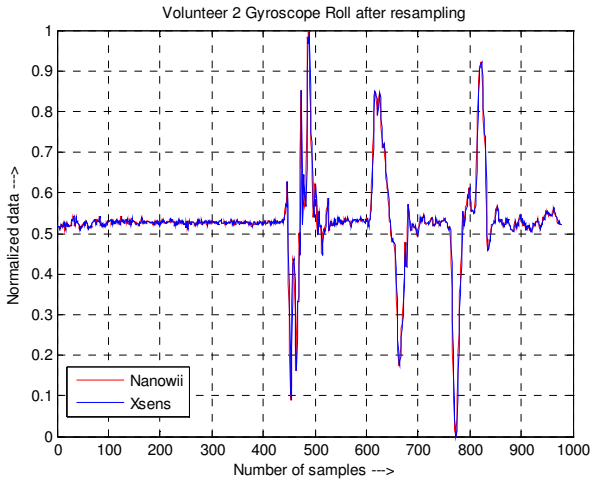


Fig 4: Volunteer 2, Experiment 1: Gyroscope roll signal after resampling

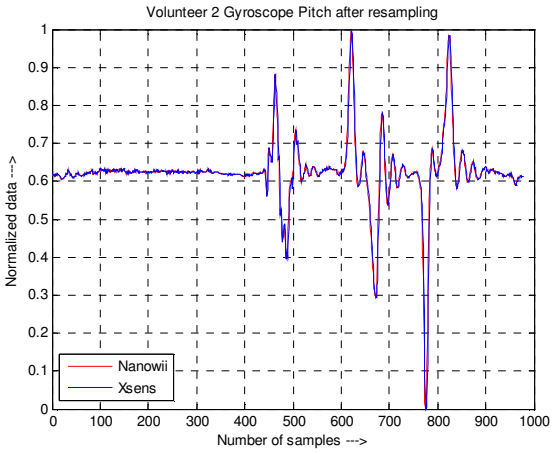


Fig 5: Volunteer 2, Experiment 1: Gyroscope pitch signal after resampling

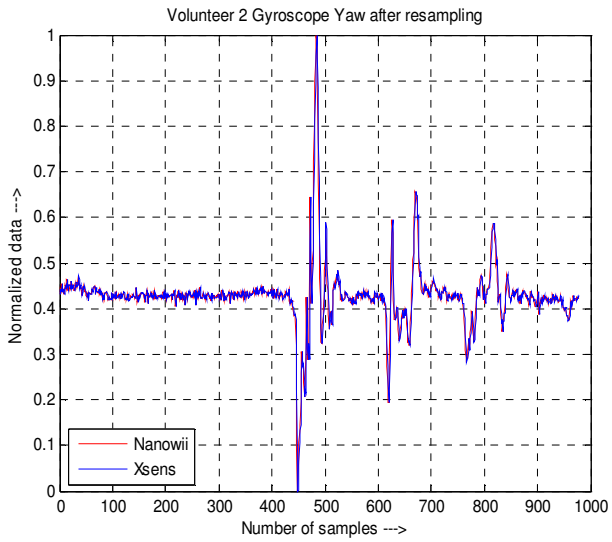


Fig 6: Volunteer 2, Experiment 1: Gyroscope yaw signal after resampling

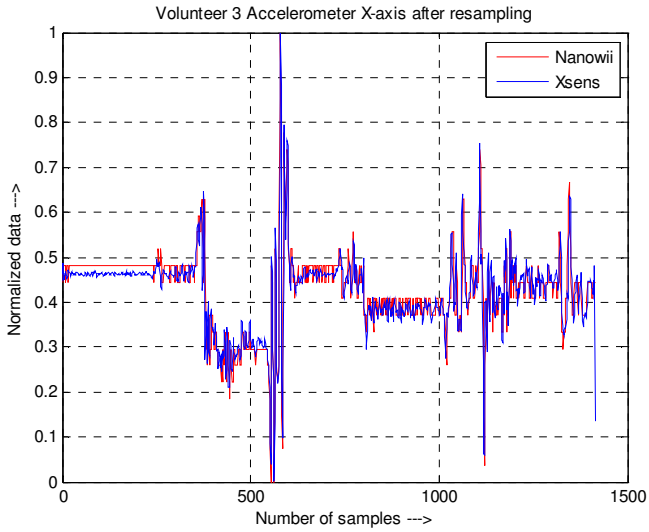


Fig 7: Volunteer 3, Experiment 1: Accelerometer X-axis signal after resampling

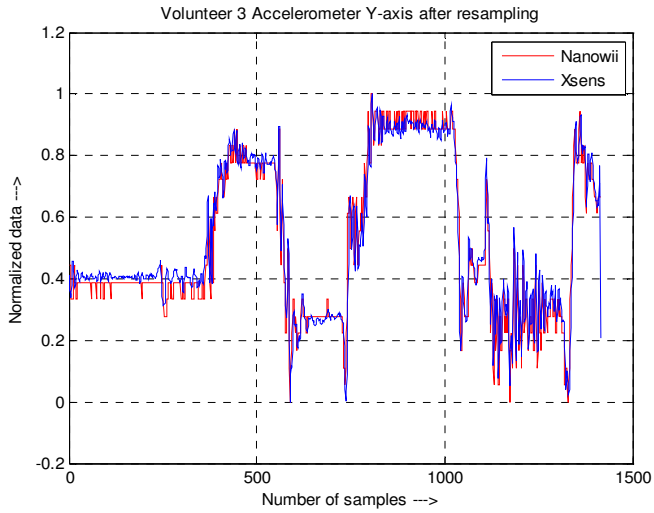


Fig 8: Volunteer 3, Experiment 1: Accelerometer Y-axis signal after resampling

