The effects of Functional Electrical Stimulation on motor-cognitive interference during gait in people with foot drop following stroke

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Declaration

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Abstract

A stroke can impair both motor and cognitive functioning, reducing the automaticity of walking and increasing susceptibility to motor-cognitive interference (MCI). There is also some evidence of an association between susceptibility to MCI and the increased incidence of falls in stroke. Functional Electrical Stimulation (FES) is commonly used for correction of foot drop due to stroke. At the start of the PhD, studies had shown FES increases walking speed. However, questionnaire-based studies found that users rated a reduction in effort and a reduced risk of tripping or falling as the two most important reasons for using FES. In these studies, the term 'effort' was not defined, but the results from a qualitative study suggested that the questionnaire respondents may have been referring to both physical and mental components. Based on this evidence the following research question was posed "Does FES reduce motor-cognitive interference during gait in people with foot drop following stroke?"

The question was first examined in a questionnaire study which collated FES user opinion from thirty current users. Respondents identified a statistically significant reduction in concentration required when walking with FES compared with walking without the device. Furthermore, the majority noted that walking without thinking about walking was easier with FES.

The second study developed and piloted a dual-task based methodology to assess the impact of FES on MCI during gait. Two participants with foot drop following stroke were evaluated over 14 weeks following first use of FES. In one participant, cognitive task performance was maintained at a similar level when walking with FES, compared with seated performance, and reduced without FES. The effects were less clear in the second participant. However, the study demonstrated the feasibility of the proposed methodology and provided the first quantitative evidence that FES can reduce MCI during gait.

In the final study of the thesis, a similar methodology was used to study the effects of MCI in a larger cohort of sixteen established FES users. Outcomes suggest that although FES can reduce the motor-cognitive interference experienced during a dual-task situation in some participants, when analysed as a group, the results did not support the existence of this effect.

Chapter 1 – Introduction

Functional Electrical Stimulation (FES) is the electrical stimulation of nerves to provide muscular contraction in such a way as to produce functionally useful movement. FES is a commonly used technique for correction of foot drop of central neurological origin and typically involves stimulation of the common peroneal nerve to elicit dorsiflexion and slight eversion of the foot during the swing phase of walking. The effectiveness of the intervention in terms of improving walking speed is well supported by evidence and a recent report by the National Institute for Health and Clinical Evidence (NICE) approved its use in clinical practice. However, at the start of this PhD there were few reports on the effects of FES on other components of gait, functioning and ability, and the NICE guidance of 2009 recommended that 'further publication on the efficacy of FES would be useful, specifically including patient-reported outcomes'.

Of the limited literature describing the effects of FES on outcomes other than gait speed, there were a small number of studies that investigated user perceptions of FES. Users reported factors other than walking speed to be the most important reasons for using FES, with a reduction in effort being cited as the principal reason. A reduced risk of tripping or falling was also highly rated by users. A reduction in the effort of walking, that is clearly seen as important by FES users, could be interpreted both as a reduction in physical and mental effort and at the start of the PhD there was some support for this concept from a qualitative study of FES users.

At the same time an emerging area of research was showing that walking is not an automated process and that its control involves higher level cognitive functions. Evidence for this comes from both brain imaging studies and gait studies in which participants are asked to perform a concurrent cognitive task whilst walking (i.e. dual-task paradigm). There were a small number of studies showing that the combined effects of motor and cognitive impairments that are common following a stroke may make participants particularly susceptible to motor-cognitive interference during walking. There was also some evidence that this effect may contribute to the increased incidence of falls in stroke.

The patient-reported effects of FES, including a reduction in effort and reduction in trips and falls required further investigation, particularly in the light of the importance placed on these effects by users. While there is some evidence that use of FES leads to a reduction in compensatory actions, such as hip hitching and circumduction, frequently used by people with foot drop to avoid foot-ground collisions during the swing phase of walking, this may not completely explain the reported reduction in effort. Similarly, although there is some evidence of improved toe clearance, this may not fully explain the reported reduction in risk of tripping and falling. There is also evidence that FES use has impact on areas of the brain serving both motor and cognitive functions. It is therefore possible that FES use may have a more complex effect than can be seen from studies of FES gait kinematics and energetics. Specifically, the user reports suggest it may reduce motor-cognitive demands during gait thus improving the ability to respond to challenges to stability and/or freeing up cognitive resources.

To explore this hypothesis, firstly, the thesis focused on building on the small number of questionnaire and qualitative studies published at the start of the PhD, by development of a questionnaire to further explore the patient-perceived effects of using FES. In particular, the questionnaire study aims were to substantiate or refute the suggestion in the literature that FES for foot drop is perceived to impact on motor-cognitive interference during gait and, if confirmed, to inform the design of subsequent experimental studies that would allow for the exploration and testing of this hypothesis.

The second aim of thesis was to investigate this hypothesis through the use of dual-task based studies. The gait laboratory studies were designed to assess the impact of FES on the cognitive control of gait. Furthermore, the aim was to collect gait parameters associated with stability to explore the contribution of FES to stability.

Thesis overview

Chapter 2 of the thesis provides a review of the background to the work. This chapter discusses the key components and functions of the neuromuscular system, a description of normal gait and concepts about the contribution of cognitive processes to the control of normal gait. A section on stroke then follows, providing an overview

of the most common effects, including a description of the effects on motor, sensory and cognitive systems. The effect of stroke on gait is then covered, highlighting the increased risk of falls and the circumstances of these. A discussion of the interaction of damage to motor and cognitive areas of the brain follows, including how this manifests in gait disturbances and are evident in dual-task study outcomes.

Chapter 2 then introduces FES, describing the device and its effects on nervous tissue to produce functional movement. The emerging evidence of its effect on brain plasticity and spinal mechanisms of motor control are discussed. This is followed by a review of the effect of FES, with a detailed focus on gait measures related to stability and fall risk and a critique of the literature reporting patient-centred outcomes. The chapter concludes with a discussion of the thesis aims.

Chapter 3 describes the development and implementation of the questionnaire study to explore the concept of 'effort' of walking. The chapter describes the process of formulation of the questionnaire content in relation to previous studies, including piloting work. Results from respondents are presented and analysed, in relation to the aims of the study. The conclusions drawn from the results, and their limitations, are discussed and their influence on the choice of tests used in the gait laboratory study is outlined

Chapter 4 describes a longitudinal gait laboratory-based of new users of FES. The study design includes a novel dual-task protocol, informed by the results of the questionnaire study reported in Chapter 3. The impact of FES on gait and performance of a cognitive task are reported.

Chapter 5 presents the results from a cross-sectional study of existing FES users, based on the same protocol as used in Chapter 4.

Chapter 6 discusses the results and draws conclusions in the context of limitations of the studies and suggests future approaches in this field of work.

Chapter 2 – Literature Review

2.1 Introduction

This chapter begins by briefly describing the key components and functions of the neuromuscular system that contribute to normal gait. This is then followed by a description of normal gait outlining the gait cycle, the spatial and temporal parameters and the main events of the gait cycle, also describing the main actions of the muscles and joints. Concepts about the contribution of cognitive processes to the control of normal gait are then defined and discussed, introducing the emerging evidence to support the interaction between the motor areas of the brain and those associated with cognitive functions.

A section on stroke follows, providing a brief overview of the most common effects, including a more detailed description of the effects on motor, sensory and cognitive systems. The effect of stroke on gait is then covered, describing the typical deviations from normal gait and, in particular, highlighting the increased risk of falls and the circumstances of these amongst the stroke population. This section is concluded by discussing the interaction of damage to both the motor and cognitive areas of the brain caused by stroke, and how this manifests in gait disturbances and evidence of increased susceptibility to cognitive interference.

The next section of the chapter introduces FES, describing the device and its effects on nervous tissue to produce functional movement. The emerging evidence of its effect on brain plasticity and spinal mechanisms of motor control are also discussed. This is followed by a review of the effect of FES on traditional outcomes of gait speed and energy cost, followed by the effect on the kinematics of gait. A more detailed review of the effects on gait measures related to stability and fall risk is provided. This is followed by a critique of the literature reporting patient-centred outcomes and the conclusions drawn from this are presented.

Finally, the chapter concludes by outlining the thesis aims.

2.2 Gait and its control

2.2.1 Functional anatomy of the Neuromuscular System

Gait is a complex behaviour, involving the coordination of many muscles and joints and processing of multiple sensory inputs for its control and adaptation (Shumway-Cook and Woollacott, 2007). Gait is controlled at various levels of the central nervous system (CNS) and the following provides an overview, based on current understanding of the functional anatomy of the nervous system, of how gait is initiated and controlled.

a) Brain

Several areas of the brain contribute to the control of gait, including the prefrontal cortex and the motor cortex; the latter comprising of the primary motor cortex, the supplementary motor cortex and the premotor cortex. Planning and preparation of coordinated, multi-joint movement is organised in the prefrontal cortex, premotor cortex and supplementary motor cortex (Kalat, 2004), with the aid of information about body position and the environment provided by the posterior parietal cortex (Rizo, 2004). Both the premotor cortex and supplementary motor cortex areas send axons (i.e. the process of an upper motor neuron that conducts nerve impulses) to the primary motor cortex, brain stem and spinal cord (Matthews, 2000). The primary motor cortex is functionally located at the end of the motor control processing scheme (Rizo, 2004) and thus outputs the motor commands, initiating movement (Kalat, 2004). Nerve fibres from the primary motor cortex form the corticospinal tract which directly controls spinal motor circuits (Matthews, 2000).

The motor cortical areas send axons to the brain stem in the corticobulbar tract (Matthews, 2000). The brain stem plans and executes anticipatory actions to stabilise the body ahead of voluntary movements (i.e. maintenance of posture) (Crossman and Neary, 2005) sending commands to the spinal cord via three major tracts of descending axons, that run parallel with the corticospinal tract. Firstly, the reticulospinal tract makes synaptic connections with motor neurons (and interneurons, which reside entirely within the spinal cord) throughout the spinal cord, providing excitory inputs that drive the central pattern generators (see section 2.1.1b following) of the spinal cord during locomotion. Secondly, the vestibulospinal tract promotes extension of the limbs and inhibits flexion. Thirdly, the rubrospinal tract promotes flexion of the limbs and inhibits extension (Crossman and Neary, 2005).

Thus, the balance of activity in the tracts will govern the equilibrium of the limbs (Matthews, 2000).

The motor cortex also sends axons to the basal ganglia. Feedback is indirectly achieved via the thalamus. The basal ganglia, thalamus and substantia nigra form three interconnected feedback loops, acting via the thalamus, allowing the basal ganglia and substantia nigra to influence the motor outputs by the motor cortex (Matthews, 2000, Rizo, 2004). The basal ganglia play a particularly important role in planning, initiating and regulating skilled movements that are normally mostly automatic (Tyldesley and Grieve, 2002), adjusts biases that allow movement to be initiated and inhibits movements that would be detrimental, thus organising sequences of movements into a smooth automatic whole (Rizo, 2004, Crossman and Neary, 2005). The basal ganglia are also involved in the acquisition of motor skills (Rizo, 2004).

