A SELF-OPTIMISING PORTABLE FES SYSTEM USING AN ELECTRODE ARRAY AND MOVEMENT SENSORS

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Declaration of originality

This thesis is submitted in fulfilment of the requirements of Doctor of Philosophy in the Department of Engineering, University of Leicester, United Kingdom. All work recorded in this thesis is original unless otherwise is acknowledged in the text reference. No part of this thesis has been submitted for any other degree either to the University of Leicester or to any other University.

Signed

Ahmed Elsaify

Acknowledgment

The work on this thesis has been an inspiring, mostly challenging, but always an interesting experience. It has been made possible by some special people to whom I owe many thanks.

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Ahmed Elsaify

A Self-Optimising Portable FES System Using an Electrode Array and Movement Sensors

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Abstract

A portable functional electrical stimulation system has been designed using embedded systems technology. The system, which was applied to patients suffering from foot drop, uses sensors to monitor foot movement and orientation in a unique way, uses sophisticated algorithms for feedback, and drives an array of surface electrodes for stimulation. This system meets British Standards and safety requirements for medical equipment.

A new technique was invented based on using the twitch response of muscles to optimise the configuration of the electrode array. This reduces the setup time in the clinic. Using feedback from the sensors, the optimum configuration of electrodes is chosen to produce correct stimulation and movement in real time. The instrument presents the patient with a ranked list of electrode combinations that are likely to be optimum; the patient can then choose a combination that is both effective and comfortable. The system is also able to vary the chosen pattern of electrodes and the stimulation signal parameters during the stimulation process. This may enable some problems associated with fatigue and skin irritation to be reduced.

Trials were carried on 30 controls and 12 patients to test the instrument and study and develop the system optimisation and control algorithms. These preliminary clinical trials showed that control of the stimulation during walking, based on the optimisation algorithms developed in this work, gives high quality correction of foot drop. This was shown by gait assessment analysis by the physiotherapists involved in the project and blind assessment using independent researchers. These trials prove that the concept of using the electrode array for stimulation has advantages over using a conventional 2-electrode system.

CONTENT

Chapter 1

INTRODUCTION

CHAPTER 1: INTRODUCTION

1.1 General background

Functional electrical stimulation (FES) is the term given to a form of electrotherapy which can be used to stimulate muscle in order to achieve a certain functional contraction which can then be used to perform a clinically useful activity. The development of assistive rehabilitation devices like functional electrical stimulation has become the field of activity for many researchers around the world. The FES system of interest in this work is the transcutaneous surface electrode functional electrical stimulation. The application of interest in this research is foot drop due to stroke or multiple sclerosis (MS). Both electrical stimulation and foot drop will be discussed in more details in this chapter and Chapter2.

Over the last 40 year the number of FES devices manufactured to restore foot drop in stroke patients alone is about (14,000), (Lyons, 2002). According to Creasey and Donaldson the numbers of stroke victims in Europe population are 12,000/million, (Creasey, 2000), and according to Burridge et al. and Leane et al. 10 – 20 % of stroke victims have experience the foot drop problem, (Burridge, 1997), (Leane, 1998). Comparing the number of manufactured stimulator devices to the number of stroke patients suffers from foot drop reflects the problems associated with these devices technology and perception. Many authors reported that this low volume of foot drop stimulators could be due to the fact that the commercial foot drop stimulation devices available are single channel open loop devices. Out of the foot drop patients who are clinically referred for FES, only 50–70% adopts surface stimulation for correction of their disability (Taylor, 1999). However, limited number of subjects from these given foot drop stimulation devices will continue to use it in the long-term; this is due to difficulty placing the electrode at the correct location on a daily basis, difficulty tolerating the sensation of stimulation, difficulty operating the equipment on a daily basis, (Taylor, 1999).

An alternative solution to some of these problems specialty the problem of finding the optimum stimulation site using surface transcutaneous electrode stimulation is to use an electrode array. One of the first attempts to use the transcutaneous electrode array was reported by Regehr et al, they used a manual switchboard to select 8 out of 61 channels for stimulation (Regehr, 1989). In 1990 Robert Patterson made use of garment electrode array, (Patterson, 1990). Patterson used two channels of a four-channel stimulator to stimulate the quadriceps muscles using the garment electrode. The other two channels are used to stimulate the peroneal nerve to achieve foot dorseflexion, (Patterson, 1990). Also Jimbo and Kawana describe a complete system with 18 stimulation channels, (Jimbo, 1992). The flexible PCB transcutaneous electrode array was introduced by FESTIVAL (EU Project Tide 1250, 1997) as a means of combining individual electrodes onto a single substrate. This did prove effective but individual circles of hygrogel were required to isolate each electrode which made them time consuming to reproduce, (Whitlock, 1997). Pancrazio et al, describe a 16-channel stimulation system for cardiac myocytes implemented in VLSI, (Pancrazio, 1998). Zeck and Fromherz use FET technology to construct a similar system for invertebrate neurons, (Zeck, 2001). Another system that combines recording and stimulation capabilities for 64 electrodes was recently described (Jimbo, 2003).

Bijelic et al, introduced manual 24 button transcutaneous electrode array control box, the electrode array was made of conductive micro-fibre silver coated textile. The conductive fields are circular and they are evenly spread over the flexible substrate which is 5 cm x 8 cm, and the conducting field hade diameter of 1 cm. The switcher box can be controlled manually using push button switches or using a PC interface to turn on and off the conduction for each electrode within the array individually. This electrode system was mainly used for fingers flexion and hand grasping investigation and clinical assessment (Popović-Bijelić, 2004), (Bijelic, 2004). In 2001 Livshitz showed that for a 2x2 array it is possible to influence the charge distribution within tissue with respect to the motor point alignment (Livshitz, 2001). Lawrence et al, designed virtual electrodes stimulation system formed from two dimensional array of small electrode elements, each one can be switched on and off. The electrodes was made of square (10 mm x 10 mm) textiles silver coated fibres and arranged in array of 4x4 with 2mm inter spacing, (Lawrence, 2004),

Heller et al, introduced the use of an 8 x 8 array of mini transcutaneous electrodes (4.5 mm diameter) with an overall size that cover the stimulation site, the optimisation method was based on finding the optimum electrode or group of electrodes that stimulates the nerve that is responsible for producing the desired movement, (Heller, 2003). Sha and Heller produced a 3D finite element model to optimise the design of self adhesive electrode array in FES applications, this 3D model was used to calculate the current density distribution in tissue in the vicinity of the electrodes, (Sha, 2004). The 3D model can help in determining the spatial selectivity of the electrode array. The model also demonstrated that for a 1mm thick hydro-gel interface a minimum resistivity of 500Ω is required to maintain selectivity, (Sha, 2004).

1.2 Clinical benefit and the motivation of this project

The best way to measure the clinical benefit of FES is to study the patient perception and rejection of using FES. Salisbury District Hospital in the UK has one of the most successful FES clinical centres world wide, especially in supplying and using foot drop devices. Salisbury group reported results from questionnaire sent to 291 patients provided with ODFS device for foot drop correction, (Taylor, 1998). The result show that 168 patients were still using the device, 64% of whom replied and 123 patients had been discharged, 43% of these replied. The condition for these users was as follow; 72% stroke, 14% MS, and the rest were other conditions. From the patient still using the device 44% reported less effort during walking when they use the device as a reason to continuo using it. About 23% continue using the device because they are less likely to trip when they use it. 14% reported that they can walk further and 9% reported more confidence. Only 4 % reported that they can walk faster as reason to use the device. This questionnaire results show that 55% uses the system every day, 40% all day. Regarding the distance they can walk with system 42 reported 10-100 yards and 30% 100-500 yards. About 50% of the users who stopped using the device experienced a problem finding the optimal electrode position, and they reported that as the main reason for discontinuing using the device. 20 % of all users reported skin irritation and 10% of all users stopped using the device because of that. Unreliability was reported by 40 % of patients stopped using the device. The rest reported other reasons for stopping using the device such as spasticity and difficulty to use, (Taylor,

1998). In 2000 Salisbury District Hospital group published results another questionnaire called IMPULSE (Taylor, 2000). This questionnaire surveyed long-term users of the ODFS single channel foot drop stimulation device. Of the 140 users surveyed, 70% (98) replied. Only 13% report that they had experienced no problems with the equipment. The most commonly experienced problem was with finding the correct electrode positions (72%); with 17% of respondents reporting this to be severe problem and 37% a moderate problem. 36% reported the sensation from electrical stimulation to be a problem. Again, they estimate, based on clinical experience, that approximately 25–30% of foot drop stimulation users ultimately reject the device (Taylor, 2000). The above questionnaire results indicate some of the clinical benefit of using FES for foot drop and also some of the problems they experienced with the ODFS device, despite the fact that this device is one of the most successful devices that benefited the foot drop suffers specially in the UK. The above results was the main motivation of this project, which was mainly to try to close the gap between the user need and the clinically available systems.

1.3 Aims and objectives

The original aims of this research as setup by EPSRC grant proposal GR/N13029 were to develop a new FES portable system with sensory input under closed loop control that will alleviate the problem of foot drop during walking.

The objectives were; to design an "intelligent" stimulator, which can have variable pulse shapes (for comfort), pulse trains of variable frequency and pulse width for more dynamic stimulation and control. The feedback was to be designed such that it would measure function using appropriate sensors.

The second aim was to use an electrode array to alleviate electrode placement problems associated with obtaining the desired movement. In order to achieve this, the third aim was third aim was to design a new system that uses a novel electrode array optimisation technique and algorithm to find the best stimulation sites automatically and in a short period of time. This new optimisation technique should produce the desired, comfortable and accurate stimulation movement.

Finally, the stimulation system was to be tested for electrode array optimisation (setting up) and walking tests to alleviate foot drop in preclinical trials in a hospital research clinic (Bristol General Hospital).

In general the research question was "*Can we use a new automatic optimisation technique based on using an electrode array to solve the problem of finding the best electrode position using transcutaneous stimulation?"*

1.4 Physiology background

The excitability of nerve and muscle fibres gives the background for therapeutic applications of FES. The following headings cover a short review of the basic neurophysiology of nerve and muscle excitation to clarify the principles of functional electrical stimulation for the purpose of this thesis.

The nervous system comprises sets of neurons connected with varying degrees of complexity. The nervous system in the human body consists broadly of two components; the central nervous system CNS, composed of the brain and spinal cord, and the peripheral nervous system, consisting of the nerves extending from the brain and spinal cord. These two can be further divided as illustrated in Figure (1.0), (Davies, 2001), (Arthur J, 1994), (Winter, 1990), (Campbell, 1984). This division is not absolute in that there is some measure of functional overlap between the two systems. In this research it is the voluntary lower motor system that is of interest. The voluntary nervous motor system, which is directly responsible for skeletal muscle movement, can be divided into upper and lower motor neurons. The upper ones are those that extend from the brain into the spinal cord. The lower motor neurons (somatic nerves) are those that go from the spinal cord to the muscle motor end plates.

1.4.1 Neurons

Neurons are irregularly shaped cells. They consist of three parts, the dendrites, the cell body, the axon and the axon terminals, Figure (1.1). The dendrites and axons are projections from the cell body. The dendrites carry information to the cell body and

the axon transfer information away from the cell body, (Winter, 1990). Typical neurons have many short-branched dendrites and a single long axon. Neurones are interconnected; the junctions are called synapses. This is a chemical junction in that a neurone-chemical transmitter passes information across the synaptic junction. The nerve fibres have an outer myelin sheath, which is composed of fatty material that electrically insulates the intracellular fluids from the extra-cellular ones. It has gaps at approximately 1mm intervals. These gaps are known as nodes of Ranvier and allow rapid transfer of information along the nerve, (Davies, 2001), (Levitan, 2001).

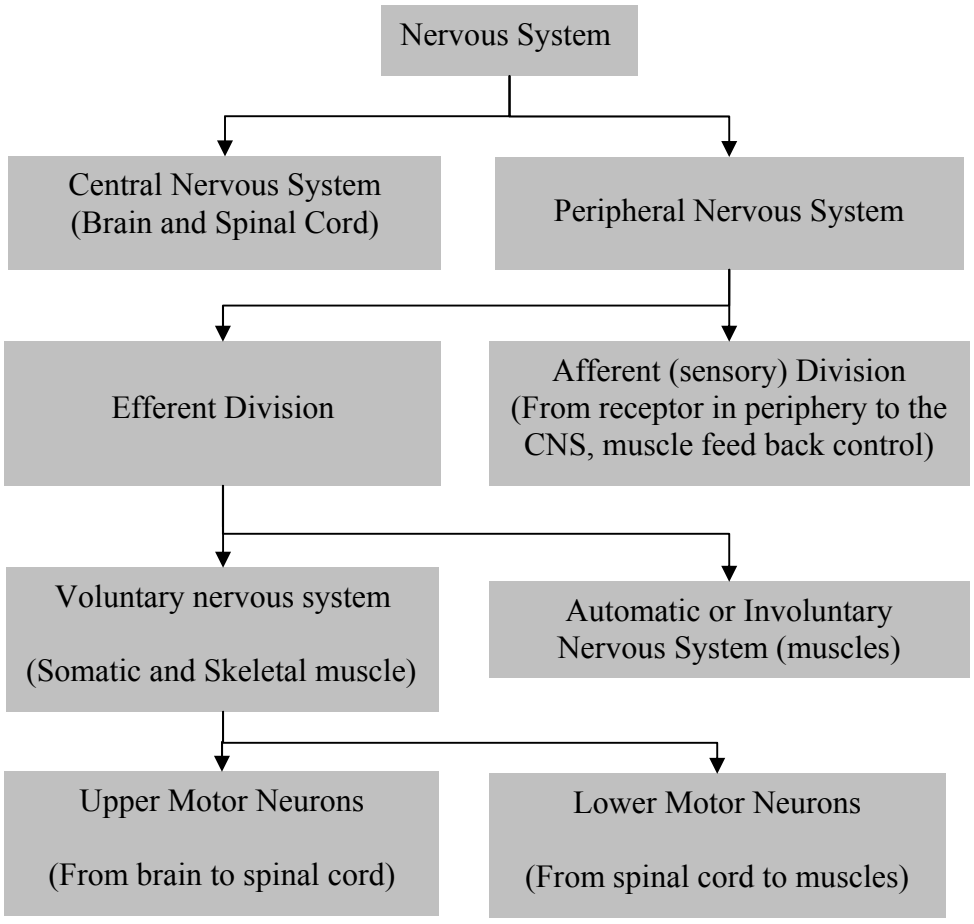


Figure (1.0) - General overview of the human nervous system

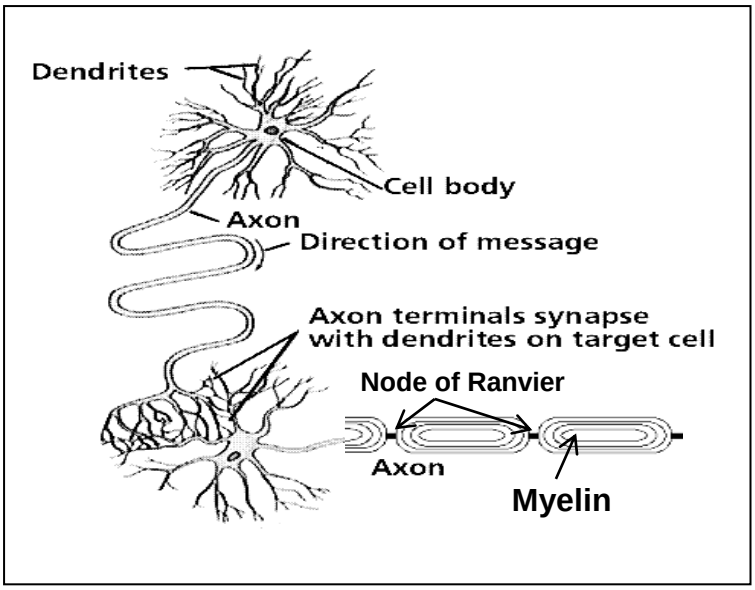


Figure (1.1) - Structure of a neurone and the direction of nerve message transmission (modified from (Winter, 1990)).

1.4.2 Lower Motor Neurones

Two different types of lower motor neurones exist, alpha motor neurones and gamma motor neurones. Alpha motor neurones are the final pathway from the nervous system. The alpha motor neurones with large cells and thick axons supply the main skeletal muscle fibres, and are responsible for the initiation of skeletal muscle contraction and for tension development in contracting muscles. The Gamma motor neurones are the final efferent from the central nervous system through which the muscle spindle activity is regulated to control muscle tone, (Hamill, 1995).

1.4.3 Motor Units

The motor unit is considered as the functional structural unit and final common path for both reflex and voluntary movement. It comprises a nerve cell whose cell body is located within the anterior horn of the spinal cord. This is the alpha motor neurone. Emerging from it is the axon, which leaves the spinal cord via the ventral nerve root. Once this axon reaches the muscle supplied, it branches and innervates a group of skeletal muscle fibres, which together with the innervating nerve cell constitute the motor unit.

1.4.4 Skeletal muscle

Skeletal muscle is composed of bundles of striated muscle fibres. Morphologically, each single striated muscle fibre consists of many myofibrils, which are organized in a parallel formation within the fibre, each being shown alternate light and dark bands, as a result of special arrangement of thick myosin filaments and thin actin filaments. Activation of the muscle causes the actin and myosin components to move towards each other, shortening the muscle.

1.4.5 Muscle Control

Spinal mechanisms play an important role in the control of movement. They alter the balance of activity between muscles and affect the sophisticated integration of peripheral and central inputs needed for rapid motor adaptation. Muscle spindles are the sensory organs in muscles that are responsible for the stretch reflexes and provide information on muscle length and the rate of change of muscle length. Figure (1.2) is a schematic drawing showing a muscle spindle and its role in controlling muscle.

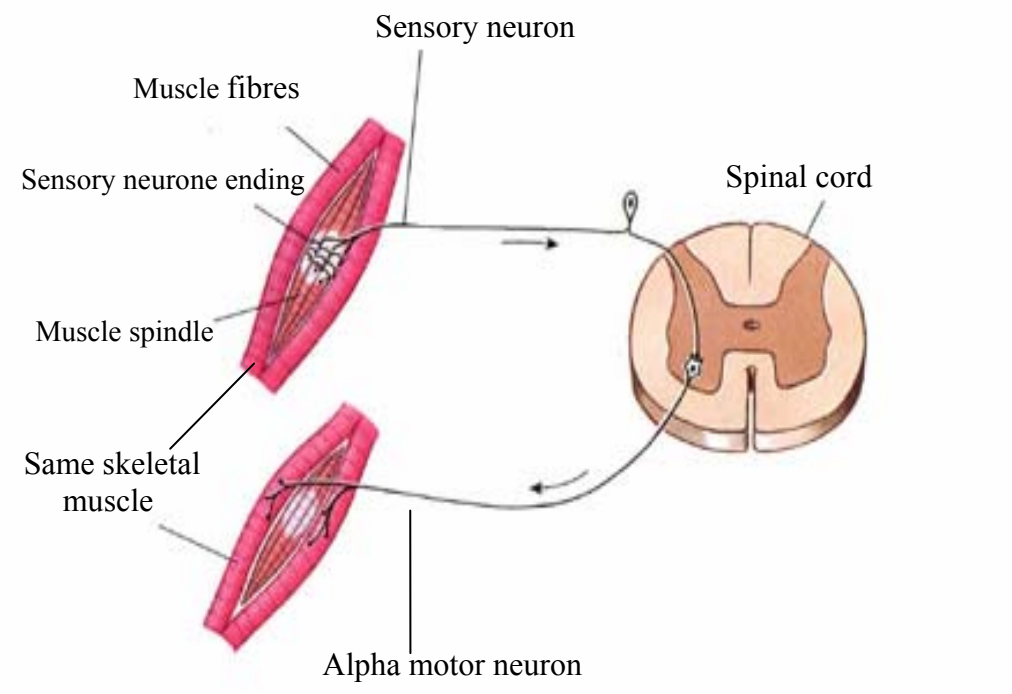


Figure (1.2) - The motor neurones used to control muscle tone in skeletal muscle, (modified from (Hamill, 1995)).

The output from the muscle spindle synapses with the associated muscle lower alpha motor neurone, the synaptic connection between the sensory neurone and the alpha motor neurone is facilitated by triggering this connection. Facilitation of a synaptic connection means that, the connection is allowed or not under the ON/OFF control of the upper motor system over the lower motor neurones. If a synaptic connection is allowed, facilitation occurs and if it is not allowed, inhibition occurs. This regulation called motor reflex integration. Figure (1.3) shows an example of this process. If a person is standing the body sways forward, the calf muscles are stretched, this fires the muscle spindles of the calf muscles. The reflex contraction helps to restore balance and the body is pushed back into the upright position. This neural circuit called the reflex arc and the associated reflex is referred to as the myotatic reflex.

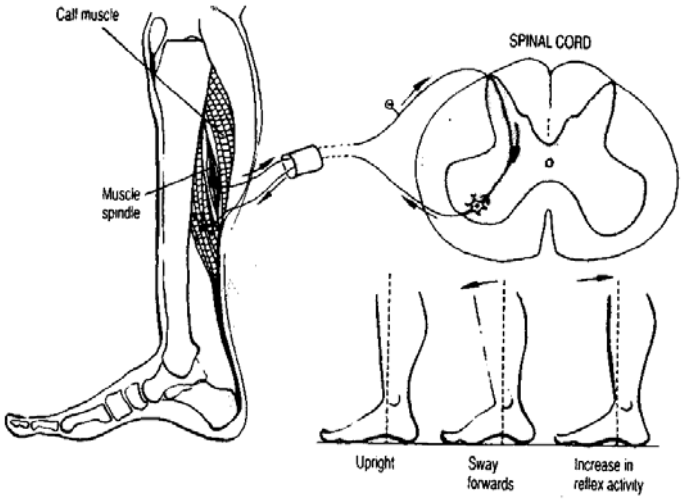


Figure (1.3) - Reflex activities in the calf muscles to maintain posture (Tyldesley, 1989).

1.4.6 Action Potential

The action potential or impulse is the mechanism by which nerve cells transmit signals and information. The event that generates the action potential can be of different kinds including chemical, electrical and mechanical stimuli (e.g. stretch). The electrical excitability of nerve tissue depends principally on the voltage sensitivity of the nerve membrane permeability and on the frequency of impulses transmitted by a nerve fibre, the number of fibres involved, and the synaptic connections made. When a neurone is not sending a signal, it is said to be "at rest." In its resting state a nerve membrane is more permeable to potassium than to sodium or

other cellular ions, the unequal ionic distribution maintains a resting membrane potential of 70-90 mV, with the inside electrical negative with respect to the outside, as shown in Figure (1.4) This principle applies to muscle fibres, (Baker, 2000), (Arthur, 1994).

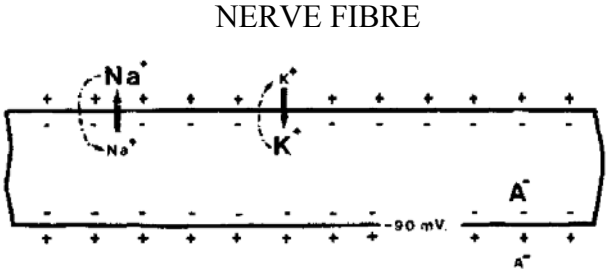


Figure (1.4) - Nerve Fibre: A membrane potential of approximately -90 mV is established in the normal resting nerve fibre. The passive diffusion of sodium and potassium (broken arrows) is countered by the active transport system (solid arrows), allowing a steady state condition to prevail (Baker, 2000)

An action potential, or very rapid reversal of membrane potential, is triggered by a stimulus, which reduces the membrane potential. This stimulus may be natural, such as touch activation of a sensory receptor, or may be induced by an externally applied electrical field or current, as is the case in electrical stimulation. The trigger stimulus, regardless of its source, results in an opening of sodium selective membrane channels and the beginning of an inward flow of sodium ions driven by a large concentration and electrostatic pressure gradient. The membrane potential is briefly reversed to a positive potential, this is the first stage of the generation of the action potential. This process is called depolarization. Immediately afterwards, a similar amount of potassium ions also cross the membrane, exiting from the nerve fibre interior. As the equilibrium chemical potential for sodium is approached, the driving force of sodium decreases and finally stops as the membrane channels for sodium close. This process is called repolarization. The restoration of selective potassium permeability to the membrane restores the original ionic concentration and electrostatic pressure gradients and results in a re-establishment of the potassium dominated resting potential. This transient process is completed in about one millisecond for nerve tissue and within a few milliseconds for muscle tissue. A graph of the membrane potential, as it varies with time, during the generation of an action potential is shown in Figure (1.5) (Baker, 2000).

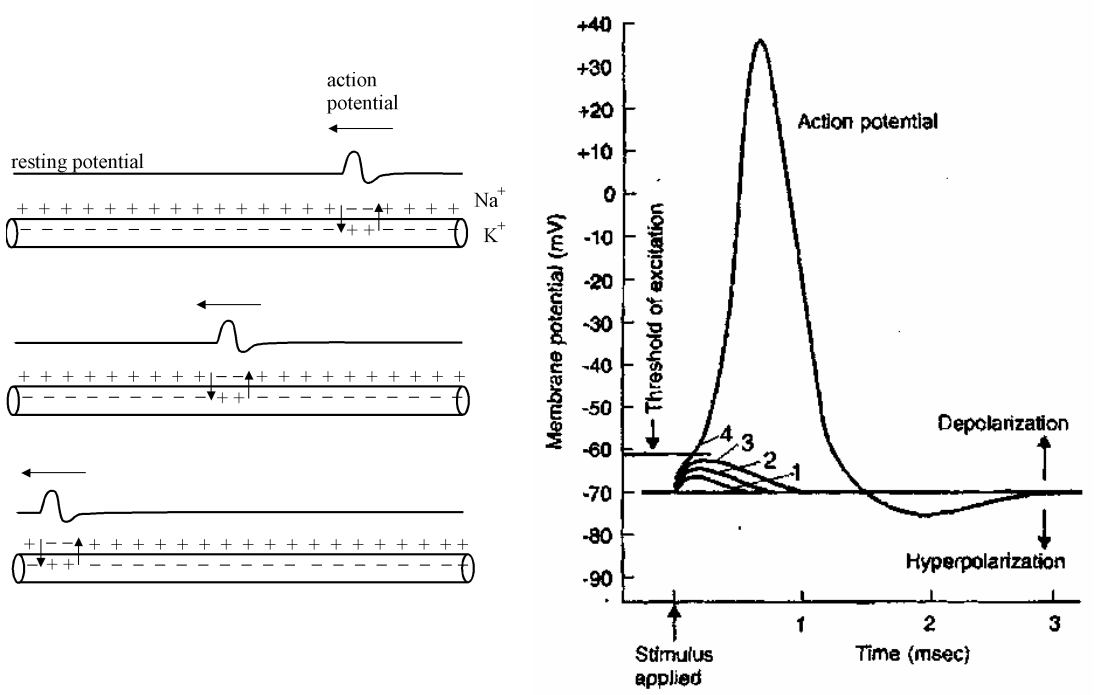


Figure (1.5) - A nerve action potential and the response of the membrane potential to several sub-threshold stimuli, numbers 1 to 3, (Carlson, 1994).

Each action potential is fundamentally identical within the same nerve ("all or none law") although slight variations occur between different nerves. An action potential, once generated, is normally self-sustaining throughout its travel along the nerve process and is propagated from the periphery to the CNS by afferent axons and between the CNS to the periphery by efferent axons (Baker, 2000), (Carlson, 1994).

In order to induce an action potential, external electrical stimuli must be of adequate intensity and of sufficient duration to equal or exceed the threshold of excitability of the cell membrane. Nerves have a lower threshold than muscle and thus electrical activation of peripheral nerves could induce muscular contraction by the normal physiological mechanism.

1.5 Lost muscle movement

It is important to state that FES is effective only when the peripheral nervous system is intact. Damage to the peripheral nerve causes muscle degeneration hence no nerve to stimulate and muscle properties change so that they become harder to stimulate. Therefore FES is more likely to be effective on stroke, multiple sclerosis (MS), moderate (partial) spinal cord injuries (SCI), cerebral palsy (CP) and traumatic brain injury (TBI). Persons with lower motor neurone damage due to peripheral nerve lesions or damage to the anterior horn cells of the spinal cord (grey matter containing alpha motor neurons), will not respond to standard FES. Of these conditions, stroke and head-injuries are by far the more prevalent problems with reported prevalence of 12 000/million for stroke and 20 000/million for head injuries as opposed to 800/million for SCI, 2000/million for MS, and 3000/million for CP, (Creasey, 2000). The primary concerns in this research are disabilities related to stroke and multiple sclerosis (MS). The following discussion will present the ways in which MS and stroke can affect the ability of movement.

1.5.1 Multiple Sclerosis

MS is a disease of the central nervous system (CNS). The pathological process starts with inflammation around groups of nerve fibres in the CNS, followed by development of patchy areas of demyelination (plaques). MS cause the myelin sheaths disappearing in patches in any area throughout the CNS and a scar is formed (sclerosis), (Matthews, 2002). In most individuals attacks of MS occur intermittently especially during the early years after diagnosis (relapse/remitting MS). Functional impairment and the recovery from impairment during remission have been stated to be dependent on interference with and restoration of conduction in the region of the plaques. MS can cause much sensory, motor and autonomic impairment that give different symptoms which vary in intensity in different subjects, presumably according to the site and extent of the lesions, some of these symptoms impair daily living activity including movements, (McDonald, 1996).

1.5.2 Stroke

A stroke occurs when blood vessels carrying oxygen and other nutrients to a specific part of the brain suddenly burst or become blocked. When blood fails to get through to the affected parts of the brain, the oxygen supply is cut off, a stroke occurs and brain cells begin to die. Strokes fall into two major categories, based on whether the disrupted blood supply is caused by a blocked blood vessel, known as an ischemic stroke, or a burst blood vessel called a haemorrhagic stroke. Stroke due to Cerebral Vascular Accident (CVA) is one of the most common causes of adult physical disability and death in the western world, (Royal College, 1989).

1.5.3 Spasticity

Spasticity is one of the common consequences of MS and stroke. It indicates that the upper motor neuron controlling the inhibition of myotatic reflexes has become isolated from its descending inhibitory system, so that Alpha and Gamma motor neurones are abnormally excitable, and as a result these reflexes are facilitated in circumstances when they would normally be inhibited. Thus if an attempt is made to execute a movement which involves stretching a muscle whose reflex arc is affected, the muscle contract through the myotatic reflex and may prevent the desired movement being executed. This condition is referred to as spasticity, (Apkarian, 1991).

1.5.4 Fatigue

Muscle fatigue is a feature of normal muscle and is “the transient decrease in performance capacity of muscle when they have been active for a certain time, usually evidenced by a failure to maintain or develop a certain expected force or power”, (Asmussen, 1979). Another definition of fatigue is that “fatigue is a gradual loss in muscle tension”, (Sandercock, 1985). The fatigue mechanism is likely to be involved for two reasons. First, the maximal contraction associated with voluntary effort, rapidly declines. Secondly, during voluntarily contraction, motor-neurones show a wide range in thresholds. This suggests that the excitability of the highest threshold units could be difficult to maintain (Garland, 1988).

1.6 Electrical stimulation

One of the attempts to use muscle electrical stimulation to improve function was a single channel stimulator designed by Liberson 1961 (Librson, 1961), to dorsiflex the ankle of dropped foot patients during the swing phase of walking gait. Shortly after that researchers started to apply muscle electrical stimulation to restore body function during long term management of these movements "such as walking, standing, hand functions and heart muscle functions", at this time the specialised term Functional Electrical Stimulation (FES) is applied.

1.6.1 Electrical stimulation techniques using electrodes

Electrical muscle stimulation can be achieved using two contacts or electrodes; this type of electrode system includes the electrode plus any mechanism or technique used to maintain contact between the patient and the stimulator. This electrode system plays a major role in determining the effectiveness of electrical stimulation and the ease with which it can be given. There are three options using different stimulation electrode system techniques, (Frank, 1990), (Baker, 2000).

I. Subcutaneous stimulation, i.e., under the skin, by having surgery to place implemental electrodes. The electrodes are either sutured to the muscle surface or are placed around the appropriate nerve bundle using a cuff arrangement. The stimulation can be powered and controlled external to the body via wires or an RF link. The stimulation has to be with the use of current in some manner and that can be only achieved by wires routed from the stimulator, which can be embedded to the electrode.

II. Percutaneous stimulation, i.e., through the skin, using fine wire and hypodermic needle electrodes, which are passed through the skin and pushed into the belly of the muscle. The optimum location for the electrodes can be determined by stimulating the muscle during the insertion surgery process. When successfully located the needle is withdrawn. The wires from the electrode are left emerging from the skin and terminated in a small junction box secured to the skin surface.

III. Transcutaneous stimulation, i.e., across the skin using surface electrodes that can be stuck or strapped to the surface of the skin. The optimum location for the electrodes can be determined by moving the electrodes during the stimulation process.

The main differences between these techniques are the amount of stimulus intensity required, and the ability to select which muscle to be stimulated and to what extent. In all cases the muscle is stimulated by placing one of the electrodes (active) as close as possible to the major motor point/ nerve bundle, with the other electrode (return) placed near the muscle tendon. The electrodes are attached in this manner so as to reduce the amount of stimulation required to produce a given contractile force.

The main disadvantages of the first two methods are both need the candidates to commit themselves to surgery, that is expensive and electrode placement needs to be very precise and this is difficult to evaluate during the surgery. Also when using wire connections much care is required to keep the entry site for the wire free from infection and to avoid electrode wire breakage during the relative movement between the muscle and the skin. Moreover these impermeable electrodes can cause permanent damage to the nerve tissue, (Frank, 1990), (Webber, 1990).

1.6.2 Transcutaneous functional electrical stimulation

1.6.2.1 Electrode tissue interface

At the electrode-tissue interface in transcutaneous electrical stimulation, an electrical stimulation pulse applied by an electric field or current between the stimulation electrodes causes a current of ions to flow and penetrate through the skin and flow through the tissues underneath the skin that includes muscles (motor points) and nerves. The polarity of the electrode depends on the type of stimulation signal pulse polarity. When using Monophasic stimulation signal one of the electrodes will be negative in polarity (active electrode) and the other will be positive in polarity (indifferent electrode). When using Alternating or Bi-phasic signals it is not possible to decide about the polarity of the electrode, as polarity at each electrode alternate from positive to negative or vise-versa.

Figure (1.6) show simplified diagram of the transcutaneous stimulation mechanism. At the positive electrodes the positive ions at the electrolyte interface are attracting the negative ions. At the negative electrode the negative ions attract the migrating positive ions. This causes electrical charged particles to flow. It is the movement of potassium and sodium ions across the axon membrane that causes the action potential and as a result a nerve impulse is produced. This nerve impulse causes the muscle that this nerve supplies to contract.

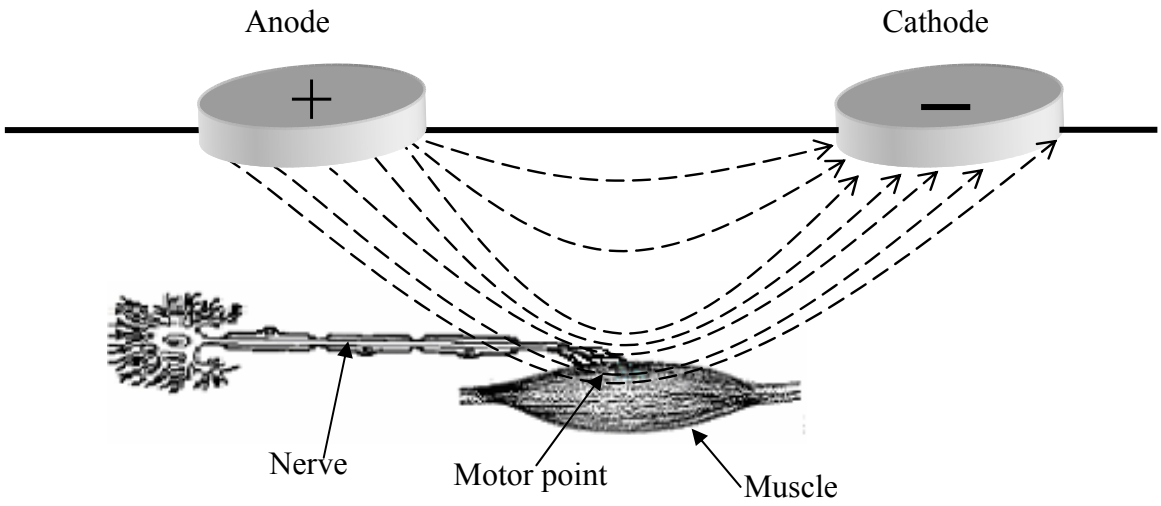


Figure (1.6) - Muscle stimulation by applying electric field between two electrodes, stimulation applied near to the motor point of the nerve.

The depolarisation or the excitation of the nerve axon occurs principally at the cathode, hyperpolarisation occurring at the anode, near the cathode the potential is lowered. If a nerve axon is in the neighbourhood, the potential difference across the membrane may be lowered sufficiently to cause an action potential. Critical to whether a given stimulus causes an action potential or not is the impedance between the electrodes and the skin, the orientation and size of the electrodes and the stimulation signal type. Also placements of the electrodes are very important to stimulate the selected muscles that are responsible for specific movement. The best place to stimulate is over the selected muscle motor point, (Baker, 2000).

1.6.2.2 Skin impedance

Examinations of skin by light microscopy show that in the top of the skin tissue there is a heavily ridged surface of flaking, dead cells (corneum) perforated by sweat gland ducts and hair follicles, which form the skin impedance. During stimulation the current will flow in the direction of least impedance. Therefore the current flows more easily through tissue with low impedance than through tissue with high impedance. Increasing the pressure on the electrode increases the contact area, as does the use of good conducting fluid or gel at the interface.

Consequently a higher voltage from the stimulator must be used to pass an equivalent amount of electric field density to reach and stimulate the nerve through a high impedance tissue than is necessary to pass the same current through tissue with low impedance (high conductivity). Ohm's Law defines this relationship: V = I.R or I = V/R. In this familiar formulation, V is the voltage output of a stimulator, the electric field generated supposed to be driving a current (I) of ions through the tissue resistance (R). Physiologic systems (body tissues), however, are not made up of pure resistance, but also contain significant capacitance. The most appropriate term to use in referring to both resistive and capacitive elements is impedance (Z), which more accurately defines the physiologic state. In Figure 1.7 the skin impedance Z is considered to be resistance parallel with capacitance and *Rs* is the contact resistance between the electrode and the skin surface (Webber, 1990).

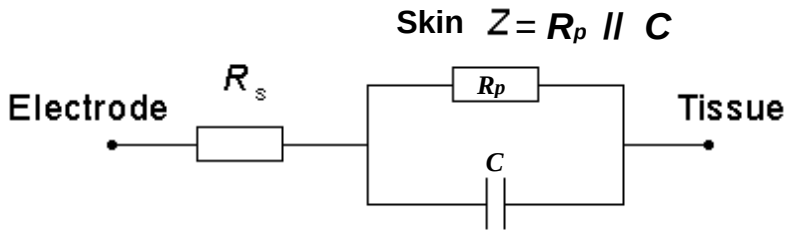


Figure (1.7) - Electrode tissue impedance interface

Research by Stephens (Stephens W.G.S, 1963) found skin impedance to surface stimulation electrodes could be modelled by a 4kΩ resistance shunted by a 0.28μF constant capacitance. Mizrahi found the resistive value to be 500Ω. Other authors have utilised a 1kΩ resistance in parallel with a 0.1μF capacitance as an

approximation to the load presented by the human body. It must be noted that the above values are considered to be typical values only and that variations will occur between individuals and different body sites (Webber, 1990).

1.6.2.3 Electrode sensation

Discomfort during Electrical Stimulation has limited the use of FES systems in various applications, (Lyons, 2002). Transcutaneous stimulation activate the sensory receptors on the skin surface, this acute sensory execution can cause irritation or discomfort, if the stimulation intensity increased above certain limit, pain nerve fibres will be recruited (Gracanin, 1975), (Bowman, 1984), (Lyons, 2004). The sensation of stimulation and the level stimulation that can trigger the pain nerve fibres vary from person to another. Some patients can not tolerate the pain or the discomfort of stimulation and they completely reject the use of FES devices. The solution for this problem is to enhance the method of applying the stimulation. Many factors affect the stimulation efficiency and comfort, these factor include the stimulation signal parameters, Electrode size and Electrode placement, (Lyons, 2004). In the following few sections some of these factors are discussed in more details.

1.6.2.4 Electrode placement

The optimum electrode stimulation site or position that produces the desired muscle contraction is very critical. Usually the best stimulation site is the nearest to the muscle motor point, which provides the greatest amount of motor excitation with the minimal stimulating intensity, (Baker, 2000). In most muscles motor endplates are located near then mid point of each fibre such that in a muscle with parallel fibres (e.g tibialis anterior) the motor point forms a band across the belly of the muscles and can be located where the nerve begins to branch into the muscle and make contact with individual muscle fibres. Depending upon the anatomy of the nerve-muscle interface, the motor point may be that area of the muscle where the nerve is most superficial. Locating motor points and placing the electrodes may depend upon both the patient and treatment goals because each individual is different and may present with slightly altered 'best' electrode placement. A 5 mm electrode movement may produce clear

change in the stimulation functional response, (Carrioni-Burnett, 2002). If the stimulation electrodes are not optimally placed the stimulation intensity required will be higher than necessary, and this will affect the stimulation comfort and effectiveness, (Robinson, 1994), (Baker, 2000).

1.6.2.5 Electrode size

The sizes of the stimulation electrodes have direct effect on the current density which should be higher than the recruited muscle stimulation threshold, (Rattay, 1988). When electrode size increase the current density decreases and vice versa, (Lyons, 2004). The optimum size of electrode will depend on the muscle stimulated and location of stimulation, (Lyons, 2004). McNeal and Baker found no difference in stimulation effectiveness between using small electrodes (20 cm^2) and larger electrode (36 cm^2), but they reported that the large electrode is more comfortable for some subjects, (McNeal, 1988). Other researchers Also reported that stimulating using large size electrode is more comfortable than small size electrode but more likely the stimulation intensity need to be increased when large electrode is used, (Patterson, 1991), (Alon, 1985). Alon et al, reported that using two large electrodes (20.25 cm^2) or (40.3 cm^2) give the same result and are more comfortable and effective more than using two smaller electrodes, (2.25 cm^2) or (9 cm^2), (Alon, 1994), (Lyons, 2004). Larger electrodes that cover more area of the stimulated muscle guarantee stimulating the motor point as it is difficult to hunt for the motor point using smaller electrodes. If an optimal stimulation site can be found smaller electrode with less stimulation intensity will be more effective and comfortable, (Baker, 2000).

1.6.3 Stimulation signal parameters

Electrical stimulation of nerve or muscle tissue using transcutaneous electrode, although evoking a response similar to that produced by normal physiological neural excitation, is not the same and some undesirable effects are inevitable. The stimulation parameters required to produce an effective motor response therefore need to be considered. Variations in these affect the stimulus applied to the tissues, which, in turn, determines the physiological response.

The stimulation signal waveform can be formed of charge balanced pulses or single monophasic pulses, the parameters that can be controlled are shown in Figure (1.8). These parameters may be illustrated as:

- Pulse shape (rectangular, sinusoidal, etc…)
- Pulse waveform (monophasic, biphasic, alternating, charge balanced)
- Stimulation signal (train of pulses) envelope (Te)
- Pulse maximum amplitude, voltage or current, (Amax)
- Pulse width, (Tw)
- Pulse repetition rate (frequency) (Tp)
- Stimulation signal envelope rise time (Tr)
- Stimulation signal envelope fall time (Tf)

Voltage and impedance will determine the current that flows. Peak current and voltage (pulse amplitude), pulse width, frequency of pulses and pulse shape or waveform all influence charge transfer and therefore energy dissipation. It is desirable to apply stimulation that minimises charge transfer and energy dissipation while eliciting an effective muscle contraction.