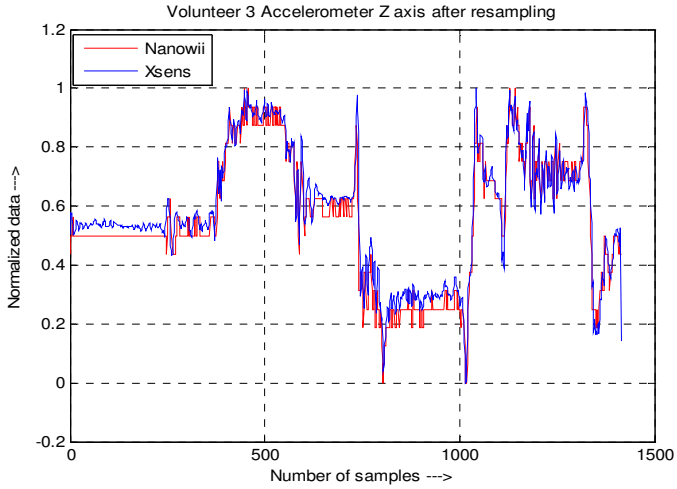


Fig 9: Volunteer 3, Experiment 1: Accelerometer Z-axis signal after resampling

Fig 10: Volunteer 3, Experiment 1: Gyroscope roll signal after resampling

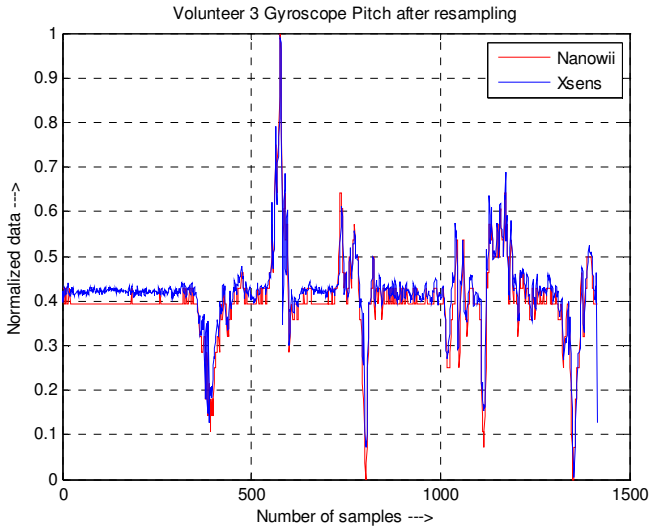


Fig 11: Volunteer 3, Experiment 1:Gyroscope pitch signal after resampling

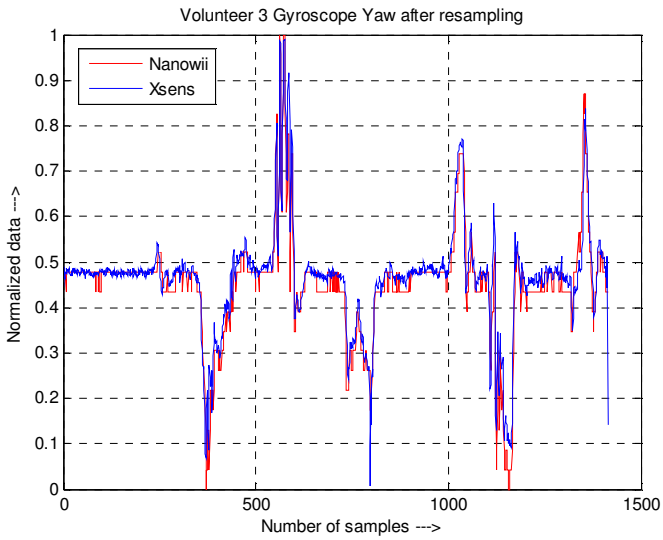


Fig 12: Volunteer 3, Experiment 1: Gyroscope yaw signal after resampling

Results from Experiment 2

The results obtained from two volunteers who participated in Experiment 2 are summarised below.