The cerebellum is another motor area of the brain. It applies incoming sensory information (e.g. from vision and proprioceptors) (Rizo, 2004) and combines this with copies of motor commands sent by the motor cortex and brain stem (Matthews, 2000) to effect continual adjustments during an ongoing movement to ensure accuracy and smooth motion (Rizo, 2004) and maintain balance – by sending feedback to the brainstem and the motor cortex via the thalamus (Crossman and Neary, 2005). The cerebellum also plays a role in motor learning (Matthews, 2000).

b) Spinal cord

The spinal cord provides sensory, autonomic and motor innervation to the trunk and limbs. It consists of grey matter in the centre which is comprised of nerve cell bodies, and is surrounded by white matter, containing ascending and descending nerve tracts (i.e. fibres). The neurons (i.e. nerve cells) that contribute their axons to the descending tracts (e.g. corticospinal) of the spinal cord, and originate from the motor cortex are referred to as upper motor neurons (Crossman and Neary, 2005). When the corticospinal tracts – one from each hemisphere of the brain - pass through the medulla (i.e. the brain stem) approximately 75-90% of the fibres decussate (cross over to the other side) and enter the contralateral lateral corticospinal tract whilst the remaining 10-25% of the fibres do not cross and enter the ventral corticospinal tract

(Crossman and Neary, 2005). This means that movement on one side of the body is largely controlled by the other side of the cerebral cortex (see Figure 2.1).

The axons in the descending tracts extend without interruption to their target neurons in the spinal cord. These are the lower motor neurons with their body in the grey matter and their axons (i.e. nerve fibres) directly innervating muscle. They are the final part of the pathway via which the nervous system controls movement (Crossman and Neary, 2005). Some motor function can be served via an indirect pathway (i.e. corticospinal fibres reach the tract by synapsing in the midbrain) but fine motor control requires intact input of the direct pathway from the primary motor cortex to the spinal cord (Rizo, 2004). Most movement requires input from both pathways.

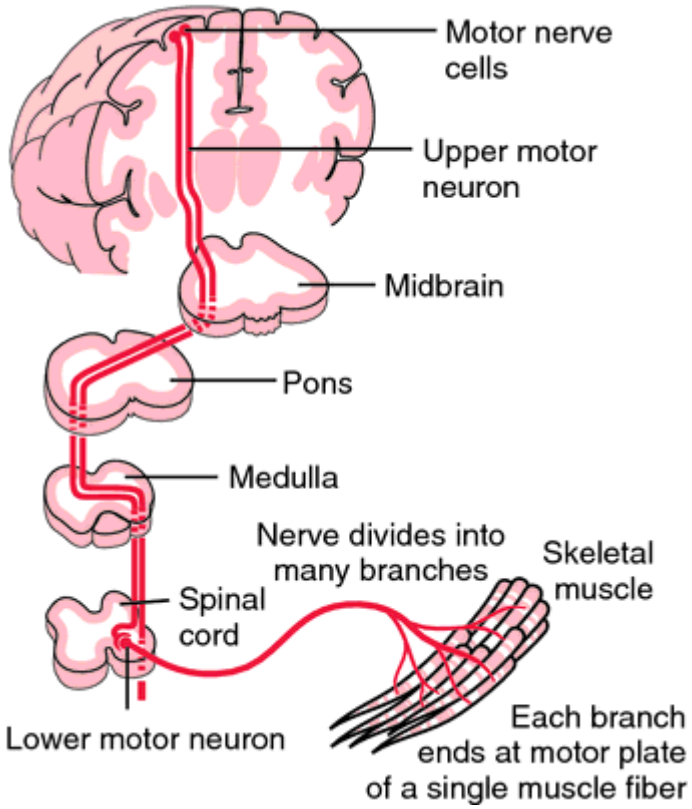


Figure 2.1: Pathway of upper and lower motor neurons (Damjanov, 2000).

The basic pattern of locomotor output is produced by spinal central pattern generators that do not require sensory input or input from the brain to generate the motor pattern (Matthews, 2000). However, without input the movements are stereotyped and easily disrupted, unable to support the body and not functional. Sensory input about joint position and muscle tension is required to adapt the pattern

to normal walking conditions. Furthermore, the brain is the normal activator of these neural circuits (Enoka, 2008).

c) Motor units

The functional unit of skeletal muscle is the motor unit. It consists of a lower motor neuron together with all the terminal branches of the axon and the muscle fibres that they innervate. The number of muscle fibres that are innervated by a single axon will vary, from a few to 2000, per motor unit and will depend on the size and function of the muscle. When the neuron transmits a message all of the fibres in the motor unit will contract (Watkins, 2009).

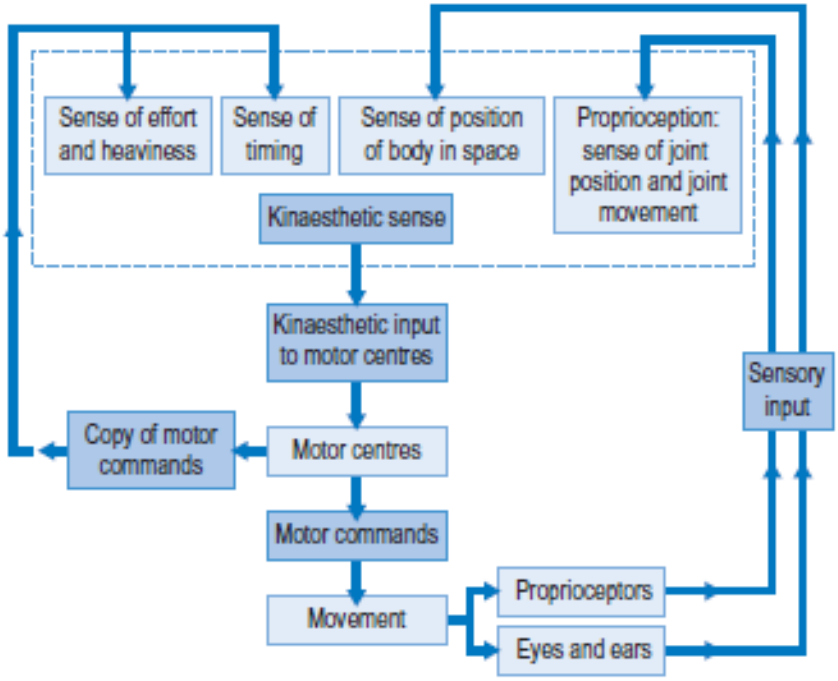


Figure 2.2: Relationship between kinaesthetic sense and proprioception (Watkins, 2009).

d) Kinaesthetic sense and proprioception

The CNS receives sensory information from a wide range of sensory organs about body position and body movement. Sources of information about the sensations of effort and heaviness, timing of movement of individual body parts, the position of the body in space, joint positions and joint movements can be regarded as the kinaesthetic sense (Watkins, 2009) (see Figure 2.2). Proprioceptors are those group of receptors located in the skin and musculoskeletal tissues that provide the sense of

joint position and movement. Within joint capsules there are two main types of proprioceptors that signal joint angle and particular information at the end ranges of joint movement: Ruffini corpuscles which appear to be mainly responsive to tension, and Pacinian corpuscles which respond to compression (Watkins, 2009). Within skeletal muscles, a number of muscle fibres will be enclosed in a capsule to form a muscle spindle, supplied by sensory nerve endings, which respond to muscle stretch (Crossman and Neary, 2005). At the junction between skeletal muscle and its tendon, Golgi tendon organs occur and provide information about the tension exerted by the muscle (Matthews, 2000).

2.2.2 Gait kinematics and muscle activations

Human walking is a method of locomotion involving the use of two legs in an alternating pattern, to provide both support and propulsion. It is characterised by a smooth and efficient progression of the body's centre of mass and distinguished from running by having at least one foot in contact with the ground at all times (Whittle, 2003). The components of gait (manner of walking) and the specific contribution of the lower limb muscles and joints to achieving this motion are described in the following paragraphs.

Gait is a cyclical movement pattern and the gait cycle can be defined as the time interval between two successive occurrences of one of the repetitive events of walking, typically initial contact (or heel strike) of one foot is chosen as the defining event. The gait cycle can be divided into stance phase, when the foot is on the ground, and swing phase when the foot is moving forward through the air. There are also periods of single support when the alternate leg is in swing phase and double support when both feet are weight-bearing (see Figure 2.3). At normal walking speeds, the stance phase for each leg lasts for 60%, and swing phase for 40% of the gait cycle. Each double support phase lasts for 10% of the cycle time, at the end of each stance phase. The speed of walking will affect these proportions, with the swing phase increasing and the stance and double support phases decreasing as speed increases (Whittle, 2003).

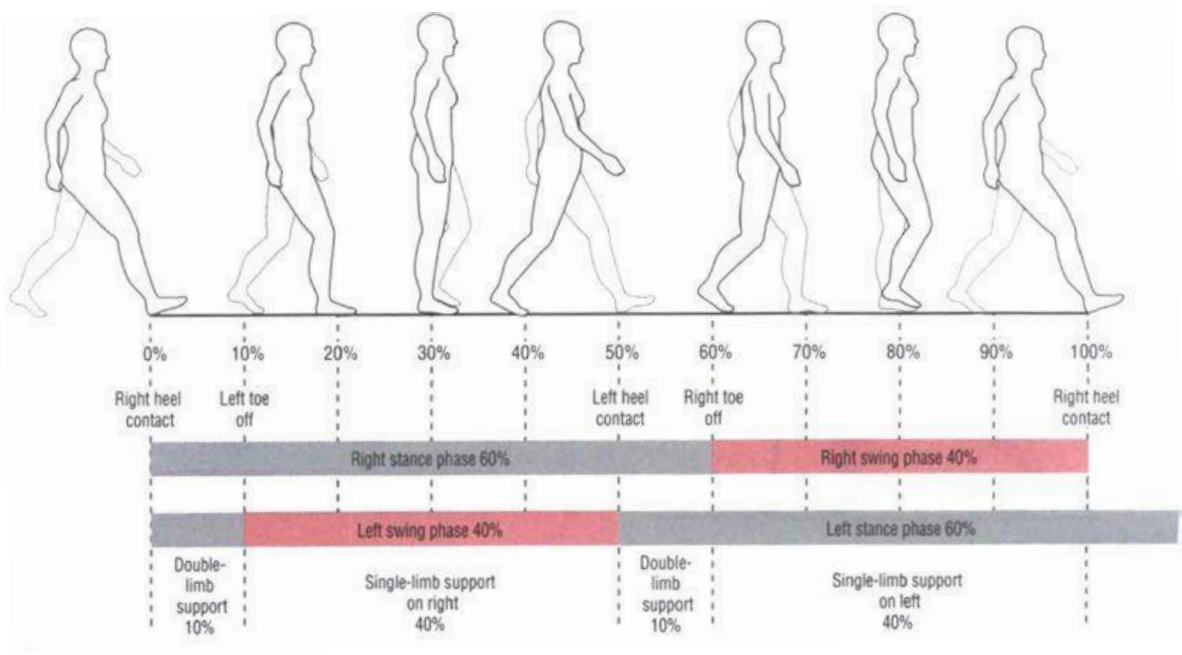


Figure 2.3: Timing of phases of gait during the gait cycle
(from http://media.lanecc.edu/users/howardc/PTA104L/104LAmbAids/104LAmbAids_print.html)

Gait can also be described in terms of spatial parameters, as shown in Figure 2.4 showing step length (i.e. the distance between two consecutive heel strikes) and stride length (i.e. the distance between two consecutive heel strikes of the same foot). Stride width is determined by the distance between the bisection of each heel (Richards, 2008).