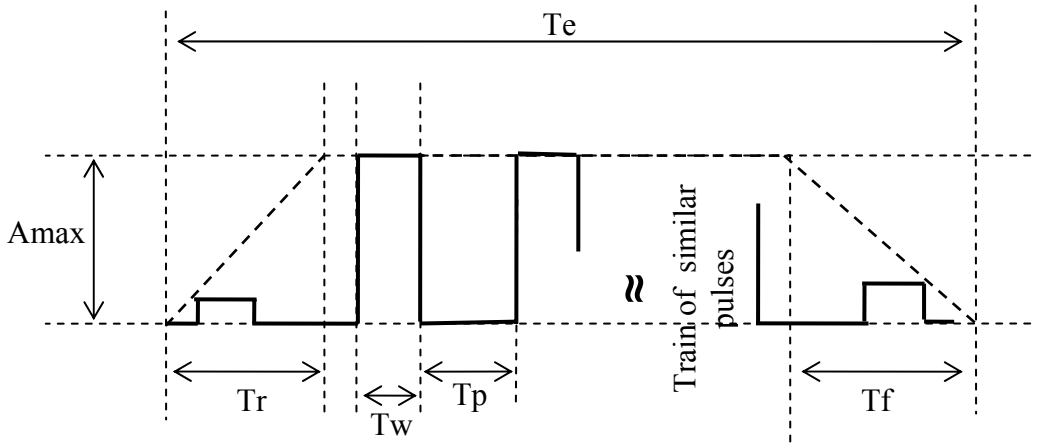


Figure (1.8) - Stimulation signal parameter (for a monophasic rectangular waveform)

Undesirable physiological responses to be considered are possible tissue damage due to a rise in temperature of the surrounding tissues and the electro-chemical formation

of toxic electrode compounds. Charge balanced stimulation pulses should always be used to avoid tissue electrolysis effects which occur when there is a net d.c. charge in the tissues. Fatigue and discomfort are also important and must be minimised for stimulation to be practical.

1.6.3.1 Stimulation pulse amplitude

The amplitude of the stimulus pulse and its duration must be adequate to meet or exceed the threshold of excitability of the stimulated tissue. Figure (1.9) shows the quality of the motor response, measured as torque production, resulting from an adjustment of stimulus amplitude (current), with pulse duration held constant. As current amplitude is increased from zero, no muscle response is observed until the threshold of the most excitable motor units is reached. As the current amplitude is increased beyond this threshold level, the torque output increases as a result of recruiting additional motor units. Increasing the amplitude beyond this up to maximal levels, results in no additional muscle force (Baker, 2000).

Malezic et al, successfully utilised pulse magnitudes in the range 20V to 80V, (Malezic, 1987). Hertzler and Kaminski found an upper magnitude limit of 67.5V to be adequate for surface stimulation (Hertzler E.C, 1968). Bogataj et al, suggest the use of a slightly larger magnitude range up to 120V and also suggest the use of 80mA - 120mA current pulse magnitudes, equivalent to the previous range when 1kΩ body impedance is considered, (Bogataj, 1989). Takebe et al, produced a stimulator with a maximum pulse magnitude of 100V, (Takebe, 1975). The adjustment of ramp-up time can be very important in subjects with muscle spasticity, and it allows better gradual control over the stimulation recruitment process of motor nerve fibres and gradual increase in muscle fibre contraction, which produces a more comfortable smooth movement (Vodovnik, 1965), (Robinson, 1994). Also, ramp-down time allows a gradual decrease in stimulation intensity, which produces a more controlled movement.

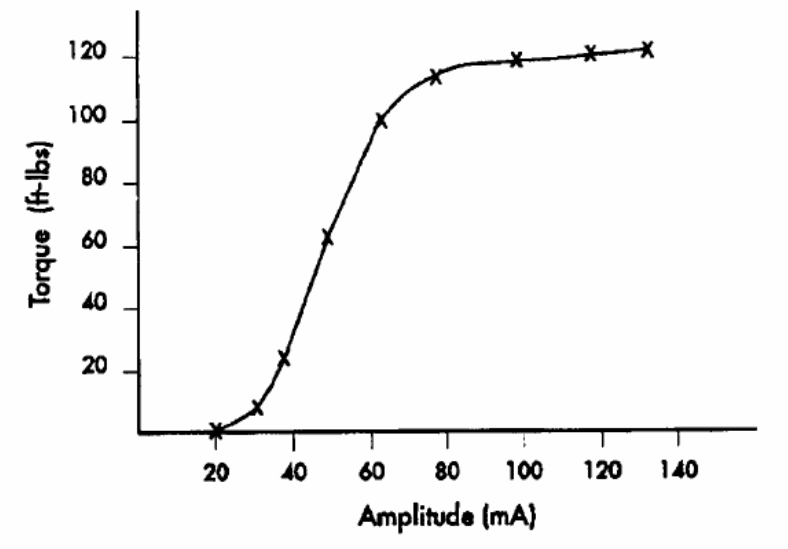


Figure (1.9) - Effect of Amplitude on force contraction, (data from the quadriceps femoris, surface electrodes, pulse duration of 300 μs and frequency of 35 Hz (Baker, 2000)

1.6.3.2 Stimulation strength and pulse duration

The event that triggers the generation of an AP is called an adequate stimulus. An adequate stimulus must be of sufficient intensity, which can be increased to equal or exceed the threshold of excitation for the tissue by increasing the duration of the pulse (usually measured in ms or μs) or the amplitude of the pulse (usually measured in mA or Volts).

To determine the basic relationship between a particular tissue response and the intensity of an adequate electrical stimulus it is necessary to limit some of the variables while adjusting others.

Consider, therefore:

i) A threshold level of stimulation - at which only the largest, most excitable, motor fibres are stimulated.

ii) A near maximal contraction - at which even the least excitable motor fibres are stimulated.

This relationship is traditionally represented as the "strength-duration" or intensity-duration curve. This curve compares the length of time and the stimulus current of a particular intensity must be applied to a tissue to excite it. Figure (1.10.a) shows a schematic representation of the variation between the excitability of nerve and muscle. Stimulation of shorter pulse duration require increasing the intensity to execute the tissue, the stimulation of very short duration will not cause depolarisation except with very high intensity, (Baker, 2000), (Stephens, 1963).

The Pulse Duration / Voltage curve shown in Figure (1.10.b) shows the voltage just sufficient to cause excitation of a particular tissue, with very long pulse durations (at least 300-1,000 ms) this is called *rheobase.* The pulse duration required for threshold activation, at a current intensity twice the rheobase is called the *chronaxie.* The chronaxie for nerve (approximately 25μs) is significantly lower than that for muscle (approximately 7 ms), (Baker, 2000), (Stephens, 1973).

As the pulse duration is decreased below 0.3ms an increasingly higher voltage is needed to evoke a muscle twitch. Pulse durations of greater than 0.3ms require only slightly less current amplitude. As charge transfer per pulse decreases with decreasing pulse width (reaching a minimum at 0.05ms) it is minimised at pulse duration of 0.3ms. (Baker, 2000), (Frank, 1990), (Stephens, 1973).

Pulse duration in the midrange between 200-400μs was reported by many researchers, Higher pulse duration reported to be uncomfortable and pulse duration of 300 or 350 μs reported to be adequate, (Bowman, 1985), (Alon, 1994), (Baker, 2000).

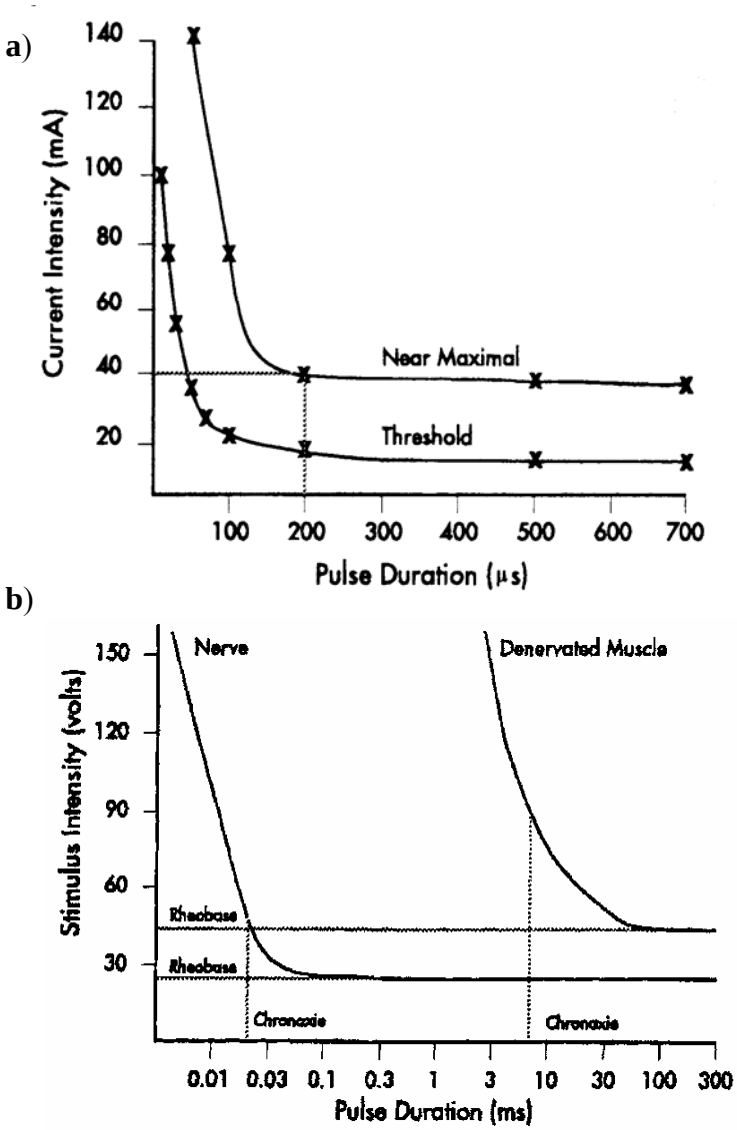


Figure (1.10 (a, b)) - The Strength / Pulse Duration curve for muscle and nerve (Baker, 2000)

1.6.3.3 Stimulation frequency

Pulse frequency or repetition rate is the rate at which pulses are emitted, and determines the sum of charge transfer in a given time. Lower frequencies therefore reduce unwanted side effects. It is important to remember that during normal neural activity, neurones are firing at different times and rates. As a result, a smooth muscle contraction is achieved with frequencies of firing of between 5 and 25 Hz. To achieve a smooth muscle contraction with electrical stimulation, a single stimulation pulse generates an action potential that propagates along the nerve and results in muscle twitch. As shown in Figure (1.11) a single muscle twitch lasts only about 100 - 200

ms, (Baker, 2000). By applying trains of pulses (3-10 Hz) the stimulated muscles experience tremor. Increasing the stimulation frequency puts the single muscle twitches closer together; they start overlapping and cannot be individually distinguished. Ultimately muscle is no longer able to relax or return to it resting status. This process of continuous muscle contraction is called "summation of contraction" or "tetanization". For stimulation frequencies of 25 - 40 Hz the tremor becomes very small and with the final fusion of fibre contraction, tetanic contraction is obtained. Increasing the stimulation frequency smoothens the tetanic contraction further, but has the disadvantage of increasing muscle fatigue, (Boonstra, 1987).

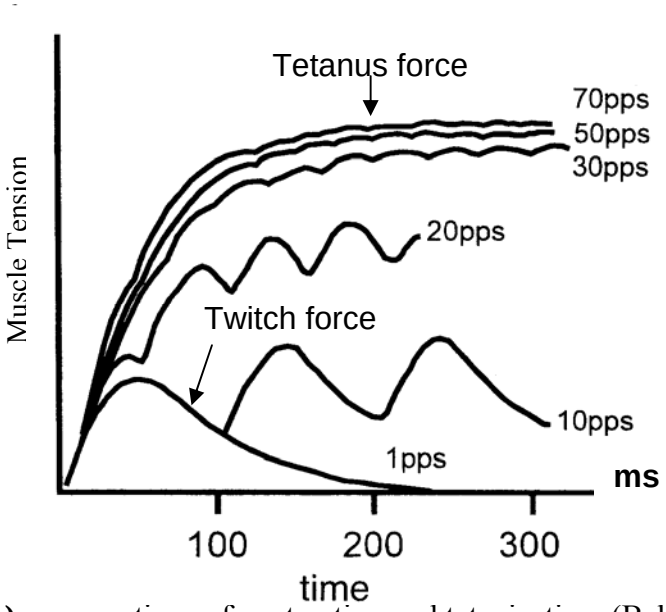


Figure (1.11) - summations of contraction and tetanization, (Baker, 2000).

During physiological contractions, the muscle fibers are activated randomly through thousands of nerve fibers. The action potentials are fired asynchronously with a firing rate between 0.3 - 5 Hz depending on the desired force and the fatigue level of the muscle. This asynchronous firing above a threshold frequency results in tetanic contraction although the stimulation frequency for a single motor unit may be low, whereas in artificially stimulated nerves the action potentials are generated all at the same time. The distribution of action potentials as produced during natural contractions cannot be generated artificially with FES. For tetanic contractions the muscle has to be stimulated with a rather high stimulation frequency around 20 Hz or higher. Physiologically firing rates of between 10 and 80 Hz are recorded depending on muscle type and its function. The high stimulation frequency reduces the rest time

of the muscle fibres and produces a faster rapid fatiguing of the muscles, (Herbison, 1971), (Symons, 1986), (Baker, 2000).

A lot of research underpins the above conclusion. Liberson et al, used pulse lengths in the range 20μs - 250μs and pulse frequencies of 30Hz –100Hz, (Librson, 1961). Eberstein A. et al, concluded that the optimum stimulation for fast muscle is intermittent bursts of impulses at high frequency (e.g. 100Hz), and for slow muscle is continuous low frequency pulses (e.g.10Hz), (Eberstein, 1996). Some researchers have advocated a stimulation pattern derived from the normal EMG signal of the particular muscle, (Petterson, 1994). Malezic et al, found the usable ranges for the pulse length to be 50 - 500μs, with the pulse repetition frequencies in the range 5 - 120 Hz, (Malezic, 1992), although they stated that the mean frequency required by patients was 30Hz. In a separate report, Malezic et al., found that 200μs widths of 20Hz produced satisfactory results for some muscles and some functions, (Malezic, 1994). A pulse frequency of 20Hz is also suggested by Carroll et al. along with pulse widths of around 150μs, (Carroll, 1989). Ranges approximating to those mentioned above have been found to be adequate for surface stimulation purposes by various authors, (Gracanin, 1975), (KJjajic, 1992), (Durfee, 1989), (Borges, 1989), (Agnew, 1989), suggest that 200μs pulse lengths and 33Hz frequency are ideal values, whereas Handa et al, suggest that 200 μs pulses and 20Hz frequency were found to produce the best results (Handa, 1992). Pulse lengths of 200μs and a frequency of 30Hz was successfully employed by Herbert and Bobechko (Herbert,1989) and Akazawa et al, (Akazawa, 1989), re-enforcing the likely required nominal parameters of a general purpose muscle stimulator. Research into the isometric recruitment relationships of muscle by Durfee and Maclean, found that l00 μs pulses at a frequency of 40Hz produced a useful torque / fatigue trade off, (Durfee, 1989). The digitally synthesised pulse trains of Hoshimiya et al., employed a 200 μs pulse width and 50Hz pulse repetition frequency for optimum results, (Hoshimiya, 1989). Carroll et al, state that peak torque was achieved by application of 150 μs pulses with the pulse repetition frequency in the range 66Hz to 83Hz (Carroll, 1989). This repetition frequency caused the mean torque to have dropped to 5% of the starting torque after thirty seconds stimulation, whilst a 50ms inter-pulse interval produced a drop to only 82% of initial torque after a similar length of time. It was also found by Carroll et al, that pulse repetition frequencies of greater than 83Hz produced rapid high frequency

fatigue, (Carroll, 1989). Therefore, it may be concluded that the pulse repetition frequency should not be greater than 66Hz, although it may be less than this value for lower torque and greater fatigue resistance.

The above results and discussion places the nominal pulse parameters at 200μs pulse width and 30ms inter-pulse interval, which produce a frequency of 33Hz. Koller et al. found that this frequency did not cause any significant neural damage, (Koller, 1992). Agnew et al, found that constant stimulation at frequency of 50Hz and above caused irreversible demyelination and axon degeneration in cats, (Agnew,1989). Wilson et al, suggests that the ideal rise and fall time is in the range 5 μs to 10 μs, (Wilson, 1968). This value for rise-time and fall-time parameters, equivalent to 1% of the nominal pulse length value, presents a fast rise-time and fall time in comparison to the pulse length.

1.6.3.4 Minimising muscle Fatigue

Depending on the muscle and the type of the system used, fatigue manifests itself as the decreasing ability of the muscle to produce a maintained tetanic contraction of adequate power. In normally innervated muscles, recruitment of the motor units is hierarchical. For low output requirements recruitment begins with the smaller fibres that are also resistant to fatigue whereas larger fibres are activated progressively as the force output demand is increased. Furthermore in an able bodied person, motor units are cyclically and asynchronously activated in order to produce overall smooth contractions, with force distributed uniformly throughout the muscle, whereas at the same time allowing the individual fibres to rest (Robinson, 1994), (Baker, 2000).

The three factors contributing to affect the physiological muscle recruitment mechanism and increase fatigue characteristics in electrically stimulated muscle compared to the natural case are:

1. Synchronous/Asynchronous recruitment of motor units:

Natural Stimulation is asynchronous

Electrical Stimulation is synchronous

2. Stimulation frequency:

Natural Stimulation mean frequency is lower due to asynchronous stimulation

Electrical Stimulation frequency is higher due to synchronous stimulation

3. Motor Units used:

In Natural Stimulation different motor units are switched in and out of use

In Electrical Stimulation a fixed block of motor units are continuously recruited.

These combined factors make fatigue in electrically stimulated muscle a significant problem. Figure (1.12) shows the higher the frequency the more rapidly the muscle fatigues. The test in this example was during a sustained contraction of the Tibialis Anterior muscle stimulated via the Common Peroneal nerve (Baker, 2000).

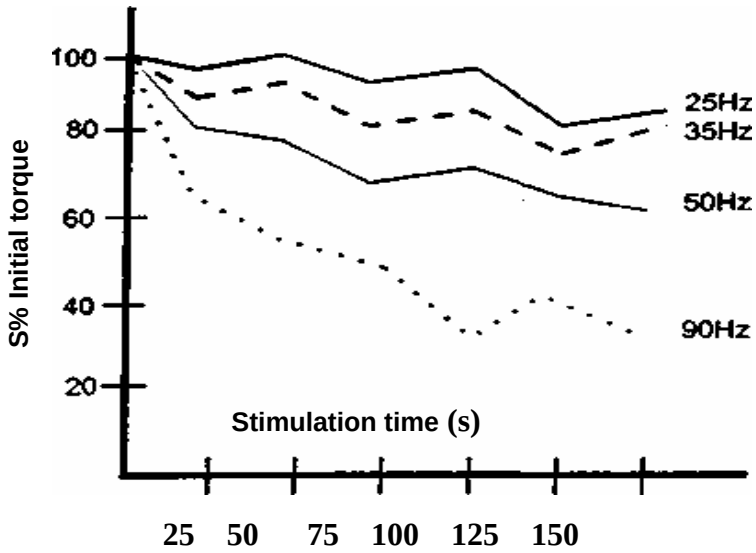


Figure (1.12) - Effects of frequency of stimulation pulses on muscle fatigue, (data obtained from tibialis-anterior transcutaneous stimulation at 300μs, (Baker, 2000).

It is difficult to address the fatigue issue when using surface electrical stimulation, since the induced electrical field activates the nerve fibres as it reaches them i.e. first the outer larger axons that are also the least fatigue resistant. This indiscriminate excitation recruits all of the accessed axons simultaneously and leaves no time for the muscle fibres to recover. Ever-increasing stimulation strength is therefore used to

sustain the required contraction by recruiting more and more motor units and this eventually leads to irrecoverable fatiguing of the muscle, (Kralj, 1989), (Mourselas, 1998), (Robinson, 1994), (Baker, 2000).

The problem of fatigue caused by electrical stimulation can be addressed in a few ways:

1. By the selection of frequencies between 20 and 40Hz to allow a smooth contraction, and minimise fatigue - slower than 20 Hz is less comfortable as it produces a jerky contraction, partial tetanus (Robinson, 1994).
2. By stimulating different sites of the same muscle using more than one electrode.
3. By using cyclic stimulation with rest periods between pulse trains, on/off time the off time is to allow ionic gradient and neurotransmitters to recover in nerve and muscles (Baker, 1988), (Reed, 1997). The dropped foot stimulator used in this research is designed to cause activation only during the swing phase of the gait cycle, allowing the muscles to rest during the stance phase.

1.6.3.5 Stimulation pulse waveform

As discussed earlier in this thesis, the first electrical stimulation was using direct current (d.c.) known as galvanic current Figure (1.13.a), although this was not suitable for inducing a tetanic muscle contraction but it was used for treating neuralgia. Alternating current (a.c.) Figure (1.13.b) sinusoidal waveform of any frequency also was used for electrical simulation. Faradic current waveform is shown in Figure (1.13.c). These waveforms have been used for neuromuscular stimulation by physiotherapists for many years. Another type of waveform familiar to physiotherapists is known as Faradism after Michael Faraday. This is a series of short asymmetrical, bi-directional pulses which provide effective nerve stimulation, but which are too short to stimulate muscle fibres directly.

Two types of waveform are most commonly used in stimulation, rectangular and exponential. Each of these can be monophasic or biphasic. Monophasic waveform Figure (1.13.d) requires the generation of unipolar pulses only and this is by far the

simplest method of stimulation pulse train production. The currents associated with monophasic stimulation are unidirectional hence the charge is always injected into the tissue at a single electrode and not recovered by a following pulse of opposite polarity. That is why this waveform is not favoured for stimulation because it creates charge imbalance and causes skin and tissue damage, Monophasic alternating rectangular pulses Figure (1.13.e) are used to overcome the problem of charge imbalance, (Campbell, 1984), (Donaldson, 1986).

Bi-phasic charge balanced Figure (1.14.f); consisting of stimulation pulses followed by opposite polarity pulses and are produced when the current is capacitively coupled. This waveform has been suggested by a number of authors as a safer method of stimulation because of the charge-balanced property of the waveform, these authors also reported that using symmetrical or asymmetrical bi-phasic waveform minimise irritation and stimulation discomfort, (Rohlicek, 1964), (Campbell, 1984), (Donaldson, 1986), (McNeal, 1988), (McCreery, 1992). The advantage of a capacitively coupled waveform is that, although it is charge balanced, because of the asymmetric shape of the pulse, depolarisation is more intense than repolarisation, allowing the threshold for generating action potential to be reached. However Rohlicek states that capacitive coupling of the pulse train to the body to remove any d.c. component is not a suitable method of charge recovery and suggests that the use of alternating pulse polarities within the pulse train produces the best compensation for the ion transport of unipolar pulses, (McCreery, 1992).

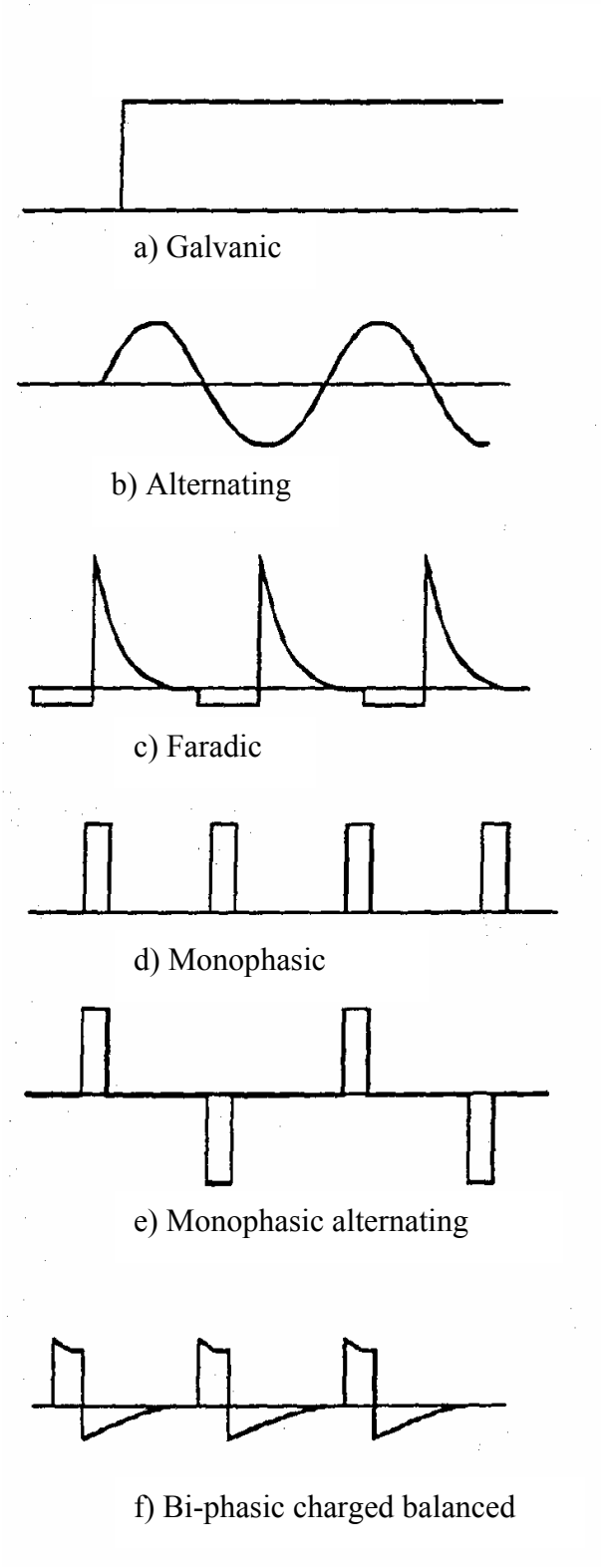


Figure (1.13) - A selection of waveforms that could be used for stimulation.

Nilsson et al, suggest that the immediate following opposite polarity pulse may follow the initial pulse at any time within the refractory period of the nerve under stimulation and in fact they achieved good results with a 200 μs delay between the positive and negative pulses (Nilsson, 1988). McCreery et al, also suggest that a further improvement on this system of alternating pulses is to replace the single pulses of the unipolar system with a positive pulse immediately followed by a negative pulse injecting an equal amount of charge with negligible inter-pulse delay, (McCreery, 1992).

1.7 Summary

Several fundamental issues were identified in this chapter to help in setting up the theme for this research thesis. At the beginning of this chapter some basic neuromuscular physiology background was introduced. This background is needed to help in understanding nerve and muscle electrical stimulation. The chapter also details some of the lost muscle movement and disabilities aspects that can be restored using the FES systems such as multiple sclerosis and stroke. The main electrical stimulation techniques were introduced including transcutaneous stimulation. Factors affecting transcutaneous stimulation were discussed. These factors included, skin impedance, electrode size, electrode placement and all stimulation signal parameters such as stimulation pulse amplitude, pulse width, stimulation frequency and pulse waveform. Details reported by other researchers using electrode arrays in transcutaneous electrical stimulation, has also been discussed. The next chapter will introduce foot drop as the movement disability selected for this research. The chapter will present detailed information about FES applications for foot drop and a general over view of what other researchers have reported.

Chapter 2

FES AND FOOT DROP

CHAPTER 2: FES AND FOOT DROP

2.1 Foot drop

Foot drop is the inability to dorsiflex the foot sufficiently to clear the ground. There is a large population of potential users of foot drop prostheses; a fact that enables researchers to select the most appropriate individuals to test newly developed rehabilitation techniques, also these people with a low degree of injury, such as foot drop, it is inherently safer to apply the rehabilitation assistive functional restoration outside the laboratory as compared with those of more severe neurological damage. A persistent, long-term disability in approximately 10 to 20% of stroke survivors is upper motor neurone foot drop, (Burridge, 1997), (Leane, 1998). This typically involves an inability to dorsiflex the foot during the swing phase of gait (drop foot), loss of normal knee flexion, inability to "push-off," and spasticity of the calf muscle group. For the above reasons foot drop due to stroke and MS is the disability problem that is the symptom of interest in this research.

Foot drop manifests itself during the swing phase of walking when the muscles in the lower leg are unable to adequately lift the toes, so that the foot does not clear the ground and is a hindrance to mobility. This is because of loss of function or over-activity in one four primary movements of the foot, shown in Figure (2.1).

- Dorsiflexion - An upward movement of the foot
- Plantarflexion - A downward movement of the foot
- Inversion - An inward rotation of the foot with the sole facing towards the centre line of the body
- Eversion - An outward rotation of the foot with the sole facing away from the centre-line of the body

Foot Drop is usually caused by a combination of muscle weakness and spasticity sometimes called spastic paralysis, which results in poor active control of the Tibialis Anterior muscle and spasticity in the extensor muscles of the ankle, particularly the triceps surae group. The effect of these two conditions is that the subject's

dorsiflexion is significantly reduced, if not eliminated and also that there may be excessive inversion, (Burridge, 1997). Foot drop can also be caused by partial weakness or denervation of the dorsiflexor muscles.

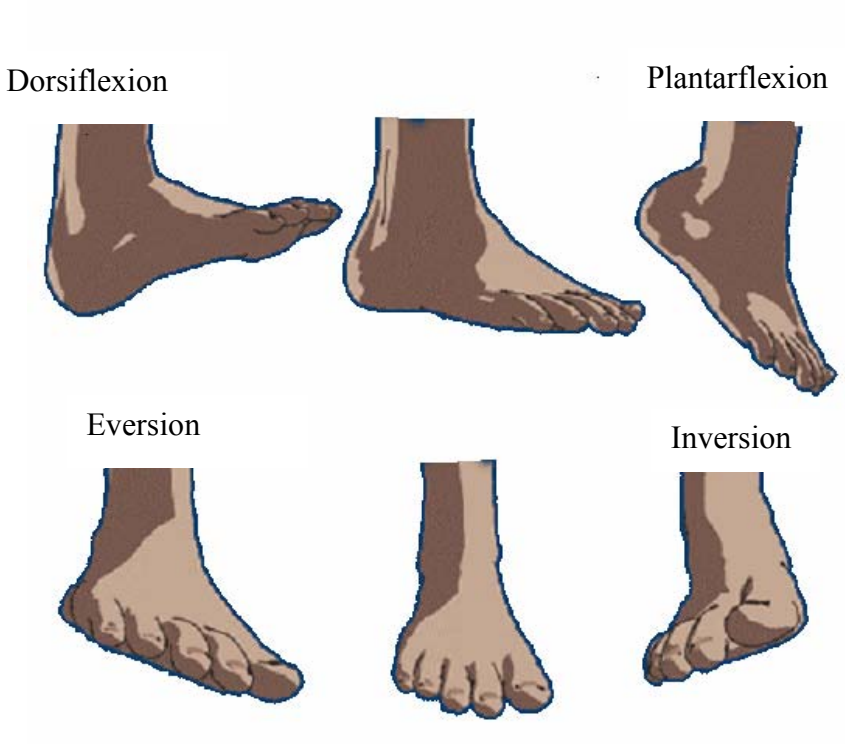


Figure (2.1) – Dorsiflexion-Plantarflexion and eversion-inversion movements

2.1.1 The effect of Foot Drop on mobility

The human gait cycle is, as is shown in Figure (2.2), composed of two phases; the stance phase and the swing phase. During the stance phase, the leg in question is supporting the body and making contact with the ground. During the swing phase, the leg actually swings through the air to propel the body. The beginning of the swing phase (which corresponds to the end of the stance phase) is identified by a gait event called "Toe Off, where the toe is lifted from the ground to initiate swing. The end of the swing phase (which corresponds to the beginning of the stance phase) is identified by a gait event called "Heel Contact", where the heel of the foot makes contact with the ground at the end of the swing phase, (Hamill, 1995), (Whittle, 1991).

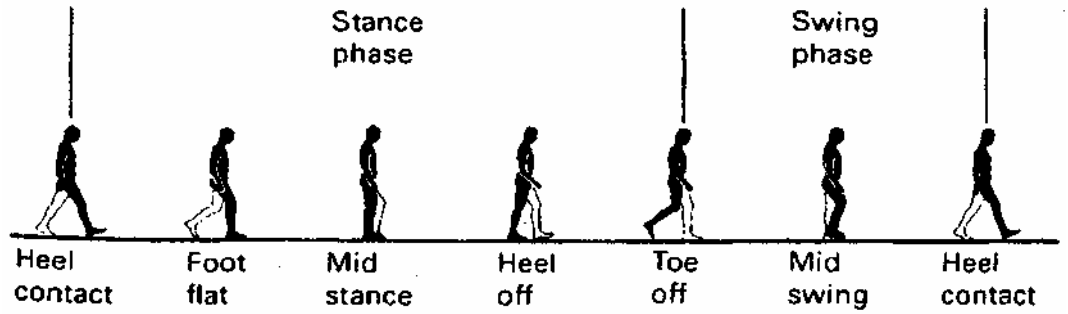


Figure (2.2) - The human gait cycle, (Whittle, 1991).

These events are given different names by different researchers, for instance heel contact is also referred to as "Initial Contact", (Vaughan, 1992). If a heel switch only is used to detect the beginning and end of swing, then the toe-off event indicating the beginning of swing will not be detected. In this case the gait event heel-off is detected by the heel-switch and is used in FES applications in conjunction with a suitable delay to indicate the beginning of the swing phase of gait. For foot drop FES applications, the terms, heel-off, toe-off and heel-contact are most commonly used.

For the leg to be effectively swung through the air during the swing phase of gait, it is necessary for the foot to be lifted and dorsiflexed to provide ground clearance. This action can be seen in Figure (2.3), where the joint angular excursions and muscle contraction patterns of a typical healthy subject during the gait cycle are illustrated. It can be seen that, soon after the toe-off event, the ankle joint moves from a plantarflexed position (approximately 40°) to the neutral position (0°) in a time period corresponding to approximately 20 % of the gait cycle. The gait cycle is typically quoted as having a period of 1 second, thus the ankle joint at toe-off undergoes a dorsiflexion action of 40° in 0.2s, (Basmajian, 1985). Thus if a person is unable to foot lift due to foot drop they will have great difficulty in obtaining ground clearance during the swing phase and as a result, the execution of walking will be severely affected. Lehmann et al, have presented data, which showed that a group of seven hemiplegic subjects had an average walking speed of 0.463 m/s and that an age-match group of seven able-bodied subjects had an average walking speed of 0.998 m/s, (Lehmann, 1987). This suggests that there is a 53 % reduction in walking speed

resulting from foot drop. The foot drop subject usually develops a characteristic compensatory gait such as hip hitching or circumduction. Hip hitching refers to the ipsilateral hip joint (affected hip joint) being lifted in the air, to effectively give the plantar-flexed foot ground clearance. Circumduction refers to the leg being rotated around the hip joint to form a cone shape, again providing ground clearance.

The foot drop person's energy consumption during walking is also increased, due to the reduction in the efficiency of walking. To correct hemiplegic foot drop, the damaged functionality must be assisted using an orthosis. Using Physiological Cost Index to measure energy consumption, (Burridge, 1997) found a 20% increase in Physiological Cost Index for a hemiplegic Foot Drop sufferer from walking without an orthosis to walking with an orthosis.

There are two orthotic approaches to the correction of hemiplegic Foot Drop:

- Mechanical Orthosis
- Electrical muscle stimulation

Orthotic-assisted hemiplegic foot drop correction in the presence of spasticity in a subject presents significant problems. Whether the orthotic approach adopted is mechanical or electrical, its objective must be to provide dorsiflexion during the swing phase of gait. When the foot is dorsiflexed during swing, the corresponding stretching of the calf muscles may trigger a spastic response of the calf, due to sensitivity of its muscle spindles to stretch and velocity of stretching with reflex inhibition removed. The calf muscles group is significantly more powerful than the tibialis anterior muscle, which is the prime mover of dorsiflexion, and as a result its contraction will overcome or significantly weaken the attempts to dorsiflex the foot. Thus, whatever orthotic approach is adopted, attention must be paid to the level of spasticity in the subject's calf muscles on the affected side and to both the amount and rate of stretching of the calf muscles produced by the orthotic mechanism.

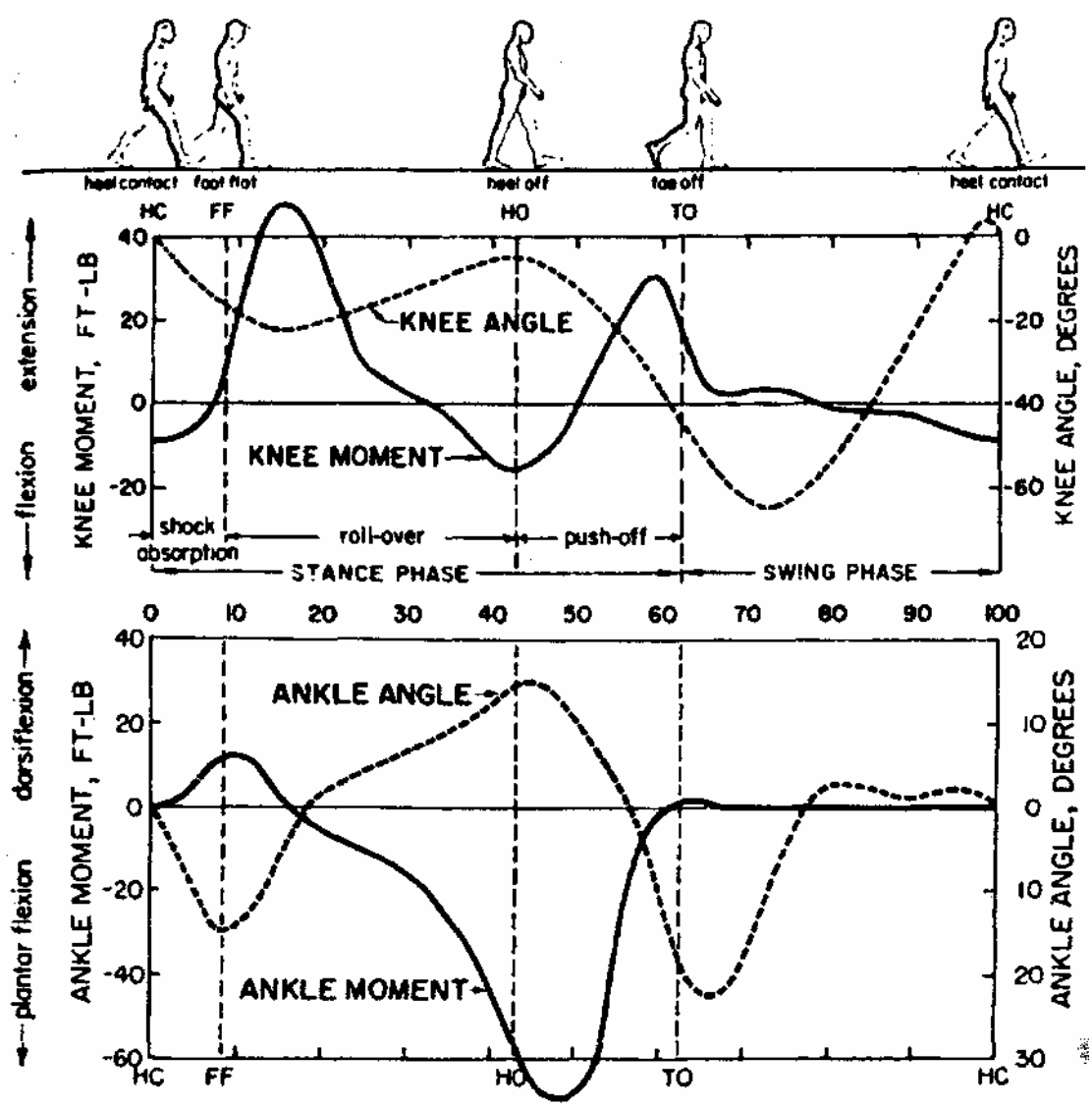


Figure (2.3) - Joint Angles and Muscle Activity during the Gait Cycle (Basmajian, 1985)

2.1.2 Electrode placement for Foot Drop correction

As described, the placement of the stimulation electrodes is a very important part of the process, as misplacement will render the system either inoperable or else performing below full capability. For the correction of Foot Drop, using the traditional two electrodes the electrodes may be placed to stimulate the common peroneal nerve and/or dorsiflexor/evertor muscle group, the active electrode (cathode, when using Monophasic stimulation signal), is placed over tibialis anterior or the

common peroneal nerve, one finger breadth below the head of the fibula and the indifferent electrode (anode, when using Monophasic stimulation signal) is located 5 cm below and slightly medially of the active electrode or behind the knee. To test the electrode position, stimulation can be applied with a very low stimulation intensity setting and the intensity can be increased until dorsiflexion produced. If dorsiflexion is not achieved, then the active electrode position is adjusted until dorsiflexion is produced, (Baker, 2000).

The active electrode position is also adjusted until desired dorsiflexion is produced, i.e. slightly eversion achieved. Bringing the active electrode slightly forward may reduce eversion and bringing the active electrode slightly back reduces inversion. This placement procedure can be explained by referring to Figure (2.4), Figure (2.5), and Table (2.1). As the active electrode position is adjusted around the branch of the common peroneal nerve, there are three possible outcomes:

1. Stimulation of the Common Peroneal, resulting in strong dorsiflexion, some plantarflexion, some eversion and some inversion.

2. Stimulation of the Deep Peroneal nerve, resulting in dorsiflexion and some inversion

3. Stimulation of the Superficial Peroneal nerve, resulting in some plantarflexion and some eversion.

Thus the placement of the active electrode attempts to balance the eversion and inversion actions, reduce plantarflexion and obtain strong dorsiflexion. The positioning of the common peroneal branch will vary from subject to subject, due to variation in the anatomy and muscle physiology of a subject and thus adjustment of the positioning of the electrodes will be required, when a foot drop stimulation system is fitted to a subject.