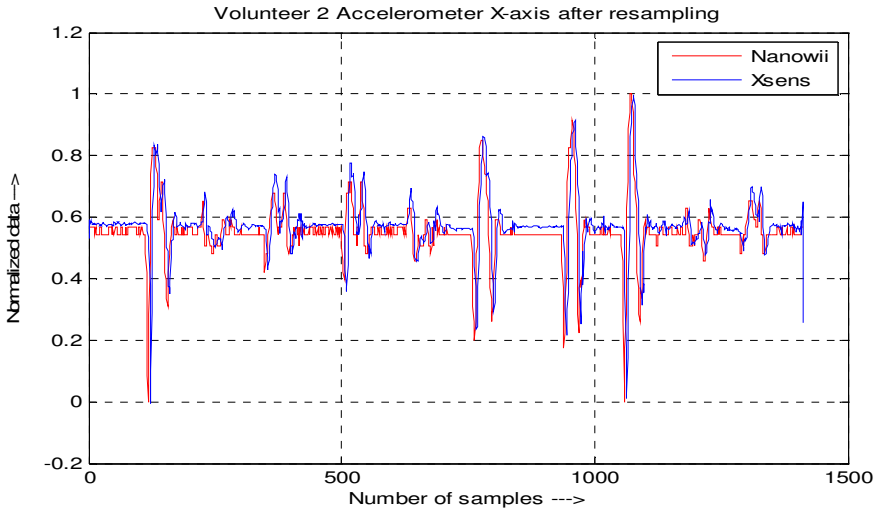


Fig 13: Volunteer 2, Experiment2: Accelerometer X-axis signal after resampling

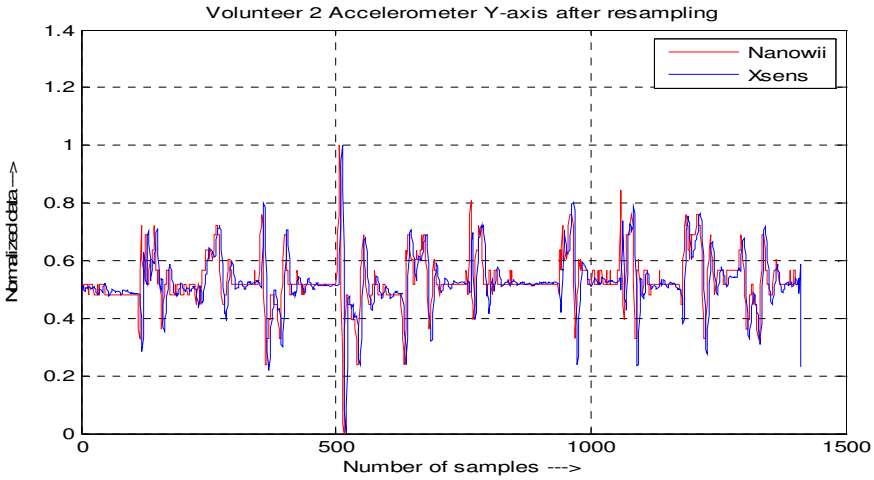


Fig 14: Volunteer 2, Experiment2: Accelerometer Y-axis signal after resampling

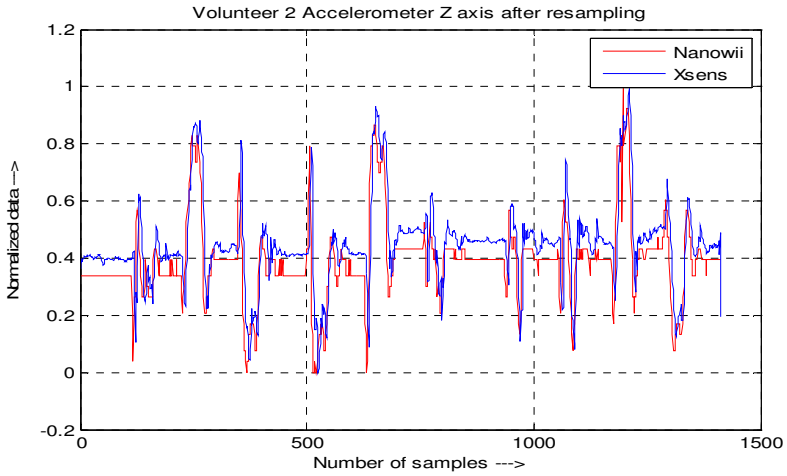


Fig 15: Volunteer 2, Experiment2: Accelerometer Z-axis signal after resampling

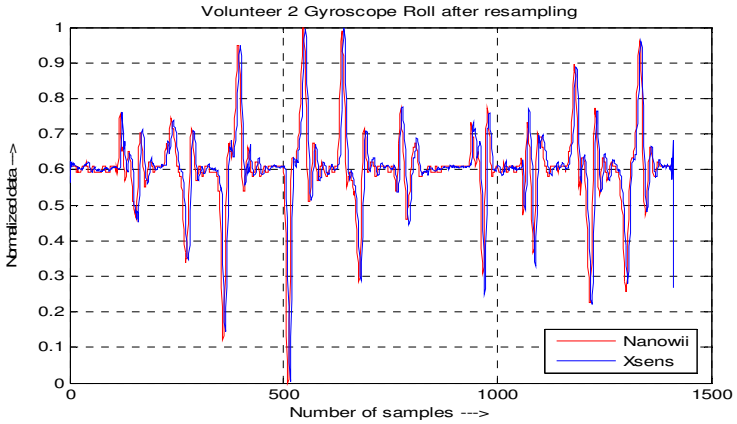


Fig 16: Volunteer 2, Experiment2: Gyroscope roll signal after resampling

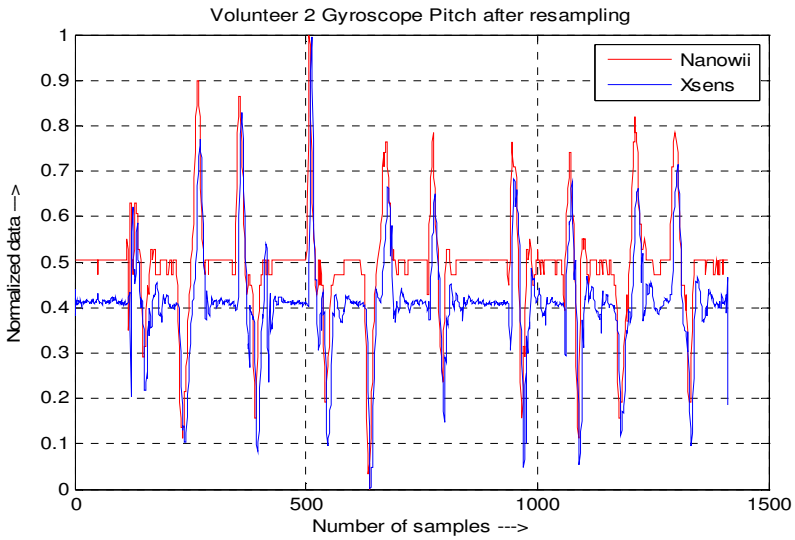


Fig 17: Volunteer 2, Experiment2: Gyroscope pitch signal after resampling

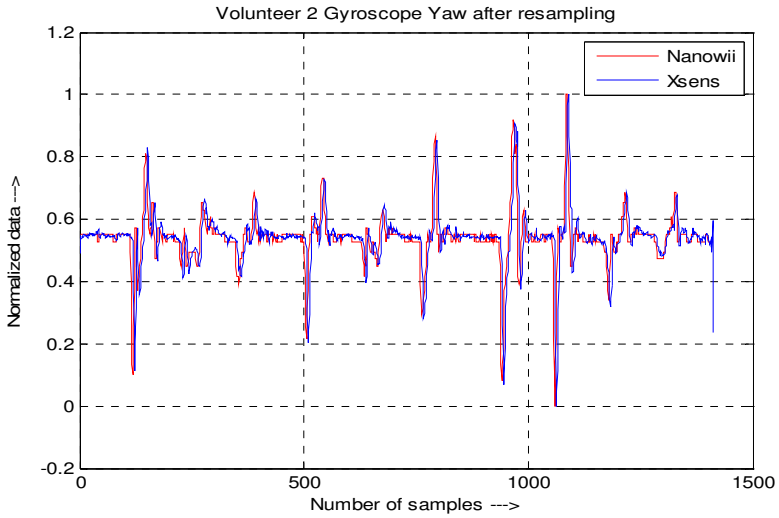


Fig 18: Volunteer 2, Experiment2: Gyroscope yaw signal after resampling

The sequence of shoulder movement by this volunteer is shoulder elevation, protraction, retraction, retraction, protraction, elevation, elevation, elevation, protraction and retraction.