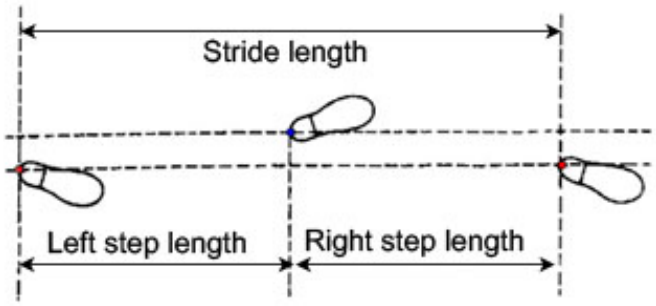


Figure 2.4: Spatial parameters of gait.
(from http://atec.utdallas.edu/midori/Handouts/walkingGraphs.htm)

Figure 2.5 shows the pattern of muscle activity during gait of the major muscle groups that act on the lower limb. Concentric contractions are those in which the force generated by the muscle exceeds the forces opposing the motion and hence the resultant force acts to shorten the muscle. Eccentric contractions are those in which the force generated by the muscle is exceeded by the opposing forces and hence the muscle elongates (Richards, 2008). The lower limb joint angle trajectories,

in the sagittal plane, of the ankle, knee and hip joints during the gait cycle are shown in Figure 2.6.

	STANCE PHASE 60%					SWING PHASE 40%		
% OF TOTAL PHASE	0-2%	0-10%	10-30%	30-50%	50-60%	60-73%	73-87%	87-100%
ILIOPSOAS	inactive	inactive	inactive	concentric	concentric	concentric	concentric	inactive
GLUTEUS MAXIMUS	eccentric	inactive	inactive	inactive	inactive	inactive	inactive	inactive
GLUTEUS MEDIUS	eccentric	eccentric	eccentric	eccentric	inactive	inactive	inactive	inactive
HAMSTRINGS	eccentric	eccentric	inactive	inactive	inactive	eccentric	eccentric	eccentric
QUADRICEPS	eccentric	eccentric	inactive	inactive	eccentric	eccentric	inactive	inactive
PRETIBIAL MUSCLES	eccentric	eccentric	inactive	inactive	inactive	concentric	concentric	concentric
CALF MUSCLES	inactive	inactive	eccentric	concentric	concentric	inactive	inactive	inactive

KEY: INACTIVE | CONCENTRIC | ECCENTRIC

Figure 2.5: Activation patterns of major muscles during gait (2004).

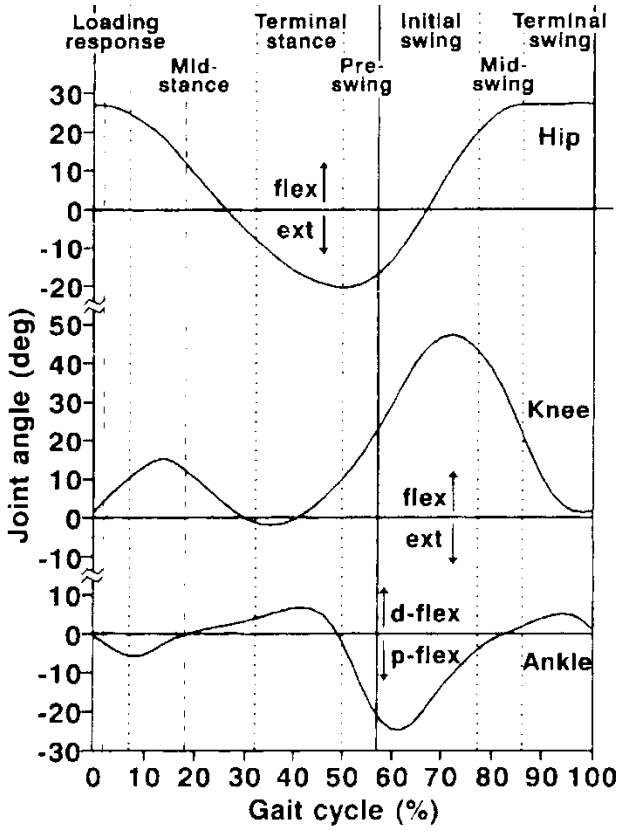


Figure 2.6: Sagittal plane joint ankles during a single gait cycle of the ankle, knee and hip joints (Whittle, 2003).

The following describes the gait cycle in terms of the major events, the action of the major muscles and the motion at the major joints. The description is a summary of the cycle as described by several authors (Trew and Everett, 2001, Whittle, 2003, Richards, 2008). At the beginning of the gait cycle the heel strikes the ground, with the ankle close to its neutral position (i.e. 0°) with the angle between the foot and the ankle at about 90° and the heel slightly inverted with the forefoot slightly supinated. The tibialis anterior is active at this point, having maintained dorsiflexion during swing phase. The knee is almost straight just before heel strike and begins to flex immediately with the aid of contraction of the hamstrings, having aided prevention of knee hyperextension at the end of swing phase. Contraction of the hamstrings and the gluteus maximus at heel strike begins extension of the hip.

The double support phase (i.e. the period between heel strike and toe off of the opposite limb) is the period during which the foot is lowered to the ground and fully loaded. The ankle plantarflexes via eccentric contraction of the tibialis anterior and is accompanied by pronation of the forefoot and internal rotation of the tibia. The knee flexes from its almost fully extended position accompanied by eccentric contraction of the quadriceps to limit the speed and magnitude of flexion. The hip begins to extend via eccentric contraction of the hip extensors, gluteus maximus and hamstrings.

At the end of the double support phase, when the opposite toe off occurs, the first period of single support begins. At this point the foot is flat on the ground, and as soon as this occurs, the ankle motion changes from plantarflexion to dorsiflexion as the tibia moves over the stationary foot. Forefoot pronation and internal tibia rotation reach a peak at about this time and then begin to reverse. Contraction of the tibialis anterior ceases and the gastrocnemius and soleus begin to contract. The knee continues to flex and the hip continues to extend.

After opposite toe off and before heel lift, the cycle enters the midstance phase, during which the tibia externally rotates and the foot supinates, reaching a peak, after which it reverses again towards pronation. The knee also reaches a peak of flexion and then begins to extend initially through eccentric contraction of the quadriceps. The hip continues to extend via inertia and gravity, rather than continuing contraction of the gluteus maximus and hamstrings. During midstance and as heel lift is approached there is significant muscle activity about the hip joint in the frontal plane

as its position is essentially maintained (except for a slight downward dip on the opposite side) by contraction of the hip abductors.

As the heel rises and the opposite foot strikes the ground, the toes remains on the ground and extension occurs at the metatarsophalangeal joints. The rearfoot inverts as the forefoot also becomes increasingly supinated and the tibia externally rotates, locking the midtarsal joints creating a stable foot for load bearing. The ankle moves into plantarflexion with concentric contraction of the soleus and gastrocnemius, with the latter aiding flexion of the knee, and the rectus femoris contracts eccentrically to prevent rapid flexion. At opposite foot strike the hip is in maximum extension and the motion reverses to hip flexion with the adductor longus acting as the primary hip flexor.

Toe off signals the beginning of the swing phase of the gait cycle. The forefoot remains slightly supinated during swing phase. Just after toe off, the ankle reaches its peak of plantarflexion at 25°. The tibialis anterior then begins to contract to dorsiflex the ankle contributing to toe clearance as the leg swings through, with knee flexion contributing most of the required leg shortening to achieve clearance. The knee reaches its peak of flexion during swing phase of between 60-70°, with the major part of flexion being facilitated by flexion at the hip. The knee then rapidly extends to close to full extension, in preparation for heel strike, with eccentric contraction of the hamstrings preventing hyperextension. The hip continues to flex at toe off, aided by contraction of the rectus femoris and iliopsoas. As the tibia reaches vertical during the swing phase, hip flexion ceases and the position is maintained by contraction of the hamstrings. At the end of the swing phase heel strike occurs and signals the completion of the gait cycle.

2.2.3 Aspects of behaviour believed to be associated with cognitive control of gait

Gait has traditionally been regarded as a largely automatic or reflex controlled motor activity involving minimal or no higher cognitive input (Dietz, 1997, Shik and Orlovsky, 1976). However functional gait requires an ability to respond to the variability of the everyday environment and to adapt to the requirements of individual's goals. In recognition of this, a large number of recent studies propose an alternative to the model of gait as an automatic activity and have demonstrated that gait is a task

involving higher level cognitive control (Sheridan and Hausdorff, 2007). This section will discuss this concept by firstly defining and describing the cognitive processes that are associated with gait control. This will be followed by a discussion of the evidence for and nature of the contribution of cognitive control of gait.

The outcome or product of all neural processes is behaviour. Cognitive control of gait refers to the contribution of neural processes that are not exclusive to the process of motor control, but also affect the everyday functioning of the individual (i.e. other aspects of behaviour). In order to explain the model, the reader is first introduced to the two aspects of behaviour believed to be involved in cognitive control of gait; cognition and executive functions (Lezak et al., 2004).

a) Cognition

Cognition is the information-handling aspect of behaviour and can be classified as; **receptive functions**, **memory and learning**, **thinking** and **expressive functions**.
Receptive functions involve the ability to select, acquire, classify and integrate information. Thus, these functions will exploit the sensations received from the five senses (i.e. sight, hearing, touch, taste and smell), as well as those associated with movement, space, balance and effort (Berthoz, 2000). Processing of the sensations received involves perception, which is a complex process engaging activities such as awareness and recognition.

Memory and learning refer to information storage and retrieval. Memory is central to all cognitive functions (Lezak et al., 2004) and can be considered as either explicit (i.e. a conscious, intentional process) or implicit (i.e. performance of knowledge without awareness) (Squire, 2000). The first can be regarded as remembering information, objects and events and the latter as acquiring cognitive and motor skills (e.g. walking). Explicit memory engages stages of processing memory, of which one is short-term memory, which involves temporarily holding information. When this information is held in the mind, internalised and used to guide behaviour it is referred to as working memory (Lezak et al., 2004).