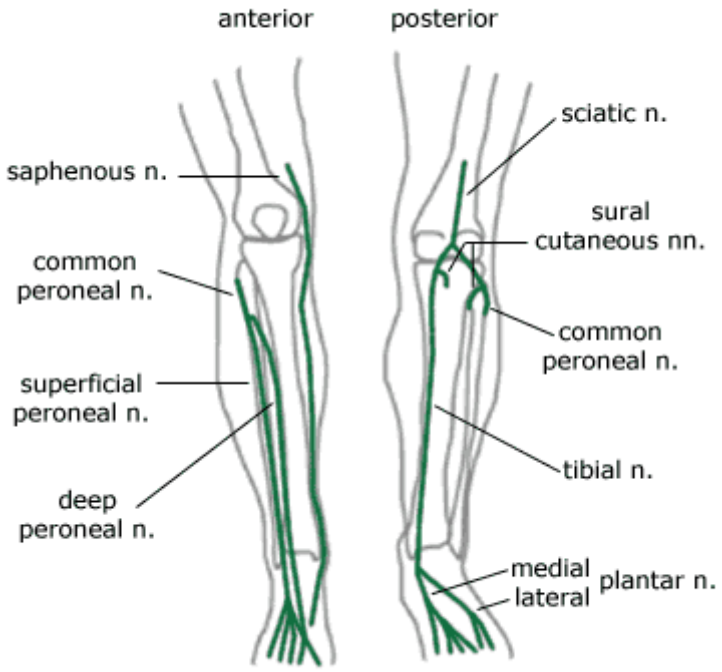


Figure (2.4) - Posterior view of the nerve supply to the lower leg, (Davies, 2001)

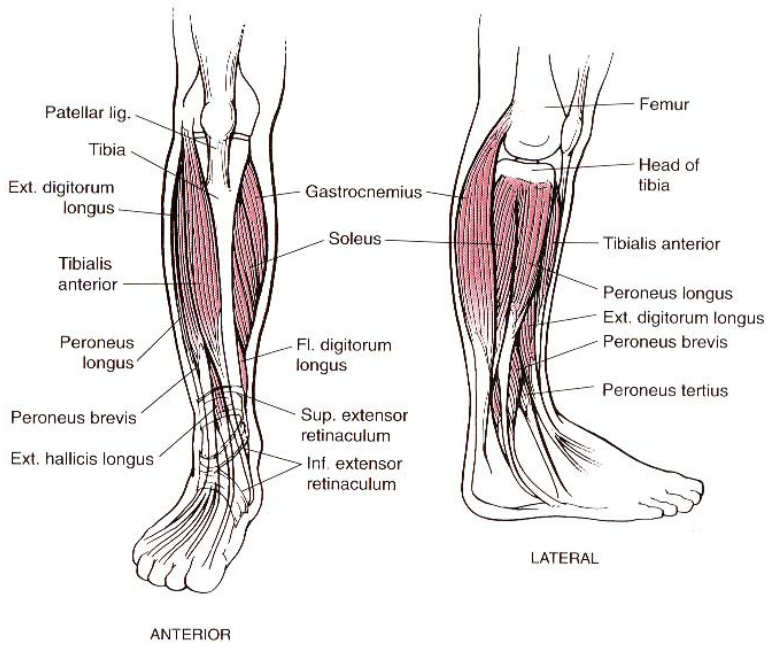


Figure (2.5) - Anterior and lateral views of the leg muscles, (Hamill, 1995)

Muscle name	Action	Innervation
Tibialis Anterior	Prime mover of dorsiflexion; Inverts foot	Deep peroneal nerve
Extensor Digitorum	Dorsiflexes foot; Prime mover of toe extension	Deep Peroneal nerve
Peroneus Tertius	Dorsiflexes foot and extends great toe	Deep Peroneal nerve
Extensor Hallucis Longus	Dorsiflexes foot and extends great toe	Deep Peroneal nerve
Peroneus Longus	Plantar flexes and everts foot	Superficial Peroneal nerve
Peroneus Brevis	Plantarflexes and everts foot	Superficial Peroneal nerve

Table (2.1) - derived from, (Hamill, 1995)

2.2 Prior foot drop FES research overview

2.2.1 Transcutaneous foot drop stimulators

The correction of the foot drop condition was one of the first successful applications of FES and has since been the most widely used both in its basic form as well as in a number of variations resulting from technological advances in the field. There are three main reasons for the relative success of the method and the persistence of the researchers to continuously improve on it. Firstly there is a large population of potential users of drop-foot FES prosthesis; a fact that enables researchers to select the most appropriate individuals to test newly developed techniques (Burridge, 1997). From these individuals a significant proportion eventually uses this method on a permanent everyday life basis. Equally important is the fact that in people with a low degree of injury, such as foot drop, it is inherently safer to apply FES for functional restoration outside the laboratory as compared with those of more severe neurological damage. Most people with foot drop retain good overall motor function and preserved sensation. Finally the relative donning-doffing of the FES system involved requires less effort and little user dexterity, it is more reliable and durable than more complex systems and hence it can be more easily given to patients to apply and use for themselves on a daily basis.

The first proposed FES application to restore foot drop was a single channel stimulator designed by Liberson in 1961 to dorsiflex the ankle of dropped foot patients during the swing phase of walking gait, Liberson's system incorporated foot triggering foot-switch, (Liberson, 1961). Following Liberson, several researchers produced similar systems. Moe and Post, (Moe, 1962), described the use of a commercial drop foot stimulator whose housing had a curved design to facilitate its use as a belt-worn device and, as discussed, proposed the use of the term FES to describe the technique. Due to the potential in using FES systems in various applications a considerable amount of research into FES for foot drop has been undertaken over the years, utilising single and multi-channel stimulators. Vodovnik, Dimitrijevic, Prevec, and Logar, (Vodovnik, 1965), from the University of Ljubljana introduced the functional peroneal splint (FPS). The FPS also incorporated foot triggering using the conventional foot-switch. Dimitrijevic et al, also described similar foot drop stimulator trigged with a heel switch, (Dimitrijevic, 1968). The work of Vodovnik and his co-workers at Ljubljana led to development of a series of commercial hard-wired single channel drop foot stimulator devices at Ljubljana, namely, the PO-8 (Bowman, 1985), and the FEPA and the MICROFES (Acimovic, 1987). The PO-8 device featured an elastic knee support with built-in electrodes. The Functional Electronic Peroneal Apparatus (FEPA)-10, featured a large intensity control knob.

In 1982 The FESE-L2 system was introduced by Griethuysen et al, it consists of a stimulator unit attached to an elastic knee band. The stimulating electrodes are fixed in the elastic band and held over selected positions on the leg that dorsiflex the foot. A heel switch placed in the shoe of the affected leg controls activation of the stimulator. Stimulation begins with the lifting of the heel and ends on heel contact or after 3 seconds, which ever occurs first. Additional delays to the on and off times can also be introduced to suit the requirements of the gait of the individual subject, (Griethuysen, 1982). In 1975, Takebe et al, used a commercial drop foot stimulator manufactured by Philips. The Philips functional electronic peroneal stimulator system consists of the stimulator box, the stimulating electrodes and a rubber insole that fits into the shoe of the unaffected leg. Electrode positioning is the same as for the previous case, whereas activation of the stimulator is controlled through the increased pressure of the toe section of the insole, transferred to the stimulator via a rubber tube, (Takebe, 1975).

The main difference from Liberson's design was the use of an air-filled insole foot-switch. The insole was connected to the stimulator using a rubber tube, which conducted the increases in air-pressure, occurring at heel-strike, to the stimulator.

The ODFS (Odstock Drop Foot Stimulator) peroneal stimulator is another typical single channel device that was used and described by , Burridge, Taylor, Hagan, and Swain, (Burridge, 1997). In 1996, Granat, Maxwell, Ferguson, Lees, and Barbenel (Granat, 1996) used a single channel surface stimulator with the added feature of recording the length of time stimulation is delivered. This feature is useful in assessing the amount of use a subject makes of the stimulator outside the clinic.

The first to introduce the use of multi-channel FES was Kralj and his co-workers from the University of Ljubljana in Slovenia (Kralj, 1971). They described the use of three channels of stimulation in their portable stimulator. The three stimulation channels enabled different muscle groups to be controlled independently, such as ankle dorsiflexors and knee flexors and extensors. A drawback of the system was that the clinician was required to make multiple adjustments to optimize the delay settings for each of the three stimulation channels following detection of the heel-off event. Kralj et al, were of the opinion that multi-channel stimulation would not become routine until the size and weight of the portable unit could be reduced. In order words, multi-channel stimulation was not practical with the integrated circuit technology available at the time (Kralj, 1971). A follow-up study by the Ljubljana group six years later in 1977, (Strojnik, 1979) evaluated six-channel stimulation. This system was designed to evaluate, in a clinical setting, the appropriate sequence of muscle stimulation required for a particular subject's pathology and thus was not a home-use system. The Strojnik six-channel stimulator system used a heel switch built into a shoe insole to control application of the six channels of stimulation. Based on Takebe's earlier finding (Takebe,1975), subjects having difficulty with system size, weight and daily placement of electrodes, a six-channel surface stimulation system is evidently not suitable as a take-home system. It would be an impossible task for a hemiplegic subject, or their carer, to correctly place six pairs of electrodes at different muscle locations on a daily basis. The implementation of multi-channel systems using hard-wired technology resulted in systems which were difficult to configure, and highlighted the need for microprocessor technology to enable a more user-friendly

programmable implementation of multi-channel stimulation. Bogataj et al, are the first to have reported the first use of microcontroller and microprocessor technology in a drop foot stimulator (Bogataj, 1984). Bogataj's system was a six-channel stimulator of six arrays of switches permit the selection of stimulation amplitude for each stimulation channel, and also gives a graphical indication of the selection. The system included a simple stride analyzer. The parameters measured were: number of steps, mean stride time, and mean heel-on times.

The experimental multi-channel stimulators, such as the six channels programmable stimulator described by Brandell, are only manually programmable via switches on the unit and do not self-adjust. This mode of operation leads to the use of a fixed open loop control strategy of the lower leg muscles, (Brandell, 1986). This system was not suitable for take-home use, as previously discussed multi-channel stimulation is only suitable for use in the clinic, thus a system like this is primarily for clinical use. In the 1990s, a portable two-channel drop foot stimulator O2CHS was developed using hard-wired technology by the group at Salisbury District Hospital, UK. Setting up different stimulation options on the O2CHS is achieved using a complex combination of DIP (dual in-line package) switches and potentiometer settings (10 potentiometer and 10 DIP switches. Some other multi-channel stimulators have been utilised, (Graupe, 1997), (Bogataj, 1989), (Davis, 1987), (Handa, 1992), (Akazawa, 1989), (Kralj, 1986), (Meadows, 1989).

The application of microprocessor technology in surface Drop foot stimulator led to a dual-channel foot drop stimulator design by the Ljubljana group in 1992 (Malezic, 1992). The stimulator programmer unit also allowed the clinician to load fixed stimulation sequence settings and the only stimulus parameter adjustable by user was stimulus amplitude. Popovic, Keller, Pappas, and Müller, described a programmable stimulator, which could potentially be applied in drop foot correction (Popovic, 2001). The stimulator is a four-channel stimulator with two sensor inputs. The unit also has a port, which can be used to cascade additional stimulators together, to communicate serially with a PC or to trigger stimulation using a push-button. The unit is programmed using a PC-based graphical user interface (GUI). Generally due to the size and complexity of the multi-channel stimulators, they remained at the experimental stage.

Significantly, the stimulation systems discussed earlier utilise fixed pulse parameters during the stride and merely activate or deactivate the pulse train sequences, while neither design incorporated the ability to perform self-adjustment of any parameters using closed loop control, they are generally adjustable to suit individual patients but fixed whilst in use. Also within all these systems, locating the electrode placement position when using all these FES systems can prove a challenging task for the user. Placement of the indifferent electrode over the tibialis communis is relative straightforward, whereas accurately identifying the peroneal nerve's surfacing can be a time consuming task. Non-optimal electrode placement may cause poor eversion and dorsiflexion or even plantarflexion of the foot (Granat, 1996). Furthermore many of these patients may have limited hand function that further restricts their ability to properly position the stimulating electrodes as well as perform the rest of the donning and doffing process. This research was focused on using transcutaneous electrode stimulation not implanted electrodes, but it important to mention that a lot of researchers are using implanted electrodes such as (Hutten, 2002), (Kottink, 2004). Hutten et al presented a study using to evaluate the stimulation responses on each channel of an implantable two-channel stimulator that stimulates the peroneal nerve branches innervating the muscles for dorsiflexion and eversion movements. both dorsiflexion and eversion direction can be set individually and with great accuracy (Kottink, 2004).

2.2.2 Foot gait detection

2.2.2.1 Foot switch

Since Liberson's development of the first drop foot stimulator to the early 1990s, most of these FES systems in use for foot drop correction typically employ foot switches (Waters, 1975), (Brandell, 1986), (Crago, 1986), (Malezic, 1984), (Bogataj, 1989), (Rushton, 1997), (Ott, 1998), such as mechanical switch, force sensitive resistors, an air pressure switch under the heel or ball of the foot to indicate the start of the gait movement and lift the toes of the affected limb, (Takebe, 1975). The problems encountered with this type of switch are mainly reliability and gait events

detection accuracy, (Vodovnik, 1965), (Waters, 1975), (Willemsen, 1990), (Haugland, 1995), (Ott, 1998), For these reasons several researchers have evaluated alternative gait sensors using either another type of gait sensor, which would be suitable for implantation, or using the body's "natural" sensors.

2.2.2.2 Natural sensors

A proposed solution to the problems of gait sensors in FES-based foot drop correction systems is to use Electromyography (EMG) measurements sensors of the pectoralis muscles' activity to detect gait events and control the stimulation; although very effective the proposed system did not provide information about gait phases, (Graupe, 1983). Another interesting method for detecting transitions between the stance and swing phases to control the timing of the stimulation sequences generated by FES systems for walking, was based on measurements of afferent nerve activity with implanted nerve-cuff electrodes. Recording nerve signals is referred to as Electroneurography "ENG". Haugland and Sinkjar described the use of recordings from a cuff electrode, on the sural nerve, to control the application of stimulus to the common peroneal nerve of a hemiplegic subject (Haugland, 1995). A few problems were identified with the system; first the need to eliminate the wires going through the skin or implanting a neural amplifier; some false detection of the heel-strike occurred. In 1999 Strange and Hoffer presented some gait detection results recorded from cats and suggested that there detection system could be used as a reliable source of feedback for closed loop control of functional electrical stimulation, (Strange, 1999). Upshaw and Sinkjaer compared the performance of natural cuff electrode sensor versus artificial standard heel contact switch sensors when used in a closed-loop foot drop electrical stimulation system, the results show a great advantage and accuracy achieved from using the natural cuff electrode sensor over the standard foot switch, (Upshaw, 1999). Systems measuring afferent nerve activity are invasive, sensitive to electromagnetic interference, and so far provide information about only one gait event.

2.2.2.3 Inertial sensors

One of the first groups to propose an alternative artificial sensor to the foot-switch as a gait sensor in foot drop stimulation systems was Symons et al. This involved the preliminary evaluation of an in-house accelerometer to detect heel strike, (Symons, 1986). Kirkwood et al, presented combined measurements from goniometers and instrumented shoe insoles to derive four distinct gait phases using inductive learning techniques. The experiments performed in their laboratory showed that the detection accuracy of the proposed system was between 70% and 90%. However they reported that this was insufficient for practical applications, (Kirkwood, 1989).

The evaluation of using alternative artificial sensors carried out by Symons was not very extensive. Willemsen et al, proposed the use of an integrated accelerometer as a replacement for the foot-switch in foot drop correction system, they calculated the equivalent acceleration of the ankle joint by using accelerometers between the ankle and the knee joint to distinguish stance and swing phases during the gait cycles, (Willemsen, 1990). In 1996 Dai et al, investigated the use of inertial tilt sensor to control of Functional Electrical Stimulation to improve the gait of persons who had a foot drop due to stroke or incomplete spinal cord injury, the system demonstrated gait improvement for some subjects with several advantages over traditional stimulators controlled by foot switches, (Dai, 1996).

Gait detection using gyroscope has proved to be another alternative technique for gait analysis, Tong and Grant showed that with the use of two gyroscopes, one placed on the thigh and the other one on the shank, one can measure the knee angle during walking, (Tong, 1999). Luinge et al, investigated the estimation of joint segment orientation, using a combination of solid-state gyroscopes and integrated accelerometers; however no clear correspondence has been established between gait events and the pattern of the gyroscope angular velocity measurements. Therefore these gyroscope inertial sensors systems were considered suitable only for applications where the subject is almost stationary or at slow movement, (Luinge, 1999).

Veltink et al, tried to distinguish between several static and dynamic activities (standing, sitting, lying, walking, ascending stairs, descending stairs, cycling) using a set of two uniaxial accelerometers. The standard deviation of the accelerometer signal and the cycle time were primarily related to the speed of the dynamic activities, and did not contribute to the discrimination of the activities. Therefore, discrimination of dynamic activities on the basis of the combined evaluation of the mean signal value and signal morphology is proposed, (Veltink, 1996).

In 2000 rule based detectors were used with a single cluster of accelerometers by Williamson et al, (Williamson, 2000). The accelerometer was attached to the shank for the real time detection of the main phases of normal gait during walking. The gait phase detectors were synthesized from two rule induction algorithms, Rough Sets and Adaptive Logic Networks. A three dimensional inertial sensing system for measuring foot movements during gait was proposed by Veltink et al, the investigation carried out using implanted two-channel foot drop stimulator. This study indicates that foot movements can be reconstructed from 3D inertial sensor signals such as to distinguish the change of foot movements during swing when the stimulation parameters of the two channels are adapted. This sensitivity is a pre-requisite for an automated balancing system for both stimulation channels of the foot drop stimulator, but the feasibility of such an automated system was not demonstrated, (Veltink, 2003). Mathie et al, reported the use of a single, waist-mounted triaxial accelerometer system to monitor a range of different parameters of human movement in an unsupervised setting. The movements were first divided into activity and rest. The activities were classified as falls, walking, transition between postural orientations, or other movement. The postural orientations during rest were classified as sitting, standing or lying, (Mathie, 2004).Tanaka et al, have developed prototype device for monitoring human posture and walking velocity in ambulatory subjects using 3 accelerometers and one gyroscope, The preliminary study using the prototype show that the initial value of the thigh angle just before starting walk could be determined and thus, the problem of the error accumulation by integration of the gyroscope signal could be eliminated, but further tests are required, (Tanaka, 2004).

2.2.3 Foot drop control

In order to control movement of the human limbs in a manner similar to that of the central nervous system, FES systems require some means of controlling the stimulation sequence. Many control architectures have been tried during the years of FES development in a continuous attempt to make these systems more successful in achieving the functionality and reliability standards required for practical use outside the laboratory. Foot drop FES systems have been the most widely used application of electrical stimulation. Also, it offers itself for experimentation with a wide range of control schemes, several open and a few closed loop systems featuring ambitious control algorithms have been tested in the laboratory and trial groups.

Stanic, Trnkoczy, Acimovic, and Gros described the use of gradually modulated electrical stimulation, where the system store the required stimulation sequence (Stanic, 1977). Prochazka and Wiles evaluated closed loop control of dorsiflexion angle using a length sensor attached across the ankle joint, (Prochazka, 1983). The recent developments in computer technologies and software engineering have led to the flourishing of radical control strategies like the neural network adaptive control and machine learning techniques, Granat and Heller (Granat, 1993), Graupe and Kordylcwski (Graupe, 1997), Abbas and Chizeck (Abbas, 1995), (Kostov, 1995, 1999), (Yamaguchi, 1990), (Khang, 1989), (Willemsen, 1990), (Haugland, 1995), (Sepulveda, 1995), (Crago, 1996). Mourselas and Granat described one of the latest prototype foot drop stimulation, which applied closed loop control of dorsiflexion angle using fuzzy techniques (Mourselas, 2000). The fuzzy controller was implemented on a microcontroller and ankle flexion was monitored using a flexible resistive goniometer. Heel contact was also monitored using a FSR foot switch. The closed-loop system consistently performed better than the open-loop system by providing improved dorsiflexion.

Most of the foot drop control methods proposed to date have been adapted from industrial control applications where the control problems are usually better defined and of a considerably lower degree of complexity. On the other hand classification of the control strategies as applied to the human body can be performed with the same criteria as for totally man made systems.

2.5 Summary

This chapter introduced the problem of foot drop. Careful attention was paid to the difference of the walking gait between normal and affected foot drop subjects. A background of the muscle and nerves responsible for the foot movements was presented. This chapter also discussed the hypothesis of how electrical stimulation can be used to correct foot movement. A literature review of developed foot drop systems by different researchers over the last 40 years has been discussed. This has included a review of foot gait detection using feedback, particularly inertial sensors used to control the stimulation. Toward the end of the chapter the problem associated with current commercially available foot drop systems was discussed. In the next chapter the new stimulation system designed during this research will be presented. This design is mainly based on the transcutaneous stimulation understanding demonstrated in the previous chapters and on the research investigation requirements, such as electrode array and combination of inertial feedback sensors.

Chapter 3

SYSTEM DESIGN

CHAPTER 3: SYSTEM DESIGN

3.1 Introduction

One of the primary aims and challenges in this research was to design and develop a stimulation system that can be used to fulfil the research investigation requirements. Current commercially available stimulation systems and devices are very simple in operation as discussed earlier; therefore they are not suitable to be used in this research. These available systems produce a fixed stimulation signal and they have very limited feedback channels. The set up process for these stimulators always takes a long time particularly to find the best electrode position. This set up process has to be done by specialists as the patients are unlikely to do it by themselves. Almost all of these available systems can not be pre-programmed with control algorithms or patterns. The available portable compact stimulation systems have a very limited number of stimulation channels. The research requirements at this level of decision making ability suggest the use of microprocessor or microcontroller based system, such a system permits the creation of software to implement the decision making procedure. The proposed system design architecture at the beginning of the design process is shown in Figure (3.1).

The key elements (functional blocks) for this stimulation systems design are:

- The user interface to give full control and monitoring over the stimulator output and feedback if required
- A stimulation pulse generator that generate the pulse, vary its shape, width and repetition rate also vary the pulse amplitude and stimulation envelope rise-fall time, the ranges of these parameters were based on the stimulation parameters discussion in chapter 1.
- An output stage amplifier that can amplify the produced stimulation signal to the required stimulation level, also this amplifier should fulfil the safety requirement for the system

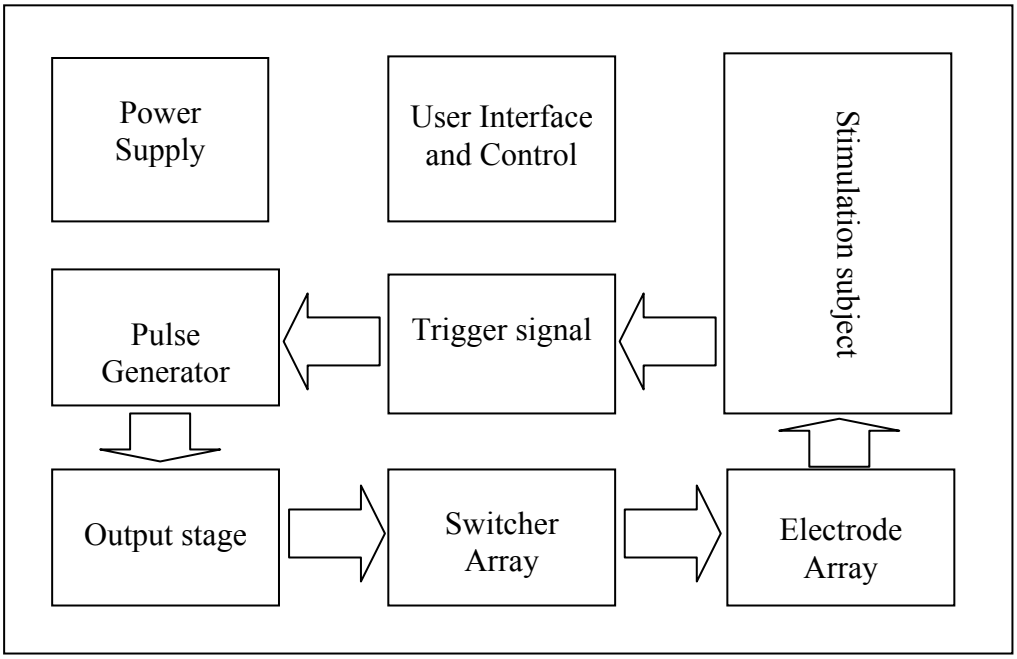


Figure (3.1) - Proposed system architecture

- An electrode array switcher to steer the amplified stimulation signal to an array of electrodes
- A battery power supply that can provide the system with the required power for as long as possible to perform its functions, also to facilitate designing a safe portable system
- Feedback sensors to give full information about the performed stimulation and movement responses in real time

The design and development process consumed a lot of time and effort and toward the end of this research three systems were designed and implemented. Each system version overcame the problems associated with the previous one and gained some more features to match the new research requirements and specification. The first two versions are discussed in appendix (B-1) and the latest version is discussed in this chapter.

3.2 Stimulation system [ST32 FES system]

This system was developed on the basis of the experience gained during designing and testing version 1 and 2 presented in appendix (B-1). The main aim was to overcome all these problems associated with the old versions and build a new system using the latest embedded system technology to produce a portable and safe stimulation system capable of providing all the research needs. The new (ST32 FES) system design specifications are listed below.

3.2.1 Specifications

- Easy user interface and control over the stimulator
- Produce 12 or more different stimulation waveforms shapes
- Digital control over the stimulation amplitude, range (0% to 100%) of the maximum output stage peak-peak voltage (400V peak to peak no load)
- Digital control for stimulation waveform pulse width, ranges (50µs Min to 500µs Max).
- Digital control over stimulation frequency range of 10Hz to 200Hz, which give a pulse repetition rate range of 100ms to 5ms.
- Producing single twitch signal pulse, manually and automatically
- Digital control over stimulation signal envelope rise time, extension time and fall time
- Digital control over 32 electrode array high voltage switching circuit.
- Modify pulse parameters on pulse-by-pulse or envelope by envelope basis
- Analogue and/or digital Interface to FSR, gyroscope and accelerometer sensors
- Process analogue and digital data from real time feedback sensors
- Ability to be programmed with various advanced control algorithms to control the system using real time feedback data
- Produce comfortable stimulation
- Portable system
- A safety stop switch to stop stimulation in an emergency (user control)
- Longer life battery powered system

- Patient isolation and safety
- Meet the British standard and safety requirements for medical equipments [BSEN 60601-1]

3.2.2 System configuration:

The system was developed to match the specifications listed above; a functional block diagram for the system is shown in Figure (3.2). This was the final stimulation system design during this research and it is the design approved by the Medical Equipment Management Organization (MEMO) of UBHT NHS Trust in Bristol and was used for patient clinical trials. This system functional blocks is discussed in detail in the following few sections.

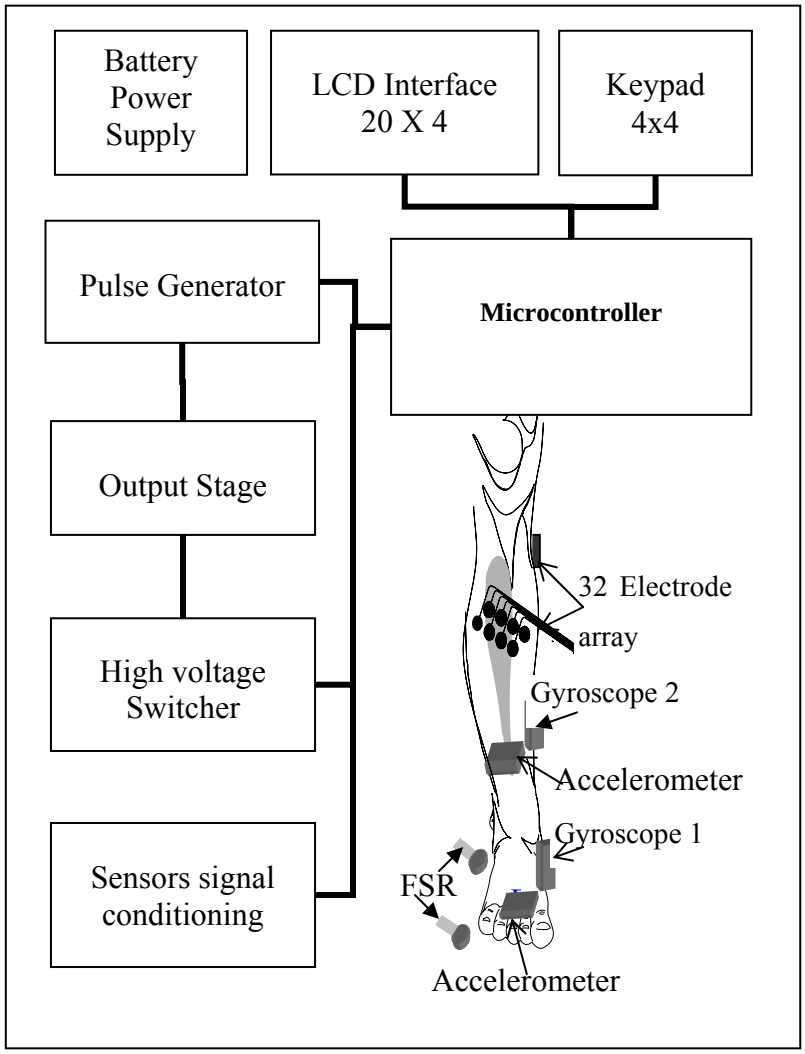


Figure (3.2) – (ST32 FES) system architecture

3.2.3 Microcontroller and embedded firmware

This latest system version used one of the latest released Microchip microcontrollers, the PIC18F8. It is a low-power high-speed flash CMOS device running at 40 MHz. This microcontroller is running at 40 MHz with 100ns instruction cycle execution speed. It has 64Kbytes program memory and 1Kbytes of EEPROM data. The PIC18F8 has 68 digital Input/Output ports, 16-channel of 10-bit ADC. It features five 16bit Capture/Compare/PWM modules with 10- bit resolution and five 8/16 bit timer modules. It has the capability of in-circuit serial programming and debugging as well as self programming. Combination of custom made assembly language (MPASM™ macro assembler) and C language using microchip PIC18C compiler, were used for programming this microcontroller. This microcontroller carry out all real time feedback signals processing and control of the overall the stimulation system as will be explained in the next few sections. The embedded microcontroller firmware code design for this system is included in the Appendix (B-4).

3.2.4 User interface and control

The user interface in this system was based on using (4x4) membrane keyboard and (4x20) line LCD as shown in Figure (3.4). The microcontroller communicated to the LCD using three control lines and eight parallel data bus and communicated to the key board using 6 lines as shown in Figure (3.4). This arrangement allowed easier user interface by allocating simple functions to each key, and displaying more information on the LCD about the stimulation processes on a step be step basis.

Figure (3.4) - ST32 system interface

3.2.5 Stimulating signal generator

This stimulation signal generator was based on the digital synthesis technique. It was programmed to allow 12 different stimulation waveform shapes to be stored. Five of these stimulation waveforms are shown in Figure (3.5) and were used in the trials. The signal generator had digital control over all the stimulation signal and envelope parameters described earlier in the specification. All these parameters could be varied using the keypad and the display even when stimulation was applied to the patient. An emergency hand held button stop switch was also used. This allowed the patient to stop the stimulation (through software control only) as a precaution should anything go wrong while using the system. The stimulation signal generator schematic circuit is shown in Figure (3.6). As shown in the schematic the microcontroller is the heart of this circuit. As stated earlier the microcontroller was flash programmable and had a large memory that could be programmed internally with preset waveform shapes including. Each waveform was formed from 200 samples and stored in the memory as digital data. These digital waveforms were converted to analogue using a parallel interfaced 8-bit MDAC that provided very high speed performance. The analogue signal amplitude was controlled by an additional Digital to Analogue Converter (DAC) connected to the reference input of the MDAC to give waveform amplitudes ranging from 10 m V to 1 V peak-to-peak by 10 mV step. This signal was not suitable to be amplified using the output stage amplifier and required additional amplification and buffering. This was achieved using a high-speed operational amplifier with a gain of 10 to boost this signal to 10V Peak-to-Peak.

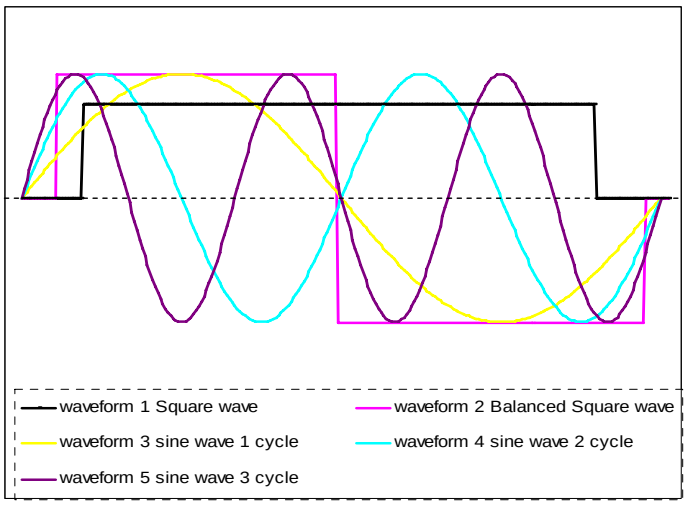


Figure (3.5) - Stimulation waveform shapes

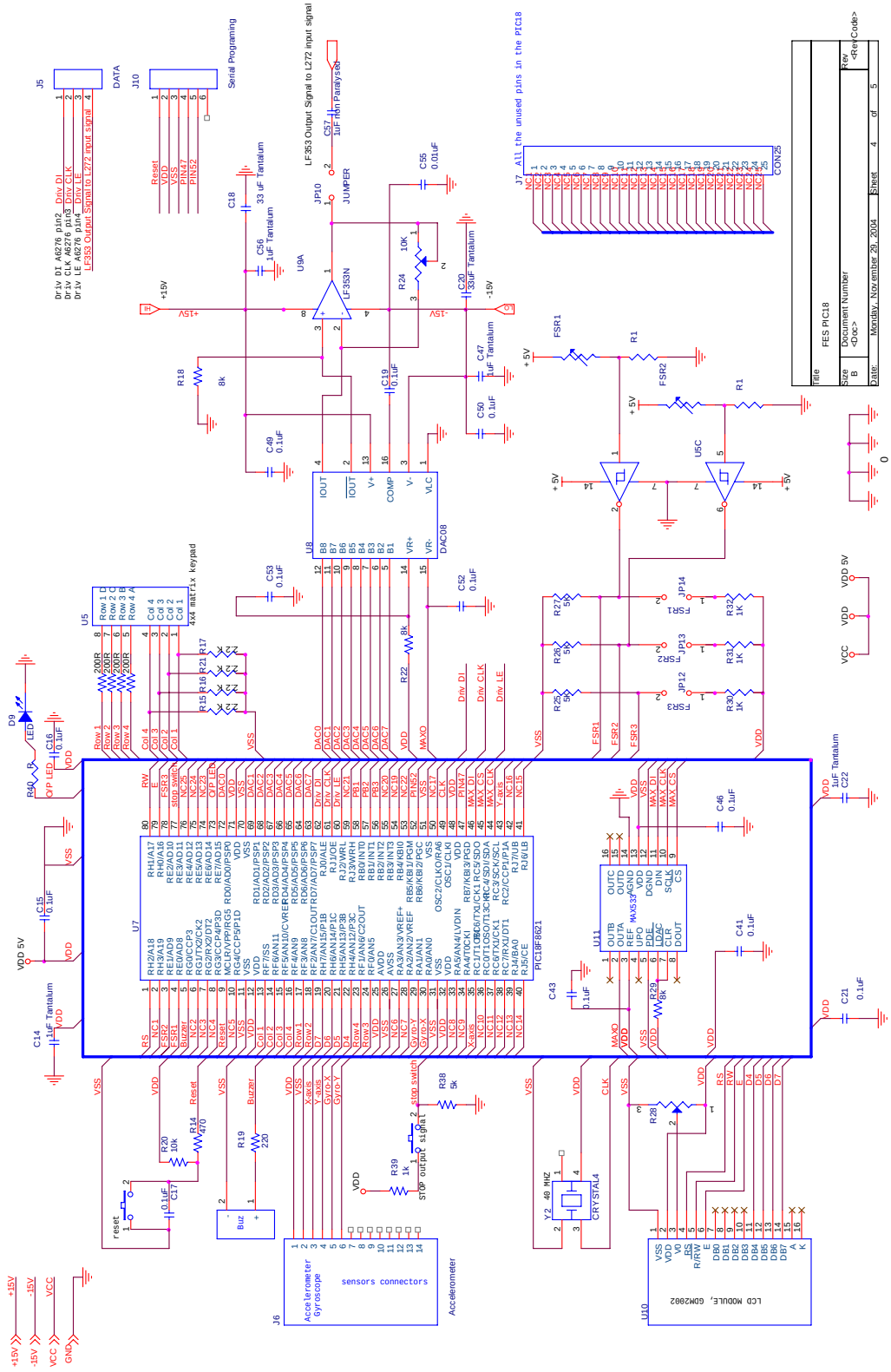


Figure (3.6) - ST32 main circuit schematic

3.2.6 Output stage

The stimulation system output stage should amplify or boost the stimulation output signal to an effective stimulation level. There are several stimulation techniques as discussed earlier in chapter 1; each stimulation technique required a specific output stage design. The output stages that were investigated in this research were the constant current and constant voltage. In both cases the execution of an action potential in the muscle depends very much on the impedance of the underlying tissue. In the following section the advantages and disadvantages of constant current and constant voltage will be discussed.

3.2.6.1 Constant current

Constant current stimulation is the most widely used technique. Most FES applications are performed with constant current stimulators. Almost all the physiological measurements in FES are also performed with constant current.

This because of the following advantages:

- Less variability and more stable stimulation due to changes in body impedance, e.g. skin
- Can control or current limit the pulse for safety e.g. cardiac pacemaker
- Circuits can be built using a low component count

The main disadvantages of the constant current stimulation are:

- Known to be painful sometimes
- Poor electrode contact cause very high current density which may give rise to skin irritation or burning of skin
- Only rectangular current pulses are mostly available

3.2.6.2 Constant voltage

The constant voltage is less popular than the constant current, sometimes it is used because of the following advantages:

- Safer than constant current in case fall of electrode contact during use

- Based on the constants voltage output stage design it can be used for stimulating and recording the voluntary Electromyogram (EMG) from the same muscle at the same time (constant current stimulation can produce pulses with long tails)
- Can produce a wide range of waveform pulse shape
- By selection of an appropriate waveform, it can reduce stimulation pain and sensation problem

The Main disadvantages of using constant voltage are:

- Stimulation varies with body load impedance variation
- Reduction in the current delivered through the electrode in case of poor electrode contact hence results less stimulation and reduction in physiological effect
- Requires more components in the circuitry

As discussed before the aim was to design an output stage that can amplify the stimulation signal produced to the required stimulation level. In this first stimulation system design a constant voltage output stage was chosen to be used. This was due to the need to stimulate using different waveforms for comfort and the need for sharing stimulation pulses over a set of electrodes in the array.

3.2.6.3 Output stage design

After investigating and designing several output stages amplifiers, including the output stage used in version 1 and 2 discussed in the appendix, a hybrid constant current and constant voltage output stage was designed. The output stage circuit schematic is shown in Figure (3.7). An L272 power operational amplifier was used, it is powered with ±15V supply voltage, consuming about 60mA when continuously stimulating an artificial body load of 1KΩ in parallel with 0.1µF. This amplifier drove "Eagle" miniature transformer. The transformer had 1.2 kΩ input impedance and 3.2Ω output impedance. The squared turns ratio is equal to the ratio of output to input impedances for a transformer, which gives a squared turns ratio n^2 =1200/3.2, therefore n = 20 approx. Used in reverse, this transformer could be used to boost the waveform amplitude to levels for use in the transcutaneous stimulation. The amplifier output was connected in series to a 1000µF non polarised electrolytic capacitor. This

capacitor was used to block any d.c. current flowing from the op amp output to the transformer primary. This reduced transformer saturation and subsequent waveform distortion.

The L272 was a dual op amp so it was decided to further increase the ability to drive a body load at full output by using an additional transformer wired in parallel. The outputs of both transformers were connected in series to algebraically combine the stimulation signals. This gave a far better quality of waveform at full output, suggesting that saturation effects had been reduced by sharing the pulse current in the body load between the two transformers and increasing the overall peak to peak pulse amplitude voltage output. This circuit amplified the ±5V stimulation pulse from the DAC to approximately 500V peak-peak (with no load) and approximately 400 V peak-peak when using the body load.

The transformers were capacitively coupled on both output leads using two high voltage polystyrene capacitors. This capacitive isolation had >15000MΩ insulation resistance at up to 200 V DC voltage. This prevented any dc component in the stimulation waveform to flow to the switcher circuit and into the patient, ie: these capacitors made the stimulation waveforms charge balanced. Additionally the capacitors also protected the patient during a system fault condition as they prevented any dc from getting onto the output leads. This insulation resistance also helps to protect the patient against d.c. leakage current. The charge balanced pulses made the stimulation very comfortable when applied to the skin but it was also necessary to filter out any digital high frequency signals from the power supplies, as this was not deemed comfortable during the development stage.

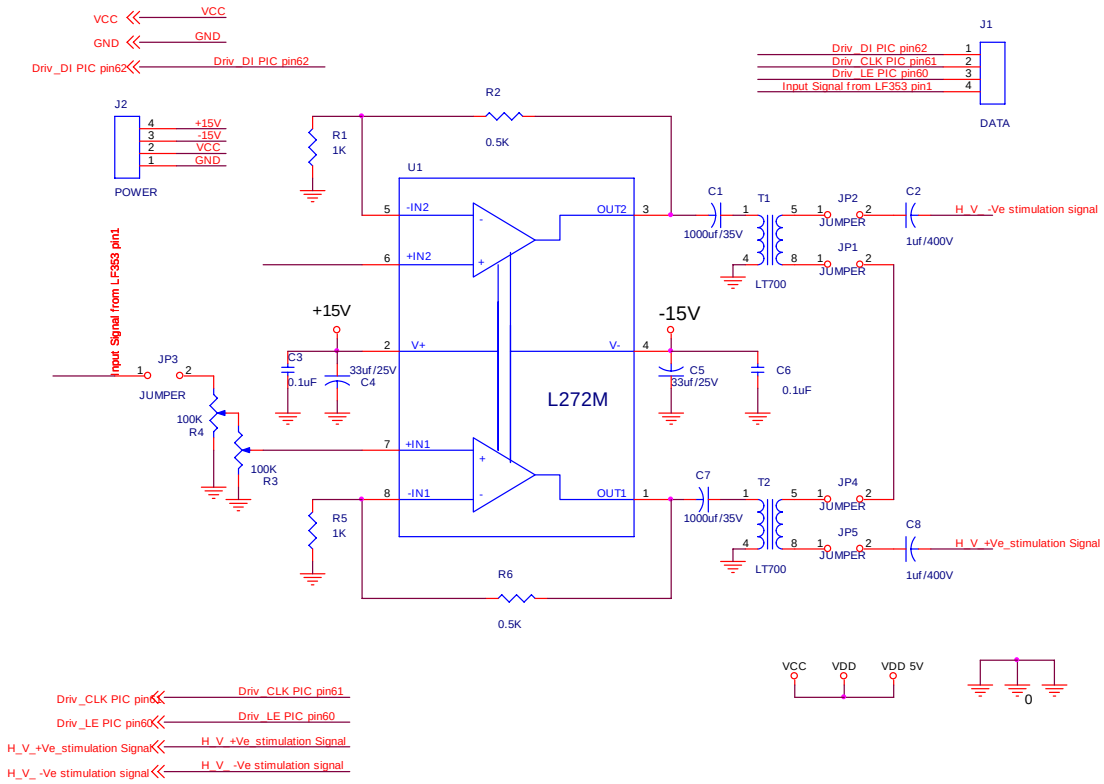


Figure (3.7) – ST32 output stage

3.2.7 Electrode Array Switcher

A switching circuit was built based on using miniature high voltage photovoltaic relays interfaced to the microcontroller using a serial controlled Light Emitting Diode (LED) array driver. The photovoltaic relay used in this circuit was the PVT412. It was a single pole normally open solid-state relay. This relay device utilised a MOSFET as an output switch controlled by an LED, which is isolated from the photovoltaic generator as shown in Figure (3.8). The switch has 4000Vrms input/output isolation and could switch up to ±400V ac/dc, 140mA. The switching speed was 500µs rise time and 200µs fall time. Each switch could be turned on and off using a simple 5V logic signal and required no additional power supply to bias the output stage.