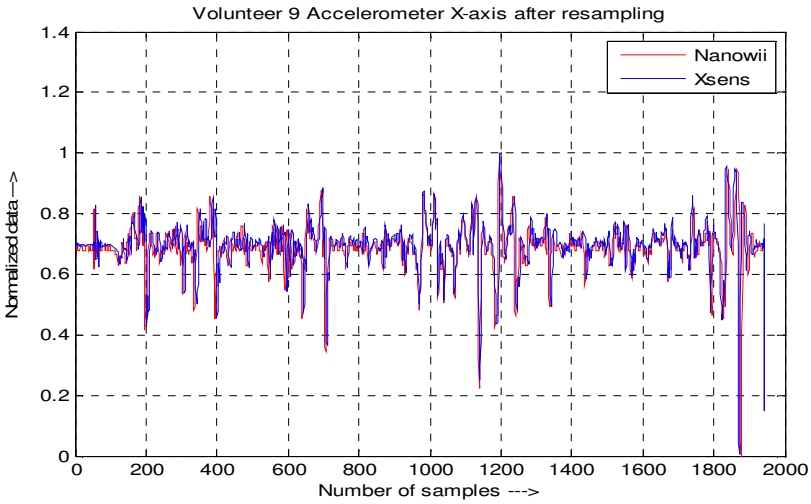


Fig 19: Volunteer 9, Experiment2: Accelerometer X-axis signal after resampling

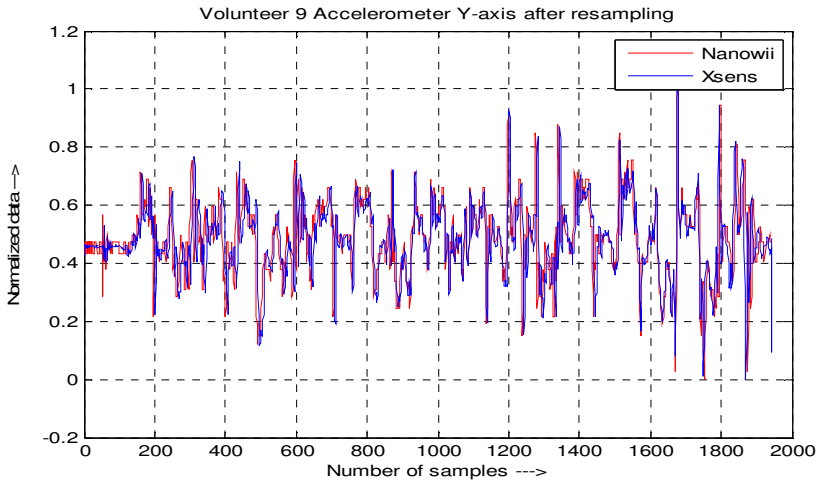


Fig 20: Volunteer 9, Experiment2: Accelerometer Y-axis signal after resampling

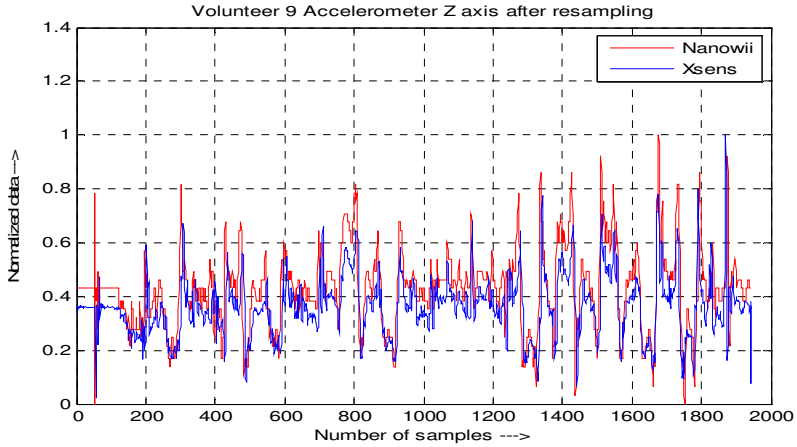


Fig 21: Volunteer 9, Experiment2: Accelerometer Z-axis signal after resampling

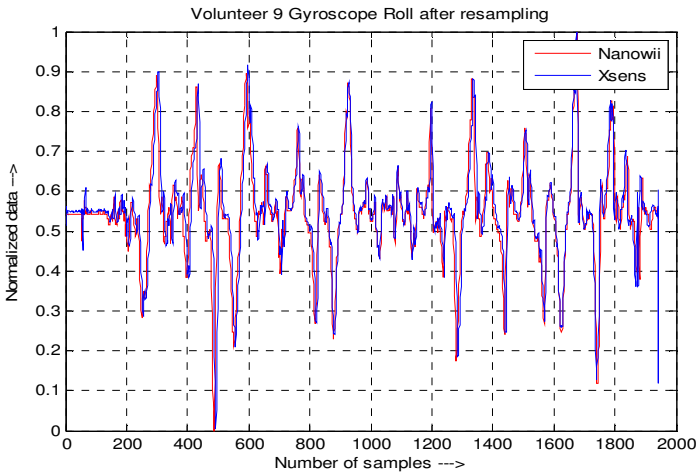


Fig 22: Volunteer 9, Experiment2: Gyroscope roll signal after resampling

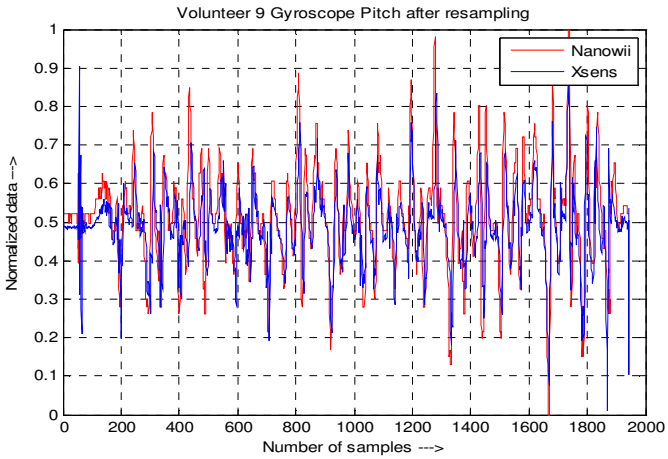


Fig 23: Volunteer 9, Experiment2: Gyroscope pitch signal after resampling

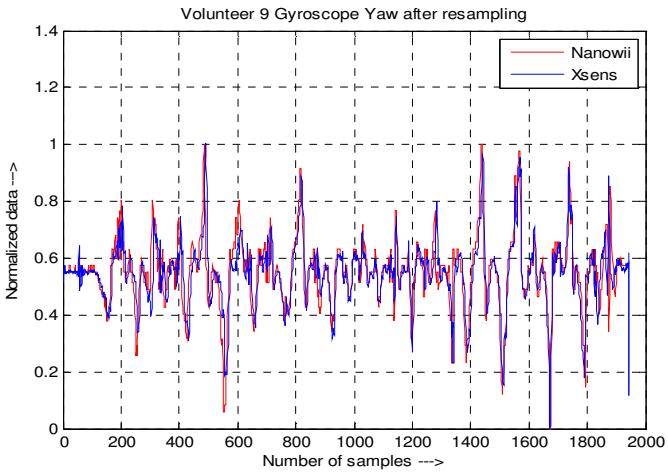


Fig 24: Volunteer 9, Experiment2: Gyroscope yaw signal after resampling

The sequence of shoulder movement produced by this volunteer is shoulder elevation, elevation, protraction, retraction,elevation,protraction, retraction, elevation, elevation, elevation, retraction, protraction,retraction, protraction, retraction, protraction, retraction and shoulder elevation. The volunteer did all the movements in quick succession and hence the signal appears noisy. While using this sensor as a shoulder position sensor, the user will not be generating this many signals in quick succession and hence this will not be a potential problem.

Appendix E

TetraGrip
Risk assessment and management

The risk analysis performed for the TetraGrip four channel FES device is summarised in this document. The level of risk has been expressed using the Occurrence – Severity – Risk table below.

Occurrence - Severity - Risk table

	Negligible	**Minor**	**Marginal**	**Critical**	**Catastrophic**
Frequent	ALARP	INT	INT	INT	INT
Probable	ALARP	INT	INT	INT	INT
Occasional	BAR	ALARP	INT	INT	INT
Remote	BAR	ALARP	ALARP	INT	INT
Improbable	BAR	BAR	ALARP	ALARP	INT
Incredible	BAR	BAR	BAR	BAR	ALARP

BAR: Broadly Acceptable Region
ALARP: As Low As Reasonably Practical
INT: Intolerable

Ectopic Heart beat or atrial fibrillation due to current passing through the heart:

No fault condition: Current flow is negligible.

Single fault condition: One electrode on the leg, one on the hand causes increased current through the thorax and therefore an increased risk.

Possible outcome: Catastrophic.