Thinking can be defined as any mental operation that relates two or more pieces of information explicitly or implicitly (Fuster, 2003) and includes a large number of complex cognitive functions e.g. reasoning, abstracting and problem solving. It is

regarded as a function of the entire brain rather than a localised area (Lezak et al., 2004). **Expressive functions** are the sum of observable behaviour, from which mental activity is inferred e.g. speaking, writing and movement (Lezak et al., 2004).

The efficiency of cognition is affected by the level of consciousness, activity rate and attentional functions. Consciousness generally concerns the level at which a person is receptive to stimulation (i.e. awake) although definitions can vary. Activity rate relates to the speed at which neural processes and motor responses are performed (Lezak et al., 2004). Attention refers to several different capacities or processes, that are related aspects of how the person becomes receptive to stimuli and begins processing incoming or attended-to excitation, whether internal or external (Lezak et al., 2004). There is an agreed assumption that there is a finite capacity for attention (Woollacott and Shumway-Cook, 2002). Attention can be categorised as follows (Grieve, 2000, Lezak et al., 2004):

- Focused or selective – capacity to orientate to the relevant stimuli whilst suppressing awareness of irrelevant stimuli, and is commonly referred to as concentration.
- Sustained – capacity to maintain attention over a period of time.
- Divided – ability to respond to more than one task at the same time or to multiple elements within one task, and is thus very sensitive to attentional capacity.
- Alternating – capacity for shifting of attention from one task to another.

b) Executive functions

Gait performance is also associated with executive functions; the capacities that enable a person to engage successfully in independent, purposive, self-serving behaviour (Lezak et al., 2004). They refer to a variety of higher cognitive processes that use and modify information from many cortical sensory systems in the anterior and posterior brain regions to modulate and produce behaviour (Yogev-Seligmann et al., 2008). Executive functions can be regarded as having four major components; volition, planning, purposive action and effective performance (Lezak et al., 2004). Impairment of one or more of the components of executive functions may impact on an ability to walk effectively and safely e.g. loss of mobility due to reduced motivation or reduced inhibition and poor decision-making causing risk-taking.

c) Evidence for higher level control of gait

i) Evidence from neuroimaging studies

Research in the area of brain neuroimaging supports the contribution to gait of areas of the brain, as well as those described in section 2.1.1a, that are also related to higher cognitive control. Empirical evidence from brain imaging studies have shown that during gait areas of the brain (e.g. prefrontal area) associated with higher cognitive functions are activated (Harada et al., 2009, Suzuki et al., 2004). These studies assessed changes in the haemoglobin oxygenation of the cortices, using a near-infrared spectroscopic imaging technique, whilst participants walked. Furthermore, these areas are also activated during imagined gait, with one study using positron emission tomography (PET) (Malouin et al., 2003) and another using functional magnetic resonance imaging (fMRI) (Bakker et al., 2008) to define active brain areas. Further studies of simulated gait (Francis et al., 2009, Sahyoun et al., 2004), also used fMRI, determining brain activity, in areas associated with higher cognitive function, during extension and flexion of the ankle; a movement normally associated with gait. Whilst the outcomes of the studies of imagined gait and of individual joint movements associated with gait, support the outcomes from the studies by Harada et al (2009) and Suzuki et al (2004) they should be viewed with some caution. Simulated or imagined gait will obviously not fully represent the neural processes involved in gait. For example, the study by Sahyoun et al (2004) restricted motion to the ankle joint whilst seated.

In addition, in a review of studies on the relationships between ageing and motor control by Seidler et al (2010) the authors suggested there is an age-related shift of movement control mechanisms, from automatic (lower level) control reliant upon peripheral sensorimotor systems, to attentional (higher level) control using central mechanisms. It is therefore possible that central control mechanisms are even more important than the peripheral sensorimotor system in maintaining postural stability in older adults (Seidler et al., 2010).

ii) Evidence from gait studies

There is also growing evidence, from gait studies, to support the role of the higher level cognitive systems in the control of gait (Al-Yahya et al., 2011, Sheridan and Hausdorff, 2007). The suggestion that gait was largely an automatic task (Dietz, 1997, Shik and Orlovsky, 1976), also implied that minimal attentional resources were

used. However, there is strong evidence to support the contribution of attention, a key factor in the efficiency of cognitive functions, in gait control via numerous studies amongst both healthy and impaired populations. In particular, dual-task research methodologies have been widely used (Segev-Jacubovski et al., 2011) to assess the contribution of cognitive resources to gait. Dual-task protocols employ the simultaneous performance of two tasks (e.g. walking and cognitive task). Thus, if attentional capacity is limited and both gait and a secondary cognitive task are both demanding of attention, performance of at least one of the tasks will deteriorate when they are performed simultaneously.

There are a number of review papers covering the growing number of studies using dual-task methodologies (Woollacott and Shumway-Cook, 2002, Yogev-Seligmann et al., 2008, Al-Yahya et al., 2011, Segev-Jacubovski et al., 2011). In dual-task studies of healthy adults, often the secondary task performance declined as well as the gait speed slowing (Yogev-Seligmann et al., 2008, Seidler et al., 2010) particularly if the performance indices were sufficiently sensitive (Seidler et al., 2010). Most studies of older healthy adults elicited the same response, although there are some studies that indicate the extent of deterioration in performance of the cognitive task during dual-tasking increases with age (Yogev-Seligmann et al., 2008, Seidler et al., 2010). Furthermore, studies of gait in participants with neurological disorders have shown that the costs to gait and cognitive task performance increase in comparison to healthy controls (Woollacott and Shumway-Cook, 2002, Yogev-Seligmann et al., 2008, Segev-Jacubovski et al., 2011, Al-Yahya et al., 2011). The results of these studies generally support the widely accepted view that gait control involves attentional processes.

The relationship between executive functions and gait performance has also been demonstrated in several studies, suggesting that it is critical in complex gait situations (Ble et al., 2005, Holtzer et al., 2006). Furthermore, it appears that the relationship is stronger if the normal gait pattern is already altered, for example in patient populations (Liu-Ambrose et al., 2007, Springer et al., 2006). There is some evidence that a decline in executive functions may contribute to an alteration in walking abilities however, a causal link is yet to be definitively demonstrated (Yogev-Seligmann et al., 2008).

2.3 Stroke

2.3.1 Stroke overview

A ‘stroke’ is defined as a clinical syndrome, of presumed vascular origin, typified by rapidly developing signs of focal or global disturbance of cerebral functions lasting more than 24 hours or leading to death (WHO, 1988). A stroke will typically be the result of either a bleed (i.e. haemorrhagic stroke) or blockage (i.e. ischaemic stroke) affecting the vascular supply to the brain leading to damage and death of nerve cells within the brain. A haemorrhagic stroke, affecting approximately 20% of cases (Rudd et al., 2000), occurs when a blood vessel either within or on the surface of the brain bursts. This type of stroke tends to be more severe and is associated with higher early mortality (Mant, 2011). An ischaemic stroke is the most common, occurring in approximately 80% of cases (Rudd et al., 2000), and is caused by a blood clot forming in the main artery to the brain, a blockage transported to the brain from another blood vessel in the body or a small blood vessel deep in the brain becoming blocked.

Stroke affects between 174 – 216 people per 100,000 population in the UK each year (Mant, 2004) and its incidence is strongly associated with age, with 75% of stroke cases occurring in people over 65 years of age (DOH, 2005). There is no absolute end to recovery after stroke, however most improvement in functioning occurs within six months of onset (RCP, 2008a), although more complex aspects of physical recovery, such as speech, may improve over years (Mant, 2011). There are more than 900,000 people who have survived a stroke living in England (DOH, 2005) with approximately half of these people dependent upon on others for everyday activities, following a period of recovery. Stroke causes a greater disability impact than other chronic conditions and a greater range of disabilities than any other condition (Adamson et al., 2004).

The clinical features of a stroke will vary between survivors and will be dependent upon the area and extent of the brain that is damaged and how quickly treatment was given after onset (Ebrahim and Harwood, 1999, Belagaje, 2010). Thus stroke can disrupt a wide range of neural processes and hence behaviours. Those affecting motor, sensory and cognitive processes will be discussed in section 2.3.2 and 2.3.3, whilst a summary of other common effects follows.

To illustrate the complexity of stroke as a condition, below are briefly listed the common secondary problems found immediately following stroke. These include dysphagia (i.e. swallowing difficulties) (Hamdy et al., 1997); incontinence (Carr and Shepherd, 2011); shoulder pain (Fawcus, 2000); apraxia which is usually associated with left hemisphere damage and is an isolated impairment of the ability to plan and execute skilled motor tasks (RCP, 2008a); and communication and speech problems (Warlow, 2007) such as aphasia; an impairment of the ability to form and understand words (RCP, 2004), and dysarthria; characterised by slow, weak, imprecise and/or uncoordinated movements of the speech musculature (Yorkston, 1996).

It is also common for stroke to result in a disturbance of mood. In particular, depression may compound any cognitive impairments that concurrently exist (Carr and Shepherd, 2002). Anxiety is almost as common as depression, although it is frequently not recognised and can be focused on specific issues such as fear of falling and the risk of stroke recurrence (RCP, 2008a). Fatigue, an enhanced perception of effort and limited endurance for sustained physical and mental activity, is estimated to occur in 50% of stroke survivors (Harwood et al., 2011). The cause is poorly understood but may include depression, fear, loss of motivation, pain, sleep disturbance and deconditioning (Harwood et al., 2011, Duncan et al., 2012).

2.3.2 Impact of stroke on key motor and sensory functions

Loss of central control of the musculoskeletal system following stroke encompasses phenomena such as lack of coordination in movement, loss of selective movement and lack of motor control (RCP 2008). The severity can range from slight coordination problems to complete paralysis of the face and upper and lower limbs on one side of the body (i.e. hemiplegia or hemiparesis). Specific initial effects of impaired innervation to the muscles, caused by damage to the upper motor neurons, will include (Carr and Shepherd, 2011):

- muscle weakness
- reduced muscle activation and difficulty sustaining muscle activity
- reduced muscle force generation and poor timing of peak forces leading to slow movements
- poor control of synergistic muscle activity
- lack of dexterity due to loss of fine motor control and impaired coordination.

After the initial effects of impaired motor control, other effects may emerge after several weeks. Spasticity is the most common and is typified by increased muscle tone, abnormal posturing and involuntary spasm that may cause discomfort and are particularly associated with higher levels of activity limitation (RCP 2008). Limitations to functional activity due to motor control impairments results in inactivity and this, plus weakness, leads to secondary adaptive changes to soft tissue and muscle. Furthermore, secondary neural and soft tissue changes may occur due to disuse and the weakness of certain muscle groups e.g. soft tissue contractures (Carr and Shepherd, 2011). Decreased activity will eventually result in a decline in physical fitness.

Loss or alteration of various somatic sensations is present in at least 50% of people and the severity of loss is probably associated with the extent of motor loss so the importance of sensory loss as an independent factor is unknown (RCP, 2008a). Sensory loss involving discrimination and proprioception is more often noted than loss of pain, touch and temperature sensitivity (Carey, 2006) thus joint position sense can be affected. The coexistence of sensory deficits will add to overall motor deficits, due to the inter-relationship of the function of both systems.