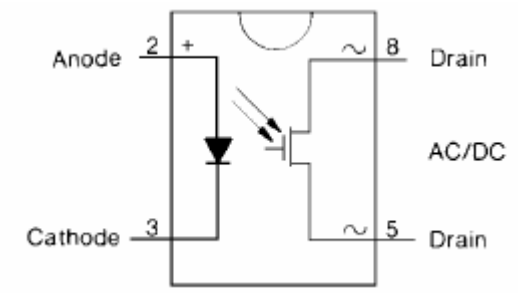


Figure (3.8) - photovoltaic relay

The LED driver used was the A6276 16-bit serial input latched, shown in Figure (3.9). The device included a 16-bit CMOS shift register, accompanying data latches, and 16 npn constant-current sink drivers. The CMOS shift register and latches allowed direct serial interfacing with the microcontroller using 3 low voltage control signals and typical serial data-input rates up to 20 MHz.

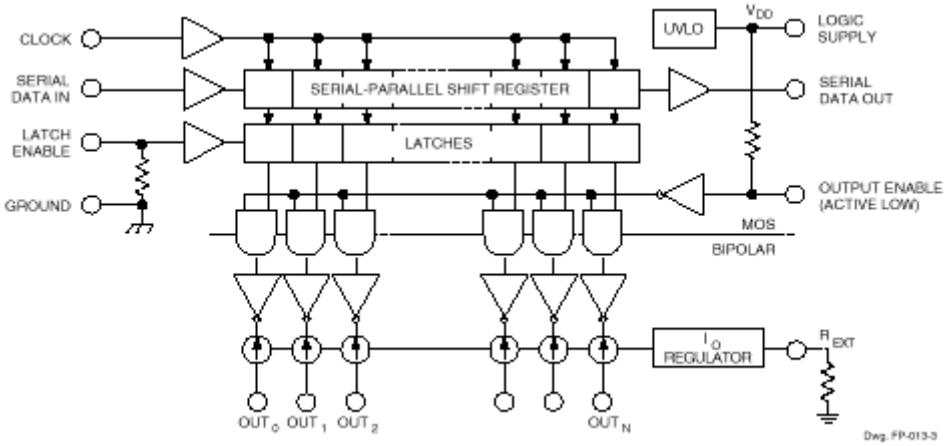


Figure (3.9) - A6276 led driver

A 32 channel switching circuit was built using two 16 channel LED drivers and 32 photovoltaic relays as shown on the switcher circuit schematic Figure (3.10). This circuit was much safer than version 2 presented in the appendix and it did not require complex safety arrangement.

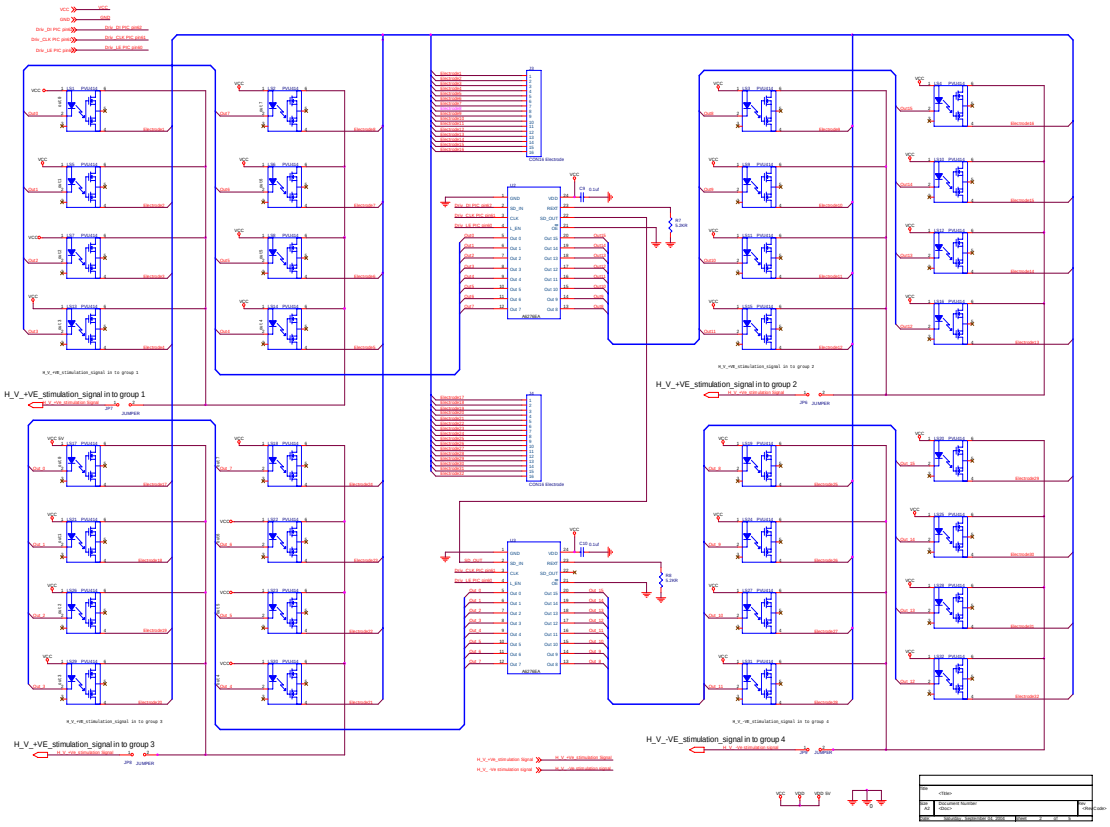


Figure (3.10) – ST32 Switcher circuit schematic

3.2.8 Power supply

The system power supply circuit was designed using MAXIM step-up switch mode d.c - d.c. converters to produce positive voltages (MAX608) and negative voltages (MAX776) from a battery. Figure (3.11) shows the circuit schematic that was used in the system. For the positive supplies, an input voltage of 1.8V to 16.5V could be used and the device could boost or cut this input voltage to regulated output voltages of either +5V, +15V through selection of a feedback resistor. This device used an external N-channel MOSFET transistor allowing an output power load of up to 10W with about 80% switching efficiency over a range of output current up to 1A. For the negative supplies, an input voltage of 3V to 16.5V could be used and the device could boost or cut this input voltage to a regulated output voltage of -15V. This device used the same technology as the +5V and +15V circuits but with an external P-channel MOSFET switch allowing to power a load of up to 5W with about 85% switching efficiency over a range of output current up to 1A. The different input voltage requirements of each device meant that a battery voltage of 4.8V was used as input. The battery pack used was made up from 4 serially connected AA 1.2V NiMH

rechargeable batteries, each capable of 2.4Ah of charge. If the -15V converter was designed for 1.85V input voltage then only 2 of these batteries would be required which would make the whole stimulator smaller and lighter and it was disappointing that this was not the case.

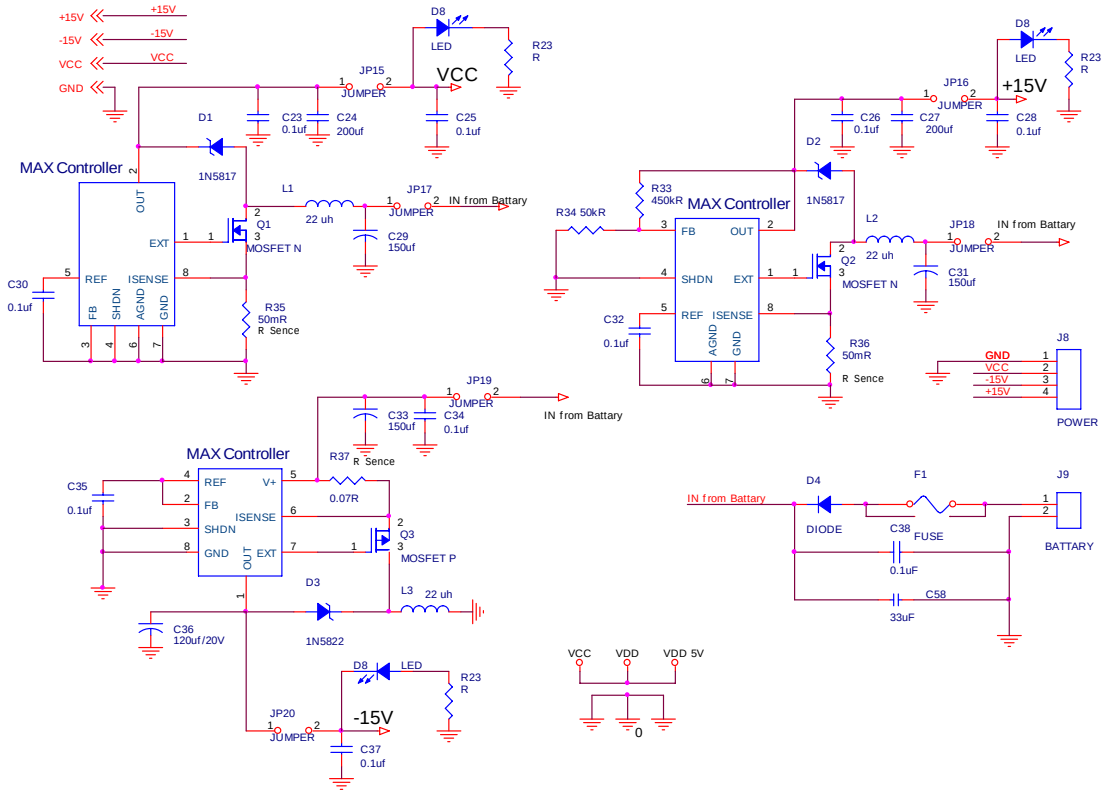


Figure (3.11) – ST32 power supply circuit schematic

These MAXIM circuits required the use of a high current inductor for each power supply to switch currents and pulse charge into a load capacitor from which the output voltage was taken. The load voltage was controlled by using a combination of pulse frequency modulation (PFM) and pulse width modulation (PWM) that provided high efficiency at heavy loads while using less than 100µA quiescent current when operating with no load. The circuits used a sense resistor to control the peak switching current through each inductor and each device had a high switching frequency of up to 300KHz which added to the overall efficiency. The switching noise generated in the output voltage required careful selection of filtering capacitors so that the peak to peak noise voltage did not exceed 150mV at a full load of 1A. This was sufficiently low to prevent digital noise getting into the output waveform.

This power supply approximately drew approximately 150mA at full stimulation signal output when continuously stimulating a body load comprising a 1kΩ resistor in parallel with a 0.1μF capacitor. A fully charged battery pack could therefore keep the stimulator powered for up to 16 hours of continuous stimulation (2400mAh/150mAh = 16 hrs). To prevent reverse battery voltages from being applied to the system during development which would have meant self destruction of all semiconductor devices on the PCBs, a low forward voltage Schottky silicon diode was placed in series with the output from the battery compartment. A short circuit of the batteries during development or fine tuning with the lid off the stimulator or component failure could cause a fire hazard as the energy density of these AA batteries was unusually high, (2400mAh). To prevent potential problems a 1A quick blow fuse was placed immediately after the power switch which could be accessed from the outside of the stimulator using a draw type fuse holder. This particular fuse holder was selected so that no special tools were required for fuse replacement and the fuse compartment was completely isolated from the power supply when open.

3.3 Real time feedback Sensors

3.3.1 Force Sensitive Resistor (FSR)

The FSR is a tactile force sensing sensor which acts as a non-linear potentiometer that responds to applied physical pressure or force by exhibiting a decreasing resistance. For more details about this FSR sensor see appendix (B-2). This FSR sensor was integrated into this system using two techniques. The first one was as a switch, this was achieved by incorporating it into the circuit shown in Figure (3.12, A). The voltage potential divider works as force to voltage circuit and the Schmitt trigger produces a clean logic level to interface to logic inputs of the microcontroller. Depending on the on/off voltage a threshold, an adjustment to the potential divider resistor R1 was made to increase or decrease the sensitivity of the force sensor. The second technique was to use one of the microcontroller ADC channels to process the feedback voltage signal from the FSR sensor potential divider circuit. By setting some voltage thresholds in software, the system was able to distinguish between the different events during the walking gait.

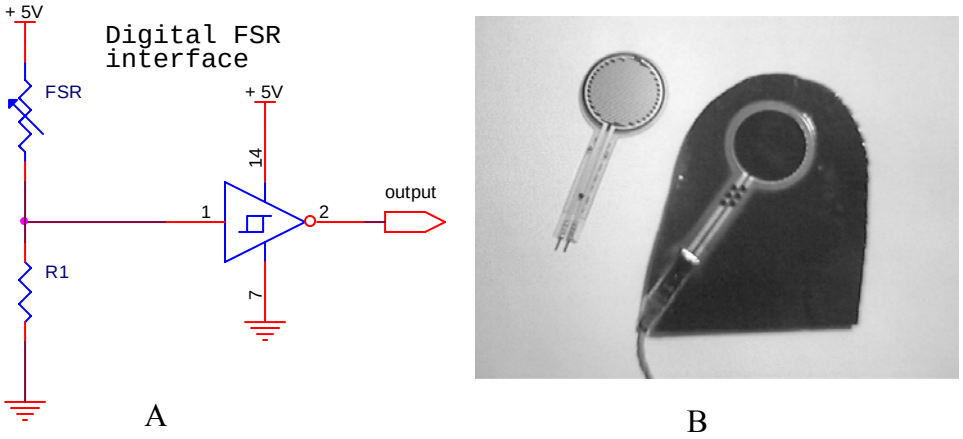


Figure (3.12) – A: Typical sensor response based on circuits shown, B: FSR heel sensor mechanical packaging

The FSR mechanical packaging was improved by mounting the sensor on a slab of rubber. This enabled the sensor to be more reliable during walking. A heel sensor is shown in Figure (3.12, B). The sensor was offset so that the wired connection was not placed under the heel which made it more comfortable when placed in the shoe.

3.3.2 Accelerometer

A miniature two axis (biaxial) ADXL202 Micro-Electrical-Mechanical-Systems (MEMS) accelerometer from "Analog Devices" was used to detect foot acceleration. The ADXL202 accelerometer theory of operation and circuit schematic is explained in more details in appendix (B-2). This particular accelerometer was chosen because it had a more sensitive response to acceleration than piezo electric accelerometers. It had a $\pm 2g$ maximal response but incorporated an amplifier that could increase the sensitivity to approximately ±5mg. The ADXL202 produced two different types of output, an analogue continuous output (voltage proportional to acceleration) and digital pulse width modulated (PWM) (ratio of pulse width to period proportional to acceleration) output. This accelerometer measured dynamic and static acceleration. The ADXL accelerometer was in a compact size, robust design. In addition to that it used a 5 V supply voltage with relatively very little power (<0.6 mA). The ADXL202

PWM output has 12.5%/g sensitivity. The analogue output sensitivity is 312mV/g at 5V supply. The typical noise floor is $\left(500\mu g/\sqrt{Hz}\right)$.

The sensor calibration was done using the microcontroller firmware provisionally using stored value or instantly in respect to the start and the end of the acceleration measurement. The digital pulse width modulated PWM output was used for tilt measurements, but some problems and difficulties was experienced using the PWM output in measuring accurately the dynamic acceleration. For this reason the analogue output signal from the same accelerometers was used, with the capability of using the digital output when needed. The accelerometer analogue output was amplified using an operational amplifier for two reasons, to be buffered before the microcontroller and to set the output voltage to be compatible with the microcontroller ADC.

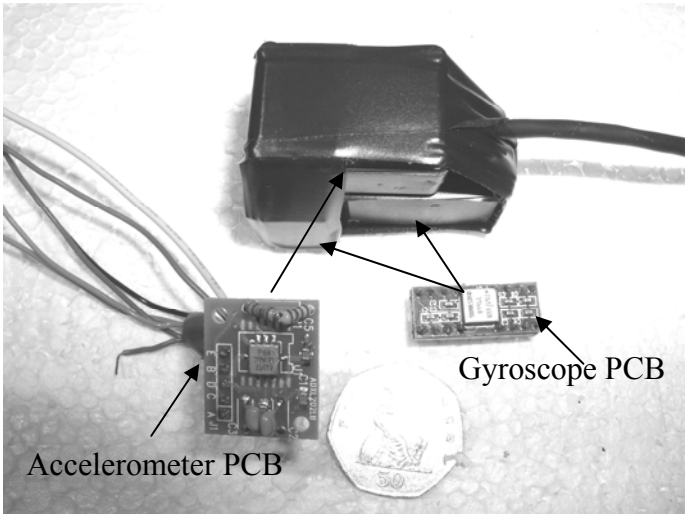


Figure (3.13) -Gyroscope and accelerometer

The accelerometer was used as a tool to investigate the measurement of static and dynamic acceleration foot movement in the direction of dorsiflexion/plantarflexion and eversion/inversion; as discussed in chapter 5. It was also used to detect the twitch movement acceleration as will be discussed later in chapter 4. It was also utilized for stride length distance calculations and as a step counter. During these investigations different acceleration bandwidths and PWM time periods were used.

3.3.3 Gyroscope

Miniature MEMS ADXRS gyroscopes from "Analog Devices" are used in this application. This gyroscope design is based on the principle of a resonator gyro. This ADXRS150 gyroscope can measure movement angular velocity < ±150°/s. It produces an analogue output voltage proportional to the angular rate. This gyroscope is a z axis sensitive device that generates positive voltage output for clockwise rotation and negative output for anti clockwise as explained in the appendix. This device typical sensitivity is 12.5mV/º/s when 5 volt supply is used. This gyroscope sensor was used to measure the foot and ankle angular rotation in the planes of dorsiflexion/plantarflexion and eversion/inversion. Some measurement accuracy problems were faced while using this gyroscope for this research application as will be discussed in detail in chapter 5. Both gyroscope and accelerometer PCBs are shown in Figure (3.13).

3.4 Electrode array

Due to a limitation in time and funding there was little chance of designing an electrode array prototype similar to the one designed during the Festival project as discussed earlier in chapter 2. Technologies using flexible PCB or conductive tracks printed onto plastic would have been suitable but were not thought of as a critical path to testing the concept of the optimisation algorithm and are left for future work. Some of these technologies have been used successfully in the past by Peasgood et al (Festival Project Report, 1994-1997). Some time was spent investigating commercially available surface electrodes and trying carefully to reshape them and form a 4x4 electrode array. These electrodes are carbon rubber rectangular (20mmX10mm) cut down from 20mm circular electrodes. They were placed on the skin with an inter electrode spacing of approximately 3mm. This 4x4 array of active electrodes was placed to cover roughly the tibialis anterior muscle. Two return 45mm square carbon rubber electrodes were used. The system can drive more electrodes but this setup was enough to cover the areas of muscle and nerves of interests, typically

the anterior and lateral lower leg compartments, as discussed in chapter 2 A typical example of electrode array is shown on Figure (3.14).

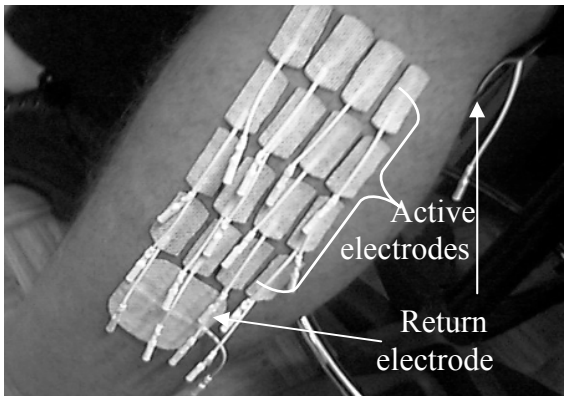


Figure (3.14) - Electrode array example

3.5 Summary

This chapter discussed the design and implementation for the FES "ST32" system developed during this research. The system was built to the specification and requirement stated earlier. It was also designed to meet the British standard and safety requirements for medical equipment (BS EN 60601-1:1990) and (BS EN 60601-2-10:2001) "*particular requirements for the safety of nerve and muscle stimulators*" and it was approved by the Medical Equipment Management Organization (MEMO) of the united Bristol health care trust (UBHT) to be used for patient clinical trials. The system performed very well during the pre-clinical trials with very little problems as will be discussed in chapter 6. The next chapter will present and describe the electrode array optimisation technique and algorithms.

Chapter 4

ELECTRODE ARRAY OPTIMISATION

CHAPTER 4: ELECTRODE ARRAY OPTIMISATION

4.1 Optimisation techniques and problems

Surface electrode stimulation based on using an electrode array was proposed in this research to try to overcome problems associated with using "transcutaneous" surface electrode stimulation such as finding the best stimulation site, irritation, and fatigue as discussed earlier in chapter 1.

When using an electrode array a group of active and return electrodes, there are many electrodes to test to find the best electrode combination that gives the optimum movement. For example, the first electrode array used in this research during the lab trials had 16 active electrodes and two return electrodes and the possible combinations of this array are (16 X 2) which gives 32 different combinations of simple pairs of active and return electrodes. More combinations need to be tested when trying more than combinations of pairs such as triples or quads.

This 16 active and 2 return electrode array was tested on normal control subjects in the early laboratory trials, Figure (4.1). This array placed on top of the groups of muscles of interest to produce the desired dorsiflexion eversion movements. The stimulation system was using the manual switcher box presented in chapter 3 system version-1 to steer the stimulation signal between the electrodes within the array. The evaluation of each of these combinations of electrodes using continuous stimulation and monitoring the movement takes a long time. This is due to ramping up and down of the stimulation signal. In addition, it is known that sometimes it is painful to apply stimulation over certain electrode sites and they are liable to fatigue the muscles. For these reasons, new techniques were needed to reduce or overcome these problems associated with the electrode array optimisation.

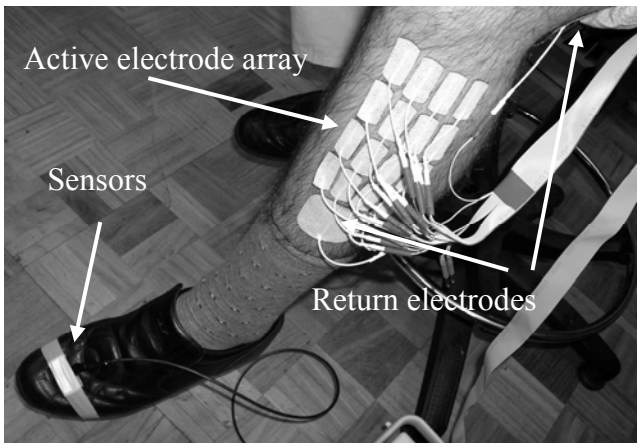


Figure (4.1) – electrode array and sensors

4.2 Monitoring the foot movement

To monitor the foot movement and twitch response several sensors were investigated. The gyroscope and accelerometers presented in chapter 3 were chosen to be the movement monitoring sensors because of their sensitivity, compact design and size and compatibility with microcontroller based embedded systems.

The gyroscope measures the angular velocity or rotation rate of the angle, which can be used to calculate the actual angle. One gyroscope was placed on the foot as shown in Figure (4.2) is used to monitor the ankle dorsiflexion/plantarflexion angle, another gyroscope placed on the foot as shown on the same Figure is to monitor the ankle inversion/eversion angle.

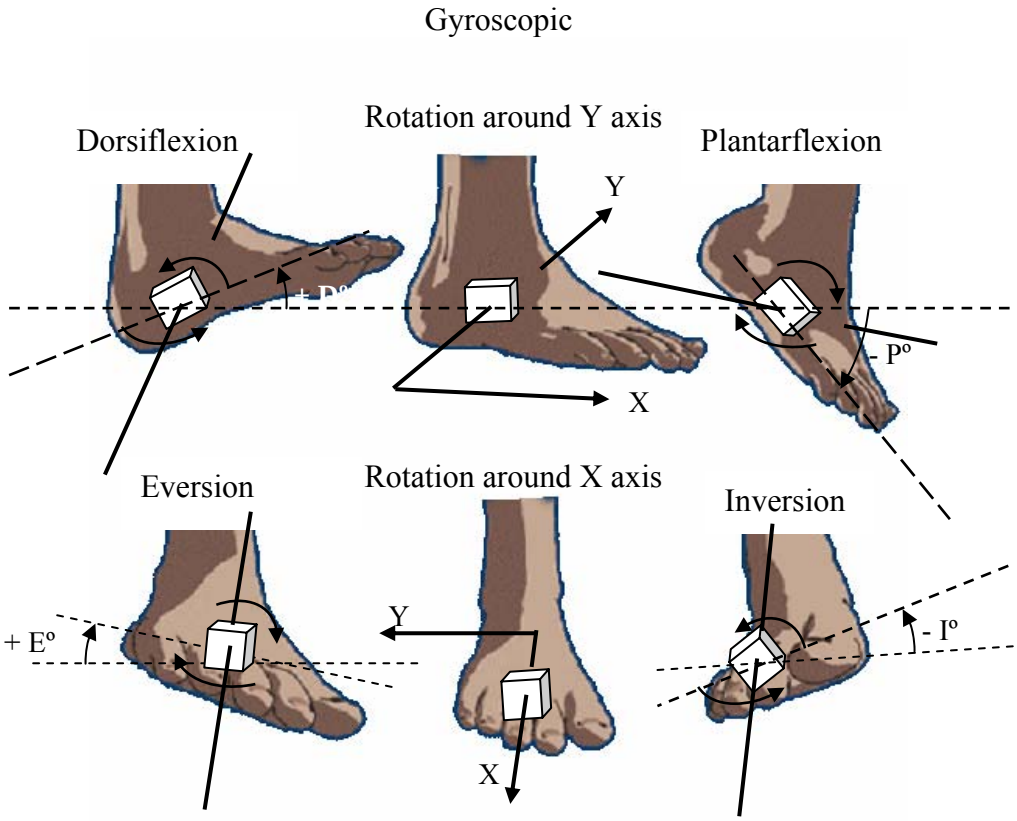


Figure (4.2) – Gyroscope orientation

The accelerometer was dual axis type and it measured both acceleration and tilt angle reference to gravity. Only one accelerometer placed on the foot as shown in Figure (4.3). The X-axis was used to monitor the ankle dorsiflexion/plantarflexion tilt angle reference to gravity and the movement acceleration response and the Y-axis was used to monitor the ankle inversion/eversion tilt angle and the movement acceleration response.

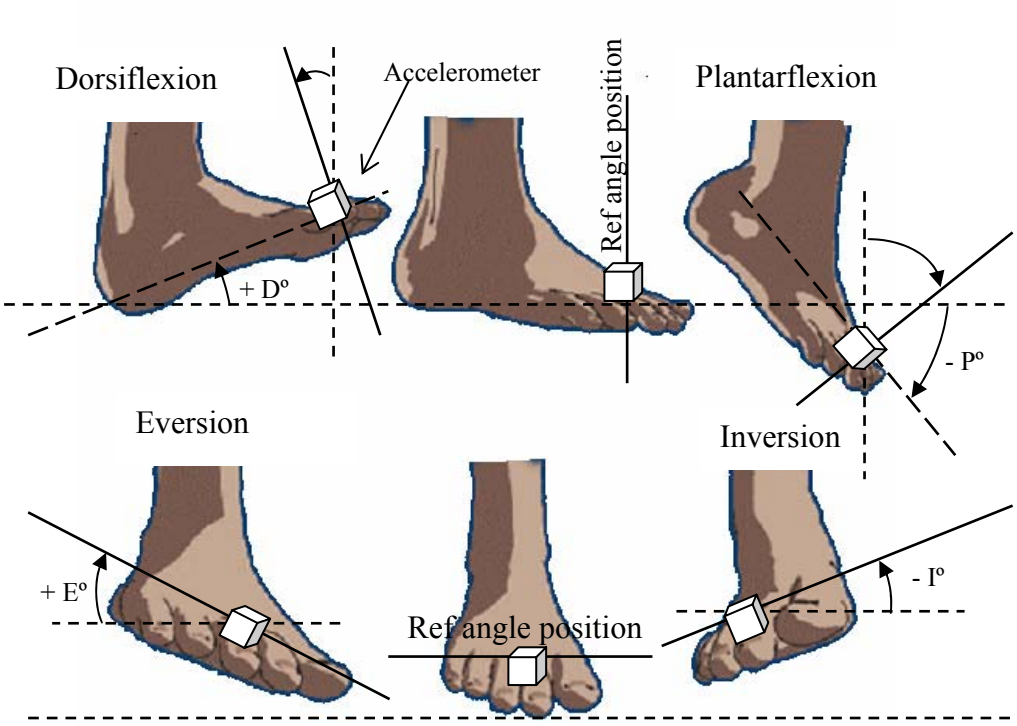


Figure (4.3) – accelerometer orientation

4.3 The twitch response

The single stimulation pulse generates an action potential in the muscle and results in a muscle twitch. When applying a train of pulses tremors start to occur. By increasing the stimulation frequency, the tremor becomes smaller and a tetanic contraction obtained. This is called continuous muscle contraction or "summation of contraction", this was discussed in more details in chapter 1

During the early laboratory investigations, the stimulator output signal was tested using different pulse frequencies (pulse repetition rate) starting from a single "twitch" pulse and then from 5ms to 200ms (5ms step) continuous stimulation. When observing this twitch response from each electrode applying the same pulse parameters it was discovered that a different twitch movement direction responses was obtained for each electrode positions. The response of the twitch stimulation was therefore very interesting and encouraging, as the response of the twitch stimulation could now be used to help in optimising and mapping the electrode array.

A sample of analogue signals from the twitch movement using both an accelerometer and a gyroscope are shown in Figure (4.4). X represents the twitch movement in the dorsiflexion/plantarflexion direction and Y represents the twitch movement in the eversion/inversion direction.

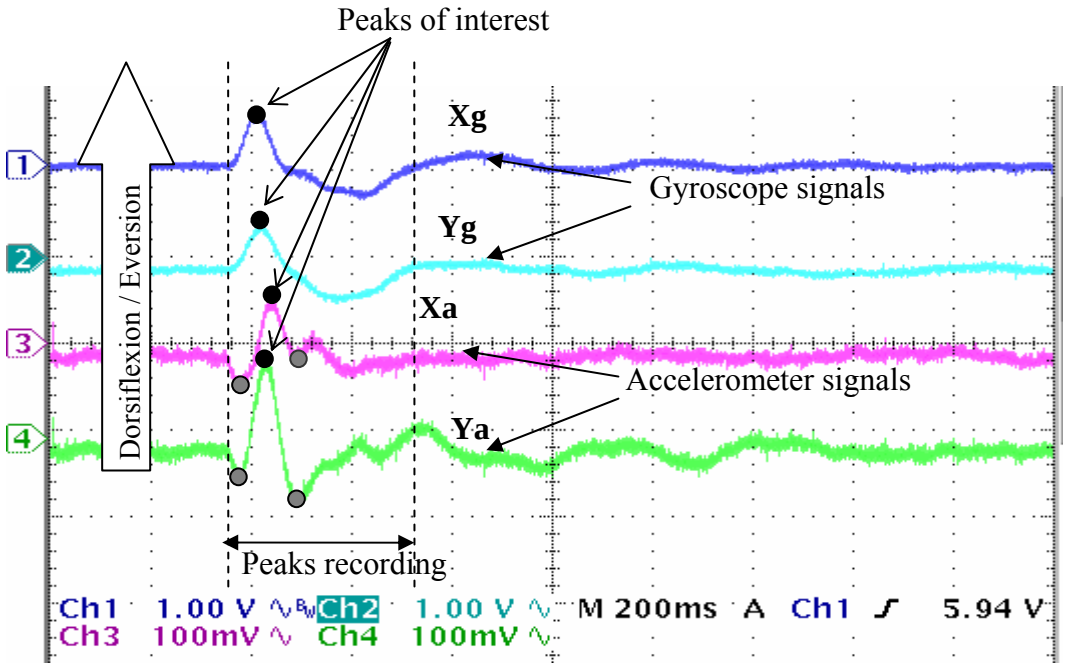


Figure (4.4) –Twitch movement response analogue sensor signals

The gyroscope signals represent the twitch movement angular velocity and the direction for this movement, this was found to be different from electrode to electrode, especially the movement direction. For example, when continuous stimulation was applied to the same electrodes, it produce the response shown in the Figure (4.4), dorsiflexion and eversion were obtained. When testing different electrodes that give plantarflexion or inversion the twitch signal recorded by the accelerometer and gyroscope was the inverse of the one in the Figure (4.4).

The accelerometer signals represent the twitch movement acceleration for both the dorsiflexion/plantarflexion and eversion/inversion movement. The accelerometer sensitivity in detecting the twitch response was better than the gyroscope, and it

captured more detail than the gyroscope signal. When applying the twitch stimulation signal to different electrodes in the array, it produces different acceleration signal responses that contain information about the movement direction due to the polarity and how strong the measured signal peak. That is why the early twitch study focused on using the accelerometers in twitch movement detection and further studies were then performed to compare the recorded signal response to the continuous stimulation response.

4.3.1 Twitch response vs. continuous stimulation response

Twitch response in the laboratory testing was carried out in four steps. The first was to choose the appropriate twitch stimulation signal parameters for a particular control subject, which would give a clear observed twitch response as measured by oscilloscope, stimulation system and by eye. The second step was recording the twitch response acceleration using the accelerometer from each combination of pairs of electrodes within the array. The third step was to apply continuous stimulation and observe the movement from each electrode in the twitch test, to help to identify the observed continuous response, i.e. Dorsiflexion/plantarflexion and inversion/eversion. The measurements were assessed by eye and ranked using the following arbitrary scale:

0 – No visible contraction
1 – Visible contraction but no clear movement
2 – Partial weak movement performed in the direction specified
3 – Normal movement performed in the direction specified
4 – Strong movement performed. In the direction specified

The fourth step was to study and analyse each twitch and continuous stimulation response data obtained from the same combination of electrodes. At the beginning of the analysis stage, the twitch acceleration response was not clear because of the acceleration peaks (spikes) positive and negative polarity.

As shown in Figure (4.5) The accelerometer twitch signal often started with a small movement in the opposite direction of the actual twitch movement, which generated acceleration peak (peak-1) response some time similar to the twitch acceleration peak (peak-2) response but in the opposite direction. Due to these artefacts, the value of the second acceleration signal peak was the one that used to predict the continuous movement.

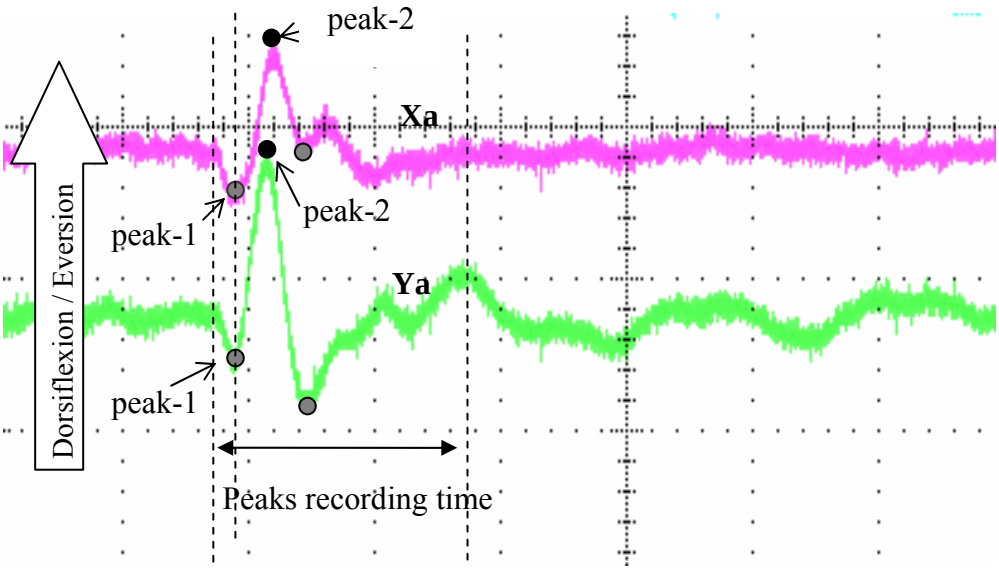


Figure (4.5) – Accelerometer twitch response signal

The twitch acceleration signals obtained from early tests on normals compared well to the movement obtained with continuous using the same electrode combination. Table (4.1) shows a typical set of data obtained from a control subject during the laboratory trial. This shows the recorded twitch stimulation second acceleration peak and the observed continuous stimulation movement. An array of 16 active electrodes placed on top of the "tibialis anterior" muscle with one return electrode behind the knee. The subject was seated with foot relaxing and not touching the ground. To help understand the results in Table (4.1) a graphical form of these results are presented in Figure (4.6), where the twitch acceleration response recorded from each electrode in the (16x1) array are in the top graph and the observed continuous stimulation scoring for each electrode are in the bottom graph.

Electrode Number	Twitch Acceleration mV + Dorsiflexion - Plantarflexion	Continuous scoring* + Dorsiflexion - Plantarflexion	Twitch Acceleration mV + Eversion - inversion	Continuous scoring* + Eversion - inversion
1	-200	-1	-50	-3
2	150	2	-20	-2
3	25	0	100	3
4	250	3	280	4
5	150	2	-90	-3
6	90	2	-10	0
7	80	0	110	4
8	80	0	100	3
9	100	3	-60	-3
10	110	3	10	-2
11	10	0	90	3
12	5	0	90	3
13	100	3	0	-1
14	110	3	0	-1
15	0	0	0	0
16	0	0	0	0
*No contraction = 0, Absent movement = 1, Weak = 2, Normal = 3, Strong = 4				

Table (4.1) – Twitch acceleration responses and observed movement scoring for control subject 1

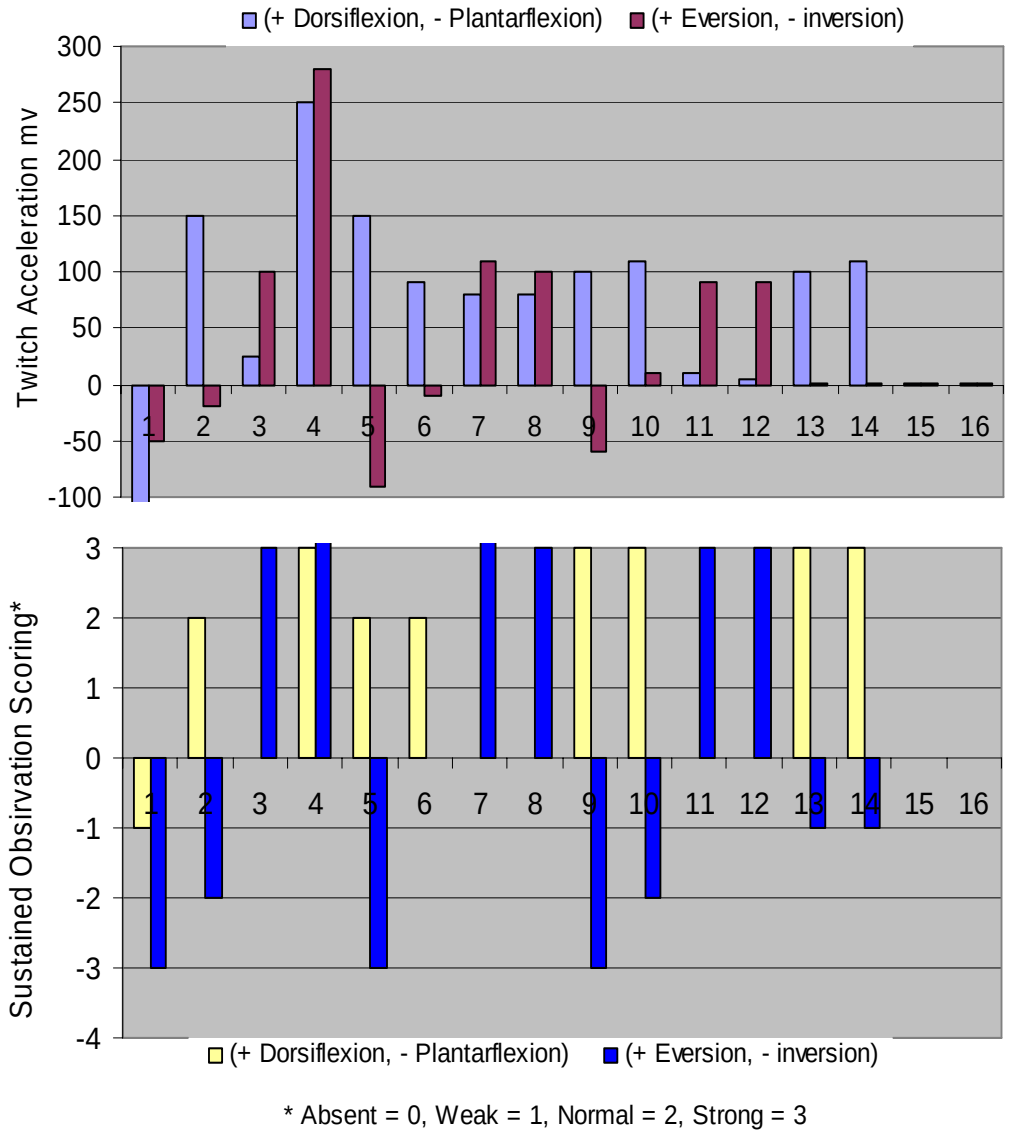


Figure (4.6)-Graphical format of data in Table 1

By examining the data, there was a clear relationship between the twitch response and the continuous response. To find how strongly they related, Pearsons's correlation coefficient was calculated between the observed sustained movement and the twitch response using Equation (4.1) Where, $1 \leq n \leq 16$.

$$Correl(X,Y) = \frac{\sum (Xn - \overline{Xn})(Yn - \overline{Yn})}{\sqrt{\sum (Xn - \overline{Xn})^2 \sum (Yn - \overline{Yn})^2}} \quad \textbf{Equation (4.1)}$$

The R correlation coefficient calculation results was, R correlation = 0.77 for the Dorsiflexion / Plantarflexion movement as shown in Figure 4.7, and 0.88 for the Eversion / Inversion movement.

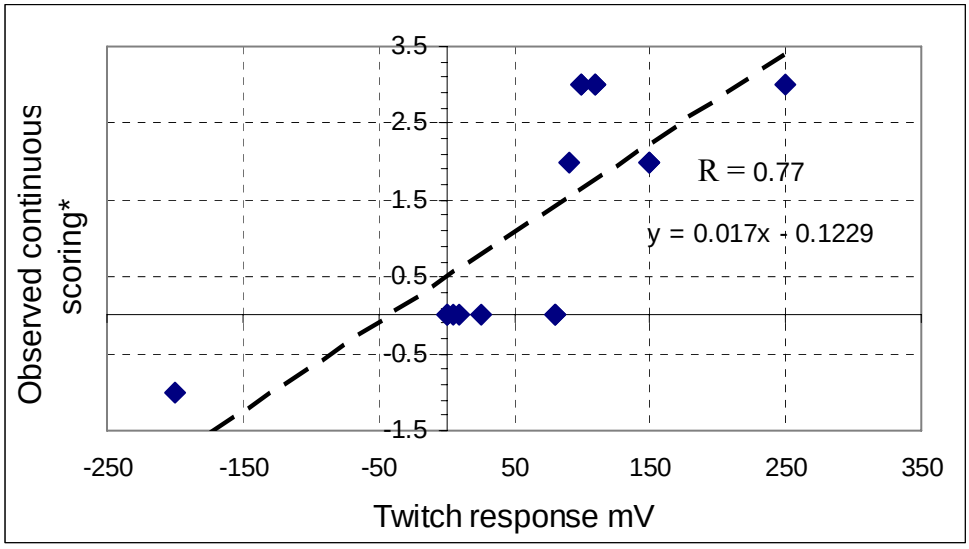


Figure (4.7) – Dorsiflexion/plantarflexion twitch/continuous movement correlation

When the correlation calculation is recalculated after considering the responses that indicates dorsiflexion or eversion and neglecting all responses from both twitch and continuous that indicates unwanted plantarflexion and inversion movements (all negative values), the correlation coefficient was as follows; (Dorsiflexion) R correlation = 0.75, (Eversion) R correlation = 0.80.