Occurrence: Incredible (no reported incidents)
Risk: ALARP

Risk: The output of the stimulator may pass through the heart if an electrode is attached to each hand. This could theoretically affect the heart, in the worst case causing heart fibrillation.

Discussion: Most work analysing the effect of electric current on the body inducing cardiac ventral fibrillation examines the effect of sinusoidal mains currents of 50 or 60 Hz. Only one study could be found that looked at the effect of short pulses of stimulation used in therapeutic stimulation. Riscili et al.[1] investigated the safety of external electrical stimulation of the chest muscles for electroventilation. Electrodes were placed symmetrically across the chests of twelve anaesthetised dogs. Using a stimulation frequency of 60Hz, pulse width of 100µs with bursts of 0.8 s, the current was increased until optimal ventilation was produced. The threshold for production of ectopic beats was then found by using single pulses at a range of widths by increasing the current until an ectopic beat was produced. The dogs were put

into a state of transitory cardiac arrest by efferent stimulation of the vagal nerve. This ensured the heart was in its diastolic period, the period in which the hearts threshold to ectopy is at its lowest. The threshold for ectopic beat production was found to fall with increased pulse width.

At 100µs an average current of 2800mA was required to elicit an ectopic beat, 25.8 times the current required for electroventilation. At 360µs, the max pulse width available from the TetraGrip, the threshold for ectopic was reduced to approximately 1500mA, 25 times the maximum output from the TetraGrip. There is therefore in excess of an order of magnitude difference between the level of the current that may affect the heart and that used in therapeutic electrical stimulation even in optimal conditions for transthoracic current path. This of course assumes that the dog model is comparable with humans and the experimental set up is comparable with circumstances likely to be encountered when using therapeutic electrical stimulation. There have been no reported cases of ectopic generation or induced fibrillation while using therapeutic stimulation.