2.3.3 Effects of stroke on cognitive function

Some cognitive loss is thought to be present in almost all people following a stroke (RCP, 2008a) and thus affects the ability of the brain to handle information (Lezak et al., 2004). Some of the most common cognitive impairments that can occur following stroke are as follows:

- Impairments of attention and concentration are probably the most pervasive cognitive deficits, especially in early stroke and when the right hemisphere is affected. This impairment may affect other unimpaired processes as attentional processing is an essential prerequisite for many cognitive and motor functions (RCP, 2004, RCP, 2008a).
- Memory problems are quite common and can be affected in several ways such as learning new information or skills, retrieving new information, remembering to do something in the future (prospective memory). Short term memory problems are the most common (CHSS, 2012). In fact, up to 25% of long-term survivors have such severe generalised impairment that they may

be diagnosed as suffering from dementia, with memory loss being a characteristic feature (RCP, 2008a).

- Spatial awareness – i.e. a person's awareness of the space around them and the space occupied by their body – can be affected by stroke. This impairment is also described as 'neglect', 'visuo-spatial neglect' or 'inattention' and is especially associated with right hemisphere stroke. In such cases a person may 'neglect' the left side of their body or fail to attend to things positioned on their left. Fatigue is particularly associated with this impairment (RCP, 2004, RCP, 2008a).
- Perceptual disorders can have a varied impact. They can range from impaired distance perception (e.g. difficulty crossing the road) to an inability to recognise an object when seen (i.e. visual agnosia) (RCP, 2004, RCP, 2008a).
- Apraxia or dyspraxia is a disorder of skilled voluntary movement that is not due to sensory or motor impairment. It is a conceptual inability to organise the actions required to perform the activity e.g. dressing. Some actions can be performed automatically, but not under voluntary control. It is more common after left cerebral hemisphere stroke (RCP, 2008a).
- Executive functioning impairments can occur, especially when the frontal lobes are affected. Effects are seen in a person's ability to plan a series of tasks, problem-solve and self-monitor behaviour. A striking effect on social behaviour can be associated with this impairment. It is relatively rare following stroke (RCP, 2004, RCP, 2008a).

2.3.4 Effects of stroke on gait and falls

a) Gait

Gait impairments resultant from a stroke will vary due to the site, size and type of brain damage and will be affected by the time since stroke, with varying degrees of impairments occurring in approximately 70% of survivors (Jorgensen et al., 1995). Although stroke typically causes a primarily unilateral motor impairment, and is often described as resulting in a hemiparetic gait pattern, it is recognised that heterogenous, variable and bilateral gait disturbances do result from stroke (Morris et al., 2010).

Of those stroke survivors in the UK, around 20% will be affected by foot drop (Burridge et al., 1997a). It is characterised by reduced function in the muscles that serve to dorsiflex the foot (i.e. flaccid foot drop), and/or spasticity in the muscles that act to lower the foot (i.e. plantarflexors). Foot drop results in reduced ankle dorsiflexion during the swing phase of gait and at initial contact with a subsequent inability to achieve heel strike at the beginning of stance phase. Instead, at the end of swing phase, the foot lands plantarflexed, with the midfoot or forefoot contacting the ground initially instead of the heel. Furthermore, the foot can assume an equinovarus appearance, due to over-activity of the calf muscles (i.e. plantarflexors) compared to the tibialis anterior (i.e. dorsiflexors), where the foot is inverted and the forefoot is plantarflexed on the hindfoot. Evidence from one study suggests that this can occur in 18% of hemiparetic patients (Verdie et al., 2004).

Despite these common features, there are wide individual variations in the deviations from the norm. For example, in a study of 15 participants with foot drop, a number of different variations of abnormal muscle activation were identified when compared with age-matched controls. According to the authors, in many cases inappropriate calf muscle activity may contribute to foot drop as much as, if not more than the inability to activate the tibialis anterior muscles (Burridge et al., 2001). The literature on post-stroke gait predominately focuses on hemiparetic gait, and there is a lack of data defining the specific characteristics of foot drop gait. Therefore, the following description of the post-stroke gait largely concerns hemiparetic gait.

Hemiparetic gait is typically slow (Morris et al., 2010), with the average walking speed ranging from 0.23 m/s (SD = 0.11) to 0.73 m/s (SD = 0.38) (Olney and Richards, 1996). Whilst a slower speed could be the result of any of the various gait deviations evident, one study of 26 participants with mild to moderate hemiparesis, has noted that gait velocity was mainly affected by weakness of the affected hip flexors and knee extensors (Hsu et al., 2003).

Hemiparetic gait is also characterised by abnormal temporal and spatial parameters. For example, step and stride length are typically reduced (Morris et al., 2010) and the swing phase duration of the affected limb is typically longer (Olney et al., 1991, Chen et al., 2005) whilst that of the unaffected limb can be shorter (Chen et al., 2005). Subsequently, hemiparetic gait can exhibit greater swing time asymmetry than

normal gait (Chen et al., 2005, Morris et al., 2010). Step length asymmetry has been noted to increase but the direction of this is not consistent i.e. either limb can exhibit a shorter step length (Chen et al., 2005).

Variability in temporal and spatial gait parameters is also a characteristic of hemiparetic gait. In a large study of 94 hemiparetic participants, who were compared to healthy controls, step length and stride time variability in the post-stroke group was greater (Balasubramanian et al., 2009). Furthermore, swing time variability increased and was greatest in the paretic leg. Although stride width increases in hemiparetic gait (Chen et al., 2005), variability of this parameter does not increase when compared to healthy controls (Chen et al., 2005, Balasubramanian et al., 2009).

As one of the key requirements of gait is foot ground clearance during the swing phase, certain hemiparetic gait patterns, including foot drop gait, typically involve compensatory mechanisms at joints proximal to the ankle. A steppage gait, involving exaggerated knee and hip flexion, will lift the foot higher than usual to achieve increased ground clearance (Whittle, 2003). If there is diminished knee flexion, this strategy is not available, thus hip hitching (or hiking) or leg circumduction (Kerrigan et al., 2000, Chen et al., 2005), are required to clear the toe of the ground during the swing phase of gait. Finally, vaulting may be used to achieve foot clearance. This involves raising onto the toe of the unaffected side during stance, thus allowing the toe on the swing phase leg to clear the ground (Whittle, 2003). In common with the other compensatory mechanisms, these patterns do not contribute to forward progression of the body and are wasteful of energy (Whittle, 2003). Adoption of compensatory strategies may maintain balance and allow for the advance of the swing leg, however the energy costs can be significant (Olney and Richards, 1996, Chen et al., 2005).

In summary, foot drop gait is typically slow, unbalanced and energy inefficient. As described in the following section, a related consequence of stroke is instability and a heightened risk of falls.

b) Falls

Stroke has been associated with a two to six-fold increase in the risk of falling by a number of prospective studies (Lord et al., 2007). A fall is defined as an unexpected

event where the participant comes to rest on the ground, floor or lower level (Lamb et al., 2005). The healthcare cost of falls annually in the UK are estimated at US$1.6 billion, based on 2008 prices (Davis et al., 2010).

Whilst high rates are reported during inpatient episodes, falls are also very common in community-dwelling survivors. The incidence varies dependent upon the time since discharge – 23-34% for 3-4 months (Smith et al., 2006, Jorgensen et al., 2002), 40-73% for 6 months (Forster and Young, 1995, Yates et al., 2002, Hyndman and Ashburn, 2003, Hyndman and Ashburn, 2004, Soyuer and Ozturk, 2007, Harris et al., 2005, Mackintosh et al., 2005a, Mackintosh et al., 2005b, Belgen et al., 2006) and 43–70% for 1 year (Watanabe, 2005, Hyndman et al., 2002, Andersson et al., 2006, Lamb et al., 2003). Furthermore, fallers in the stroke population are more likely to become repeat fallers i.e. two or more falls in the last 12 months (Hyndman et al., 2002) with reports of incidences of between 21–57% (Forster and Young, 1995, Watanabe, 2005, Hyndman and Ashburn, 2003, Hyndman and Ashburn, 2004, Harris et al., 2005, Mackintosh et al., 2005a, Mackintosh et al., 2005b, Belgen et al., 2006, Hyndman et al., 2002, Andersson et al., 2006, Lamb et al., 2003).

The circumstances of falls amongst community-dwelling stroke survivors have been reported in several studies. The most frequently identified activity at the time of the fall was walking, most often whilst indoors, followed by transfers (Weerdesteyn et al., 2008). People have described losing their balance or getting their foot stuck whilst walking or transferring (Forster and Young, 1995). Another group of stroke survivors reported that impaired balance or other personal factors were causative factors. (Jorgensen et al., 2002). Other studies found reasons for falls to be dressing, mis-stepping, their foot getting stuck and imbalance (Belgen et al., 2006) plus self-perceived balance problems, including dizziness and spinning sensations, whilst dressing (Lamb et al., 2003).

Finally, in a study that described the circumstances of falls and near falls amongst a community sample of people with stroke (Hyndman et al., 2002), participants cited losing their balance and their foot dragging as causes. This study also reported participants describing reasons for their fall as: “Someone started talking and that distracted me”; “I didn’t concentrate enough on what I was doing”; and “I didn’t get my

brain into gear". Furthermore, participants described the suspected cause of a near fall as: "I misjudged the distance of the step"; "I did not lift my foot up high enough" and "I wasn't concentrating enough and my foot hit the curb".

It is recognised, from the extensive literature on falls in the general population, that the circumstances and possible causes of falls are multi-factorial, and much time and effort has been spent attempting to identify specific risk factors. According to Lord et al (2007), there is consistently strong evidence to support limitations of activities of daily living (ADL), impaired gait and mobility, reduced peripheral sensation, muscle weakness and impaired cognition as important falls risk factors. These are all possible consequences of stroke and heighten its impact as a stand-alone risk factor. In particular, the contribution of cognitive impairments to falls following stroke, as also indicated by the statements of participants in the Hyndman et al (2002) study, has attracted further research.

A study of community stroke survivors (Hyndman and Ashburn, 2003) highlighted that attention deficits were common among the sample studied, and correlated with poor performance on functional measures and falls. Findings suggested that repeat fallers had greater attention deficits, plus greater balance and ADL impairments in comparison to those who did not report any instability. Therefore, results indicated that attention deficits might contribute to accident-prone behaviour and falls. In a study prior to this, general inattention was significantly associated with fall risk and impulsivity was suggested as an important factor (Rapport et al., 1993). Impulsivity, manifesting as initiating behaviours quickly and without consideration of the consequences may compound the impact of other post-stroke effects, such as poor spatial awareness. Fall risk has also been associated with the memory score on the Functional Independence Measure (FIM) (Wada et al., 2007). Finally, results from a study of stroke survivors six months after discharge noted that those with extensive involvement of the left hemisphere had a higher number of falls than those with similar involvement of the right. The authors attributed this to the greater impact on cognitive functions and reduced impact on motor functions with left, as opposed to right, hemisphere lesions (Alemdaroglu et al., 2012).