Reasonably good correlation was found from this control subject when considering or neglecting the unwanted plantarflexion and inversion movements.

4.4 Twitch response Laboratory testing

To study the relationship between the twitch and continuous response, the same test were applied to 12 normal healthy control subject 4 Females and 8 Males, age range 18 - 56 , weight 53 - 102Kg, and height 155-185cm, Table (4.2). The correlation calculations for each subject are presented in Table (4.3) and graphical format for the correlation results are presented in Figure (4.8) and (4.9).

Subject number	Gender	Age	Weight kg	Height cm
1	**Male**	**18**	**60**	**165**
2	**Male**	**42**	**85**	**175**
3	**Male**	**41**	**82**	**174**
4	**Female**	**26**	**53**	**160**
5	**Female**	**56**	**102**	**160**
6	**Female**	**29**	**82**	**175**
7	**Male**	**21**	**75**	**183**
8	**Male**	**22**	**93**	**171**
9	**Male**	**36**	**90**	**179**
10	**Male**	**27**	**80**	**160**
11	**Female**	**26**	**60**	**160**
12	**Male**	**26**	**85**	**171**
Mean	**4F/8M**	**30.833**	**78.917**	**169.417**

Table (4.2) – Laboratory trial 12 subjects

Control Subject number	Dorsiflexion Plantarflexion Correlation	Eversion Inversion Correlation	Dorsiflexion Correlation	Eversion Correlation
1	0.766	0.884	0.752	0.797
2	0.886	0.800	0.886	0.735
3	0.937	0.984	0.917	0.997
4	0.859	0.558	0.849	0.882
5	0.378	0.609	0.378	0.839
6	0.813	0.888	0.813	0.891
7	0.945	0.938	0.938	0.886
8	0.742	0.701	0.470	0.495
9	0.897	0.817	0.539	0.632
10	0.657	0.854	0.657	0.443
11	0.679	0.777	0.488	0.785
12	0.790	0.823	0.790	0.696
Average	0.779	0.706	0.803	0.756

Table (4.3) – correlation results for all 12 subjects

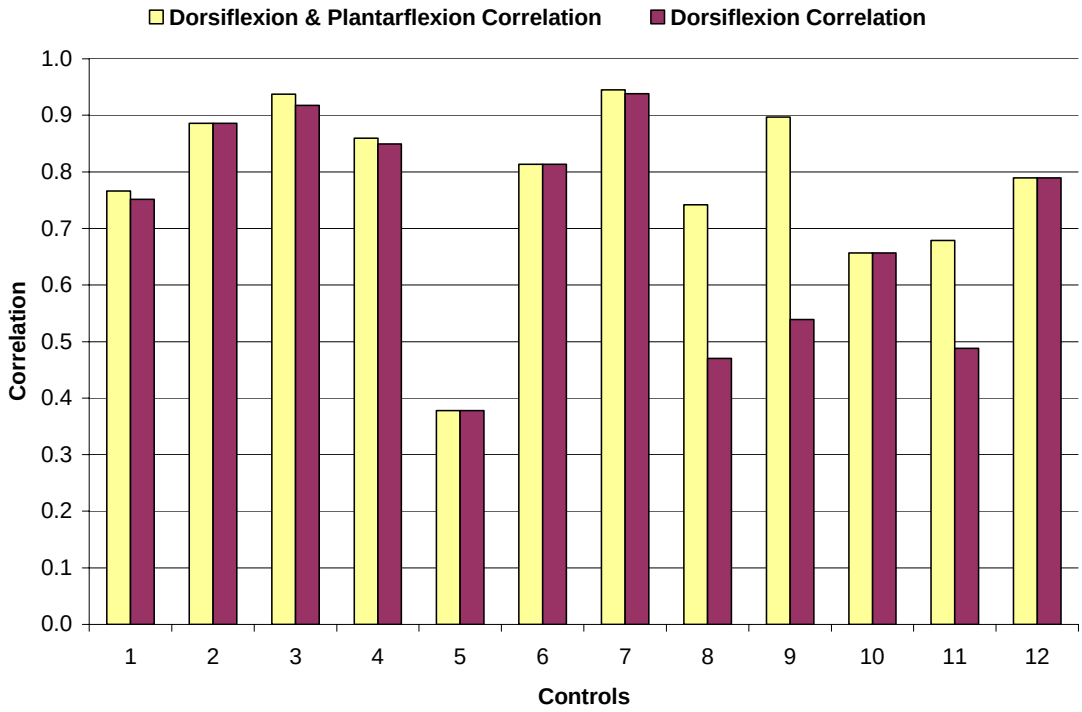


Figure (4.8) – dorsiflexion/plantarflexion correlation results for all 12 subjects

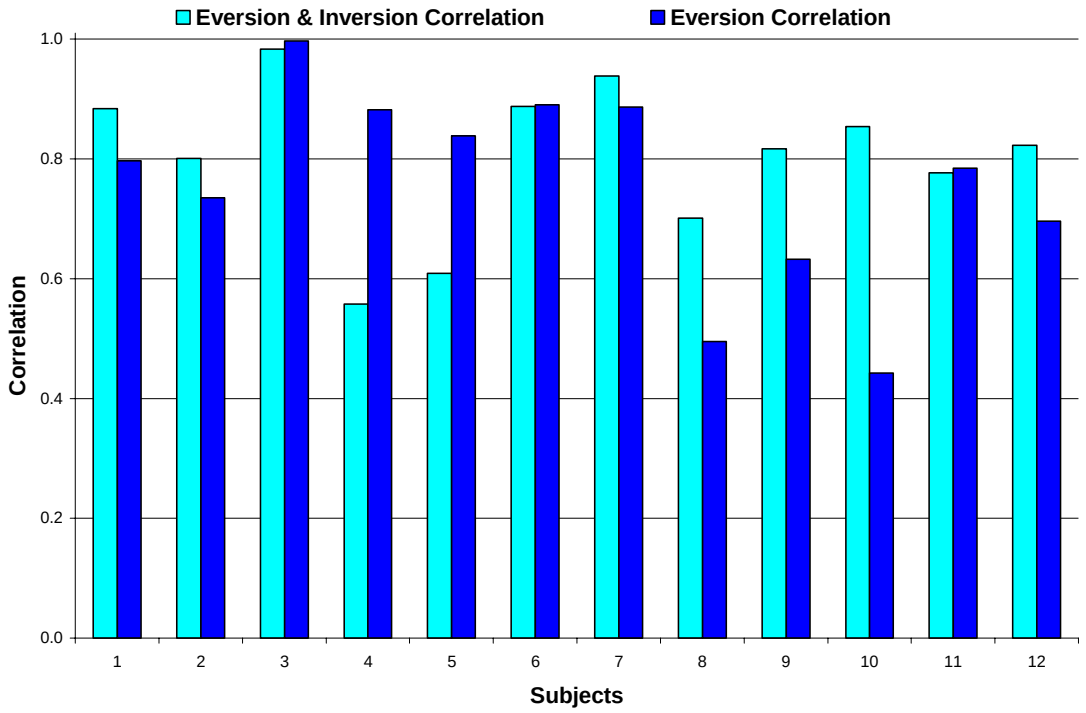


Figure (4.9) – Eversion/inversion correlation results for all 12 subjects

From these data, it is clear that there is a high correlation in more than half of the subjects between the twitch and continuous stimulation response. This gives rise to the possibility of using the twitch stimulation response instead of continuous stimulation to optimise the electrode array.

4.5 Twitch signal problems and solutions

In some subjects there was poor twitch response and continuous stimulation correlation, and due to this it will not be very accurate to use the twitch response in optimising the electrode array. However, after studying the acceleration signals that gave poor correlations, the problem was found to be mainly due to noise and the accuracy of recording the acceleration.

The accelerometer is very sensitive, sometimes it record noise, and spikes as shown in Figure (4.10). These will affect the recorded acceleration and it should be neglected when determining the acceleration peaks.

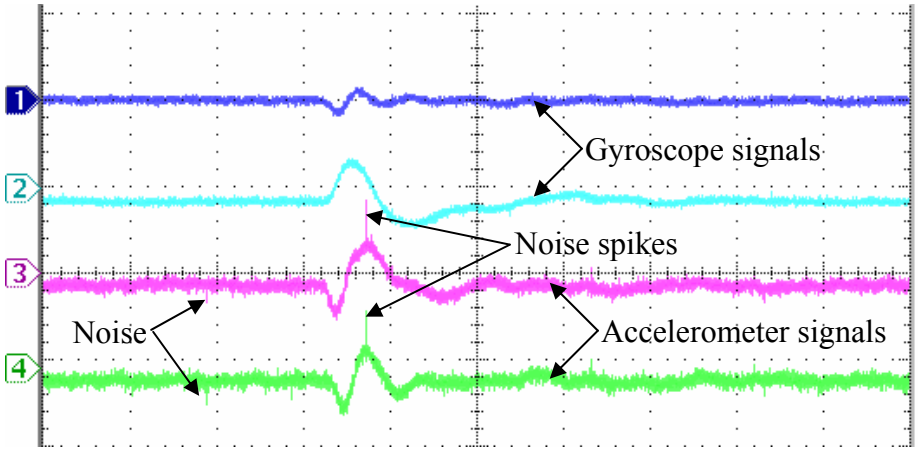


Figure (4.10) – Accelerometer twitch signal show noise spikes

As discussed earlier the second peak is the one that gave the correct twitch movement information that correlated strongly with the continuous movement. The peak detection algorithm ensures that it is the correct second peak that is recorded and that it is not missed due to any unusual peaks. The system will wait after firing each twitch for at least 2s to make sure that there is no noise or amplitude variations in the baseline accelerometer signals due to foot movements. The system was designed to record the first 3 peaks in the twitch acceleration signal. The peak recording algorithm also insure that the recorded peak are not within the noise level and the recorded signal have smooth normal rise and fall time. Chart (4.1) shows how this algorithm works.

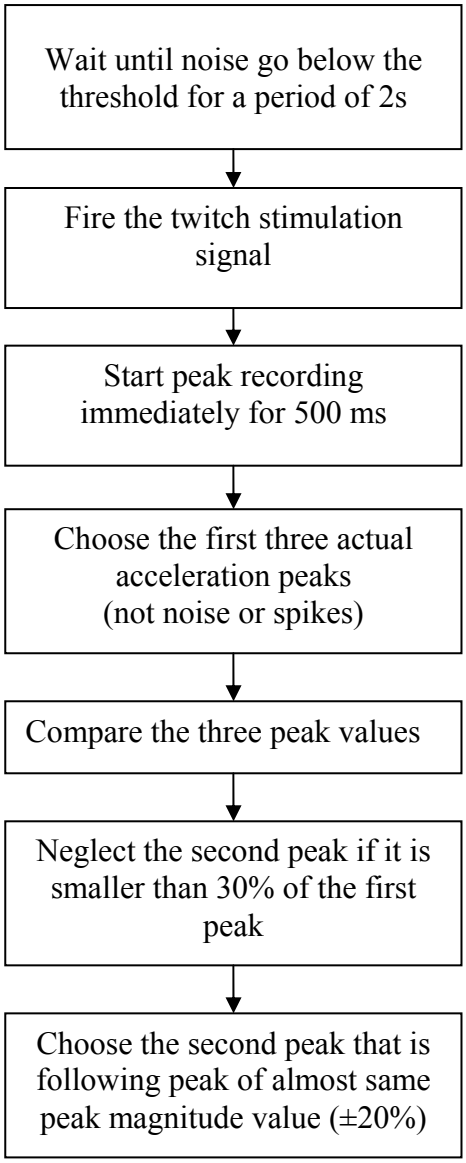


Chart (4.1) – peak recording algorithm

When applying this peak recognition and recording algorithm to the accelerometer signal recorded from these 12 subjects, better correlation was obtained in some subjects as shown in Table (4.4).and Table (4.5). If no improvement was found, effectively the correlation was left unchanged and this was recorded as a 0% improvement.

Control Subject number	Old Dorsiflexion Correlation	New Dorsiflexion Correlation	Percentage of improvement %
1	0.752	0.776	3.2%
2	0.886	0.886	0.0%
3	0.917	0.917	0.0%
4	0.849	0.892	5.1%
5	0.378	0.880	132.8%
6	0.813	0.813	0.0%
7	0.938	0.938	0.0%
8	0.470	0.819	74.3%
9	0.539	0.539	0.0%
10	0.657	0.657	0.0%
11	0.488	0.488	0.0%
12	0.790	0.809	2.4%
Average	0.706	0.784	11.0%

Table (4.4) – New correlation after applying peak recording algorithm

Table (4.4) shows a comparison between the new correlation and the old correlation results. There is clear correlation improvement in many subjects after applying the peak recording algorithm, and the general average improvement was 11 % for the dorsiflexion correlation and 5.2% for the eversion correlation. This shows that using this recording algorithm improves the optimisation process accuracy.

Control Subject number	Old Eversion Correlation	New Eversion Correlation	Percentage of improvement
1	0.797	0.981	23.1%
2	0.735	0.735	0.0%
3	0.997	0.997	0.0%
4	0.882	0.882	0.0%
5	0.839	0.839	0.0%
6	0.891	0.955	7.2%
7	0.886	0.886	0.0%
8	0.495	0.745	50.5%
9	0.632	0.632	0.0%
10	0.443	0.443	0.0%
11	0.785	0.663	-15.5%
12	0.696	0.785	12.8%
Average	0.756	0.795	5.2%

Table (4.5) – New and old correlation result comparison

4.6 Laboratory trials

The aims of these trials were to test the ST32 system, to confirm the effectiveness in using the twitch response and to develop the optimisation algorithm. The outcome of these trials was mainly the base of the optimisation algorithm development explained earlier in this chapter. These trials took place in the engineering lab on eight healthy normal subjects, the details for these subjects are shown in Table (4.6).

Subject number	Gender	Age	Weight kg	Height cm
1	**M**	**26**	**78**	**181**
2	**F**	**31**	**71**	**175**
3	**M**	**25**	**85**	**168**
4	**M**	**23**	**78**	**165**
5	**M**	**28**	**79**	**173**
6	**M**	**25**	**70**	**169**
7	**M**	**36**	**65**	**173**
8	**F**	**24**	**75**	**179**

Table (4.6) – Lab trial normal subject's details

In these trials the test was done on the left leg and the subject was asked to sit on a chair higher from the floor (i.e. foot not touching the floor) with foot relaxed in the plantarflexion relaxing position. The tests were done on the left leg using 4x4 active electrodes placed roughly on top of the tibialis anterior muscle and one return electrode behind the knee or at the end of the tibialis anterior motor point.

Both continuous stimulation and twitch stimulation were applied to each electrode. During these tests the ST32 stimulation performance was excellent as it provide all the required stimulation signals parameters ranges, also the stimulation was very comfortable.

4.6.1 Continuous and twitch stimulation movement recording

The same method explained in section (4.3.1) was used to record the twitch stimulation acceleration response from the accelerometer signal after applying the signal processing algorithm. Additionally the same method was used to observe the continuous stimulation movement but the visual ranking score was reduced to Absent = 0, Weak = 1, Normal = 2, Strong = 3.

The correlation between the obtained twitch and continuous stimulation test results was calculated same as in section (4.3.1). The correlation results from all the eight subjects are presented in Table (4.7).

Control Subject number	Dorsiflexion Plantarflexion Correlation	Eversion Inversion Correlation	Dorsiflexion Correlation	Eversion Correlation
1	0.950	0.909	0.907	0.779
2	0.939	0.919	0.934	0.862
3	0.909	0.863	0.841	0.757
4	0.956	0.907	0.895	0.742
5	0.840	0.931	0.806	0.782
6	0.912	0.876	0.874	0.838
7	0.699	0.884	0.841	0.679
8	0.941	0.909	0.939	0.884

Table (4.7) - Twitch and continuous correlation result for all 8 subjects

The high correlations found for all the 8 subjects confirms the concept of using the twitch accelerating response to optimise the electrode array, but still to be tested and approved on real patients.

4.6.2 Electrode array mapping

The electrode array optimisation algorithm was originally based on these laboratory test trials. In these trials every single (active) electrode within the array was tested using continuous stimulation as explained before to compare it to the twitch response. These continuous response data for all the 8 subjects are shown on the electrode map Figure (4.11). These maps indicate the observed movement obtained (dorsiflexion, eversion, plantarflexion, inversion) by continuous stimulation from every electrode in the array.

As explained earlier a score was giving according to the strength of observed contraction, absent = 0, weak = 1, normal = 2, strong = 3. These results were plotted in the following format for each electrode:

D	P
E	I

Where:
D = Dorsiflexion
E = Eversion
P = Plantarflexion
I = Inversion

This means that data that produces the "wanted" movement ie: Dorsiflexion and Eversion will appear on the left hand side.

The continuous stimulation using single (active) electrode results show that in some subjects it was difficult to obtain good dorsiflexion with some eversion. For this reason all possible combination of pairs of active electrodes was tested. The best pair of electrodes was chosen on the basis of obtaining the desired comfortable dorsiflexion/eversion movement; this was achieved by trying each combination of paired electrodes in turn. The chosen pair of electrodes is highlighted in a different colour on the same maps. The box at the top of the active 4x4 electrode array map indicates the use of a return electrode behind the knee, the box at the bottom of the map indicates using the return electrode at the lower end of the tibialis anterior muscle.

These maps were generated to see if there was evidence that the selected combination of electrodes selects similar patterns of electrodes between subjects and to see if there were other electrodes that might, in combination, be used to effect a similar overall movement for the same subject. By examining these maps it is clear that not withstanding the different physical differences in geometry of different people, that there is no clear electrode pair that contributes to an overall pattern. Each electrode pair chosen shows unique differences. The chosen electrode pair after ranking mainly includes dorsiflexion and eversion movements, with small differences in N2 and N8, which show inverter movement, N1 shows evidence of one electrode with plantar movement selected. The results also show that it may be possible to combine electrodes that have everter and inverter movement so that they cancel out whilst still giving dorsiflexion.

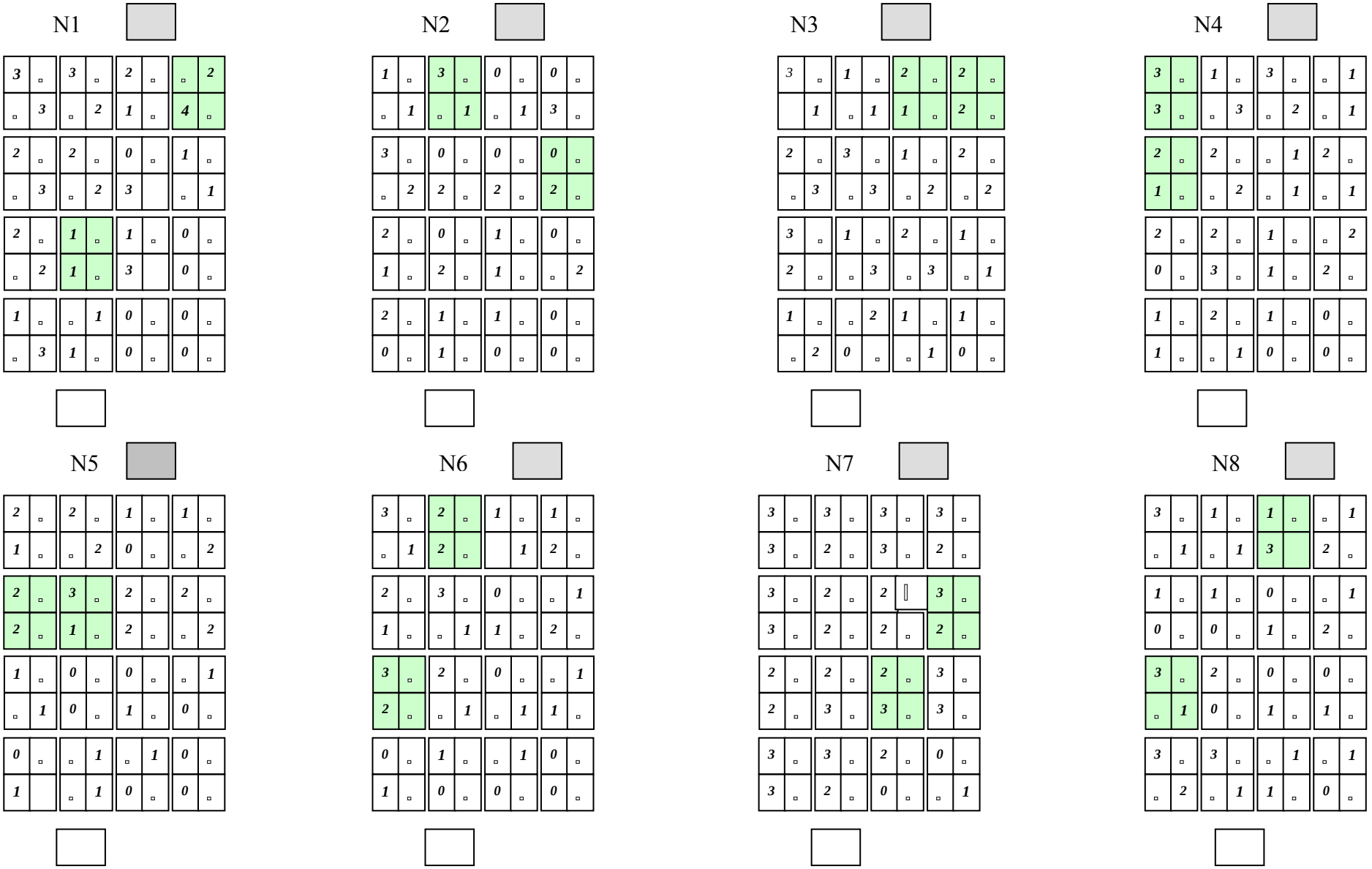


Figure (4.11) – Normal Subjects Electrode Optimisation Map

4.7 Electrode array optimisation algorithm

Various optimisation techniques were investigated based on the twitch response including using combinations of electrodes and comparing the twitch acceleration response to that obtained with continuous stimulation. The best optimisation result was obtained when using a trial and error algorithm that used a mixture of the individual electrode twitch responses and the continuous movement response of combinations of electrodes.

The following section explains in details how the electrode optimisation algorithm worked. It is important to mention that the algorithm presented in this section was the latest version after a long investigation and development during the laboratory and the clinical trials, Chapter (5, 6).

4.7.1 First step:

The first step in the electrode optimisation process was to specify the numbers of electrodes used and work out all combinations of pairs between these active and return electrodes.

The ST32 system could use up to 32 channels; 24 channels were used to drive active electrodes and 8 used to drive 8 return electrodes as shown in Figure (4.12). The number of combinations between each active and return electrode was 24 x 8 = 192, and the combinations will be as follow (25 & 1, 25 & 2, 25 & 3……25&24), (26&1, 26 & 2, 26 & 3….26&24) …… (32&1, 32& 2, 32 &3……..32&24)

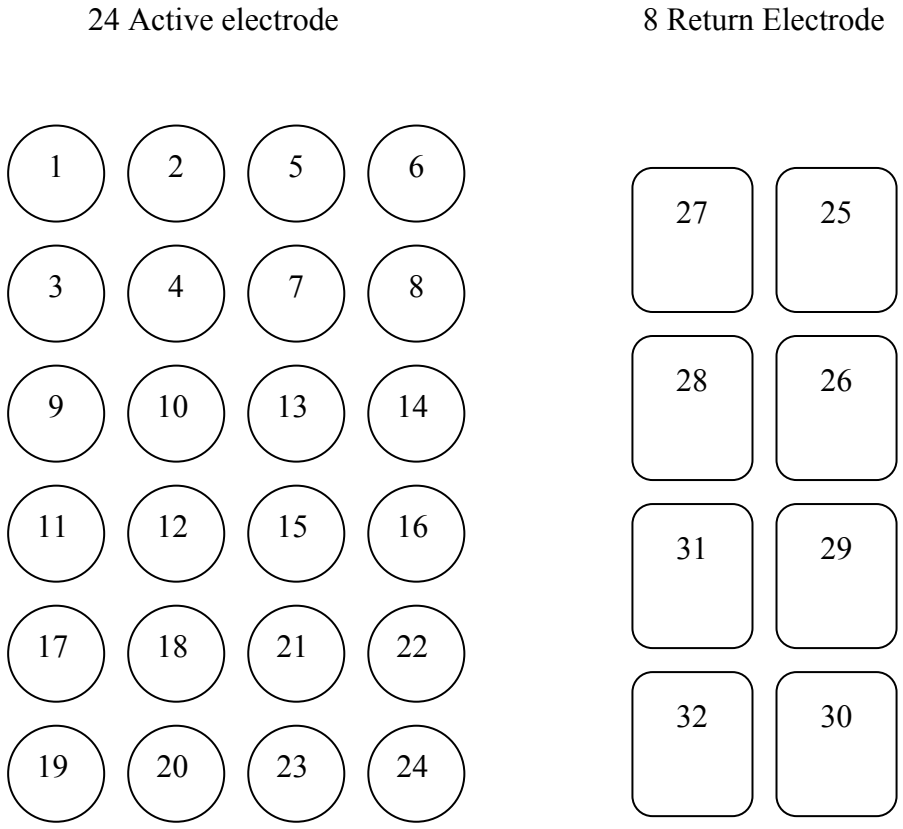


Figure (4.12) – Electrode array

4.7.2 Second step:

The second step was to send a twitch stimulation signal with the tuned twitch pulse to each combination of electrodes.

Before firing this twitch signal, it was important to make sure there was no noise or signal detected by the accelerometer due to any activity like involuntary movement or any vibration or unexpected movement due to the previous twitch. The twitch response can last up to 1 second, only the first 500 μs carry useful information. A waiting period of at least 2 seconds between the twitches was found to be required to allow the muscle to relax preventing any possibility of mixing twitches responses.

After the inactivity-waiting period the stimulator would fire the twitch and then record the first three peaks in the twitch acceleration signal from both the X and Y accelerometer sensors. This was repeated for each electrode combination and the twitch feedback data was saved.

4.7.3 Third step:

The third step applied the peak recording algorithm presented in section (4.5) to the accelerometer signal peaks data saved during last step.

4.7.4 Fourth step:

This fourth step processed the chosen acceleration peaks data.
- For X axis the selected peak may be +ve = dorsiflexion or -ve = plantarflexion.
- For Y axis the selected peak may be +ve = eversion or -ve = inversion

Example
An example of the data obtained from the last step is presented in Table (4.8).

Electrode combination	Accelerometer X Dorsiflexion (+) Plantarflexion (-)	Accelerometer Y Eversion (+) Inversion (-)
(25,1)	+ 49	-12
(25,2)	+ 85	+27
=	=	=
(27,23)	+ 9	+ 5
(27,24)	- 7	-35
(28,1)	+ 65	+23
(28,2)	+ 53	+20
=	=	=
(32,23)	-28	- 5
(32,24)	0	0

Table (4.8) -Example of peak processing data

4.7.5 Fifth step:

These data obtained from the fourth step were ranked into four (strong, normal, weak, nothing). This ranking depended on the twitch acceleration response and it was different from the ranking procedure explained earlier for the continuous movement observation.

The ranks were defined by finding the maximum +ve and –ve acceleration responses and the minimum value, which was usually zero. The difference between the maximum and minimum was then divided into 4 and each quarter of the difference represented 1 rank. This ranking process was applied separately for each of the X-axis data that represented dorsiflexion and plantarflexion and the Y-axis data that represented the eversion and inversion.

Example

In this example the ranking algorithm was applied to the data in Table (4.8), and assumed that this data contained all maximum and minimum values for all different responses

The dorsiflexion maximum value is 85 and minimum is zero, therefore (85 – 0)/4 = 21.25 per rank.

0 - 21.25	21.25 - 42.5	42.25 - 63.75	63.75 - 85
Nothing	Weak	Normal	Strong

The plantarflexion maximum value is 28 and minimum is zero, therefore (28 – 0)/4 = 7 per rank.

0 - 7	7 - 14	14 - 21	21 - 28
Nothing	Weak	Normal	Strong

The eversion maximum value is 27 and minimum is zero, therefore (27 – 0)/4 = 6.75 per rank.

0 - 6.75	6.75 - 13.5	13.5 - 20.25	20.25 - 27
Nothing	Weak	Normal	Strong

The inversion maximum value is 35 and minimum is zero, therefore (35 – 0)/4 = 8.75 per rank.

0 - 8.75	8.75 - 17.5	17.5 - 26.25	26.25 - 35
Nothing	Weak	Normal	Strong

The results of the ranking of this example are shown in Table (4.9).

Electrode combination	Accelerometer X Dorsiflexion (+) Plantarflexion (-)	Accelerometer Y Eversion (+) Inversion (-)
(25,1)	+ D Normal	- I Weak
(25,2)	+ D Strong	+ E Strong
=	=	=
(27,23)	Nothing	Nothing
(27,24)	- P Weak	- I Strong
(28,1)	+ D Strong	+ E Strong
(28,2)	+ D Normal	+ E Normal
=	=	=
(32,23)	- P Strong	Nothing
(32,24)	Nothing	Nothing

Table (4.9) – Ranked data example

4.7.6 Sixth step:

In the sixth step, every active and return electrode combination would have a dorsiflexion/ plantarflexion rank and eversion/ inversion rank. The algorithm assumed "combination numbers" for all theoretically possible ranking combinations are as follows:

1. Strong D & strong E
2. Strong D & normal E
3. Strong D & weak E
4. Strong D & nothing
5. Strong D & strong I
6. Strong D & normal I
7. Strong D & weak I

Strong Dorsiflexion & any other movement

8. Normal D & strong E
9. Normal D & normal E
10. Normal D & weak E
11. Normal D & nothing
12. Normal D & strong I
13. Normal D & normal I
14. Normal D & weak I

Normal Dorsiflexion & any other movement

15. Weak D & strong E
16. Weak D & normal E
17. Weak D & weak E
18. Weak D & nothing
19. Weak D & strong I
20. Weak D & normal I
21. Weak D & weak I

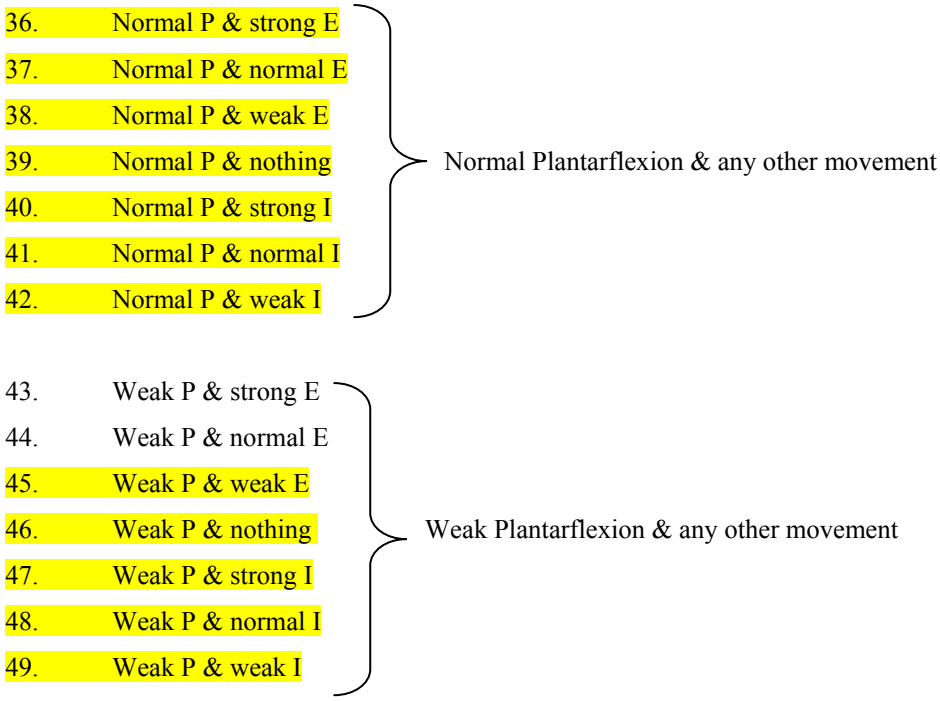
Weak Dorsiflexion & any other movement

22. Nothing & strong E
23. Nothing & normal E
24. Nothing & weak E
25. Nothing & Nothing
26. Nothing & strong I
27. Nothing & normal I
28. Nothing & weak I

Nothing & any other movement

29. Strong P & strong E
30. Strong P & normal E
31. Strong P & weak E
32. Strong P & nothing
33. Strong P & strong I
34. Strong P & normal I
35. Strong P & weak I

strong Plantarflexion & any other movement



The optimisation Algorithm was designed to look for the combinations that gave good dorsiflexion and some eversion. The highlighted combinations were expected to produce unwanted movement (plantarflexion or inversion) and this was proven during the laboratory trials and clinical trials as discussed later in chapter 6. By neglecting these highlighted combinations and keeping the combinations that give dorsiflexion and/or eversion, the combinations number reduced from 49 to 22.

As a result of the laboratory and clinical trials a ranking process was developed to rearrange or rank these remaining combinations from best to worst for the optimum electrode combinations as shown in Table (4.10):

Rank	Original combination number	
1	2	Strong D & normal E
2	3	Strong D & weak E
3	4	Strong D & nothing
4	1	Strong D & strong E
5	9	Normal D & normal E
6	10	Normal D & weak E
7	11	Normal D & nothing
8	8	Normal D & strong E
9	7	Strong D & weak I
10	14	Normal D & weak I
11	6	Strong D & normal I
12	5	Strong D & strong I
13	15	Weak D & strong E
14	16	Weak D & normal E
15	17	Weak D & weak E
16	18	Weak D & nothing
17	21	Weak D & weak I
18	22	Nothing & strong E
19	23	Nothing & normal E
20	24	Nothing & weak E
21	43	Weak P & strong E
22	44	Weak P & normal E

Table (4.10) – Optimum electrode combinations ranking

Example

From the previous example, Table (4.9), these are the available combination:

Combination number	Electrode numbers	Combination response
14	(25,1)	+ D Normal, - I Weak
1	(25,2)	+ D Strong, + E Strong
25	(27,23)	Nothing, Nothing
47	(27,24)	- P Weak, - I Strong
1	(28,1)	+ D Strong, + E Strong
9	(28,2)	+ D Normal, + E Normal
32	(32,23)	- P Strong, Nothing
25	(32,24)	Nothing, Nothing

After neglecting the unwanted responses and ranking the remaining combination are presented in Table (4.11):

Combination rank	Original Combination number	Electrode numbers	Combination response
3	14	(25,1)	+ D Normal, - I Weak
1	1	(25,2)	+ D Strong, + E Strong
1	1	(28,1)	+ D Strong, + E Strong
2	9	(28,2)	+ D Normal, + E Normal

Table (4.11) – Ranked remaining combinations

4.7.7 Seventh step:

In the seventh step, the electrode combinations were ranked in order of the desired good dorsiflexion and/or eversion movement according to the trials. However, not all these ranks gave dorsiflexion and eversion together. Trials using this technique prove the effectiveness in using groups that mix the electrode combinations that produce dorsiflexion and eversion. These groups can be groups of two, three, or four combinations, but it was found that when using more combinations i.e. more electrodes, the process became more complicated, and the resulting movement become more difficult to predict based on the individual movement combination responses. Also because of the size of the electrodes used (2 cm x 1 cm) during the trials there was the possibility of fatiguing the muscle because of stimulation at different sites at the same time and repeating the stimulation. For these reasons, the algorithm formed groups of two combinations of electrodes, which was found to give the desired movement as discussed in the results later on chapter 5 and 6. These groups were put in order from 1 to 15 as shown below according to the existence and availability of the combinations in Table (4.10). It should be noted that these 15 groups may contain in practice two electrodes, three electrodes, or four electrodes, depending on whether one or two return electrodes are used. By using more return electrodes increased the combinations of getting a repeated movement.

Optimisation grouping results:

1) First available + repeated* first available
2) First available (or repeated) + second available (or repeated)
3) First available (or repeated) + third available(or repeated)
4) First available (or repeated) + fourth available(or repeated)
5) First available (or repeated) + fifth available (or repeated)
6) Second available + repeated second available
7) Second available (or repeated) + third available (or repeated)
8) Second available (or repeated) + fourth available (or repeated)
9) Second available (or repeated) + fifth available (or repeated)
10) Third available + repeated third available
11) Third available (or repeated) + fourth available (or repeated)

12) Third available (or repeated) + fifth available (or repeated)
13) Fourth available + repeated fourth available
14) Fourth available (or repeated) + fifth available (or repeated)
15) Fifth available + repeated fifth available

Repeated* in the above, means that different electrodes combination gives almost the same movement results.

These 15 groups are out of all the possible combinations of groups which originally were 49 possible combinations of response representing 192 electrode combinations. These possible 49 combinations can form (49x49) = 2401 groups of combination. So these 15 groups were chosen out of the total 2401 possible combination groups.

Example

Applying this grouping algorithm to the example presented in Table (4.9) gives these electrode groups ranked as :

1) (25,2) + (28,1)
2) (25,2) + (28,2)
3) (28,1) + (28,2)
4) (25,2) + (25,1)
5) (28,1) + (25,1)
6) (28,2) + (25,1)

4.7.8 Final step:

The final selection of the best pair of active electrodes from the 15 groups of electrodes selected by the algorithm depended on a final user test with the physiotherapist using the continuous stimulation and observing the movement obtained and recording whether the stimulation was comfortable.

A summary of the optimisation algorithm is shown in Chart (4.2).

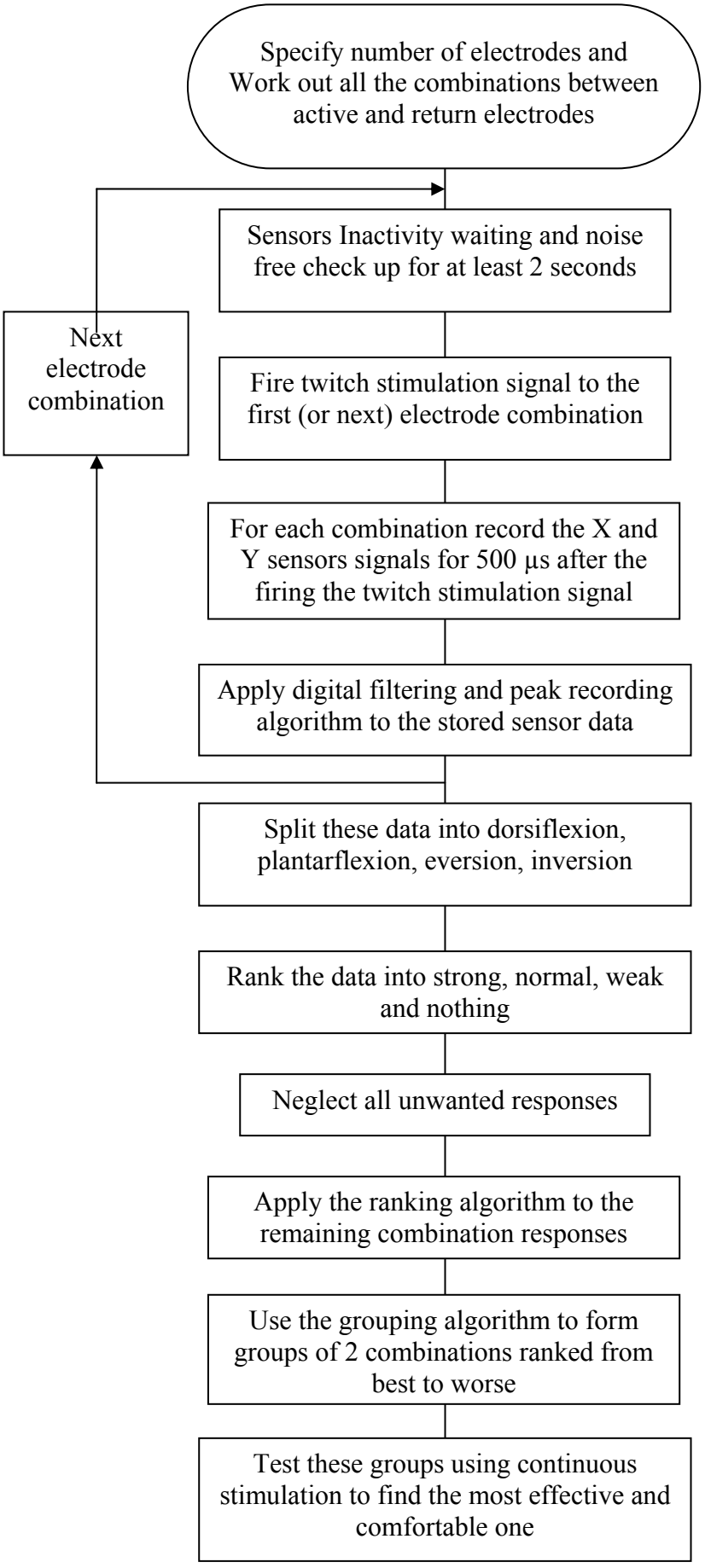

Specify number of electrodes and Work out all the combinations between active and return electrodes
Sensors Inactivity waiting and noise free check up for at least 2 seconds
Next electrode combination
Fire twitch stimulation signal to the first (or next) electrode combination
For each combination record the X and Y sensors signals for 500 μs after the firing the twitch stimulation signal
Apply digital filtering and peak recording algorithm to the stored sensor data
Split these data into dorsiflexion, plantarflexion, eversion, inversion
Rank the data into strong, normal, weak and nothing
Neglect all unwanted responses
Apply the ranking algorithm to the remaining combination responses
Use the grouping algorithm to form groups of 2 combinations ranked from best to worse
Test these groups using continuous stimulation to find the most effective and comfortable one

Chart 4.2

4.8 Summary

At the beginning of this chapter the system electrode array arrangement and topology was discussed. The chapter discussed the sensors and the methods used to monitor the foot movement. The philosophy behind the use of the twitch response was presented. The basic behind uses a single pulse to each electrode, thereby avoiding muscle fatigue and pain and reducing the setup time in comparison with continuous stimulation. Trials were carried on 20 volunteer normal subjects in the engineering laboratory, to study the relationship between the twitch response and the continuous response. The effectiveness of using the twitch technique for optimising was supported with some experimental results. The chapter also discuss how an accelerometer feedback system was developed and used for optimising the electrode array by measuring the twitch response. A signal processing algorithm was developed to extract the useful twitch movement data from the accelerometer signal. This chapter also discuss the new automatic electrode optimisation algorithm based on the use of the twitch response. The result of the optimisation process is 15 combinations of pairs of electrodes that are highly effective in producing the desired stimulation. The user can select any of these combinations based on the comfort and the effectiveness. The main advantage of using this array optimisation technique based on the twitch response was the time required to find the best stimulation site.

Chapter 5

FOOT-DROP CORRECTION DURING WALKING

CHAPTER 5: FOOT-DROP CORRECTION DURING WALKING

The previous chapter discussed the electrode array optimisation process. The result from this process was the best group of electrodes that gave the desired comfortable good dorsiflexion movement with some eversion. This chapter will discuss the foot drop correction during walking and how the foot gait monitoring sensors feedback was used to control the stimulation which corrected and optimised the walking gait.

5.1 Foot-Drop monitoring

The human normal walking gait and foot drop walking gait has been discussed earlier in chapter 2 in this thesis. The foot gait events during walking stance and swing phases that need to be detected to control the stimulation process are the beginning and end of the swing phase as shown in Figure (5.1), heel contacts, toe contact, foot angles and ground clearance during the swing phase. Investigations were carried out using various sensors to find the best method to measure and monitor these gait events.