Action taken to mitigate risk: The user manuals instruct the users of the equipment to not handle the electrodes while the stimulator is turned on and only apply the electrodes as described in the manual.

Grip/Grasp accidents

No fault condition: Reduced risk of dropping the objects the person is trying to grip or grasp provided the user is selected and treated appropriately.

Single fault condition:

1. Failure of FES system due to electronic component failure
2. Failure due to shoulder position sensor
3. Failure due to electrode lead
4. Failure due to channels not being connected in the proper sequence
5. Failure due to flat battery
6. Failure due to incorrect fitting
7. Failure due to incorrect patient assessment
8. Excessive or insufficient stimulation level
9. Incorrect use.

Possible Outcome: Marginal (serious injury to the person if they try and fail to grasp a heavy or hot object)
Occurence: Improbable
Risk: ALARP

The other possible risk assessment for is as follows.

Possible Outcome: Marginal/ minor (Minor injuries or bruises to the user)
Occurence: Remote

Risk: ALARP

Discussions and actions taken to mitigate the risks:

1. **Failure of the FES device due to electronic component failure:**
   The failure of the FES device due to electronic component failure is unlikely as the electronic components used in the device are standard quality components. During the device design, additional precaution was taken to ensure that the voltage and current for all the components remain within the given range.

2. **Failure due to shoulder position sensor:**
   The electronics used in the sensor are widely used components which are known to be reliable. Hence the chances of electronics failure are minimal. Other possibilities are wear and tear of the cable that connects the sensor to the stimulator. The user will be provided with a spare cable in case of a cable failure. The instructions for the cable replacement are provided in the user manual and the user will also be briefed during their visit to the clinics. The device also has an emergency stop button which terminates the stimulation once pressed. The user can use this button if the sensor fails during stimulation.

3. **Failure due to the electrode lead:**
   The insulation of the electrode leads becomes stiff and brittle over a period of time. This may cause the device to malfunction. The user manual instructs the user to regularly inspect the electrode leads.

4. **Failure due to channels not being connected in the proper sequence:**
   The TetraGrip, being a four channel FES device, is programmed in such a way that each channel is designated to activate a specific muscle group. If the channels are connected to the wrong muscle group, then the sequence of muscle stimulation will be altered and the user may not be able to achieve the desired functional movement. In order to prevent this, the front panel of the device clearly indicates the channel numbers, the electrode leads are also labelled and the user manual clearly describes the electrode placements and the connections.

5. **Failure due to flat battery:**
   Since the TetraGrip uses rechargeable Lithium ion battery to power the circuits, the user needs to connect the device to the mains using the charger provided in order to recharge the battery. LED indicators are also available to indicate the status of the battery. The user manual describes the status LEDs in detail.

6. **Failure due to incorrect fitting:**
   Upper limb FES devices require precise positioning of the electrodes. Improper fitting of the device can result in stimulation of a different group of muscles which in turn might cause the device to malfunction. It is the clinician's responsibility to identify the motor points of the target muscle group and precisely place the electrodes. It is the clinician's responsibility to explain the electrode placement to the user and the carer and mark the position of the electrode or provide photographs of the electrode placements which will help the user and/or the carer with the electrode placement.
   The shoulder position sensor should be strapped across the shoulder such that the sensor faces forwards. The positioning of the sensor is explained in the user manual and the user and the clinicians are required to be acquainted with the position of the sensor in order to generate the proper command signals. Improper placement of the sensor can either result in false trigger or may result in no trigger at all.

7. **Failure due to incorrect patient assessment**
   Upper limb FES devices are not suitable for each and every individual. It is the clinician's responsibility to select the patients appropriately. The clinicians are required to follow the inclusion and exclusion criteria mentioned in the volunteer information sheet and the user manual.

8. **Failure due to insufficient stimulation**
   The TetraGrip relies on a delicate balance between the finger flexors (Channel 2) and finger extensors (Channel 1) to hold the wrist in a neutral position. Excessive stimulation on either of the channels can result in the wrist in an overly flexed or overly extended position which might prove extremely uncomfortable to the user.

   During the setting up, the clinician sets the device up with best possible current settings for all the channels making sure that the user is able to achieve best possible hand movement to perform the required activities. The clinician enters the value of the current for each channel with the help of a keyboard and a serial monitor. The device is programmed to provide step by step instructions to the clinician on how to set the parameters and proceed with the setup.

   The user cannot manipulate the currents to any of the channels there by eliminating the changes of excessive stimulation or under stimulation. The user however has access to adjust the pulsewidth of the channels 3 and 4 which control the movement of the thumb. This allows the user to adjust their grip / grasp while the stimulation is ON. The pulsewidth however does not go above 360 µs or below 3 µs which is the standard maximum pulsewidth settings for the upper limb stimulators. This ensures that the stimulation does not exceed the maximum or go below the minimum values there by mitigating the failure due to insufficient stimulation.

9. **Incorrect use**
   The device will not be able to assist the user in grip and grasp functions if it is not set up properly. The device will fail to function if the user forgets to turn the device ON or release the pause button before generating the command signal.

Mains / Power Supply:

No fault condition: Minimum current flows through the body.

Single fault condition: The user may be subjected to mains voltage

Possible outcome: Catastrophic.
Occurrence: Incredible
Risk: ALARP

Discussion: The chances of the user being subjected to mains voltage are minimal because the device is powered with the help of Lithium ion rechargeable battery. In order to charge the battery, a charger with good isolation approved for use along with medical devices, is used. The cable that connects the TetraGrip with the computer also has mains voltage isolation. The laptop will not be connected to the mains supply when the device is connected to the user. Hence the device will be totally isolated from mains supply thereby mitigating the risk of the user being subjected to the mains supply voltage.