The fear of falling has been reported to be as important as falling itself in stroke survivors (Kim et al., 2012) as it can act as a barrier to functional recovery and is

associated with reduced community reintegration (Schmid et al., 2011); one study noting that it was present in 88% of those who had fallen (Watanabe, 2005). As well as those who have fallen, fear of falling was also reported in people who had not experienced a fall (Schmid et al., 2009). It often leads to reduced physical activity through a complex process (Botner et al., 2005, Weerdesteyn et al., 2008). Fear of falling is also associated with loss of confidence and depression (Kim et al., 2012), which can contribute to a reduction in activity levels and social functioning (Weerdesteyn et al., 2008). Fear of falling has a complex relationship with the other factors associated with falls and Figure 2.7 gives an indication of its relationship with other factors for the individual. Figure 2.7 does not, however show the impact that the worries of carers of stroke survivors who have fallen may have on the range and frequency of activities performed by an individual following stroke (Forster and Young, 1995).

In summary, the risk of falls is heightened as a result of stroke, which in itself can be an obstacle to re-establishing independent function. Figure 2.7 gives an example of the interactions between risk factors and consequences of falls. It is particularly worth noting the contribution of both physical and cognitive impairments as risk factors.

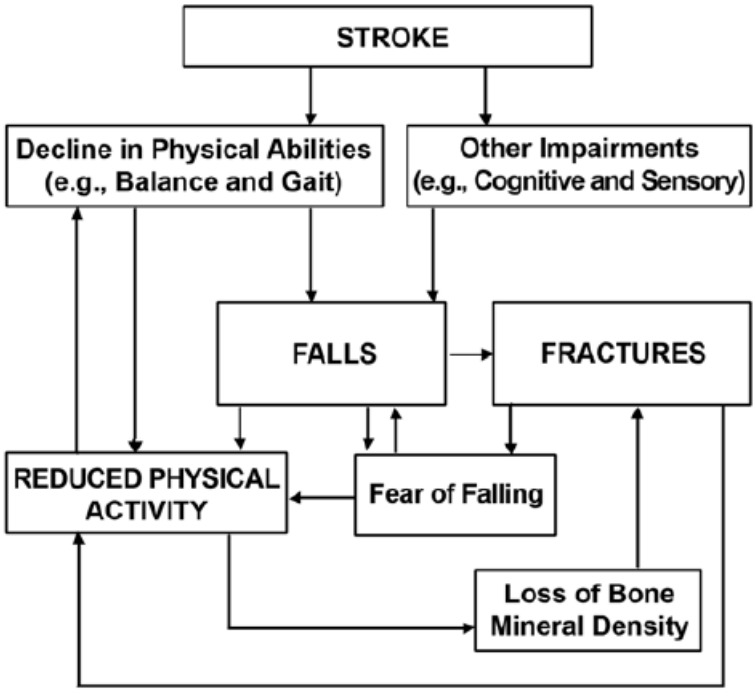


Figure 2.7: Interactions between risk factors, falls and consequences of falls following stroke (Weerdesteyn et al., 2008).

2.3.5 Cognition and gait post stroke

As has been described in sections 2.2.1 and 2.2.3, gait is initiated and controlled by a combination of the motor pathways and cognitive processes. Stroke will affect both motor and cognitive processes as a result of damage to the brain. In particular, the cognitive deficits that result from stroke are various as discussed in section 2.3.3. There is a growing body of evidence to support the importance of the effect of these deficits in gait abilities post-stroke. Apart from the research evidence indicating the contribution of cognitive deficits to falls, there are numerous studies that demonstrate the interaction between cognitive deficits post stroke and gait.

Mulder (Mulder et al., 2002) proposes a persuasive model of the interaction between cognitive and motor function and its central role in functional recovery following nervous system damage. In line with much of the work described in sections 2.2.1 and 2.2.3, he proposes that the two systems are closely interrelated and that measurement of one aspect alone is insufficient to characterise functional recovery. As an example, walking speed is a commonly used outcome to measure recovery or the effect of an intervention. However, use of this alone as an outcome measure will not necessarily uncover the adaptive and compensatory strategies being used while performing the walking test and hence the level of functional recovery. In post-stroke gait, in addition to conventional measures of motor performance, a measure of the concentration or mental effort required to walk may reflect the level of functional recovery i.e. the level of reliance on a conscious mode of motor control. To assess the level of functional recovery over time or the lessening need for compensation Mulder et al (2002) proposed two approaches; measurement of cognitive involvement or visual dependency.

In line with Mulder's proposal, and as discussed earlier, dual-task protocols require division of attention between walking and a cognitive task. Thus, attentional capacities are challenged and test the assumption that if motor control of gait is operating at a normal or optimal level, then simultaneous execution of an additional task should not affect gait nor performance of the additional task (Yogev-Seligmann et al., 2008). Conversely, if attentional capacities are limited, performance of at least one of the tasks will deteriorate (Segev-Jacubovski et al., 2011). Dual-task methodology is reflective and typical of real world situations where stroke patients are required to 'walk and talk', take note of their surroundings and remember and follow

directions. As discussed earlier, it has been widely used to investigate the cognitive effects on gait, balance and fall risk particularly amongst elderly populations (Woollacott and Shumway-Cook, 2002, Yogev-Seligmann et al., 2008, Segev-Jacubovski et al., 2011).

There are also a growing number of studies in post-stroke gait that have used a dual-task design to assess gait. Several studies have used gait speed as an outcome, finding a deterioration in gait speed under dual-task conditions (Bowen et al., 2001, Canning et al., 2006, Hyndman et al., 2006, Plummer-D'Amato et al., 2008, Dennis et al., 2009, Pohl et al., 2011). Studies have also noted a reduction in performance of the cognitive task (Plummer-D'Amato et al., 2008, Dennis et al., 2009, Pohl et al., 2011, Hyndman et al., 2006, Kemper et al., 2006).

There are a small number of studies using other gait parameters as outcomes. The addition of a cognitive task had an adverse effect on balance with double-support time increasing in two studies (Bowen et al., 2001, Plummer-D'Amato et al., 2010). A small longitudinal study (Cockburn et al., 2003) compared stride duration initially after stroke and then 1-9 months later. Stride duration improved over time with recovery more so than cognitive performance during walking. A recent pilot study noted that paretic single limb stance time as particularly susceptible to dual-task interferences (Plummer-D'Amato and Altmann, 2012). Interestingly, in a dual-task study by Hyndman et al (2006) the participants were also assessed as fallers and non-fallers based on their fall history. Fallers coped less well with a competing cognitive task than non-fallers during walking, with a significant reduction in stride length.

The interaction between cognitive function and gait is a growing area of research in healthy, older and gait-challenged populations, including fallers and those with neurological disorders. Thus, treatments for gait disorders as a result of central neurological dysfunction may require a consideration of deficits in cognitive function when assessing effectiveness. As has been discussed, stroke can result in both cognitive and motor impairments, with the latter manifesting in some stroke survivors as foot drop gait. Thus, the effectiveness of interventions to address this could be measured taking into account co-existing cognitive impairments. This point will be revisited following the next section which reviews one of the interventions available to those with foot drop following stroke.

2.4 FES

There are a number of treatment options for foot drop as the result of stroke. Apart from physiotherapy, and the use of Botulinum Toxin (BoTox), there are two orthotic interventions, ankle foot orthoses (AFO) and functional electrical stimulation (FES), the second of which is the focus for the thesis. This section of the literature review firstly describes the most common application of FES to address foot drop and the function of each component. Secondly, the effect on the nervous system is described both at local and central levels. Finally, a comprehensive literature review of the effects of FES is provided, with a particular focus on patient-centred outcomes.

2.4.1 Description of FES

FES can be described as the electrical stimulation of either nerves or muscles deprived of appropriate nervous control, to provide muscular contraction and thereby produce a functionally useful movement (Sujith, 2008). When used to restore movement of upper or lower limbs the FES device works as a neuroprosthesis, operating as a bypass (i.e. replacement) of the impaired sensory-motor pathway (Popovic, 2004) and the benefit is realised when the system is actively stimulating (Kilgore, 2004). Since this thesis is focused on foot drop of central origin, the subsequent discussion is restricted to systems used to stimulate muscle innervated by intact lower motor neurons.

FES systems comprise three basic elements; stimulator, sensors and electrodes (Lyons et al., 2002). The stimulator is used to generate and regulate stimulus pulses. The pulse and hence stimulation magnitude is adjusted by pulse width and amplitude. Sensors are used to gather command signals, typically based on the user's motion or muscle activity, and electrodes provide the electrical interface with the body. Both implanted and surface electrodes are available, although systems based on surface electrodes are most common. A surface electrode usually comprises a wire to connect to the stimulator and a conductive woven backing mesh covered by a layer of highly conductive, adhesive hydrogel.

By far the most common embodiment of FES for foot drop is the use of electrical stimulation of the common peroneal nerve (or its branches) to restore active dorsiflexion and/or eversion during the swing phase of gait. Stimulation is applied for a specific period in the gait cycle (typically from heel rise to heel strike) (Kilgore,

2004) and the initiation and termination of stimulation is controlled by one or more sensors (e.g. gyroscopes, accelerometers, foot switches) (Kilgore, 2004), the most common of which is the foot switch.

An example of a foot drop device and electrode placement is shown in Figure 2.8. Although other arrangements are possible, in this case the cathode is placed on the skin over the head of the fibula bone, where the common peroneal nerve is most superficial and just before it bifurcates into the deep and superficial branches; and the anode is placed over the motor point of the tibialis anterior muscle (Sujith, 2008). Table 2.1 illustrates the muscles that are recruited and their actions by stimulation of the common peroneal nerve. This device uses a foot switch as the sensor to trigger stimulation, with the stimulator being worn either at the waist or in a trouser pocket. Other commercially available clinical systems use an accelerometer (Sujith, 2008) and a cuff housing the surface electrodes (see Figure 2.9).

Figure 2.8: Example of a surface-based FES device (ODFS Pace).

Action	Superficial branch of CPN		Deep branch of CPN			
	Peroneus longus	Peroneus brevis	Tibialis anterior	Extensor hallucis longus	Extensor digitorum longus	Peroneus tertius
Dorsiflexion			X	X	X	X
Plantarflexion	X					
Inversion			X			
Eversion	X	X			X	X

Table 2.1: Actions of muscles innervated by two branches of the common peroneal nerve.