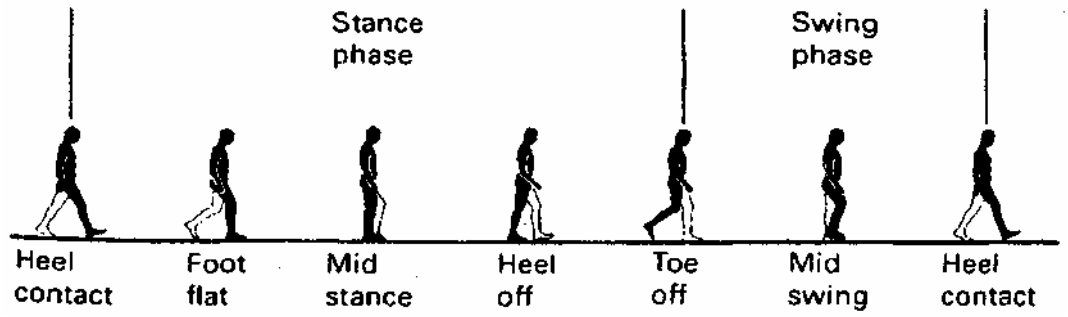


Figure (5.1) - The human gait walking cycle, (Whittle, 1991).

5.1.1 FSR sensor

The force sensitive resistor presented in chapter 3 was used to detect the heel and the toe contact. They can provide some information about the force and the body load applied on them when they are placed under the foot heel and toe Figure (5.2). Calibrating these FSR sensors will allow using them as a foot switch. This was achieved by setting force thresholds to detect the force change as the heel or toe is in contact with the floor.

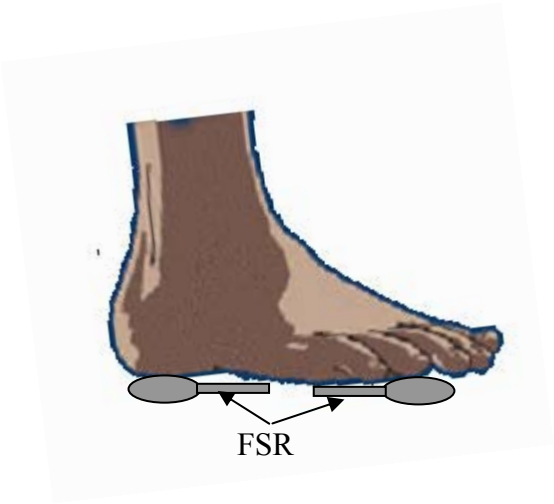


Figure (5.2) - Force sensitive resistor placed under the heel and the toe

5.1.2 Gyroscope

During early investigations the gyroscope had been used to measure the foot dorsiflexion/plantarflexion and eversion/inversion angular velocity (rotation rate) during the foot swing phase as shown in Figure (4.2) in the previous chapter. The ankle rotation angle was calculated from the angular velocity by integration if the rotation movement start and stop time can be detected accurately. Foot switches were used to detect the heel and the toe contact (on) and (off) and this information used to define the time interval for the ankle angle integration calculation from the angular velocity. The accelerometer was used to reset the foot tilt angle. The main problems faced while using the gyroscope was defining the time interval and the starting angle accurately, foot orientation during walking, integration drift and sensitivity to slow movement.

5.1.3 Accelerometer

The accelerometer uses the force of gravity as an input vector to determine the orientation of an object in the space. The same accelerometer used in measuring the twitch movement responses can be used to measure tilt referenced to gravity but this is in a static condition (no walking movement). Placing this accelerometer on top of the toe in the same place as used in measuring the twitch responses Figure (5.4) allow it to measure the tilt or the angle between the foot and the ground reference to gravity with typical sensitivity up to *17.45 mg* per degree of tilt when the axis is perpendicular to the force of gravity parallel to the earth surface while goes down to *14.38 mg* per degree at 40º (ADXL202 datasheet).

In this application the X axis is used to measure the dorsiflexion/plantarflexion tilt angle reference to gravity and the Y axis to measure the eversion/inversion tilt angle reference to gravity. However, this angle cannot be used in monitoring the ground clearance angles or the ankle angle because of two reasons. The first reason is the measured angle will depend mainly on the ground level angle reference to gravity, which will change when going up or down hill also the foot orientation changes during walking. The second reason is that the accelerometer can only measure the tilt angle during static conditions and it cannot measure it during movement as there is a dynamic acceleration component resulting in a superimposed unwanted interference signal added to the tilt angle.

A new technique has been introduced in this research to measure the foot angle using the same accelerometer. This technique is based on measuring the foot angle reference to the leg shank. This was done using two accelerometers, placed parallel to each other as possible, one on top of the foot and the other on top of the shank Figure (5.3). Calculating the tilt angle difference between them will produce the absolute angle. The X-axis difference is representing the dorsiflexion/plantarflexion (ankle angle) and the Y-axis difference is representing eversion/inversion. As both of the accelerometers placed on the same leg the difference in angle between them is not affected by the ground level as both have the same angle reference to ground gravity.

This new foot angle measurement cannot work in the dynamic condition while the foot is moving, unless the tilt angle sensor signal, which is lying within a certain frequency domain, is extracted. After a long investigation and trials to find the best way of extracting the static tilt angle information, specific analogue and digital filtering was designed to filter the dynamic acceleration component and noise from the accelerometers tilt signals.

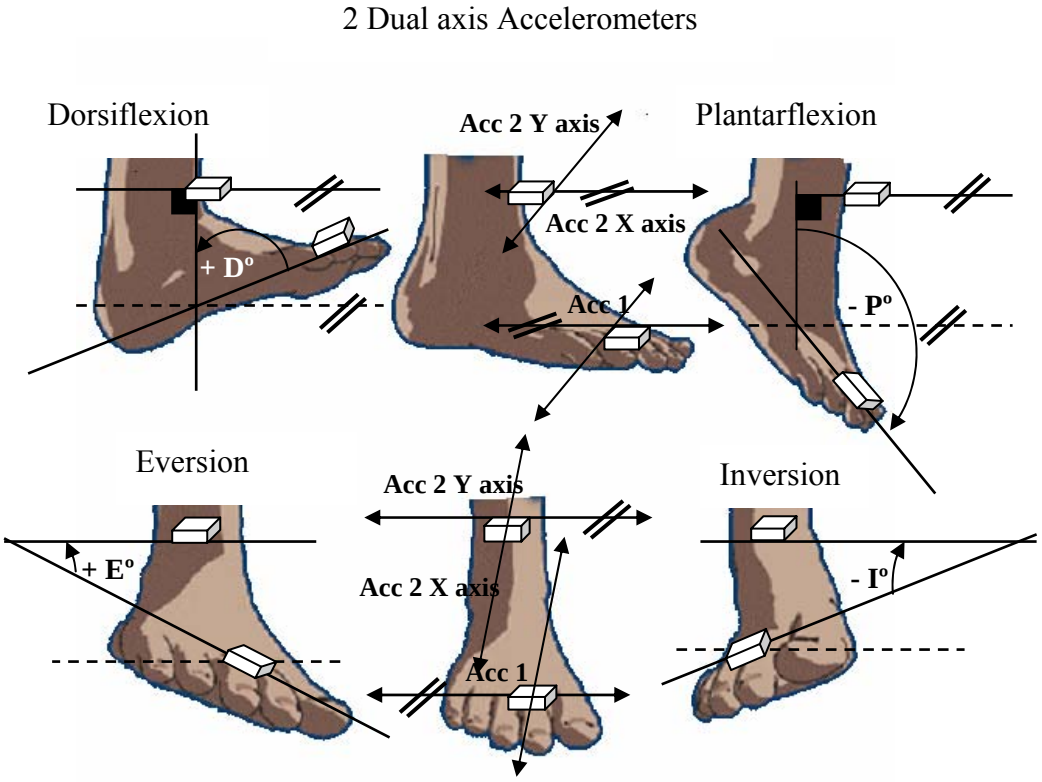


Figure (5.3) - Measuring ankle angles using the tilt difference between two parallel dual axis accelerometers

5.1.4 Filter design

When the accelerometer discussed in chapter 3 is used to measure tilt or static (gravitational) acceleration it requires a very low noise floor which necessitates restricting the bandwidth of the accelerometer, while dynamic acceleration is using wide bandwidth. The accelerometer is setup to acquire acceleration from 0 to 50 Hz (bandwidth of the maximum frequency of interest) using a low pass analogue filter as

described earlier in chapter 3, this set is used to filter the analogue output of the accelerometer that is used in both twitch and tilt measurement. This will result a noise floor of *6.1 mg*, Equation (5.1), (ADXL202 datasheet, Analog Devices).

$$Noise(rms) = \left(500(\mu g/\sqrt{Hz})\right) \times \left(\sqrt{BW \times 1.5}\right) \qquad \text{Equation (5.1)}$$

This noise has to be reduced more for the tilt measurement and this can be achieved using a digital filter. Different types of digital filters were designed and tested including FIR (finite impulse response, non-recursive filter) and IIR (infinite impulse response, recursive filter). The best filter performance during these trials was the FIR low pass filter and this is due to its stability and phase linearity compared to IIR. The filter cut off frequency is 1.5Hz and this is reduces the noise floor to *0.75 mg*, using Equation (5.1) above. This filter uses a Blackman-Harris window in its design based on complex cosine offset window shown in Equation (5.2), which produces the desired frequency response effect. The filter uses 51Hz sampling frequency that has been chosen to match the microcontroller analogue digital converter specification. The implemented filter transfer function, which has 32 coefficients presented in Equation (5.3). The coefficients were calculated using "Filter Solution" design software package (*http://www.filter-solutions.com/*). These coefficients are included in Appendix B-3.

W(n) = .35875 - .48829*cos(n/(N+1)) + .14128*cos(2.*n/(N+1))-.01168*cos(3.*n/(N+1))

Equation (5.2)

$$\frac{Yn}{Xn} = \frac{a31\,Z^{31} + a30\,Z^{30} + a29\,Z^{29} + \ldots\ldots\ldots\ \ldots\ldots\ldots\ \ldots\ldots\ldots\ . + a2\,Z^{2} + a1\,Z^{1} + a0}{Z^{31}}$$

Equation (5.3)

The filter frequency response is shown in Figure (5.4), it has almost 0dB magnitude up to 10mHz, -3dB at about 1.5 Hz and any frequencies above 6.4 Hz or below -83dB will be distorted. The filter has 160ms group time delay which was found to be acceptable for our application. Any additional delay resulting from the filter simply added a small delay in measuring the final target angle from the accelerometers during stimulation to lift the toes. This delay did not affect the function of the stimulator during the walking tests. The impulse, step and ramp time responses are shown in Figure (5.5)**.**

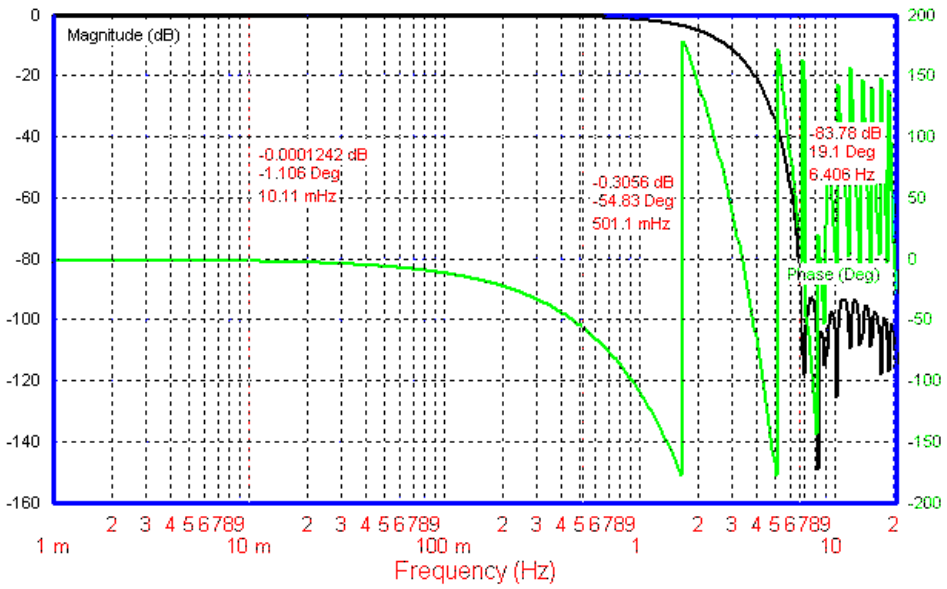


Figure (5.4) Digital FIR filter frequency response

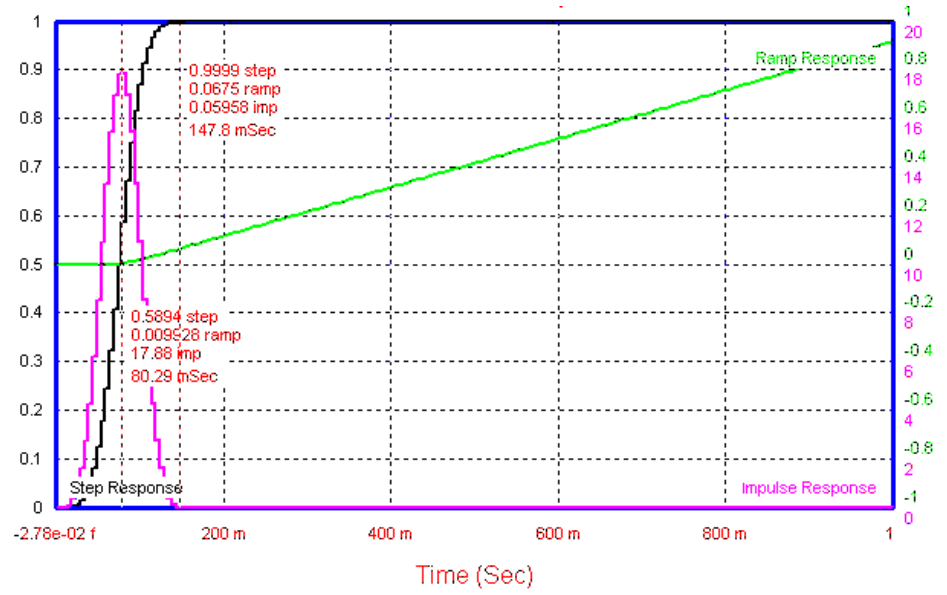


Figure (5.5) Digital FIR filter time response

5.3 Foot-Drop correction algorithm

The foot drop walking gait was different from normal gait. One of the main differences was the ankle angle at the start of the swing phase. In normal walking, before and after the Heel off the foot tends to dorsiflex first to about 80° (between foot and shank) or less, this is because of moving the body forward. This was followed by plantarflexion just before the toe was off to about 95° (between foot and

shank) or more, while still touching the ground for push off to maintain the body balance(Basmajian, 1985). When the toe left the ground the swing phase starts and during this swing the foot must be dorsiflexed to prevent the toes catching the ground. Foot drop patients do not perform all swing events through the gait cycle as normal; they cannot dorsiflex the foot to prevent the toes from catching the ground during the swing phase. The stimulation was intended to help foot drop patients to dorsiflex the foot and clear the ground.

The walking algorithm was mainly based on placing an FSR sensor under the heel to detect heel contact (on/off) as shown in Figure (5.2), and another FSR to detect toe contact (on/off). Two accelerometers were mounted parallel to each other as presented earlier in section (5.1.3), one mounted on the foot and the other mounted on the shank of the lower leg (Tibia) to measure the dorsiflexion/plantarflexion angle and the eversion/inversion angle. These combinations of accelerometer and FSR sensors have been used as real time feedback to the stimulation system. According to this feedback information the system controlled the stimulation signal envelope (start/stop time, rise/fall time, extension time) and also controlled the stimulation pulse parameters (amplitude, duty cycle).

This sensor combination provided the system with many feedback channels, but because of the microcontroller's speed there was a problem in reading and filtering all the channels at an acceptable sampling rate. For this reason an investigation was carried out using the dorsiflexion/plantarflexion angle with the heel and toe FSR as feedback sensors to optimise the walking control algorithm.

The algorithm was originally developed based on normal subject trials comprising 18 volunteers, before trying it on real patients. After trying it on real patients some modification was required to follow the unusual different patients walking gait pattern, such as changing the FSR positions or depending only on heel FSR and ankle angle in the control algorithm and excluding the toe event. Therefore more than one algorithm was programmed into the ST32 system. The foot drop correction algorithm using all the feedback channels (heel FSR, toe FSR, dorsiflexion angle, and eversion angle) to correct foot drop during walking is illustrated in chart (5.1, 5.2, 5.3, 5.4, 5.5, 5.6) along with Figure (5.7) to help understanding it more clearly.

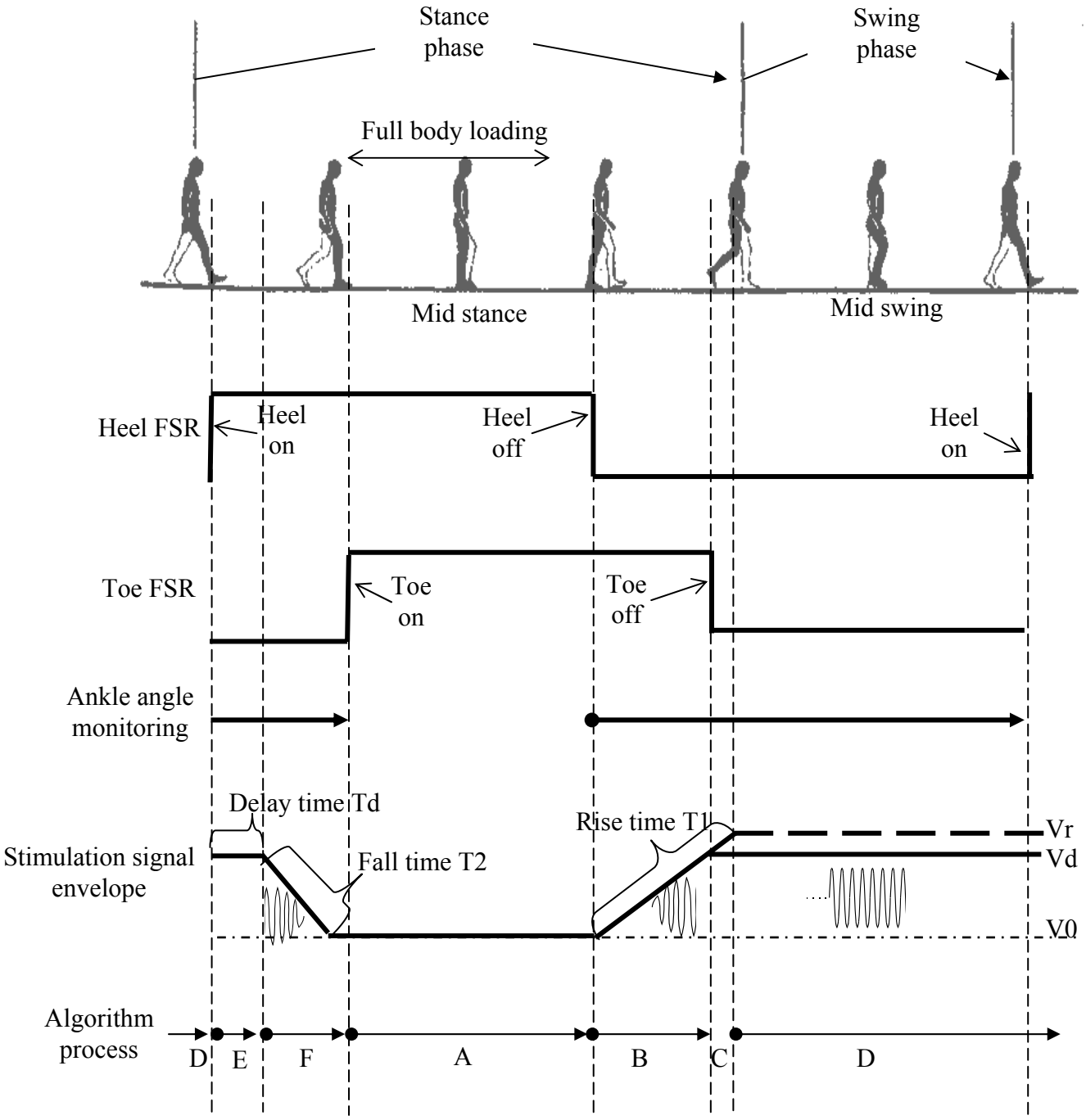


Figure (5.7) – walking algorithm diagram

5.3.1 Detailed algorithm description

Process a, chart (5.1): During stance phase

As shown in Figure (5.7), at the stance phase (processes A) the body is loaded on the ground, at this event both heel and toe FSR sensors is on. During process A the algorithm is disabling all S32 system stimulation channels, stop generating stimulation signal, reset signal amplitude and pulse width to defaults. Also during this process the algorithm is always waiting for the heel-off event, which indicates the end of the stance phase (process B) and the start of the swing phase.

Process B, chart (5.2): From stance to swing

Process B is one of the main features of this algorithm as it optimises the stimulation signal amplitude to maintain the desired dorsiflexion. In this process the heel-off event is used to trigger the start of the stimulation signal and also the start of ankle angle monitoring. When the stimulation signals start, it starts from zero amplitude and start to increase gradually using the rise time T1 up to the default amplitude Vd. This rise time is needed mainly to make and sustain smooth dorsiflexion/eversion movement as well as helping in body balancing.

During this stimulating signal amplitude increasing in process B after the heel-off event, if the ankle target angle is not reached, the algorithm will continue increasing the stimulation signal amplitude to the default amplitude Vd using the rise time T1. If default stimulation amplitude is reached and the ankle target angle is not achieved then the algorithm starts process C.

During this stimulating signal amplitude increasing in process B after the heel-off event, if the ankle target angle is reached, the algorithm will check if this is due to moving the body forward or not and this is done by knowing if the toe FSR is on or not. If the toe FSR is off while the ankle target angle is achieved, that mean the foot is clearing the ground and there is no need to increase the stimulating signal amplitude to the default amplitude Vd and the algorithm will go to process D. this is because there is enough stimulation to dorsiflex the foot to the target ankle angle to prevent the toe from catching the ground. If the target angle is reached and the toe FSR is still

on then the algorithm continues to increase the stimulation signal amplitude to the default Vd using the rise time T1. If the target angle is reached and stimulation signal default amplitude is also reached while the toe FSR is on then the algorithm starts process C.

Process C, chart (5.3): Increase stimulation amplitude and pulse width

In this process both the stimulation signal amplitude and pulse width will be increased in turn to help reach the target ankle angle or lift the toe if the target ankle angle is reached, but the toe sensor still in contact with the ground. This is the second main optimisation feature in this algorithm.

Each time the stimulation signal amplitude increased it will be increased gradually by 5% of the original default amplitude and each stimulation signal pulse width is increased by 50μs. The counter N is controlling the numbers of increase, three times of increase is allowed for each of the stimulation signal amplitude and pulse width, starting with the amplitude. This counter will be reset to 0 in process A (stance phase) while resting and the stimulation signal amplitude and pulse width are set to the default values. The time between the increases is about 15% of T1 but have to fire 2-4 pulses at least before deciding to increase signal amplitude and pulse width more or not.

Process C starts first checking if the ankle angle target is reached or not , if not and the N counter did not finish the allowed increasing then start increase the stimulation signal amplitude and increase counter N by 1. If the ankle angle target is still not reached and the N counter still did not finish the allowed increase, then the algorithm will start increasing the stimulation signal pulse width by 50μs, the algorithm will check the ankle angle again and do the increasing process three times again. During this process if the ankle angle is reached at any time or if the allowed signal amplitude and pulse width increasing is used then the algorithm will start process D.

Process D, chart (4.5): Swing phase

The main two aims of this process are to make sure that the foot is clearing the ground during the swing phase by maintaining the target ankle angle and to wait for the end of the swing phase detected by the heel FSR. During the process if the heel FSR becomes on at any time the algorithm will start process E. To maintain the ankle angle during the swing phase process the algorithm is always checking if the ankle angle has decreased lower than the target or not, if yes it has been decreased and the stimulation signal amplitude did not reach the default then the amplitude will be increase until the target angle is reached. If the ankle angle is still less than the target and the stimulation signal amplitude equal to or greater than the default then the algorithm will start process C. For safety reasons, if the toe FSR become on during the swing phase, while the target ankle angle is achieved, this is an indication of an unexpected gait event or a problem with the stimulation system. If this happens the algorithm will wait for 0.5 s and check again, if the FSR toe on confirmed the algorithm will stop the stimulation signal immediately and restart from process A again.

Process E, chart (5.5): Stimulation extension time

This process starts at any time the heel FSR become on during swing phase (process D or B or C) as it detects the end of swing phase just before the start of the stance phase. In this process when the heel FSR become on the stimulation signal will continue for the extinction or delay time Td. If the toe FSR still off the extension time will continue its end and then process F starts. During this extension time if the toe FSR become on at any time the stimulation signal will stop and process A will start.

Process F, chart (5.6): Start of the stance phase

At the start of the stance phase after the heel touch the ground and FSR become on this process will start after the extension time (process E). This process decreases the stimulation signal amplitude using the delay time Td to zero amplitude. If during this stimulation amplitude decrease the toe becomes on the stimulation signal will be stopped and process A will start.

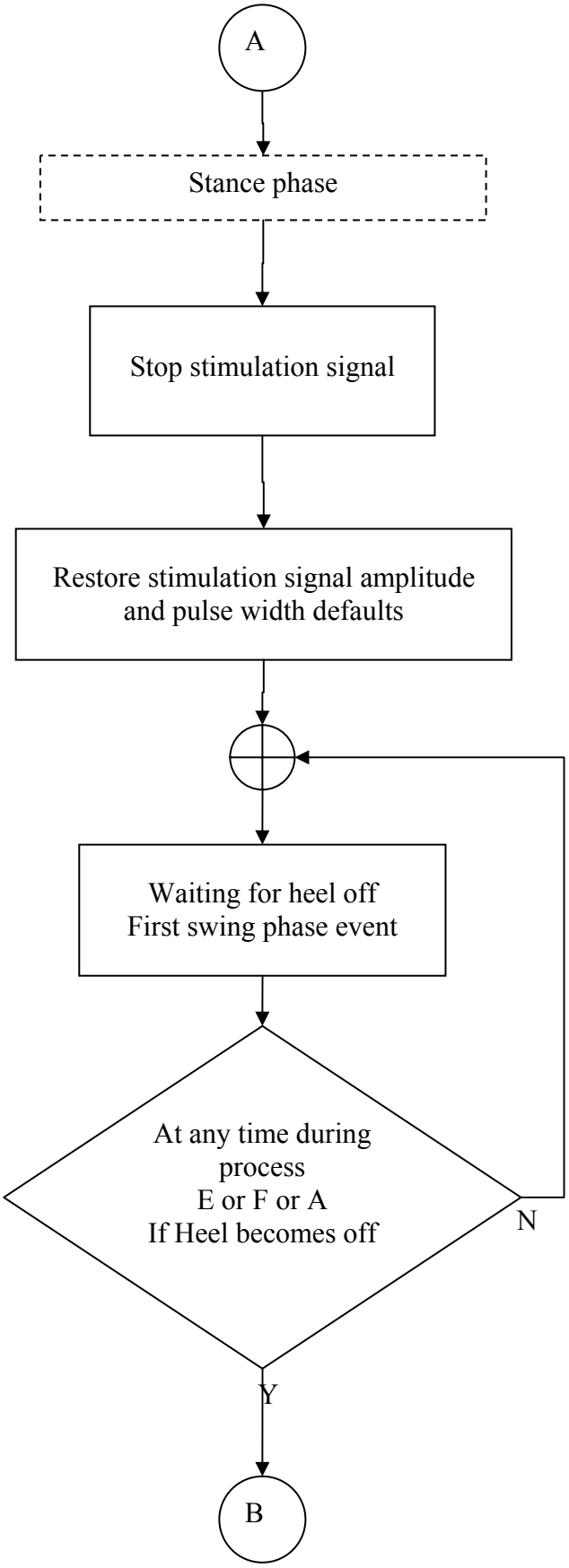

A
Stance phase
Stop stimulation signal
Restore stimulation signal amplitude
and pulse width defaults
Waiting for heel off
First swing phase event
At any time during
process
E or F or A
If Heel becomes off
N
Y
B

Chart (5.1)

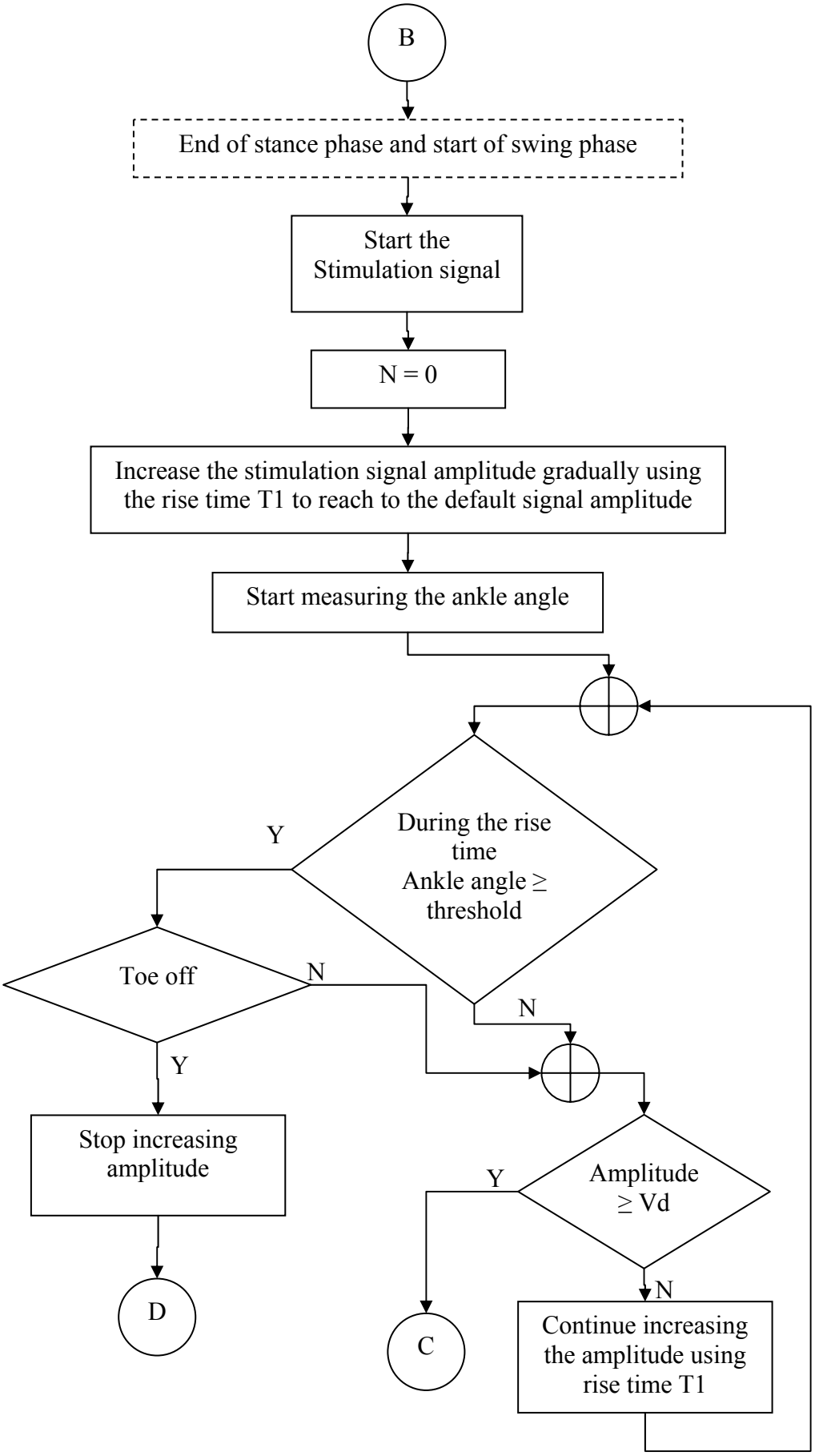

B
End of stance phase and start of swing phase
Start the Stimulation signal
N = 0
Increase the stimulation signal amplitude gradually using the rise time T1 to reach to the default signal amplitude
Start measuring the ankle angle
During the rise time Ankle angle ≥ threshold
Y
N
Toe off
N
Y
Stop increasing amplitude
D
Amplitude ≥ Vd
Y
N
C
Continue increasing the amplitude using rise time T1

Chart (5.2)

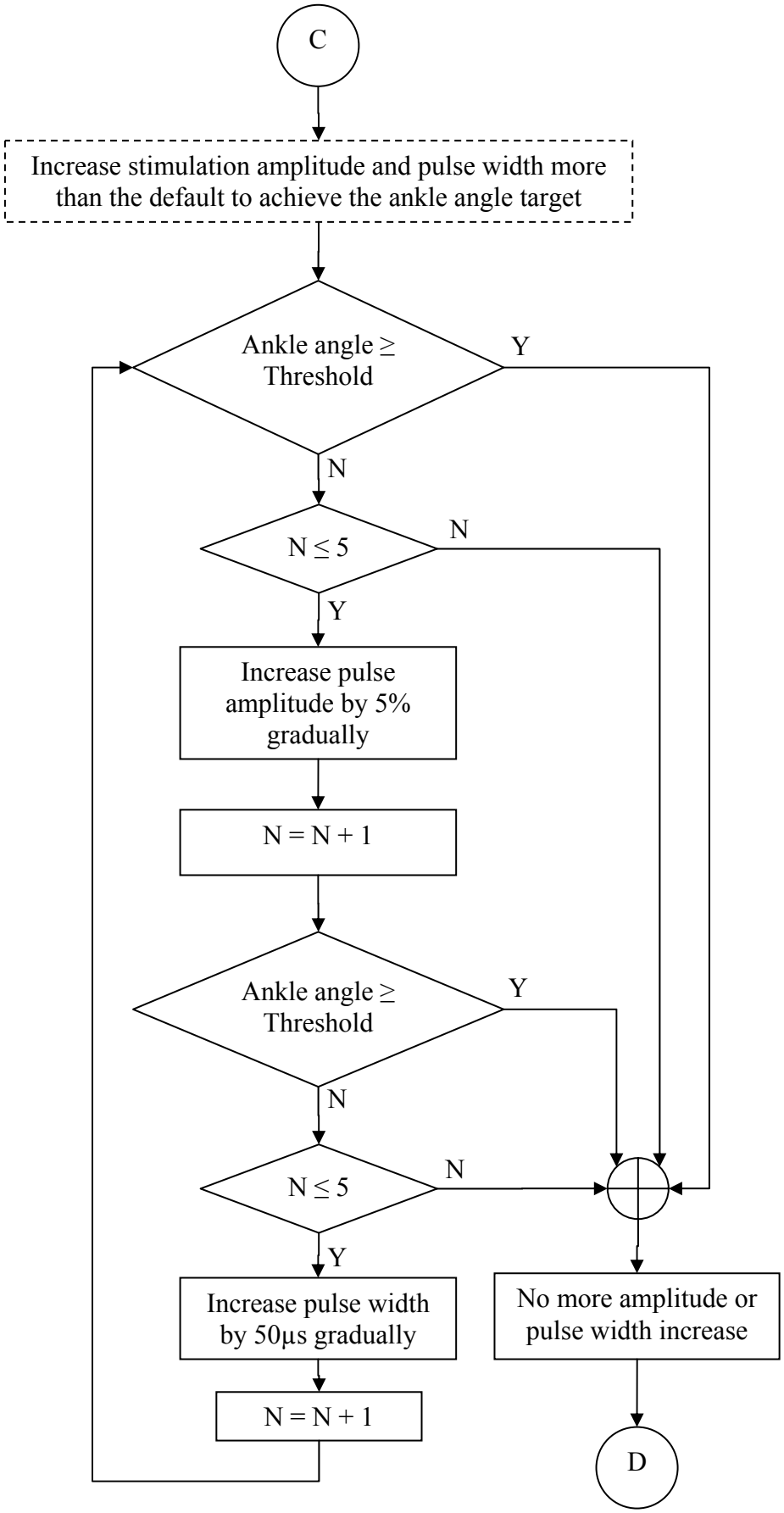

C
Increase stimulation amplitude and pulse width more than the default to achieve the ankle angle target
Ankle angle ≥ Threshold
Y
N
N ≤ 5
N
Y
Increase pulse amplitude by 5% gradually
N = N + 1
Ankle angle ≥ Threshold
Y
N
N ≤ 5
N
Y
Increase pulse width by 50µs gradually
N = N + 1
No more amplitude or pulse width increase
D

Chart (5.3)

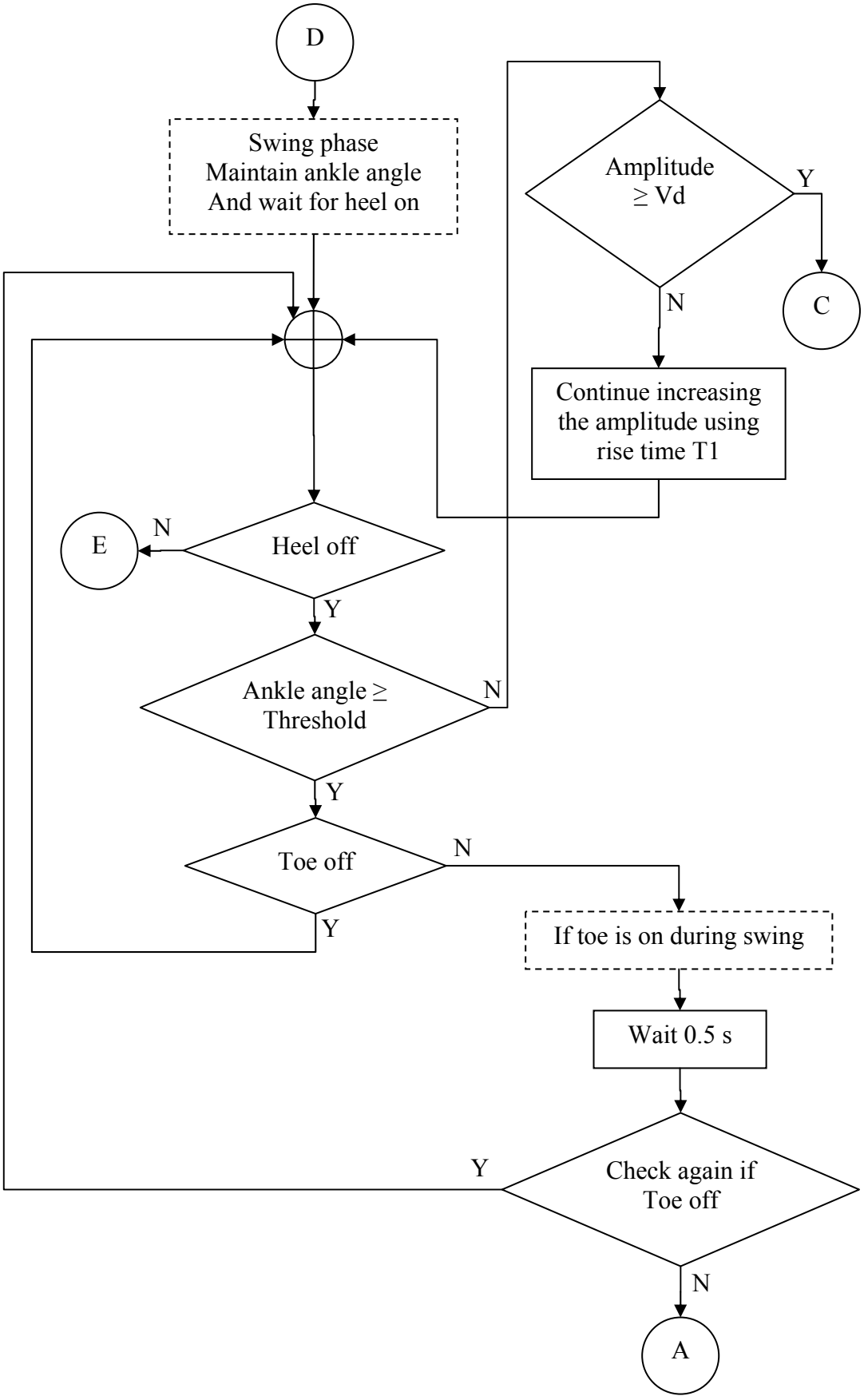

D
Swing phase
Maintain ankle angle
And wait for heel on
Amplitude
≥ Vd
Y
N
C
Continue increasing
the amplitude using
rise time T1
E
N
Heel off
Y
Ankle angle ≥
Threshold
N
Y
Toe off
N
Y
If toe is on during swing
Wait 0.5 s
Y
Check again if
Toe off
N
A

Chart (5.4)

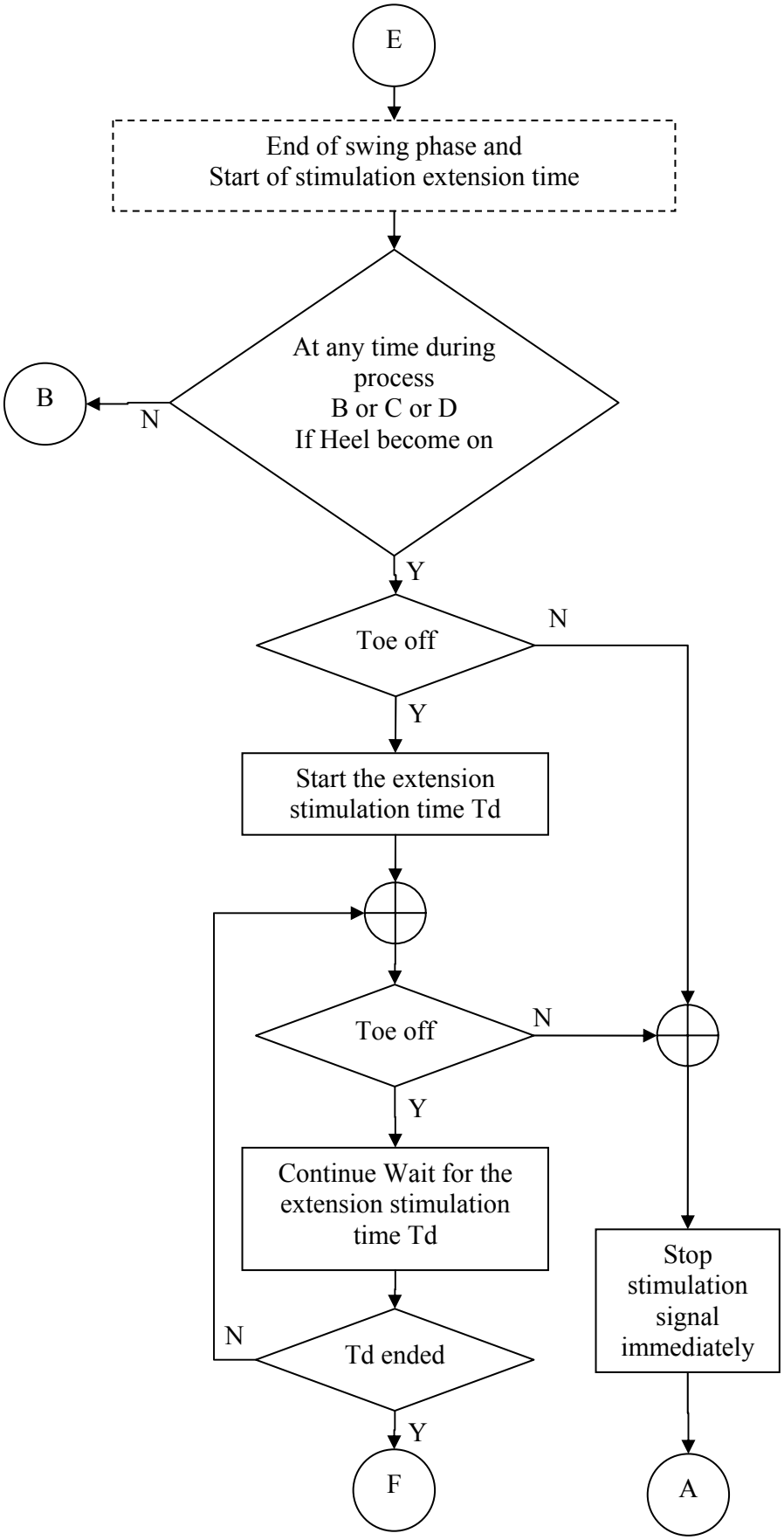

E
End of swing phase and
Start of stimulation extension time
At any time during
process
B or C or D
If Heel become on
B
N
Y
Toe off
N
Y
Start the extension
stimulation time Td
Toe off
N
Y
Continue Wait for the
extension stimulation
time Td
Td ended
N
Y
F
Stop
stimulation
signal
immediately
A

Chart (5.5)

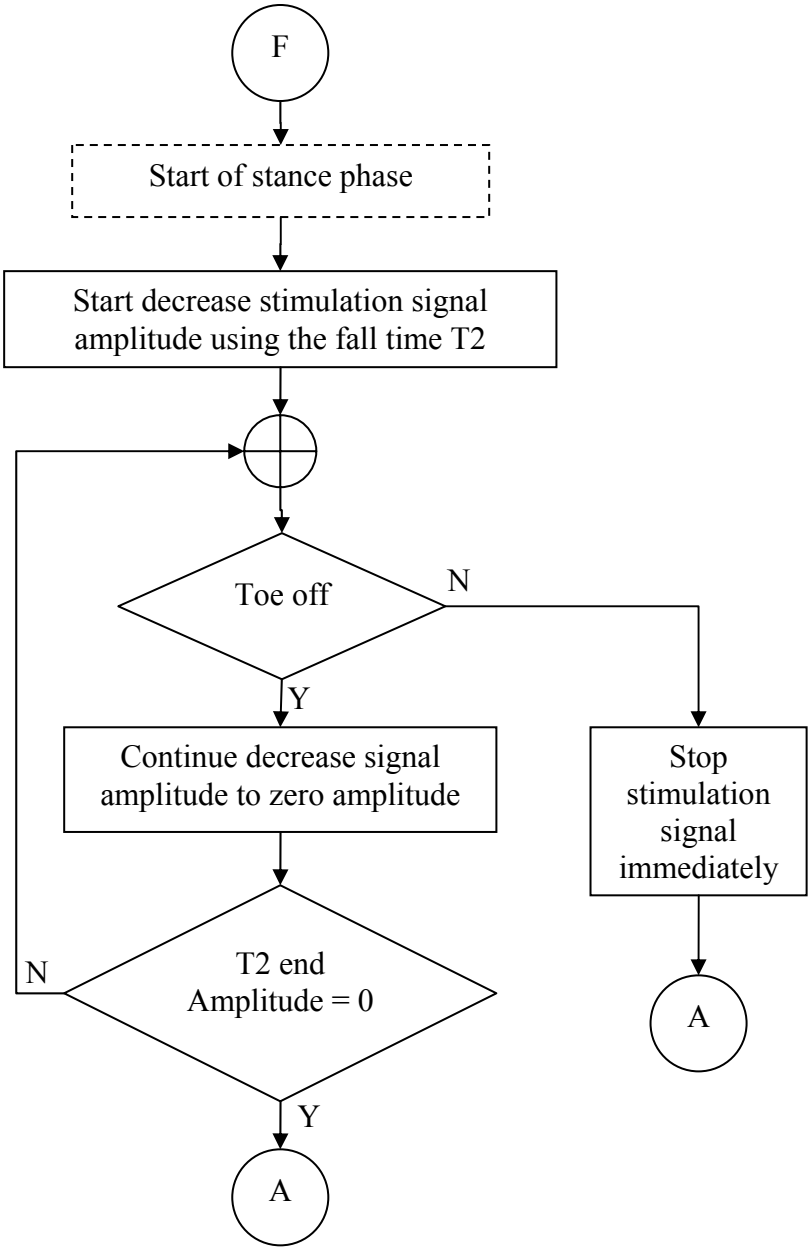

F
Start of stance phase
Start decrease stimulation signal amplitude using the fall time T2
Toe off
N
Y
Continue decrease signal amplitude to zero amplitude
Stop stimulation signal immediately
T2 end Amplitude = 0
N
Y
A
A

Chart (5.6)

5.4 Summary

This chapter discussed the investigation carried out using foot switches, gyroscopes and accelerometers to monitor the foot movements. Two dual-accelerometer sensors were utilised in a unique way to measure the angle that the foot makes with the shank of the lower leg during walking. This chapter also discussed the signal processing required for the measurements. In this chapter also the walking algorithm developed for foot-drop correction was presented and discussed. This algorithm was mainly used to make sure the foot did clear the ground and to maintain dorsiflexion at an appropriate target angle. The testing results for using this algorithm to correct foot drop based on the foot switch and accelerometer feedback was presented in chapter 6.