Skin allergy / reaction

No fault condition: Allergy to electrodes

Single fault condition:
1. Poor electrode care
2. Poor skin (patient selection)
3. Poor electrode contact
4. DC output due to Transformer failure

Possible outcome: Minor (minor discomfort, could prevent use of the device)
Occurrence: Occasional (reported by approximately 1 in 4 users over a period of 3 years[3])
Risk: ALARP

Discussion and actions taken to mitigate risks:

This is the most common complication to use of the TetraGrip. Tolerance to the materials used in the electrodes will vary from user to user. However, skin reaction will be exacerbated by the following circumstance:

1. Poor electrode care

As electrodes are used their condition slowly deteriorates. The electrodes pick up debris from the skin (chiefly dead skin cells) and lose their adhesiveness. Long term use will also lead to irregularities in the electrode surface such as pitting. This will cause uneven current distribution. High current density can be associated with increase skin reaction.

The user is told which electrodes are recommended for use with the TetraGrip. They are instructed to regularly inspect the electrodes and replace them after a maximum of one month or sooner if they deteriorate.

2. Poor skin (patient selection)

If the TetraGrip user has poor skin quality due to circulatory dysfunction or dermatological conditions, there may be an increased risk of skin reaction to the electrodes. This is also the case if the skin is broken due to a cut, rash or other skin complaint. Shaving of the hairs in the electrode site can cause small scratches and should be avoided. The user manual instructs that the electrodes must not be placed over poor quality or broken skin.

3. Poor electrode contact

If an electrode begins to peel off due to poor electrode condition or a mechanical force, the area of contact decreases so that the potential current density increases. The output stage of the TetraGrip is matched for an output impedance of 2K Ohms. This means that as the electrode area is reduced and the load impedance rises, the output current will reduce. This is illustrated in figures 1 and 2.

FIGURE 1 CHANGE IN TETRAGRIP OUTPUT VOLTAGE AND CURRENT WITH LOAD RESISTANCE (LOG R)

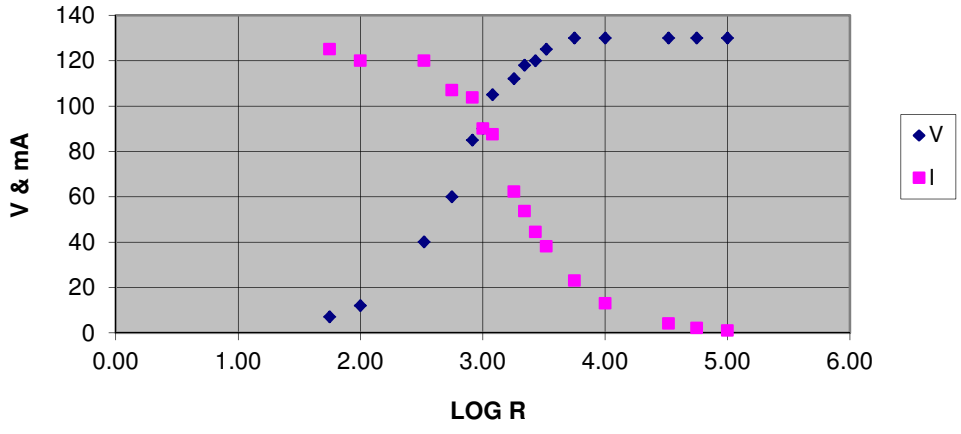
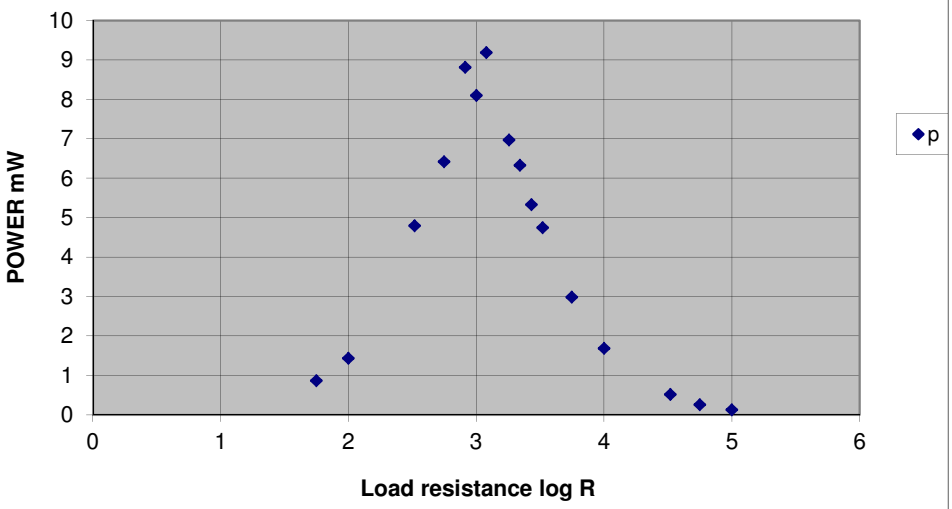


FIGURE 4. CHANGE IN TETRAGRIP POWER OUTPUT WITH OUTPUT LOAD RESISTANCE (LOG R)



4. DC output due to Transformer failure

A constant DC output from the stimulator will cause ion migration between the electrodes that will lead to skin irritation.

DC output is prevented by transmission of the output current through a transformer. This prevents passing of a DC current. If the transformer insulation failed, a DC current could only occur if the user was touching another part of the circuit. This could not occur in the normal operation of the device.

Discomfort due to high stimulation level

No fault condition: Improper setting of the controls

Single fault condition: Failure of the pulse width level control

Possible outcome: Minor (minor discomfort)
Occurrence: Occasional
Risk: ALARP

Discussion and actions taken to mitigate risks:

The clinician sets the current by entering the value through a keyboard into the software interface which allows the stimulator to use the entered value of current to generate the stimulation envelope. The user does not have access to changing the current which will mitigates the risk of discomfort due to high level of current. The current is set so that the desired movement is produced with the stimulation level in the middle of its range.