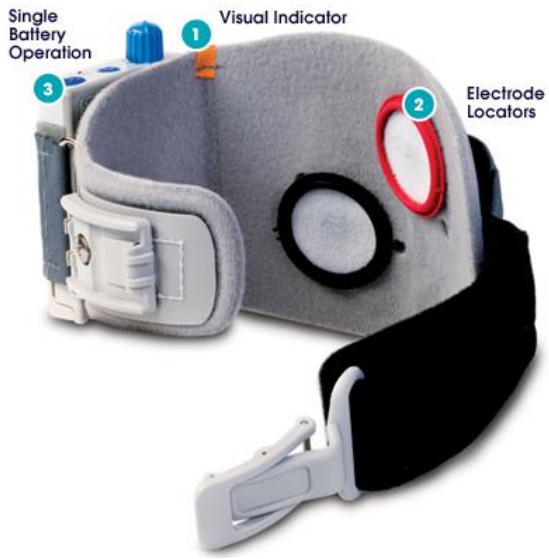


Figure 2.9: Example of surface-based FES device in which electrodes are housed in a cuff. (http://www.hanger.com/orthotics/services/WalkAide/Pages/HowWalkAideWorks.aspx)

Other foot drop devices have been developed that utilise implanted electrodes. These electrodes intimately connect to the relevant nerve itself, either in the form of a cuff electrode (Rushton, 1997) that wraps around the nerve or an intraneural or subepineural electrode that is located under the epineurium of the nerve (Kilgore, 2004). An external stimulator unit stimulates the electrodes. Figure 2.10 depicts an example of a commercially available device that uses a nerve cuff electrode, as well as a wireless foot switch.

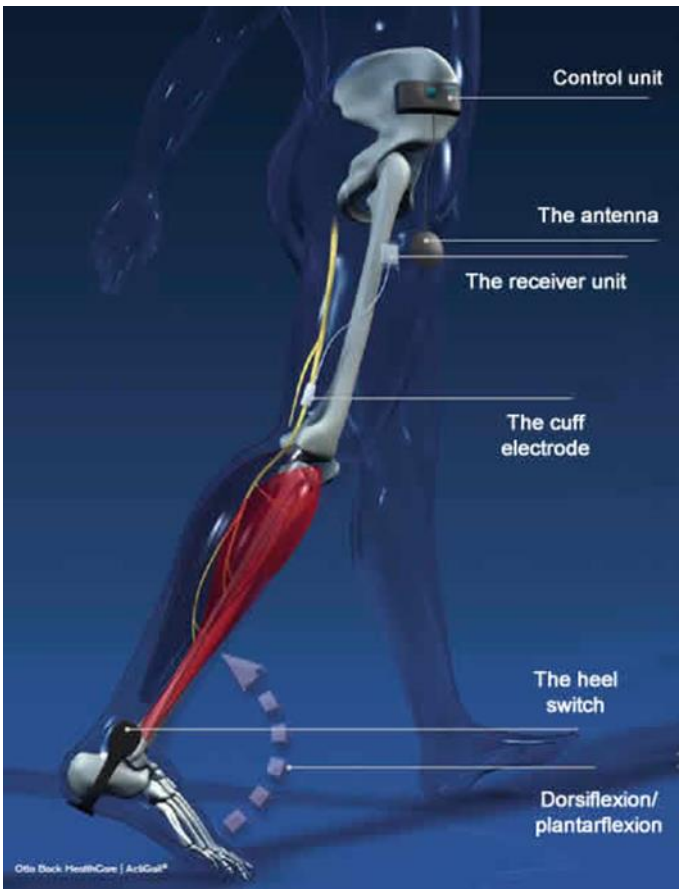


Figure 2.10: Example of an implanted FES device (Otto Bock).

2.4.2 Action of stimulation on nervous system

The stimulus generated by the FES device and transferred via electrodes to the body stimulates or excites peripheral nervous tissue. The stimulus will either be of the nerve directly or of the motor point of the nerve proximal to neuromuscular junction (Sheffler and Chae, 2007). The following section gives a background of nerve function and how FES stimulates the peripheral nervous system. There then follows a brief discussion of emerging evidence in support of the effect of FES on the CNS.

a) Functional effect

Nerves comprise bundles of neurons. The typical structure of a neuron is illustrated by Figure 2.11 showing the neuron cell body and myelinated axon. Multiple processes arise from the cell body. Firstly, the dendrites which conduct impulses towards the cell body from other neurons (Kalat, 2004). Secondly, the axon, which also arises from the cell body and conducts impulses away, and in most cases is longer than the dendrites. Neurons can vary in length from a few millimetres to more than 1 metre; axons of the motor neurons with their cell bodies in the spinal cord will extend for over a metre to the muscles in the lower leg and have several branches

which end in a presynaptic terminal - the point at which the axon releases chemicals that cross the junction (i.e. synapse) between one neuron and the next, or to muscle fibres (Kalat, 2004).

Nerve impulses, called action potentials, are brief electrical discharges produced by an electrochemical process. When the resting membrane potential of the neuron is momentarily altered (i.e. depolarised from -70mV to 30mV) (Kalat, 2004) an action potential is generated. This is as a result of an ionic exchange between the inner part of the cell and the extracellular fluid, facilitated firstly by the permeability of the cell membrane to sodium and potassium ions, which is altered by the arrival of the stimulus, and secondly by sodium-potassium ionic pumps within the membrane (Watkins, 2009). Whenever the membrane is depolarised to the threshold value, an action potential of constant magnitude is produced (i.e. the 'all-or-none' phenomenon), and this travels along the cell membrane as a flow of electrical current as each adjacent region of the membrane is depolarised (Kalat, 2004). This in turn causes the release of neurotransmitters at the motor-end plate - the junction between the nerve endings and the muscle membrane (Crossman and Neary, 2005), which excites the muscle causing contraction.

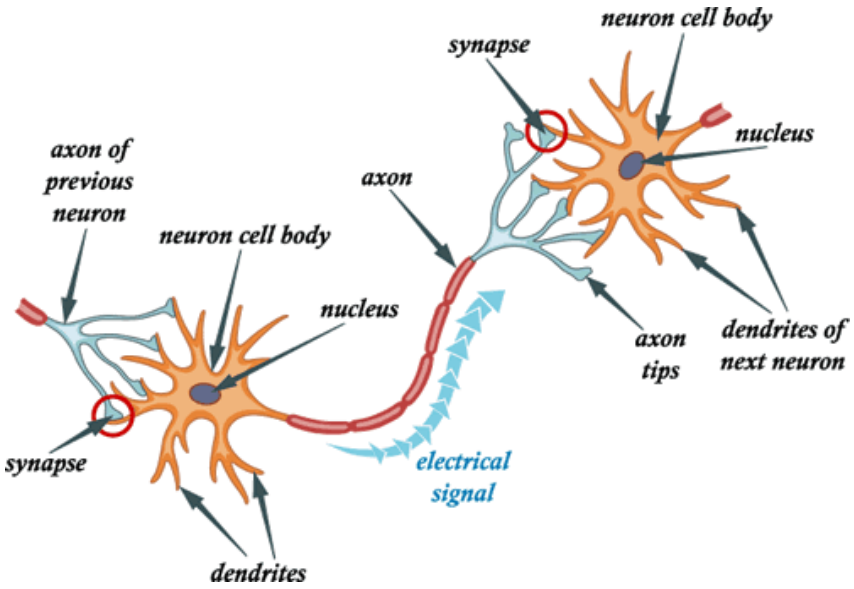


Figure 2.11: Typical neuron structure
(http://andreeasanatomy.blogspot.co.uk/2011/04/you-need-to-step-up-on-step-to-reach_23.html)

The stimulus generated by FES is an application of an external electrical field to the individual nerve cells (i.e. neurons) via the cathode (negative) electrode and anode (positive) electrode. If the stimulus is of sufficient strength, it generates an artificial action potential, by causing a depolarisation of the neuron membrane near the cathode as sodium ions are attracted by the negative electric field, reducing the positive charge on the outside of the membrane. The properties of the artificially generated action potential resultant from FES are identical to the action potential produced by physiological processes (Sheffler and Chae, 2007). However, the action potential travels in both directions along the nerve axon membrane; both towards the muscle fibres along the axon away from the cell body (orthodromic impulse) and away from the synapse towards the cell body (antidromic impulse). When the action potential reaches the muscle fibres a twitch of activity results (Watkins, 2009). To achieve functional muscle activity that is longer than a twitch, stimulation is delivered as a train of pulses, characterised by stimulus frequency, as well as amplitude and pulse width (Sheffler and Chae, 2007). The frequency of stimulus, typically a fixed parameter in clinical stimulators of around 40 pulses per second, acts to summate the individual twitches and thus produce a sustained muscle contraction. The strength of the muscle contraction will be the direct result of the number of the motor units that are recruited at one time, which is determined by the amplitude and width of the stimulus pulses (Sheffler and Chae, 2007).

b) Central nervous system effects

i) Brain

FES for foot drop at an appropriate level has a clear and immediate effect on muscles around the ankle, to produce dorsiflexion and/or eversion at appropriate periods during gait. However, there is also evidence, discussed in the following section, demonstrating that FES induces neuroplasticity (Chipchase et al., 2011) - i.e. changes in neural pathways and synapses due to changes in behaviour, environment and neural processes (Pascual-Leone et al., 2011). These changes in neural pathways may in turn partly explain the widely reported ‘therapeutic effect’ of FES. Originally this effect was referred to as the ‘carryover’ effect, as it was noted as lasting for a short time (i.e. minutes, rather than hours or days). However, with increasing numbers of studies, the therapeutic effect is more often used to describe the maintenance of changes in gait following removal of FES, that is sustained over long periods of time (Robbins et al., 2006, Stein et al., 2010, Laufer et al., 2009,

Embrey et al., 2010, Israel et al., 2011). Although there is little evidence in this area, these changes may be facilitated by changes in neural processes.

Use of FES has been shown to impact on cortical activity patterns. Functional magnetic resonance imaging (fMRI) studies have shown activation of the somatosensory cortex and supplementary motor cortex in response to electrical stimulation of wrist extension (Han et al., 2003, Kimberley et al., 2004, Shin et al., 2008). In addition, functional improvements seen in response to EMG-triggered upper limb stimulation therapy are associated with increased cortical activation patterns (von Lewinski et al., 2009). In the lower limb, an fMRI study reported that stimulation of muscles results in a dose-response relationship between stimulation intensity and volume of activation of relevant areas of the brain (including the primary sensory and primary motor cortex and the cerebellum) (Smith et al., 2003). A more recent study showed that regular use of FES for foot drop strengthens the activation of motor cortical areas and their corticospinal connections (Everaert et al., 2010). Finally, when FES is combined with voluntary ankle dorsiflexion, activity in the primary motor and sensory cortexes was increased compared with FES-only induced activity (Gandolla, 2012).

ii) Spinal

It is also possible that FES impacts on the functioning of the CNS via spinal mechanisms (Sheffler and Chae, 2007), and this has been hypothesised by Rushton (2003). In healthy subjects the conductivity of the synapse between the corticospinal tract cell and the anterior horn cell is maintained by normal neural activity of an intact system. Furthermore, the strength of the synapse is thought to be increased by the coincidence of presynaptic and post-synaptic activities. After stroke, for example, neural activity in the corticospinal tract may be severely depleted and synapses weakened. Rushton (2003) postulates that FES, in particular for foot drop, promotes functional recovery via stimulation of the anterior horn cells (i.e. the ‘motor’ part of the spinal grey matter) (Young et al., 2008). The nerve impulse generated by FES travelling towards the spinal cord (antidromic impulse), will reach the anterior horn cells. If the FES pulses occur at approximately the same time as the person attempts to initiate voluntary dorsiflexion, descending volleys from the motor cortex will arrive at the corticospinal tract/anterior horn synapse in synchrony. This effect over time is believed to strengthen the connectivity of the relevant synapses. The proposed

strengthening effect is based on the 'Hebbian learning theory' described by Donald Hebb (Hebb, 1949) in which a change in the strength of synaptic connections is a function of both the pre and postsynaptic neural activities. Strengthening of the synaptic connectivity may manifest in subsequent functional recovery.