Chapter 6

PRELIMINARY CLINICAL STUDY

CHAPTER 6: PRELIMINARY CLINICAL STUDY

6.1 Introduction

During the designing process of the new FES system (chapter 3), the system was tested within the laboratory to help in the development of a new electrode array optimisation technique (chapter 4) and also the development of the foot drop walking control algorithm (chapter 5). Toward the end of this laboratory based trials the new ST32 FES system was completed successfully and embedded with all the optimisation and control algorithms software.

The laboratory based trials on control (normal healthy) subjects was a preparation for the preliminary clinical study on real foot drop patients. The preliminarily clinical study was carried out between December 2004 and February 2005 in association with the United Bristol Health care Trust (UBHT) MS Research Unit in Bristol General Hospital. This MS research unit is one of the few clinical centres in the country who have in depth experience in using the FES technology and testing its application with neurological disability such as foot drop, (Jones, 1991, 1993, 1994, 1998, 2000), (Whitlock, 1997).

6.1.1 The study objectives

1. Using the ST32 system on real foot drop patients
2. Test the ST32 system readability and compatibility
3. Ensure the ST32 stimulation signal comfort and effectiveness
4. Validate the correlation between the twitch and continuous stimulation response
5. Validate the use of the sensors feed back information in the algorithms developed
6. Examine the electrode array optimisation algorithms developed
7. Examine the foot drop control and correction algorithms developed during walking

6.1.2 Study technical requirements

Before starting the study the ST32 FES system was tested and approved by the Medical Equipment Management Organization (MEMO) of the UBHT, this approval was mainly to confirm the system safety according to the (BS EN 60601-1:1990) "*Medical Electrical Equipment Part 1 General requirements for safety*" and (BS EN 60601-2-10:2001) "*Medical Electrical Equipment Part 2.10, particular requirements for the safety of nerve and muscle stimulators*".

The study protocol was approved by the UBHT local ethical committee. According to the study protocol the system had to be tested first on control normal subjects before testing it on patients. The number for the controls recruited has to be at least half the patient number. The system should be tested on foot drop MS and Stroke patients only. All participants should be screened according to the inclusion/ exclusion criteria prior to entering the study. All study participants have to be introduced to the study phases with the required information. They also have to sign a consent form on their first visit to the MS Research Unit and were asked to consent to video registration using the standard UBHT video/film consent form where appropriate. The study had to follow the UBHT data protection policy, for this reason the collected data was recorded originally on forms kept within the UBHT MS research unit.

6.1.3 Study participants recruitment

Ten control subjects and 14 foot drop patients were recruited in this study. These subjects were recruited by a physiotherapist from Bristol General Hospital and by notices placed in relevant departments of the hospital. These volunteer subjects were not selected particularly for the study they were randomly selected MS and Stroke foot drop patients. Some of them experienced using other FES systems and the others did not. Due to this wide sample of foot drop patients two were excluded from the beginning of the study and some of them did not complete all phases of study as discussed later in this chapter in more detail.

6.2 Study methodology

The study was divided into three phases, starting with the subject assessment and then the seated study phase and finally the walking study phase. The procedure and methodology followed in each of these phases are presented in the following few sections.

6.2.1 Subject assessment phase

The following assessment was carried out for each subject with the help of the physiotherapist to study the condition of each subject individually.

- Gender, Age, Weight, Height
- Disability type (MS, Stroke) and time since diagnosis
- Foot drop whether present on left or right leg or both

- Expanded Disability Status Scale(EDSS).

  Kurtzke EDSS Scoring System (Kurtzke, 1983, 1989)

  10 - Death from MS

  --

  8 - Require Wheelchair

  --

  6 - Intermittent or unilateral assistance to walk 100 meters

  --

  3 - Moderate disability in one Functional Systems or mild in 3-4 Functional Systems

  --

  0 - Normal

  Full scale details presented in the Appendix C-1

- Eligibility and inclusion checklist.

    - Control subjects: healthy adults
    - MS patients: diagnosis of MS (8>EDSS), ability to walk at least 20 meters with and without an aid.
    - Stroke patients: hemiplegia causing visible foot drop, ability to walk at least 20 meters with and without an aid.

- Exclusion checklist

    - Control subjects: any lower limb weakness or limitation of movement, lower limb skin abrasion, pregnancy, cardiac pacemakers or any electrical implants.
    - MS patients: recent relapse (prior 3 months), EDSS>8, lower limb skin disorder, pregnancy, cardiac pacemakers or any electrical implants, ataxic gait (lose of coordination during walking), fixed deformity at the ankle.
    - Stroke patients: sensation loss in affected leg , skin disorder at affected leg, expressive and/or receptive dysphasia, pregnancy, cardiac pacemakers or any electrical implants, fixed deformity at the ankle.

- Muscle strength motricity index scale (MOT), this scale is used to assess the motor impairment in a patient who has had a stroke or MS (Demeurise G, 1980), (Collin C, 1990). The scale is presented in Appendix C-1

- Ashworth scale of lower limb calf muscle spasticity, (Bohannon,1987).

  Modified lower limb spasticity scoring scale

    0. No increase in muscle tone
    1. Slight increase in tone with a catch and release or minimal resistance at end of range
    2. Same as 1 with minimal resistance through range following catch at less than half of the ROM range

3. More marked increase tone through ROM but affected part easily moved
4. Considerable increase in muscle tone, passive movement difficult
5. Affected part rigid in flexion or extension

- Goniometry range of movement (ROM)

  Goniometer Alignment
  - Axis – lateral malleolus
  - Stationary arm – aligned with fibular head
  - Moving arm – aligned with fifth metatarsal

  Ankle at $90^0 = 0^0$
  Flexion = + Degrees
  Extension = - Degrees

6.2.2 Seated phase tests

Following the subject assessment and inclusion criteria the subject goes through the seated phase. The seated phase aimed to achieve four testing targets, in the following section each test target and how it was achieved is explained in details.

Test 1:
The aim of this test is to set up the stimulation parameters defaults for both the twitch and continuous stimulation according to the subject comfort to achieve effective stimulation movement.

To achieve this aim this test included the following:

- Trying different wave form shapes, square, single sine, double and triple sine
- Varying the stimulation pulse amplitudes (10%-80%) of the maximum amplitude
- Varying the stimulation pulse width (150µs-500µs)
- Tuning the stimulation frequency (20Hz-60Hz)

Test 2:

The aim of this test is to confirm the use of twitch stimulation acceleration response to optimise the electrode array.

To achieve this aim this test included the following:

- Recording the twitch acceleration response from each electrode in the array.
- Observing the movement obtained (dorsiflexion, eversion, plantarflexion, inversion) by continuous stimulation from every electrode in the array. A score was giving according to the strength of observed contraction, Absent = 0, Weak = 1, Normal = 2, Strong = 3; this observation was done by more than one physiotherapist.
- Correlating the twitch and the continuous stimulation responses.

Test 3:

The aim of this test is to test the electrode array optimisation algorithms software.

To achieve this aim this test included the following:

- Applying the optimisation algorithm manually to the collected electrode array twitch responses
- Compare the ranked 15 group of electrodes generated from the manual algorithm processing to the automatic software processing
- This test was performed on some randomly selected subjects but not on all subjects due to time limitation and subjects availability.

Test 4:

The aim of this test is to test the automatic optimised selection of groups of electrodes and select the preferred most comfortable group, which deliver the desired dorsiflexion with some eversion movement.

To achieve this aim this test included the following:

- Trying each electrode group from the top 15 that is selected by the optimisation algorithm starting from the highest ranked group.
- Tune the stimulation pulse parameters

Summary of data collected from the seated phase tests:

- Optimised default parameters for the twitch and continuous stimulation:
  - Pulse shape
  - Pulse width
  - Pulse amplitude
  - Stimulation frequency (pulse repetition rate)
- Twitch response for each electrode within the array
- Observation and scoring for movement obtained by every electrode in the array
- Best group of electrodes out of the automatic optimised selected groups of electrodes

6.2.3 Walking phase tests

Following the study seated phase test the walking phase test starts. The walking phase aimed to achieve four testing targets, in the following section each test target and how it was achieved is explained in details.

Test 1:

The aim of this test is to tune the stimulation pulse parameters and to set up the walking stimulation signal envelope parameters that are needed for the walking algorithm, these stimulation envelope parameters are the rise time, fall time and the extension time.

To achieve this aim this test included the following:

- Asking the subject to walk with the system and observing the foot drop gait and the walking speed as well as the subject comfort.
- Tune the stimulation pulse and the stimulation envelope parameters to give the best observed results by the researchers and the subject themselves.

Test 2:

The aim of this test is to set up the targeted ankle angles thresholds that are required for the walking algorithm.

To achieve this aim this test included the following:

- Choose stimulation parameters that gave enough angles to lift the foot and clear the ground during the swing phase.
- Defining the desired ankle angles thresholds between the foot and the shank that is measured by the sensors.

Test 3:

The aim of this test is to study the effect of using the system on the subject walking speed, stride length and also the change in the gait cycle.

To achieve this aim this test was done using the technique recommended by (Wade, 1987). This technique was based on using a stop watch to measure the time taken to walk 10 or 11 meter with 2 meters run in and run out distance, so that their gait was not affected by accelerating and de-accelerating from/to standing. In 1999 O'Keeffe's study, a comparison of measuring walking speed using stop watch against using optical beam and no significant difference was found between the 2 methods, (O'Keeffe, 1999).

- Practise and exercise walking with the system for some time before doing any walking recording
- Recording the time taken and the number of steps to walk 10 metres with and without the ST32 system. Walking commenced before the timed 10 metres and subjects were asked to walk beyond the 10 metres "the subjects were wearing the devices all the time during the test, with out knowing if it is on or off.
- Video recordings were used to confirm the recorded results and to allow more gait analysis with and without the ST32 system.

Test 4:

The aim of this test is to record the subject's feedback on the stimulation comfort, ankle movement achieved and ability to walk with and with out the ST32 system.

To achieve this aim the subject was asked make a mark on the following Visual Analogue Scale (VAS) scores:

0 _____ 10

Worst Best

- VAS score for the stimulation comfort
- VAS score for movement achieved at ankle
- VAS score for perception of walking ability with and without the ST32 system

Summary of data collected from the walking phase tests:

- Final stimulation pulse parameters
    - Pulse width
    - Pulse amplitude
- Stimulation signal envelope parameters
    - Rise time
    - Fall time
    - Delay (extension) time
- Ankle angles thresholds
- Number of steps recorded over 10 metres without the ST32
- Number of steps recorded over 10 metres with the ST32
- Time taken to walk 10 metres without the ST32
- Time taken to walk 10 metres with the ST32
- Video recording to support all the walking collected data
- VAS score for comfort of stimulation
- VAS score for movement achieved at ankle
- VAS score for perception of walking ability with and without the ST32 system

The final step in the study was to analyse the patient's walking gait with and without the ST32 system. This was done initially during the walking by the research physiotherapist, who is helping in the study. At the end of the study two independent assessors watched the walking video recording for all patients and reassessed the walking gait without knowing which walk was with the ST32 system switched on and which one was switched off. After that they agreed on one final assessment results.

6.3 Study Results and Analysis

6.3.1 Control subjects

Ten control subjects 4 male, 6 female, within wide normal ranges of age and normal ranges of height and weight were recruited as presented in Table (6.1). All controls were recruited as healthy normal subjects.

Subject number	**Gender**	**Age**	**Weight kg**	**Height cm**
1	Male	30	77	178
2	Female	47	75	170
3	Female	62	75	156
4	Female	22	51	165
5	Male	34	80	178
6	Female	25	70	165
7	Female	23	65	165
8	Female	20	60	172
9	Male	38	72	177
10	Male	23	82	189
Average	4M/6F	32.4	70.7	171.5

Table (6.1) - Control subjects details

In this phase the subject was asked to sit high from the floor (i.e. foot not touching the floor) with foot relaxed in the plantarflexion relaxing position as shown in Figure (6.1). The test was done on the left leg using 4X4 active electrode placed roughly on top of the tibialis anterior muscle and one return electrode behind the knee or at the end of the tibialis anterior motor point.

Figure (6.1) – subject during seated test phase

6.3.1.1 Seated phase results and analysis for control subject

The study seated phase tests were carried out on all 10 control subjects according to the phase seated tests procedure explained earlier.

Test 1

The twitch stimulation signal parameters that were chosen during the seated phase and the continuous stimulation signal parameters that were chosen after completing both the seated phase and the walking phase are presented in Table (6.2).

Control subject number	Twitch pulse shape 1 – 6*	Continuous pulse shape 1 – 6*	Twitch pulse width µ sec	Continuous pulse width µ sec	Twitch pulse amplitude % **	Continuous pulse amplitude % **	Continuous stimulation frequency Hz
1	3	5	350	300	65	52	40
2	3	4	350	350	40	34	33
3	3	4	400	350	40	32	33
4	3	5	350	300	40	35	33
5	3	3	350	300	55	43	40
6	3	3	400	350	55	48	33
7	3	5	400	350	50	45	40
8	3	3	400	350	65	50	40
9	4	5	400	350	50	45	40
10	5	4	400	350	60	55	33

*pulse shapes

Pulse shape 1 = no wave stored

Pulse shape 2 = square wave

Pulse shape 3 = biphasic square wave

Pulse shape 4 = sine wave

Pulse shape 5 = double sine wave

Pulse shape 6 = triple sine wave

Pulse shape 7-12 = no wave stored

** This is a percentage of the maximum amplitude (400 V peak-peak with out load)

Table (6.2) - Chosen stimulation signal parameter for control subjects

The results show that in twitch stimulation the square biphasic charge balanced pulse shape was selected the most with pulse width either 350 µs or 400 µs and amplitude varying between 40% and 65 % of the maximum amplitude.

In continuous stimulation the parameters were slightly different, the biphasic square sine and double sine biphasic charge balanced pulse shape are used mostly, the pulse width were either 300 µs or 400 µs and the amplitude varied between 32% and 55 % of the maximum amplitude at 33 Hz or 40 Hz stimulation frequency.

Test 2

The twitch stimulation acceleration response was extracted and recorded from the accelerometer signal after applying the signal processing and filtering using the algorithm described in chapter 4. A typical set of twitch acceleration responses and observed movement scoring for control subject number 1 are presented in Table (6.3).

To help understand the result in Table (6.3) a graphical form of these results are presented in Figure (6.2), where the twitch acceleration response recorded from each electrode in the 16x1 array are in the top graph and the observed continuous stimulation scoring for each electrode are in the bottom graph. From observing these Tables and graphs is clear that there is relation between the twitch response results and the observed continuous movement scoring. To study this relationship, the Pearsons's correlation coefficient between the observed continuous movement and the twitch response was calculated using Equation (4.1) same as in section (4.3.1). The dorsiflexion and plantarflexion R correlation was calculated for the same subject (control number 1) as shown in Figure (6.3).

According to the optimisation algorithm discussed in chapter 4 most of the negative twitch responses that represent plantarflexion or inversion will be neglected and only the positive twitch responses for dorsiflexion and eversion are left. The R correlation coefficient was calculated for the same subject based on dorsiflexion data only and presented in Figure (6.4).

Electrode Number	Twitch Acceleration mV + Dorsiflexion - Plantarflexion	Continuous scoring* + Dorsiflexion - Plantarflexion	Twitch Acceleration mV + Eversion - inversion	Continuous scoring* + Eversion - inversion
1	48	1	-48	-2
2	211	3	64	2
3	43	1	35	1
4	142	2	116	3
5	51	1	-87	-2
6	115	2	-8	0
7	163	3	53	1
8	18	0	27	2
9	126	2	-23	-1
10	59	1	10	-1
11	-20	-1	62	2
12	7	0	79	2
13	57	0	-11	-1
14	97	2	0	1
15	54	1	0	0
16	2	0	0	0
* Absent = 0, Weak = 1, Normal = 2, Strong = 3				

Table (6.3) - Twitch acceleration responses and observed movement scoring for control subject 1

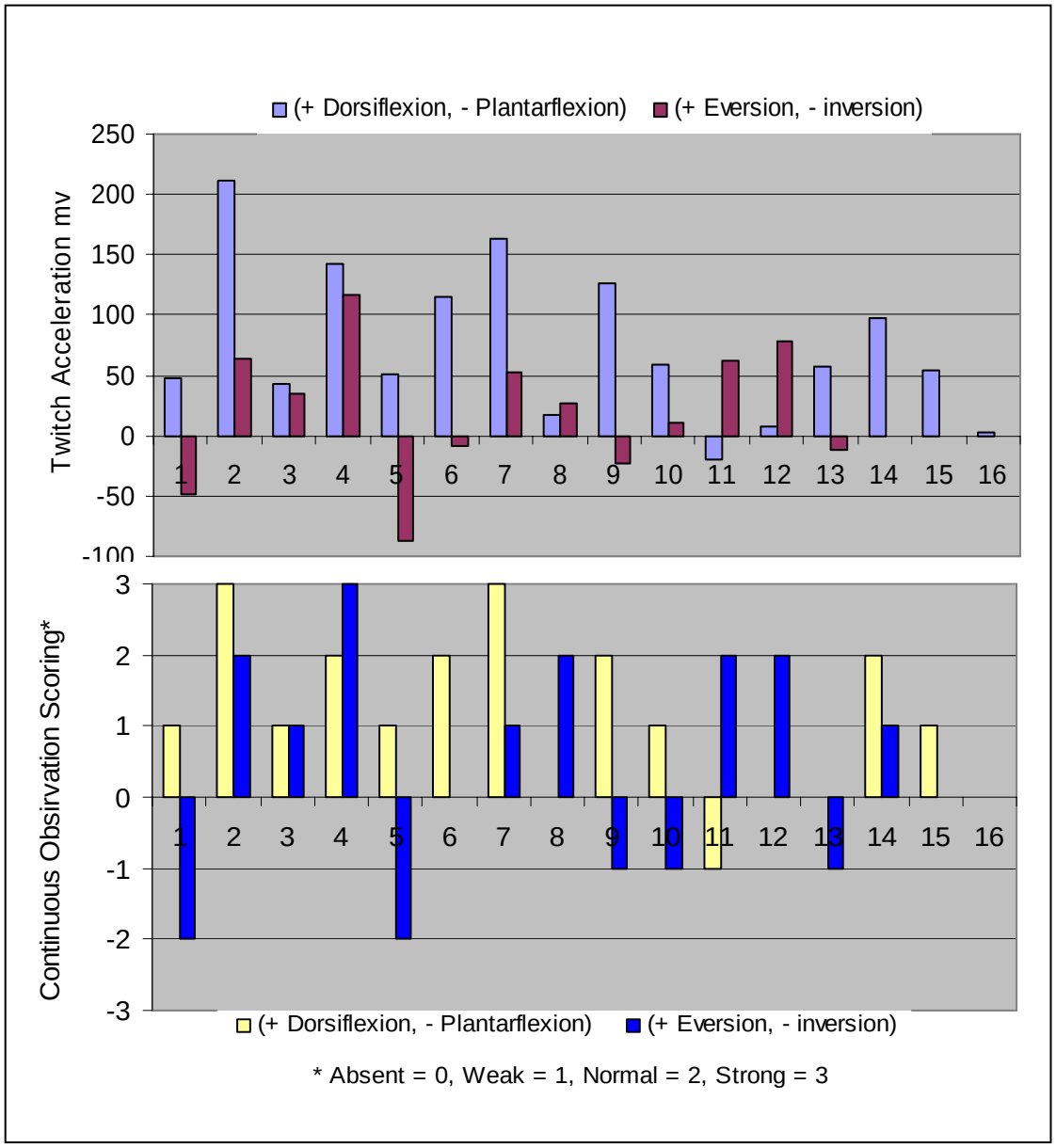
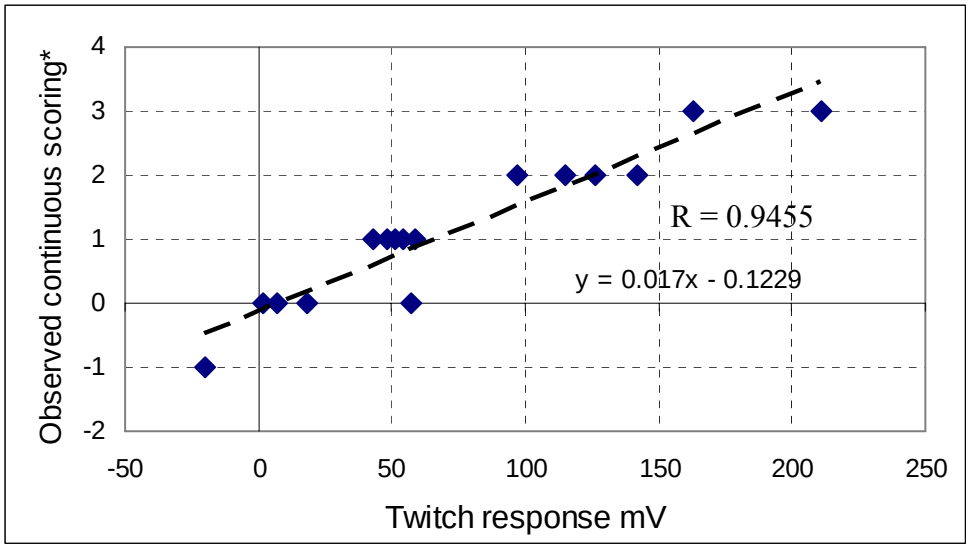
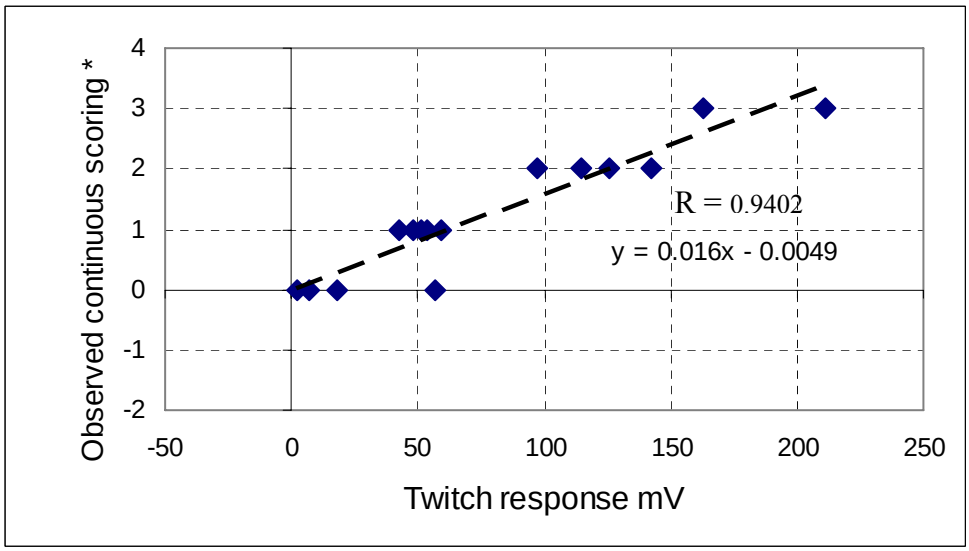


Figure (6.2) - Twitch acceleration responses and observed movement scoring for control subject 1



Absent = 0, Weak = 1, Normal = 2, Strong = 3

Figure (6.3) - dorsiflexion/plantarflexion twitch acceleration responses and observed continuous movement scoring correlation for control subject 1



Absent = 0, Weak = 1, Normal = 2, Strong = 3

Figure (6.4) - Control subject 1 twitch acceleration responses and observed continuous movement scoring correlation for dorsiflexion only

Test 3

For more statistical analysis the correlation coefficient was calculated for all 10 control subjects between the observed continuous movement and the twitch response. This calculation include; dorsiflexion and plantarflexion together, dorsiflexion only, eversion and inversion together, eversion only. All the correlation results are presented in Table (6.4) and also in graphical format in Figure (6.5). High correlations were found for all 10 control subjects. This confirms the concept that was suggested from the laboratory trials that twitch accelerating response can be used to optimise the electrode array, but still to be tested on real patients.

Control Subject number	Dorsiflexion Plantarflexion Correlation	Eversion Inversion Correlation	Dorsiflexion Correlation	Eversion Correlation
1	0.946	0.914	0.940	0.818
2	0.891	0.931	0.859	0.795
3	0.913	0.948	0.895	0.869
4	0.893	0.984	0.849	0.960
5	0.829	0.932	0.785	0.898
6	0.873	0.922	0.837	0.920
7	0.966	0.925	0.965	0.854
8	0.952	0.947	0.947	0.880
9	0.954	0.963	0.958	0.983
10	0.959	0.876	0.948	0.872

Table (6.4) - Twitch and continuous correlation result for all 10 control subjects

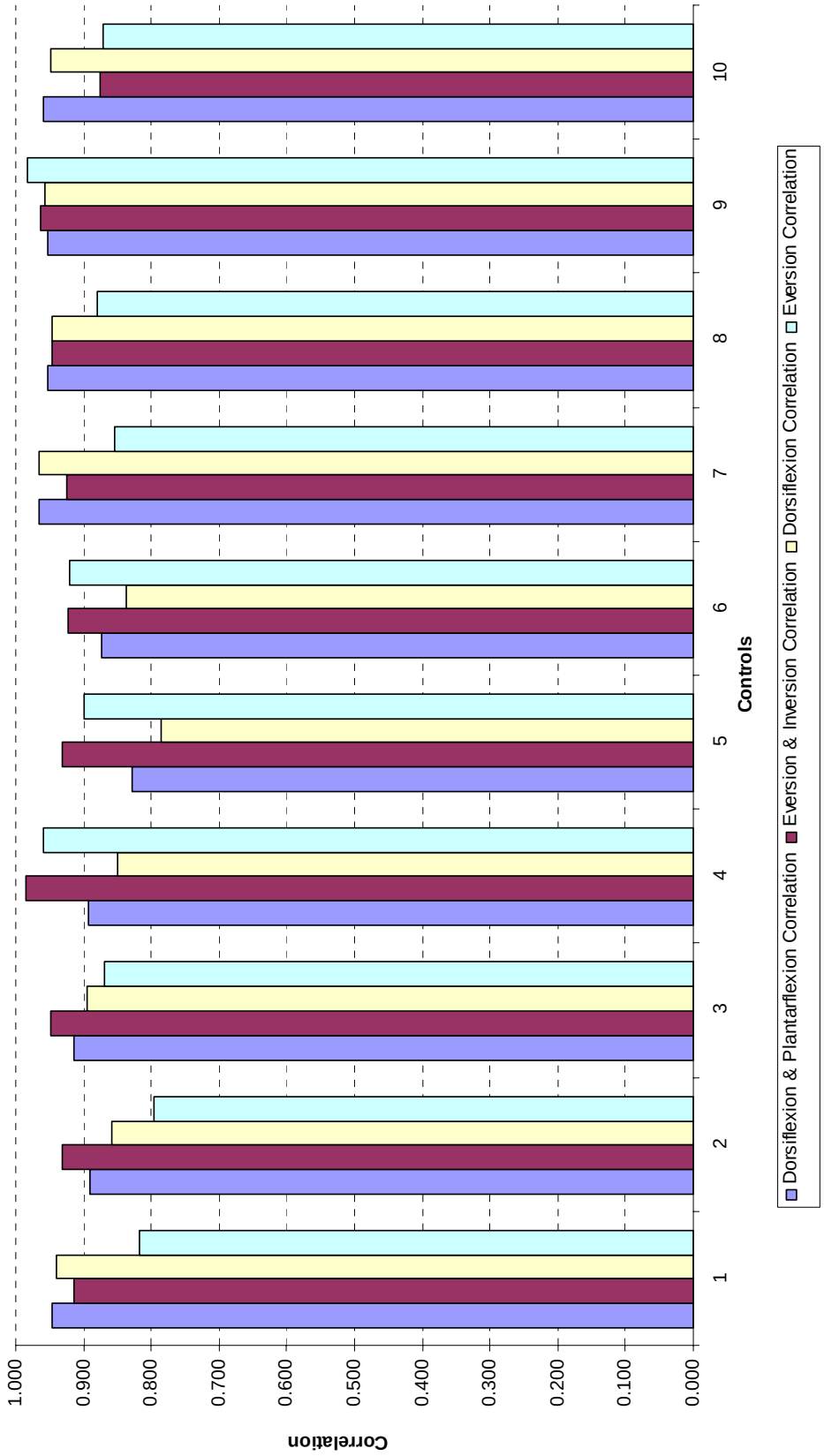


Figure (6.5) - twitch and continuous correlation result for all 10 control subjects

Test 4:

This was the automatic electrode array optimisation test, which was performed by the ST32 system software. The outcome of this optimisation process is 15 groups of pairs of active and return electrodes ranked from 1 to 15 out of all the possible electrode combinations (2 x 16 = 32) as explained earlier in the electrode array optimisation algorithm, chapter 4. Each of these groups is then selected and tried in turn until the best electrode group that gave comfortable good dorsiflexion with some eversion was found. The selected electrode group ranks for each of these 10 control subjects are presented in Table (6.5).

Control Subject number	selected Group rank
1	2
2	2
3	1
4	1
5	1
6	5
7	1
8	2
9	3
10	2

Table (6.5) - Chosen electrode group ranks for each of these 10 control subjects

This electrode group rank results prove that the optimisation algorithm is very satisfactory as good stimulation movement was achieved usually within the top three ranked electrode groups from the original 15 group. This small variation of rank was due few factors like the comfort and combining two pairs of electrodes instead of one as explained in the optimisation algorithms, which was modified slightly based on these results.

6.3.1.2 Electrode mapping analysis

Figure (6.6) is shown the electrode mapping of all the 10 control subjects. The test following the same procedure explained section (4.6.2) for recording the continuous stimulation response from each single active electrode but the observation scoring was done this time by two physiotherapists.

As discussed earlier the electrode array optimisation algorithm used the twitch response to select the optimum 15 group of electrode as explained earlier in chapter 4. The subject chose the best combination that give the desired comfortable dorsiflexion with some eversion, this was achieved by trying the electrode combinations in turn starting from the highest ranked. The final chosen combination of pair of electrodes is highlighted in a different colour on the same maps. The box at top of the active 4x4 electrode array map indicates the use of return electrode behind the knee, the box at the bottom of the map indicates using the return electrode at the lower end of the tibialis anterior muscle. By examining these maps it is clear that there is no common electrodes that are used and this may be due to human muscles physiological and geometry differences. This is a similar result to the electrode maps for the normal group. Each electrode pair chosen shows unique differences. The chosen electrode pair after ranking mainly includes dorsiflexion and eversion movements, with small differences C6, C8, C9, and C10 which show inverter movement. These results show that the electrode combinations chosen using the optimisation algorithm based on individual electrode twitch was a successful way of optimising the electrode array.

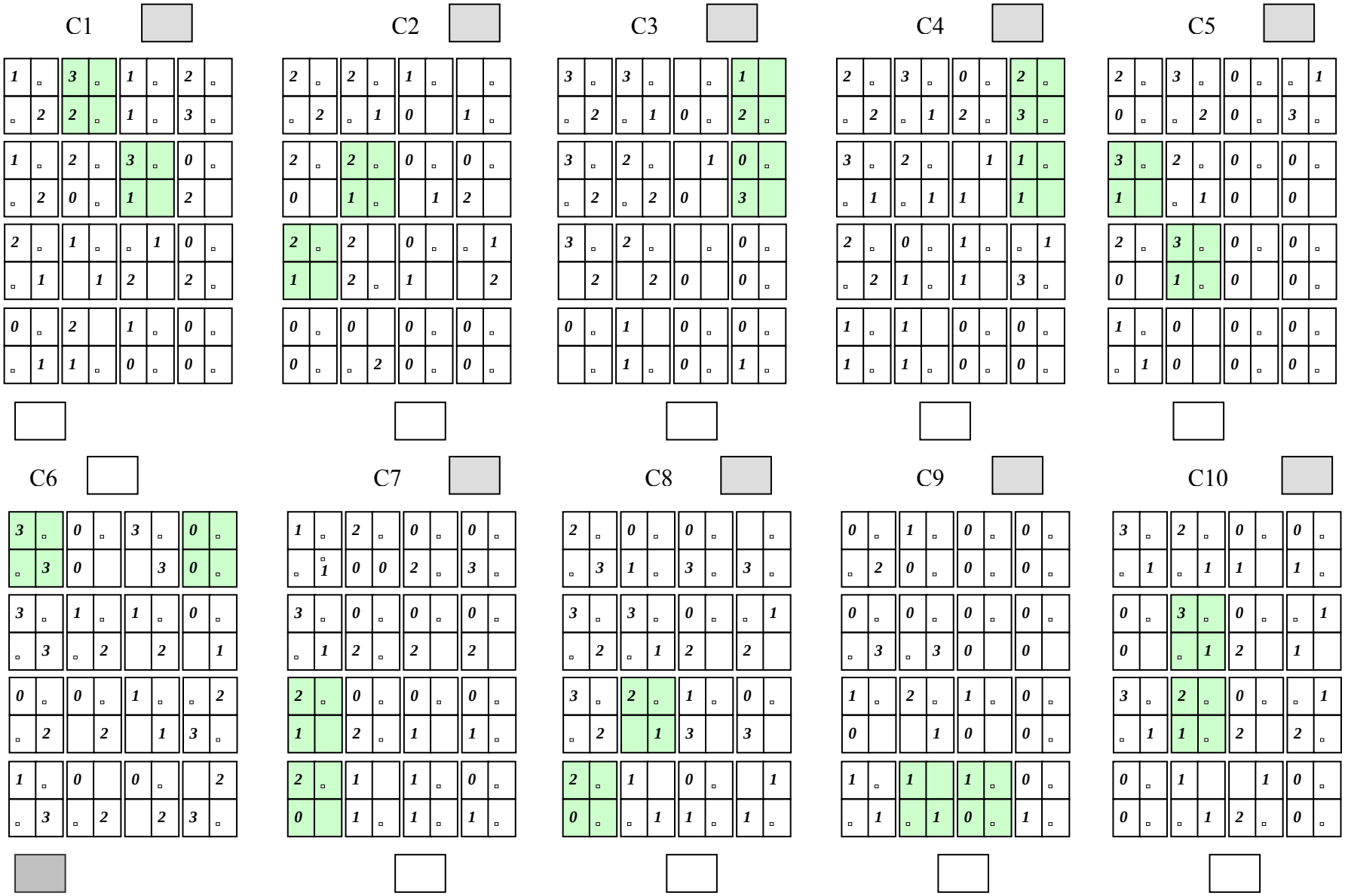


Figure (6.6) – Control Subjects Electrode Optimisation Map

6.3.1.3 Walking phase results and analysis for control subjects:

Walking studies were carried out immediately after the seated phase on 5 randomly selected control subjects from the original 10 using the parameters and electrode groups selected by the ST32 system during the seated testing.

Test 1

The first step in this test was to set up the stimulation signal envelope parameters required for walking, which were the stimulation rise time and fall time and also the extension time if required. The subjects were asked to walk for few meters using the default parameters, which was 80ms rise and fall time and zero extension time. Then by observing the walking gait and the movement obtained by the stimulation these parameters were tuned. The stimulation envelope rise time and fall time was set mainly to optimise the subject's comfort and speed. The extension time was not needed and was always kept at zero. The chosen parameters for the 5 controls subjects who did the walking are presented in table (6.6).

Control subject number	stimulation envelope rise time (ms)	stimulation envelope fall time (ms)
1	120	80
4	160	40
5	200	120
9	80	80
10	120	40

Table 6.6 – Control subjects walking stimulation envelope parameters

Test 2

This was the ankle angle threshold test. This was done by measuring the ankle angle using the ST32 system sensors. Once the ankle angle is observed to be enough so that the toes cleared the ground during the swing phase, the target angle was saved by pressing a button on the ST32 system. The chosen ankle angles for the 5 controls subjects who did the walking are presented in Table (6.7). The results show that the measured ankle angles for these subjects vary within the normal range 65° – 80°. This was also dependent on the sensor placement accuracy.

Control subject number	Ankle angle threshold ( )°
1	72
4	68
5	74
9	81
10	63

Table (6.7) – Control subjects ankle angle thresholds

Test 3

After the walking parameters set-up, the subjects were asked to practise using the system for 15-30 minutes. Then the walking test over 10 meters was performed. In the 10 meters walking test the subjects walk 10 meters without FES and 10 meters with FES. The number of steps and time taken was recorded with and without FES. The results obtained from the 5 control performed this test are illustrated in Table (6.8). Video registration was taken for one control subject walking with and without FES for gait comparison.

	10m walk without FES			10m walk with FES		
Subject no.	No.steps	Time (s)	Speed m/s	No.steps	Time (s)	Speed m/s
C01	15	8	1.2	14	8.1	1.2
C04	15	7.1	1.4	15	7.4	1.3
C05	14	8.1	1.2	14	7.7	1.2
C09	7	9	1.0	9	9.9	1.0
C10	14	7	1.2	13	7.2	1.3

Table (6.8) – Control subjects walking test results

These results show that the stimulation did not interfere with the normal walking speed for these control subjects.

Test 4

After the walking test each subject was asked two questions to be answer on a visual analogue scale based on walking with and without the device:

1. On a scale of 0-10 how would you rate how you are able to walk with the device? 0 = worst, 10 = best
2. On a scale of 0-10 how would you rate how comfortable the stimulation feels on your leg whilst walking with the device? 0 = most uncomfortable, 10 = most comfortable

subject	Comfort of stimulation	Ability to walk
C01	8	8
C04	9	9.8
C05	10	10
C09	7.4	7.2
C10	9.1	10
Mean score	8.7	9

Table (6.9) - VAS scores test results

The results of VAS scores shown in Table (6.9) show that the ST32 system is comfortable to use and is not upsetting or disturbing the normal walk of these healthy control subjects.

6.3.2 MS and Stroke patient subjects

6.3.2.1 Assessment of Subjects

After applying the eligibility and exclusion criteria explained earlier of the 14 volunteer patient subjects recruited in this study, 12 patients were found to be eligible to take part in the study one patient was excluded due to having a cardiac pacemaker and another patient was excluded due to severe lower limb skin sensation. A summary of these patients assessment results are presented in Table (6.10).