The user can fine tune the grasp by changing the pulse width of the stimulation envelope. Since the pulse width is set to be in the middle range (180 µs in case of the TetraGrip), the change in intensity due to the accidental change in the pulse width will be proportional, causing relatively small change in the contraction strength or sensation.

The device is programmed in such a way that the pulse width does not exceed the maximum level when the user is trying to increase it to get a better grasp. However, if the shoulder position sensor fails with the pulse width at its maximum value and causes discomfort to the user, then the user can use the emergency stop button to terminate the stimulation.

Induced increase risk of epileptic fit

No fault: Incorrect patient selection

Possible outcome: Marginal / Critical (fitting could cause fall, could prevent use of the device)
Occurrence: Improbable (can occur in exceptional circumstances)
Risk: ALARP

Discussion and actions taken to mitigate risks:

The causal relationship between use of FES and increases risk of epilepsy has never been formally demonstrated. However, there is anecdotal evidence of an association at least between the precursor symptoms that can precede a fit. This has been reported in individuals who have a history of epilepsy. However, many of the TetraGrip users have an increased risk of epilepsy due to lesions within the brain. Therefore the instruction manual contraindicates use of the TetraGrip for people who have poorly controlled epilepsy.

Autonomic dyreflexia in the TetraGrip users with Spinal Cord Injuries:

No fault: Incorrect patient selection

Possible outcome: Catastrophic (Severe rise in blood pressure could lead to a stroke, could prevent use of the device)
Occurrence: Incredible (Because symptoms will subside as soon as stimulation stops, it is highly unlikely that a dangerous situation could ever be reached)
Risk: ALARP

Discussion and actions taken to mitigate risks:

It is known that electrical stimulation can induce autonomic dysreflexia (AD) in patients with spinal cord lesion above the level of T6 [4]. It is also known that the effect is transient and ends as soon as the stimulation is removed. The instruction manual instructs that the TetraGrip users with SCI lesions of T6

and above are made aware of the risk of AD and taught how to recognise the effect (a rise in blood pressure leading to headache. Most SCI patients who are at risk of AD will have been taught how to recognise the symptoms by the spinal injury care team). If effected, they are instructed to discontinue use of the device.

Unknown effects of electrical stimulation on unborn foetus

No fault: Incorrect patient selection

Possible outcome: Critical (damage to the developing foetus)
Occurrence: Improbable (no reported incidences)
Risk: ALARP

Discussion and actions taken to mitigate the risks:

There has been speculation that electrical stimulation may affect the unborn foetus in two ways [5]. Firstly, in the first trimester, that electrical stimulation may result in abnormal development of the foetus. Secondly, in the third trimester, that electrical stimulation may cause premature labour. There is little evidence to support these theories but no investigations to demonstrate the safety of electrical stimulation in pregnancy. The Instruction manual informs the user that the safety of electrical stimulation in pregnancy is unknown.

Damage or breaking of the outer casing

No fault: Inappropriate handling of the device
Possible outcome: Marginal (Damage to the internal electronics and disconnection of the circuits)
Occurance: Improbable
Risk: ALARP

Discussion and actions taken to mitigate the risks:

The box that encases the electronics of the TetraGrip is sturdy and adapts to the minor wear and tear. The device will be mostly used in the clinics where the clinicians will handle it with care so the chances of dropping the device from a good height are minimal. If the device is made as a take home device in the future, the user and the carer will be asked to place the device securely in the user's wheelchair so as to avoid dropping the device or running over it.

Appendix F

BS EB 60601-1 TEST PROTOCOL CHECKLIST

Equipment Title: TetraGrip 4 channel Stimulator											Engineer: Lalitha Venugopalan								
Serial No: N/A											Date: 15/03/16								
Test	Compliant?			Test	Compliant?			Test	Compliant?			Test	Compliant?			Test	Compliant?		
1	X			46			X	91	X			136	X			181			
2	X			47			X	92	X			137	X			182			X
3			X	48			X	93	X			138	X			183			X
4			X	49			X	94			X	139	X			184			X
5			X	50			X	95			X	140			X	185			X
6			X	51				96		X		141			X	186			X
7	X			52				97	X			142			X	187			X
8			X	53	X			98			X	143			X	188			X
9			X	54	X			99			X	144			X	189	X		
10			X	55			X	100			X	145	X			190	X		
11			X	56			X	101			X	146			X	191	X		
12	X			57			X	102			X	147	X			192	X		
13	X			58			X	103			X	148			X	193	X		
14			X	59			X	104			X	149			X	194	X		
15			X	60			X	105			X	150			X	195	X		
16			X	61			X	106			X	151			X	196	X		
17			X	62			X	107			X	152			X	197	X		
18			X	63			X	108			X	153			X	198	X		
19			X	64			X	109			X	154			X	199	X		
20			X	65			X	110			X	155				200			X
21	X		SW	66			X	111			X	156			X	201			X
22	X			67	X			112		X		157			X	202	X		
23			X	68			X	113				158			X	203	X		
24			X	69			X	114				159			X	204			X
25	X			70	X			115				160			X	205	X		
26				71	X			116				161			X	206			X
27				72				117				162			X	207		X	
28				73			X	118				163			X	208			X
29				74			X	119			X	164			X	209			X
30				75			X	120			X	165			X	210	X		
31				76			X	121			X	166			X	211	X		
32			X	77			X	122			X	167	X			212	X		
33				78			X	123			X	168			X	213			X
34	X			79	X			124			X	169			X	214			X
35	X			80	X			125			X	170			X	215	X		
36	X			81	X			126	X			171			X	216		X	
37	X			82			X	127	X			172			X	217	X		
38	X			83			X	128			X	173			X	218	X		
39			X	84			X	129	X			174			X	219			X
40			X	85			X	130			X	175			X				
41			X	86				131			X	176			X				
42			X	87			X	132			X	177							
43			X	88	X			133	X			178							
44	X			89			X	134	X			179							
45	X			90			X	135	X			180							