No.	background	Walking aid	Muscle . strength	Spasticity/ ROM
P01	49 yrs. Male, 83Kg, 165cm, MS, diagnosed 10yrs. EDSS 6.0. Left footdrop Chronic back pain INCLUDED	Occasionally 1 stick ODFS outside, not in house. Used AFO in past	R leg- full strength. L leg: hip and knee- full range against some resistance but weaker than R. Ankle- some movement, not full range, not against resistance	Spasticity: none Ankle ROM some movement, not full range. Passive dorsiflexion 100^0 Active dorsiflexion 128^0
P02*	41yrs female, 55Kg, 175cm, MS, diagnosed 14 yrs. EDSS 5.5. Footdrop on left but only when fatigued or affected by heat. INCLUDED no footdrop 10m.	walking aid: nil Has been given an AFO to wear when needed.	R leg: full L leg: knee- full strength, hip and ankle- full range against some resistance but weaker than other side.	Spasticity, moderate Ankle ROM: passive dorsiflexion 70^0, active dorsiflexion 78^0 Tremor left upper and lower limb
P03	54 yrs female, 61Kg, 174cm, MS, diagnosed 30 years ago, EDSS 6.5. Footdrop on left when fatigued . INCLUDED	walking aid: 2 sticks Previously used an ODFS ,when used to walk longer distances. Now effort of putting it on outweighs benefit.	R leg and L leg: full strength	Spasticity, mild ankle range of movement passive dorsiflexion 78^0, active dorsiflexion 85^0
P04*	56 yrs. Male, 79Kg, 179cm MS, diagnosed 35 years ago, EDSS 6.0. LOST TO FOLLOW UP (walking study)	walking aid: 1 stick	R leg: hip, knee and ankle- less than full strength, can move against resistance. L leg: hip- not move against resistance, knee- full strength, ankle- move against resistance, not full strength.	Spasticity: moderate. Ankle ROM passive dorsiflexion 90^0, active dorsiflexion 102^0
P05	56yrs, male. 81Kg, 178cm Stroke 7 months ago. Ready for discharge from hospital. Right hemiplegia INCLUDED	walking aid: 1 stick Early stages post stroke. Leaning against the wall as well as using 1 stick.	L leg: full strength. R leg: hip and knee- no movement , knee- can move against gravity but not against resistance	Spasticity : mild Ankle ROM passive dorsiflexion 80^0, active dorsiflexion 130^0 (no active range)

No.	Background	Walking aid	Muscle . strength	Spasticity/ ROM
P06	47 yrs. Male. 74Kg, 186cm Stroke 16 months ago. Left hemiplegia. INCLUDED	walking aid: 1 stick Uses an ODFS	R leg: full strength. L leg: Hip and knee- movement against resistance, not full strength. Ankle- no active movement.	Spasticity: marked Ankle ROM: passive dorsiflexion 93^0, active dorsiflexion 130^0 (no active range)
P07*	47yrs. Male MS, 89Kg, 156cm diagnosed 7 years ago, EDSS 6.0. INCLUDED no footdrop 10m	Walking aid: 1 stick, intermittently	L leg: full strength. R leg: knee- full strength. Hip and ankle- movement against resistance but not full strength.	Spasticity: mild ankle ROM: passive dorsiflexion 77^0, active dorsiflexion 77^0
P08*	39 yrs. Female. 72Kg, 176cm Stroke 2 months ago. Left hemiplegia. Inpatient receiving rehabilitation. INCLUDED	Walking aid: 1 stick Walks with an ankle splint to correct lateral instability.	R leg full strength. L leg: hip- movement seen but not against gravity, knee- contraction but no movement, ankle- no movement.	Spasticity: severe ankle ROM: passive dorsiflexion 110^0, active dorsiflexion, No movement, 145^0
P09	54 yrs. Male, MS 85Kg, 176cm Diagnosed 5 years ago. EDSS 6.0 INCLUDED	Walking aid: 1 stick	L leg: full strength. R leg: Knee- full strength, hip- move against gravity but not against resistance, aAnkle- palpable contraction but no movement.	Spasticity: mild Ankle ROM: passive dorsiflexion 100^0, no active dorsiflexion 136^0
P10#	Female MS EXCLUDED (abnormal Sensation)			
P10	50 yrs. male MS 75Kg, 173cm diagnosed 5 years ago. EDSS 6.0 INCLUDED	Walking aid: 1 stick	L leg: full strength. R leg: hip, knee, ankle- movement against gravity but not against resistance	Spasticity- none ankle ROM passive dorsiflexion 106^0, no active dorsiflexion 130^0
P11*	66yrs. female 80Kg, 171cm Stroke 14 months ago INCLUDED	Walking aid: 1 stick	L leg: full strength. R leg: knee- full strength, hip- move against gravity but not against resistance, ankle- palpable contraction but no movement.	Spasticity- mild ankle ROM passive dorsiflexion 100^0, no active dorsiflexion 136^0
P12	59 yrs. Male 75Kg, 176cm Stroke 3 years ago. Hemiplegia right side INCLUDED	Walking aid: nil	L leg: full strength. R leg: hip and knee- move against resistance but weaker than the other side. Ankle- no movement.	Spasticity- marked ankle ROM passive dorsiflexion 90^0, no active dorsiflexion 153^0
P13#	Male Stroke pacemakers EXCLUDED			

Table (6.10) – Patients assessment results

The assessment data show that the selected volunteered patients subject are varying in disability (7 MS, 5 stroke), gender, wide ranges of age(range 39-67), height and weight also are in normal range.

6.3.2.2 Seated phase test results and analysis for patient subjects

Seated studies were carried out on all 12 patient subjects using the same 4X4 electrode array following the same procedure explained earlier. The only difference was performing the test on the affected leg (left or right).

Test 1

The twitch stimulation signal parameters that been chosen during the seated phase and the continuous stimulation signal parameters that been chosen after completing both the seated phase and the walking phase are presented in Table (6.11).

These results show that, in continuous stimulation the biphasic square, sine and double sine biphasic charge balanced pulse shape are used mostly, the pulse widths were 300 μs or 350 μs or 400 μs and the amplitude is varying between 42% and 58 % of the maximum amplitude at 33 Hz or 40 Hz stimulation frequency. In twitch stimulation the square biphasic charge balanced pulse shape was selected the most same as in controls with fixed 400 μs pulse width, the amplitude varying between 50% and 70 % of the maximum amplitude which was slightly higher than the controls.

Patient number	Twitch pulse shape 1 – 6*	Continuous pulse shape 1 – 6*	Twitch pulse width µ sec	Continuous pulse width µ sec	Twitch pulse amplitude % **	Continuous pulse amplitude % **	Continuous stimulation frequency Hz
1	3	4	400	350	60	52	40
2	3	4	400	350	50	46	33
3	3	5	400	350	50	42	33
4	3	3	400	400	70	48	40
5	3	3	400	400	50	40	33
6	3	3	400	350	50	43	33
7	5	4	400	350	50	47	40
8	3	3	400	350	50	41	33
9	4	4	400	350	50	42	40
10	4	3	400	350	50	47	40
11	3	4	400	400	50	46	33
12	5	4	400	350	70	58	33

*pulse shapes

Pulse shape 1 = no wave stored

Pulse shape 2 = square wave

Pulse shape 3 = biphasic square wave

Pulse shape 4 = sine wave

Pulse shape 5 = double sine wave

Pulse shape 6 = triple sine wave

Pulse shape 7-12 = no wave stored

** This is a percentage of the maximum amplitude (400 V peak-peak with out load)

Table (6.11) - Chosen stimulation signal parameter for patient subjects

Test 2

One of the aims of this test is to record the twitch stimulation acceleration response and the continuous stimulation observation same as done for controls before. A typical set of twitch acceleration responses and observed movement scoring for patient number 1 are presented in Table (6.12). These results are presented in a graphical form in Figure (6.7), where the twitch acceleration response recorded from each electrode in the 16x1 array are in the top graph and the observed continuous stimulation scoring for each electrode are in the bottom graph.

Studying these twitch and continuous stimulation responses obtained from foot drop patients show clear relationship between the twitch response results and the observed continuous movement scoring. To analyse this relationship, the Pearsons's correlation coefficient between the observed continuous movement and the twitch response was calculated using Equation (4.1) same as in section (4.3.1). The dorsiflexion and plantarflexion R correlation was calculated for the same subject (control number 1) and the results was R = 0.95. According to the optimisation algorithm discussed in chapter 4 most of the negative twitch responses that represent plantarflexion or inversion will be neglected and only the positive twitch responses for dorsiflexion and eversion are left. The R correlation coefficient was calculated for the same subject based on dorsiflexion data only and the result was R = 0.94.

Electrode Number	Twitch Acceleration mV + Dorsiflexion - Plantarflexion	Continuous scoring* + Dorsiflexion - Plantarflexion	Twitch Acceleration mV + Eversion - inversion	Continuous scoring* + Eversion - inversion
1	23	0	43	1
2	148	3	27	0
3	169	3	-17	-1
4	35	0	78	2
5	0	0	49	1
6	23	0	41	1
7	0	0	0	0
8	42	1	7	0
9	114	2	0	0
10	24	0	36	1
11	13	0	21	0
12	126	2	0	0
13	97	3	3	0
14	111	2	-37	-1
15	92	2	-19	-1
16	38	1	-15	-1
* Absent = 0, Weak = 1, Normal = 2, Strong = 3				

Table (6.12) - Twitch responses and observed movement scoring for patient number 1

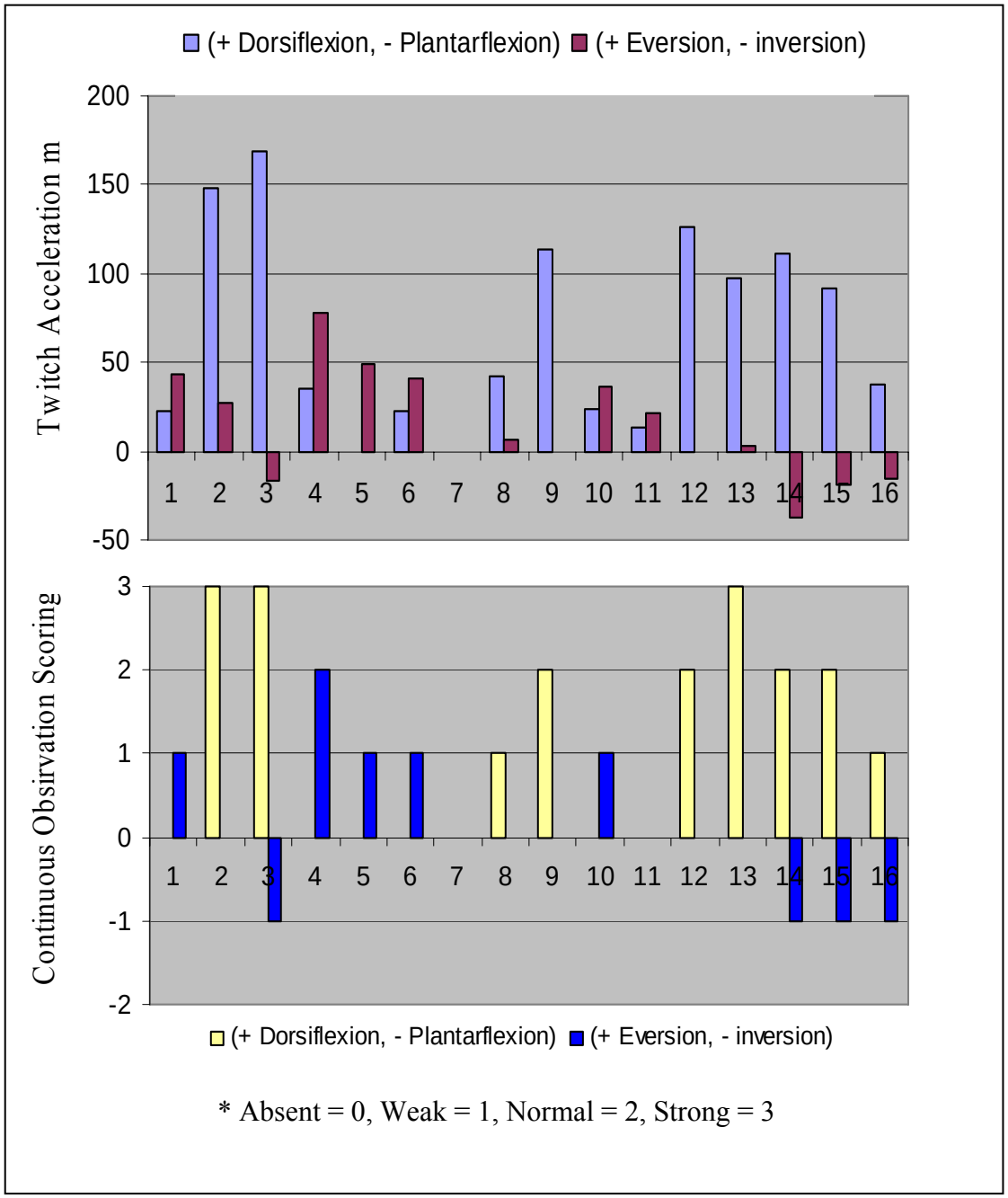


Figure (6.7) - Twitch responses and observed movement scoring for patient number 1

Test 3

To prove that the twitch response could be used to optimise the electrode array used for patients suffering from foot drop. The correlation between the observed continuous movement and the twitch response was done for all the 12 patients recruited in the study. This calculation include; dorsiflexion and plantarflexion together, dorsiflexion only, eversion and inversion together, eversion only. All the correlation results are presented in Table (6.13) and also in graphical format in Figure (6.8). Good high correlations were found for all 12 patients. This confirms that concept that twitch accelerating response can be used to optimise the electrode array on real patients.

Patient number	Dorsiflexion Plantarflexion Correlation	Eversion Inversion Correlation	Dorsiflexion Correlation	Eversion Correlation
1	0.94	0.96	0.94	0.94
2	0.97	0.95	0.97	0.97
3	0.82	0.90	0.82	0.79
4	0.97	0.94	0.91	0.89
5	0.94	0.91	0.94	0.78
6	0.87	0.95	0.87	0.86
7	0.92	0.91	0.89	0.89
8	0.98	0.91	0.86	0.89
9	0.93	0.85	0.92	0.85
10	0.91	0.96	0.89	0.76
11	0.93	0.88	0.93	0.88
12	0.87	0.96	0.85	0.87
avarage	0.92	0.92	0.90	0.87

Table (6.13) - Twitch and continuous correlation result for all 12 patients

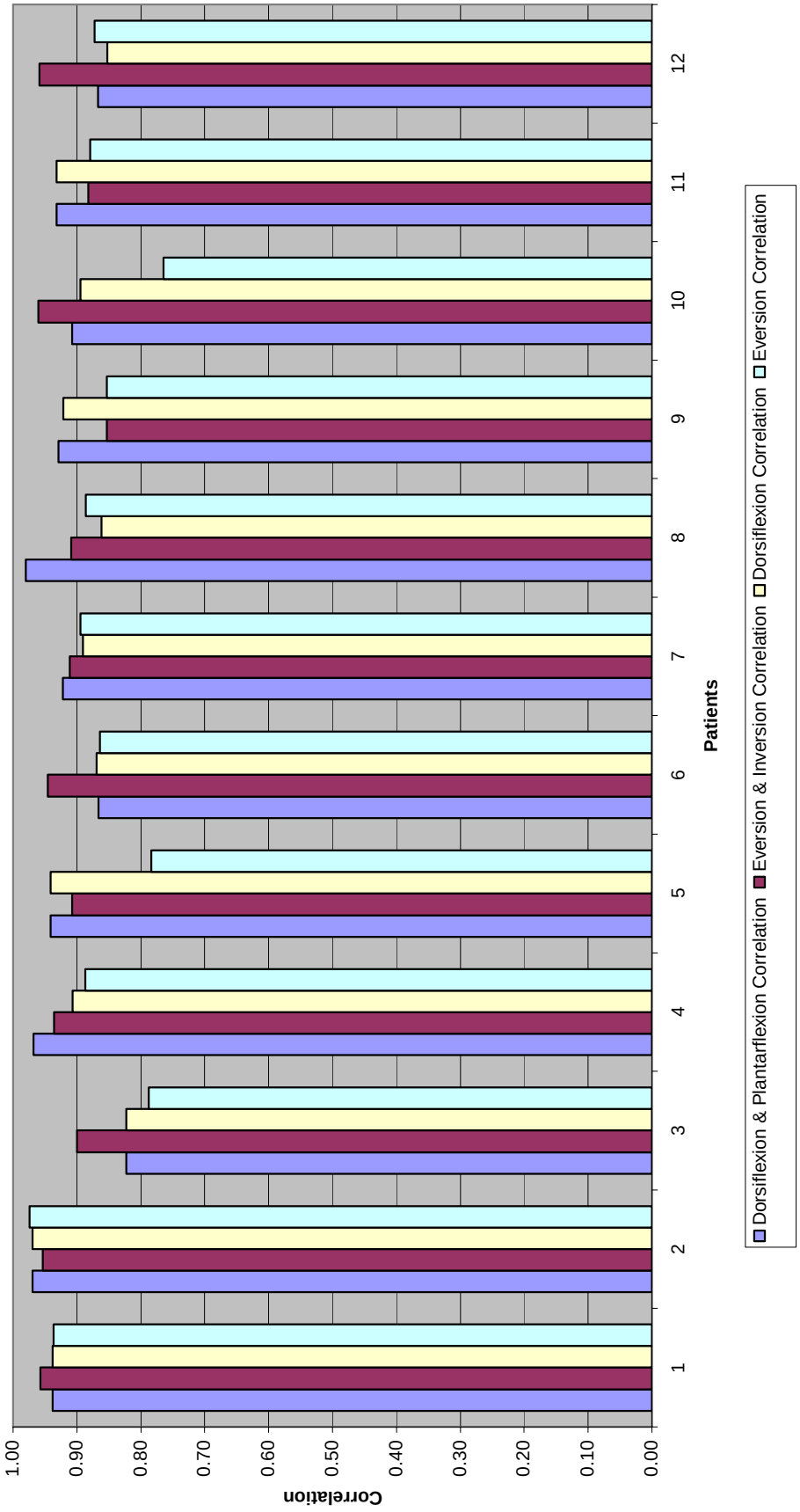


Figure (6.8) - twitch and continuous correlation result for all 12 patients

Test 4:

This was the automatic electrode array optimisation test, which was performedby the ST32 system software. The outcome of this optimisation process was 15 groups of pairs of active and return electrodes ranked from 1 to 15 out of all the possible electrode combinations (2 x 16 = 32 groups) as explained earlier in the electrode array optimisation algorithm, chapter 4. Each of these groups was then selected and tried in turn until the best electrode group that gave comfortable good dorsiflexion with some eversion was found. The selected electrode group ranks for each of all 12 patients are presented in Table (6.14).

Patient number	selected Group rank
1	1
2	3
3	4
4	2
5	2
6	1
7	2
8	2
9	3
10	1
11	2
12	1

Table (6.14) - Chosen electrode group ranks for each of these 12 patient subjects

By examining the Table, it can be seen that for most patients the algorithm selects one of the top 4 electrode groups that gives dorsiflexion with some eversion. This proves that the optimisation algorithm works for patients. The variation of the selected rank was due to few factors like the comfort and combining two pairs of electrodes instead of one as explained in the optimisation algorithms.

6.3.2.3 Electrode mapping analysis

Figure (6.9a) and Figure (6.9b) shows the electrode mapping of all 12 patients. The test followed the same procedure explained in section (4.6.2) for recording the continuous stimulation response from each single active electrode but the observation scoring was done this time by two physiotherapists. The electrode array optimisation algorithm uses the twitch response to select the optimum 15 groups of electrode as explained earlier in chapter 4. The subject chose the best combination that gave the desired comfortable dorsiflexion with some eversion, this was achieved by trying the electrode combinations in turn starting from the highest ranked. The final chosen combination of pairs of electrode is highlighted in different colour on the same maps.

By examining the data presented in Figures (6.9) it is clear that there is no clear electrode pair that contributes to an overall pattern. Each electrode pair chosen shows unique differences. This may be due to different physical differences in anatomy of different patients. The maps show that there is certainly a predominant selection of dorsiflexion movement as required, but now there is also inverter movement in 7 of the 12 patients. This may reflect differences in motor control of the patient group and is interesting in that there is sometimes a general lack of everter movement in most electrodes from the 7 patients showing inverter movement. By examining each patient electrodes in turn it is evident that from observed movement, it may be possible to combine electrodes that have everter and inverter movement so that they cancel out whilst still giving dorsiflexion. The ranking algorithm electrodes showing weak, normal or strong Inversion with Dorsiflexion would always be ranked lower than those with Eversion and Dorsiflexion, which excludes certain combinations of electrodes as pairs. This was designed so that the minimum amount of time was required to setup the electrode array, otherwise if all paired combinations were demonstrated this would have taken (16!/(16-2)!)/2 = 120 more measurements for a 4x4 array. In conclusion it would seem that the electrode combinations chosen by the algorithm produce the desired response using the simple ranking procedure based on individual electrode twitch.

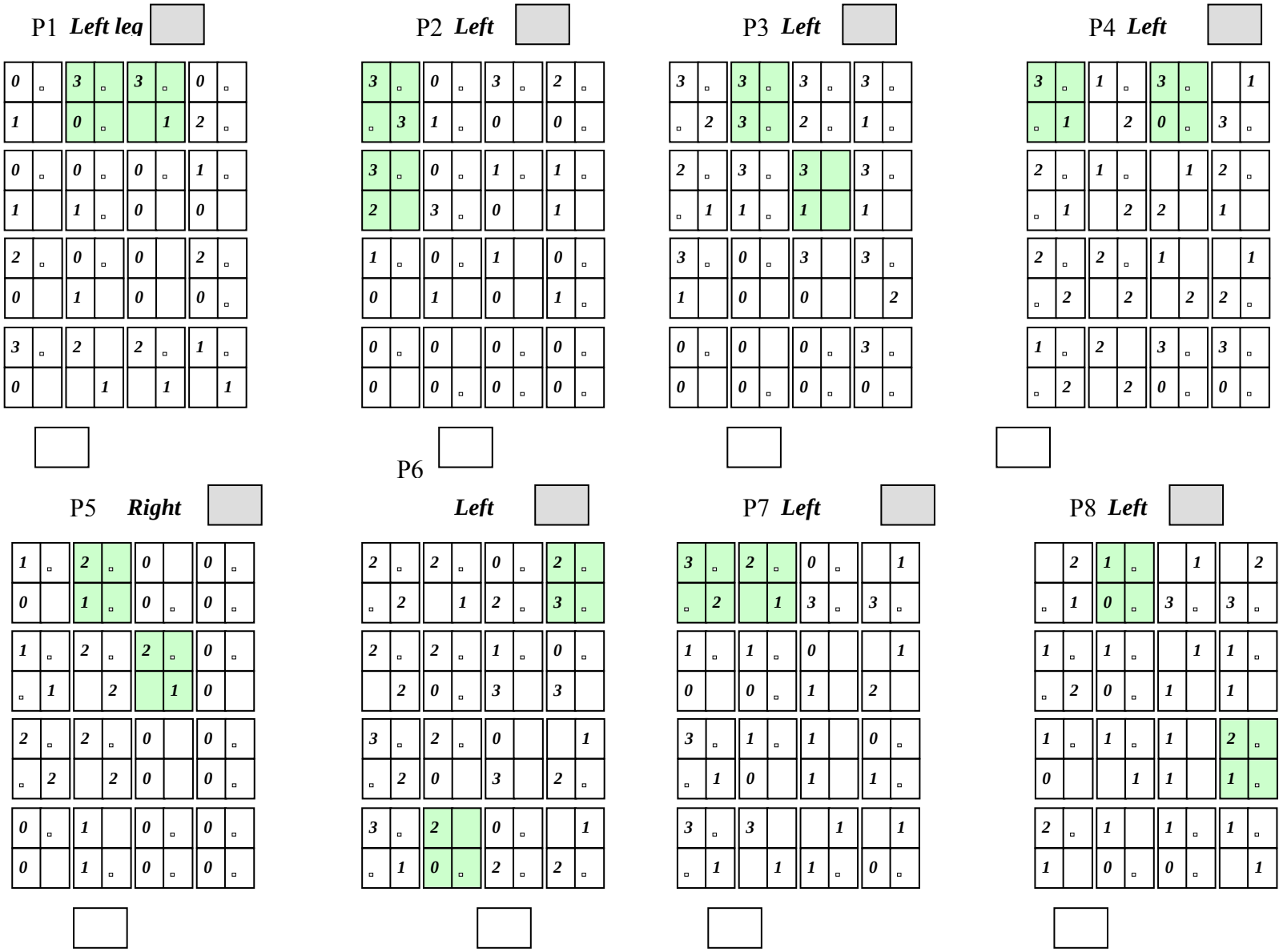


Figure (6.9a) – Patient Subjects Electrode Optimisation Map

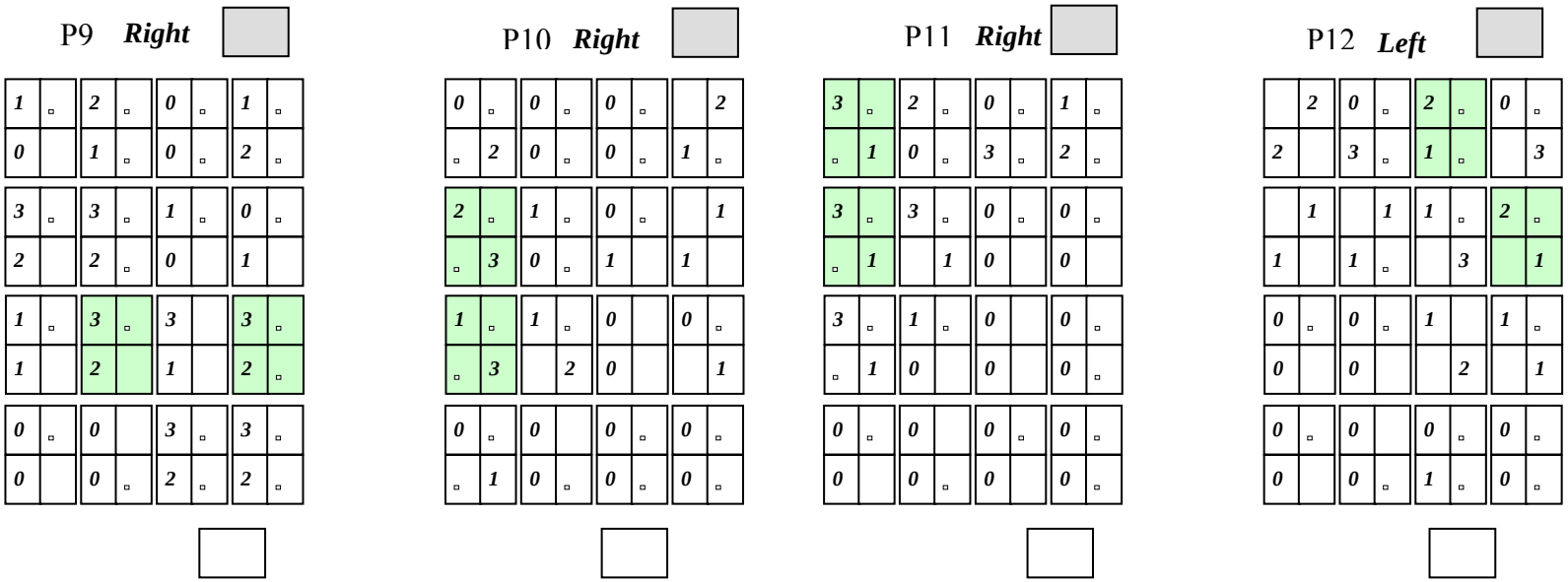


Figure (6.9b) –Patient Subjects Electrode Optimisation Map

6.3.2.4 Walking phase results and analysis for patient subjects:

Walking studies were carried out immediately after the seated phase on the patients using the parameters and electrode groups selected by the ST32 system during the seated testing. Patient 4 did not have enough time to do the walking test. Patients 2 and 7 were excluded from the walking test because they only have foot drop when they experience muscle fatigue. Patient 8 was also excluded because of severe spasticity on the affected leg and patient 11 was excluded because of an unusual walking gait that caused the system sensors to find some difficulty in detecting the walking gait events.

Test 1

The first step in this test was to set up the stimulation signal envelope parameters required for walking, which were the stimulation rise time and fall time and also the extension time if required. The patients were asked to walk for a few meters using the default parameters, which was 80ms rise and fall time and zero extension time. Then by observing the walking gait and the movement obtained by the stimulation these parameters were tuned. The stimulation envelope rise time and fall time was set mainly to optimise the subject's comfort and speed. The extension time was not needed and was always kept at zero. The chosen parameters for all patients who performed the walking are presented in Table (6.15).

Test 2

This was the ankle angle threshold test. This was done by measuring the ankle angle using the ST32 system sensors. Once enough ankle angle is observed to be clearing the ground during the swing phase it will be saved by pressing a button on the ST32 system. The chosen ankle angles for the 5 controls subjects who did the walking are presented in Table (6.7). The results show that the measured ankle angles for these subjects vary within the normal range 64° – 74°. This was also dependent on the sensor placement accuracy.

Patient subject number	stimulation envelope Rise time (ms)	stimulation envelope fall time (ms)
1	160	60
3	80	20
5	80	40
6	100	40
9	160	60
10	100	40
12	180	40

Table 6.15 – Patients walking stimulation envelope parameters

Patient subject number	Ankle angle threshold ( )°
1	64
3	72
5	71
6	66
9	70
10	74
12	68

Table (6.16) – Patients ankle angle thresholds

Test 3

After the walking parameters were set up the patients were asked to practise using the system for 15-30 minutes. Then after that the walking test over 10 meters was performed. In the 10 meters walking test the subjects walk 10 meters without FES and 10 meters with FES. The number of steps and time taken was recorded for each with and without FES. The results obtained from the patients performed this test are given in Table (6.17). Video registration was taken for patients walking with and without FES for gait analysis. Table (6.19) show how the patient steps and time taken to walk 10 meters was improved, this Table also show how the speed and stride length was improved.

10m walk without ST32 FES					
Patient number	steps	Time s	Speed m/s	steps/min	stride length (m)
P01	23	16.9	0.59	81.8	0.87
P03	53	38.4	0.26	82.7	0.38
P09	20	14.4	0.69	83.3	1.00
P05	38	46.0	0.22	49.6	0.53
P06	30	49.4	0.20	36.4	0.67
P10	30	22.8	0.44	78.8	0.67
P12	20	13.6	0.73	88.1	1.00

Table (6.17) – patients walking test without FES

10m walk with ST32 FES					
Patient number	steps	Time s	Speed m/s	steps/min	stride length (m)
P01	18	10.7	0.94	101.3	1.11
P03	42	31.5	0.32	79.9	0.48
P09	17	11.6	0.86	87.8	1.18
P05	26	41.0	0.24	38.1	0.77
P06	21	21.0	0.48	60.0	0.95
P10	26	20.3	0.49	76.8	0.77
P12	18	11.2	0.89	96.3	1.11

Table (6.18) – patients walking test with FES

Remove similar columns

subject no	Steps decrease %	Walking time improvement %	Walking speed improvement %	Stride length improvement %
P01	21.8	36.8	58.3	27.8
P03	20.8	18.0	21.9	26.2
P09	15.0	19.3	23.9	17.7
P05	31.6	10.9	12.2	46.2
P06	30.0	57.5	135.3	42.9
P10	13.3	11.0	12.4	15.4
P12	10.0	17.6	21.4	11.1

Table (6.19) – patients walking improvement using FES

The stride length is constant and walking speed is increased, the gait cycle time must get smaller as walking speed= (stride length)/(gait cycle time). When walking at average walking speed a subject instantaneous velocity is not fixed, instead their trunk slows down and speeds up during each gait cycle, (Rosie, 1994).

Test 4

After the walking test each patient was asked four questions to be answer on a visual analogue scale based on walking with and without the device:

3. On a scale of 0-10 how would you rate how comfortable the stimulation feels on your leg whilst walking with the device?
   0 = most uncomfortable, 10 = most comfortable
4. On a scale of 0-10 how would you rate your ankle movement with the device?
   0 = worst, 10 = best
5. On a scale of 0-10 how would you rate how you are able to walk without the device?
   0 = worst, 10 = best
6. On a scale of 0-10 how would you rate how you are able to walk with the device?
   0 = worst, 10 = best

The results of VAS scores shown in Table (6.20) show that the patients find the ST32 system comfortable and their ankle movement and ability to walk was improved

Patient number	Comfort of stimulation	Ankle movement	Ability to walk without FES	Ability to walk With ST32 FES
P01	7	7.8	1.2	5.2
P03	6.7	7.1	3.8	7.9
P09	6.1	8.1	1.3	7.6
P05	7	7	5	6
P06	9.7	8.2	2.1	10
P10	9.2	4.9	4.5	4.5
P12	10	7.1	6.8	9.6

Table (6.20) - VAS scores test results

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6.3.2.4.1 Patients visual walking gait analysis

Two independent gait analysis physiotherapist assessors have watched the recorded gait videos for the patients without knowing any information about the patients and without knowing if the FES system was ON or OFF. These assessors used the *Rivermead* visual gait analysis scoring system.

0: normal
1: mild deviation from normal
2: moderate deviation from normal
3: severe deviation from normal
x: no data available

There were variations in scores between the two video assessors; this is not surprising as no training or discussion of the assessment took place prior to viewing the videos. The 2 assessors did collaborate after the assessment and watched the video again (involving a 3rd assessor) and agreed scores concentrating on the main parameters of gait that are known to be affected by FES. The assessment main gait cycle features [1,2,3] are: [1] heel strike, are presented in Table (6.21), [2] inversion are presented in Table (6.22)., and [3] plantarflexion presented in Table (6.23).

Subject	Stance phase		
	Heel strike no FES	Heel strike with FES	change
P01	1	0	1
P03	2	0	2
P05	2	0	2
P06	2	0	2
P09	1	0	1
P10	0	0	0
P12	2	0	2

Table (6.21) - Heel strike score

Subject	Swing phase		
	Inversion no FES	Inversion with FES	change
P01	2	1	1
P03	1	0	1
P05	2	1	1
P06	3	1	2
P09	1	0	1
P10	2	0	2
P12	1	1	0

Table (6.22) - inversion score

Subject	Swing phase		
	Plantarflexion no FES	Plantarflexion with FES	change
P01	1	0	1
P03	0	0	0
P05	2	1	1
P06	3	0	3
P09	0	0	0
P10	2	0	2
P12	2	0	2

Table (6.23) - Plantarflexion score

These results show that the ST32 FES system has succeeded in this group of patients to correct the heel strike to normal and reduce the inversion and plantarflexion to normal and also helps the toes to be off and clear the ground.

6.4 Summary

This chapter discussed the ST32 system clinical trial that was carried out by professional physiotherapist researchers in (UBHT) Bristol General Hospital. In these trials 10 randomly-selected normal and control subjects and 14 patients were recruited. The study objectives, requirements and methodology were discussed in detail. The testing was split into three stages. The first stage was the clinical assessment which was done in cooperation with a physiotherapist to study the condition of each subject individually. The second stage was the system set up testing that included using the system to optimise the best electrode stimulation site and choosing the stimulation signal parameters. In this second stage the twitch acceleration data from each electrode was collected as well as the continuous stimulation response from each electrode. This data helped in developing the optimisation algorithms during the trials. The third stage was to use the system to correct foot drop during walking, based on the optimisation results and the walking control algorithms.

In this chapter the trials results was presented in a different format to help in the analysis. The correlation between the twitch response and continuous stimulation response showed the validity of using the optimisation algorithms. The electrode mapping analysis showed that stimulation of pairs of combinations of active electrodes with a single return electrode always produced the desired movement for the controls and patients in the trials. It was noticed that during the development of the optimisation algorithm the use of two active electrodes simultaneously for continuous stimulation gave a better overall effective movement than using a single active electrode. However all combinations of pairs of active electrodes to give similar movement to the top chosen pair were not investigated. Walking trials on controls showed that the system did not affect their walking gait, under active stimulation. Clinical trials on patients showed clear improvements in walking speed and stride length when used with active stimulation compared to when the stimulator was not used. The stimulation pulse output was reported to be comfortable by most of the subjects. The walking gait for each patient was recorded and assessed by independent physiotherapists. These trials prove the concept of optimising the electrode array automatically in a very short time based on the twitch response.

Chapter 7

CONCLUSION AND FUTURE WORK

CHAPTER 7: CONCLUSION AND FUTURE WORK

7.1 The main objectives of the project were

1. To design an "intelligent" stimulator, which can have variable pulse shapes (for comfort), pulse trains of variable frequency and pulse width for more dynamic stimulation and control), and feedback (for measuring function using appropriate sensors),

2. To use an electrode array to alleviate electrode placement problems associated with obtaining the desired movement,

3. To design an algorithm that can drive the array using an appropriate selection of electrodes.

The project achieved all of these main objectives.

Foot drop correction during walking was chosen as an application for this research as it is the most common disability that is responsive to this type of therapy.

Three prototype stimulation systems have been built during this research to achieve objectives [1] and [3]. The final prototype was based on the latest embedded and microcontroller system technology with the following key specifications:

- LCD and keypad user interface
- Twelve differently-shaped digitally-synthesised stimulation waveforms with variable pulse width and repetition rate
- Digital control of the amplitude rise time, extension time and fall time of the stimulation signal envelope
- Ability to produce single twitch signal pulses, manually and automatically

- Digital control of 32-electrode array using a high voltage switching circuit
- Pulse parameter modification on a pulse-by-pulse or envelope-by-envelope basis
- Analogue and/or digital interface to force-sensitive resistor, gyroscope and accelerometer sensors providing real-time feedback
- Comfortable stimulation
- The prototype is small enough to be portable and is battery powered
- Built to meet the (BS EN 60601-1:1990) "*Medical Electrical Equipment Part 1 General requirements for safety*" and (BS EN 60601-2-10:2001) "*Medical Electrical Equipment Part 2.10, particular requirements for the safety of nerve and muscle stimulators*".

Initial trials were carried out on the prototypes using volunteer subjects in the engineering laboratory. More rigorous clinical trials on the final version of the instrument were supervised by professional physiotherapist researchers in (UBHT) Bristol General Hospital. The results from these clinical trials were collected and assessed by professional therapists at UBHT from within and outside the MS research unit (in the case of independent assessments).

A new electrode optimisation technique was invented based on the use of the twitch response. This uses a single pulse to each electrode, thereby avoiding muscle fatigue and pain and reducing the setup time in comparison with continuous stimulation. Trials were carried on 30 normal and control subjects and 12 patients (42 in total), to study the relationship between the twitch response and the continuous response. Generally a good correlation was found ($70\% < R < 98\%$).

An accelerometer feedback system was developed and used for setting up the electrode array by measuring the twitch response. A signal processing algorithm was developed to extract the useful twitch movement data from the accelerometer signal.

An automatic optimisation algorithm for the electrode array was designed based on the twitch response. This optimisation process finds the 15 combinations of pairs of electrodes that are highly effective in producing the desired stimulation. The patient

may then choose the most comfortable and effective combination. During clinical trials the patient usually chose a combination within the best 5 ranks, which show that the algorithm is effective.

The main achievement of using this array optimisation technique based on the twitch response was the time required to find the best stimulation site, as it takes between 2-5 minutes to decide about the best electrodes to use within the electrode array.

These algorithms were based on (and the results were obtained using) a specific electrode array size, shape, topology and material. The algorithm may need to be developed if these are changed. These results were based on 30 randomly-selected normal and control subjects and 12 patients, all of whom were volunteers. Whilst this is a reasonable sample size for testing the prototypes, a larger sample would guarantee these techniques and algorithms would work on most patients.

The electrode mapping analysis showed that each subject and patient was unique; this may be due to different physiological differences of the leg and muscles. The result of the trial presented in chapter 6 shows that, in most cases the stimulation of pairs of combinations of active electrodes and return electrodes is more effective in producing the desired movement than using a single active and return electrode in the array.

A method was developed, using two dual-accelerometer sensors, to measure the angle that the foot makes with the shank of the lower leg during walking. A walking algorithm for foot-drop correction was developed to maintain dorsiflexion at an appropriate target angle, making sure that the toes do leave the ground at the start of the swing phase using dynamic feedback control.

Investigation of the different stimulation signal parameters during the laboratory and clinical trials using constant-voltage stimulation suggests that specific parameter ranges are common to the different subjects:

- Square and Sine wave biphasic charge balanced stimulation signal
- 300 – 400 μs pulse width
- 30 – 40 Hz stimulation frequency

- 30 – 75% of the maximum amplitude (400Vp-p with no load)
- Stimulation envelope rise time 40-180 ms
- Stimulation envelope fall time 20-80 ms

Trials on "normals" and controls showed that the system did not inhibit their normal walking. Preliminary clinical trials on patients showed good improvements in ankle angle movement, walking speed, and number of steps required to walk a given distance (in this case 10m). In all cases the stimulation was found to be comfortable. These trials showed that control of the stimulation during walking, based on the optimisation algorithms developed in this work, gives high quality correction of foot drop. This was shown by gait assessment analysis by the physiotherapists involved in the project and independent researchers at UBHT. These successful trials showed the efficacy of using the concept of the electrode array for assisted foot-drop correction using FES stimulation. This concept was proved for both automated setup and during FES assisted walking. This may lead to an array based stimulator having some advantages compared to using a conventional 2 electrode based single channel conventional stimulator system. These include easier setting up, as it can optimise the electrode array automatically and find a useable and effective stimulation site in a very short time, and it may lead to benefits for the end user of maintaining stimulation usage for longer by reducing the effects of muscle fatigue but this is left for future work.

7.2 Future Work

The electrode array uses standard carbon hydrogel electrodes; for this project 16 individual electrodes were placed on the lower leg. These are not linked to a substrate and some effort is required to design a single array with simplified wiring which allows easier placement for donning and doffing. The electrode optimisation algorithm may not be optimal in using all available electrodes to give the desired movement. Further work is required to see if more electrodes can be combined to give similar desired movements. Further patient trials should be performed to apply the electrode array concept to a wider range of subjects to see if it can be used on a broader range of patients.

The stimulator has been designed so that individual electrodes can be stimulated on a pulse by pulse basis. If through further work on combining electrodes for the desired movement and the electrode array shape and size was re-addressed, it may be possible to switch to different combinations of electrodes to see if muscle fatigue can be slowed. This would mean the electrode array stimulator would be more widely accepted for use on a day to day basis and would alleviate one of the main problems with existing 2 electrode stimulators.

The stimulation system could be applied to hand function to optimise pinch and grip, without any major modification, other than adding more feedback channels and accelerometer sensors.

The stimulator may be more acceptable if production units were smaller than the prototypes. A simpler interface than that required for the trials could be also developed.

Part of this research outcome was presented in more than 8 national and international conferences and meetings and generated a lot of international interest. Four scientific papers were published on some of the work (Elsaify, 2002), (Elsaify, 2003), (Elsaify 2004, IFESS),(Elsaify, 2004, IFESWS) two more journal papers are being prepared. The project sponsors (EPSRC) and reviewers considered the project outcome as Nationally Standing for Research Quality and Tending to Internationally Leading for Scientific Impact in the final assessment report. It envisaged that this device can be improved further via additional funding to work towards a device that would be available through the NHS and have real benefits in improving patient quality of life. This thesis is a cornerstone representing a true feedback controlled stimulator that measures function directly. It is this principal that has been maintained throughout the development process and has clearly proved to be beneficial in allowing the system to adapt to physiological differences of the lower leg muscles in the patient groups, without prior knowledge of these physiological differences.

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APPENDIX – A: PUBLICATIONS

APPENDIX – B

B-1) Stimulation System Version 1 & 2

B-2) Feedback Sensors

B-3) Digital filter coefficients

B-4) Stimulation System Manual

B-5) Microcontroller Embedded Firmware
(CD-ROM Enclosed)

B-6) MEMO Safety Test Results
(CD-ROM Enclosed)

APPENDIX – C

C-1) Clinical Assessment

C-2) Clinical Study Forms