Furthermore, effects of FES at the spinal level are thought to have an anti-spastic effect. Stimulation of paretic muscles via FES leads to reciprocal inhibition of spastic antagonists through the stimulation of spinal interneurons (Schuhfried et al., 2012).

2.4.3 Effects of FES on gait and other recorded outcomes

The effect of FES in stroke populations has been the subject of several reviews and many research studies. A search of research articles published was performed using MEDLINE and Web of Science electronic databases using the following keywords; (electric* OR stimulat*) AND (stroke OR 'cerebrovascular accident' OR hemipleg*) AND (gait OR walk* OR 'drop* foot') (Roche, 2009). Other evidence was obtained from conference proceedings.

There are several studies that report the effect of FES combined with other therapies e.g. body-weight supported treadmill training, botox injections. The following review does not include these studies, but focuses on those concerning use of FES alone.

a) FES early after stroke

Several authors have hypothesised that the benefits of FES demonstrated in chronic stroke populations could be realised in earlier phases of stroke recovery (Granat et al., 1996, Robbins et al., 2006, Roche, 2009). There has been limited research of the effect of FES in the acute phase (i.e. less than 2 weeks) (Dunning et al., 2009, Yan et al., 2005, Kunkel et al., 2012) and only a small number of studies in the sub-acute phase (i.e. 2 weeks to 6 months) (Bogataj et al., 1995, Granat et al., 1996, Sheffler et al., 2007, Salisbury et al., 2012). They have not provided conclusive evidence to support widespread use in these phases of recovery. However, despite small numbers of participants, there is some evidence to indicate the feasibility of use during these phases and of a positive benefit. The vast majority of studies have been performed with participants in the chronic phase. This is the focus of work in this thesis, and these studies are discussed in subsequent sections.

b) Effects of FES on gait speed and energy cost

FES is effective in improving gait speed in the chronic stroke population (i.e. 6 months or more post-stroke) as evidenced by two systematic reviews and a meta-analysis (Kottink et al., 2004, Robbins et al., 2006, Roche, 2009) and by studies published since these reviews (Shiels et al., 2011, Stein et al., 2010, Embrey et al., 2010, Laufer et al., 2009). Kottink's (2004) review calculated a pooled improvement in walking speed, when using FES, from six of the eight studies reviewed, of 0.13 m/s (0.07–0.2) or 38% (22.18%–53.8%). The authors noted that this could be regarded as a clinically relevant improvement. There have been a small number of studies of implantable FES devices (Burridge et al., 2007b, Kottink et al., 2007, Kenney et al., 2002). These devices have been shown to be similarly effective at increasing gait speed as surface FES systems.

A meta-analysis (Robbins et al 2006) studied the therapeutic effect of FES (i.e. changes occur and are maintained in gait after removal of FES, also referred to as the carryover effect) in contrast to the orthotic effect (i.e. changes in gait during use of FES) as reviewed by Kottink et al (2004). The analysis showed a positive therapeutic effect of previous use of FES on gait speed in participants post stroke. In contrast to this, the review by Roche et al (2009) concluded that research supporting this effect was less conclusive than for the orthotic effect. Since this review, a study followed twenty-six FES users over eleven months of use, measuring a continual increase in speed after removal of FES, reaching a 28% improvement (Stein et al., 2010). Furthermore, a study not included in the review by Roche et al (2009) found a significant therapeutic effect upon speed amongst thirteen FES users after twelve months use (Laufer et al., 2009). A study that combined intensive, repetitive walking with FES applied to both dorsiflexors and plantarflexors also found that walking speed improved without FES use, and this was evident three months after FES use was discontinued (Embrey et al., 2010). A case series since this study suggested that FES used on a more limited basis of three times a week over six weeks produced a therapeutic effect measured as a decrease in time to complete the modified Emory Functional Ambulation Profile (mEFAP); a measure of walking ability consisting of five walking tasks (Israel et al., 2011). Whilst the review by Roche et al (2009) could not find conclusive evidence of the therapeutic effect of FES, several studies provide support for this effect that is noted by both clinicians and patients.

Kottink's (2004) and Roche's (2009) reviews also collated evidence from the few studies that have used physiological cost index (PCI) as an outcome measure, indicating that the energy cost of gait may be reduced with use of FES. Further studies since have agreed with this conclusion (Stein et al., 2010, Hausdorff and Ring, 2008) plus a therapeutic effect on PCI has been noted in one study with a significant decrease over time, measured over an eleven month period of FES use (Stein et al., 2010). In a study which provided FES as part of a daily rehabilitation program over 12 weeks, PCI reduced and cardiorespiratory responses (i.e. heart rate, oxygen consumption, carbon dioxide production) improved (Sabut et al., 2010).

c) Effect of FES on kinematics of gait

The most common application of FES for post stroke gait is to improve toe clearance by correcting swing phase foot drop, via stimulating only ankle joint dorsiflexors (i.e. single channel FES). This application is clinically effective at increasing ankle joint dorsiflexion with research evidence supportive of this observed outcome. Ankle joint dorsiflexion, in a group of experienced FES users, increased at toe off and during swing phase by an average by 9.9° (SD 4.2°) (Voigt and Sinkjaer, 2000). With use of an implantable device after twenty-six weeks use, ankle joint dorsiflexion during swing phase, whilst using FES, increased (i.e. a significant decrease in plantarflexion of 5.5°) (Kottink et al., 2012). Toe clearance was measured, using the maximal vertical displacement of a marker placed over the fifth metatarsal joint, in a group of new users, finding that FES resulted in a significant increase, although the origin could not be assumed to be changes in ankle joint dorsiflexion as this was not assessed (Robertson et al., 2010). In another group of new FES users the peak angle of ankle joint dorsiflexion was significantly increased during swing phase and ankle plantarflexion was found to be reduced at toe-off (Kesar et al., 2010). In a further study (Kesar et al., 2009) FES was delivered to both plantarflexion and dorsiflexion muscles (i.e. dual-channel FES), delivering stimulation of the plantarflexion muscles during the terminal double-support phase. Application of stimulation at this point in the gait cycle should improve forward propulsive force generated by the ankle plantarflexors, increasing leg kinetic energy at toe-off and thereby increasing knee flexion during swing phase. Increased ankle plantarflexion angles were achieved at toe-off, as well as an increase in peak anterior ground reaction force (GRF) and an increase in percentage contribution of the hemiplegic leg

to total propulsion. However, peak ankle joint dorsiflexion during swing was reduced compared with stimulating only the dorsiflexor muscles.

It has been an accepted effect of FES that knee and hip flexion occurs during swing phase, as the sensory stimulus generated by FES facilitates a flexor withdrawal response at the knee and hip (Burridge et al., 1997b). In contrast to this anecdotal note, kinematic analysis of eight experienced FES users found no uniform effect was measured in the sagittal plane at the hip or knee (Voigt and Sinkjaer, 2000). Similarly, a study of an implantable device used by nine new users, found no change in hip or knee flexion after twenty-six weeks use, although this may be explained by the need for the use of less current to achieve adequate dorsiflexion and no cutaneous stimulation, and hence the withdrawal response may not be triggered (Kottink et al., 2012). With stimulation of dorsiflexion alone, FES can result in a decrease in knee flexion during the swing phase (Kesar et al., 2010) rather than an increase. This effect is believed to be associated with decreased plantarflexion at the ankle joint at toe-off. When plantarflexion is also stimulated, knee flexion increased and counteracted the effects of dorsiflexion stimulation alone (Kesar et al., 2009). Finally, two recent case studies (van der Meulen, 2012) have noted improvements in pelvic obliquity (i.e. hip hiking) and hip circumduction with FES use, thus showing a reduction in compensatory strategies used to improve toe clearance.

d) Effects of FES on stability, trips and falls

An improvement in toe clearance due to FES is presumed to contribute to a reduction in the risk of tripping and the number falls experienced by users, and an improved ability of users to negotiate uneven surfaces and obstacles during walking. Despite this there are only a few studies that have addressed any of these issues. Walking speed and PCI were assessed in thirteen FES users over even and uneven ground, both with and without FES (Burridge et al., 2007a). A trend for greater improvement, with FES use, in speed and PCI over uneven surface was found. The authors suggested that the effect of FES on the effort of walking was important to users rather than increased speed. A study of sixteen FES users after one year of use again showed a trend towards a greater increase in speed when walking on carpet and speeds also increased when avoiding obstacles, compared with speeds without FES (Laufer et al., 2009). Two comparison studies with AFOs also used obstacle avoidance as an outcome measure. In the earlier study, when assessed using the

mEFAP (modified Emory Functional Ambulation Profile), FES significantly improved ambulation on carpet and there was a trend towards improvement on the obstacle test in comparison to use of no device (Sheffler et al., 2006). There was no difference between both carpet and obstacle tests when AFOs and FES were compared. In contrast, in a later study of twenty four AFO users who were fitted with FES, performance on an obstacle avoidance test whilst walking on a treadmill measured higher success rates with FES than with AFO and these gains were clinically most relevant for those participants with relatively low leg muscle strength (van Swigchem et al., 2012).

The number of falls experienced by participants of a study by Hausdorff and Ring (2008) was collated two months prior to their entry in the study and during the two months of FES use whilst participating in the study. During participation in the study there was a 92% reduction in the number of falls. In a study prior to this (Daly et al., 2006), using intramuscular electrodes to deliver FES during four sessions a week over twelve weeks, the Tinetti gait scale was used to assess co-ordinated gait components. This scale is a measure of falls risk. In this group of sixteen participants there was an improvement in the scale with FES use that equated to a potential reduction in the frequency of falls.

A small number of studies have explored other spatiotemporal parameters which may be related to walking stability. In a study of eight experienced FES users, hemiplegic walking patterns were analysed with the use of FES in comparison to walking without (Voigt and Sinkjaer, 2000). Gait symmetry, evaluated by calculating the ratio between the stride length of both legs, was not improved by the use of FES. In contrast, a study using swing time to calculate gait asymmetry showed an improvement of 45% after two months use, which was maintained after one year of use (Laufer et al., 2009). Furthermore, in the RCT by Kottink et al (2012) of an implantable device, significant changes were measured in gait cycle phases. Stance and double support phases were reduced on the paretic side whilst on the contralateral side single support phase increased with FES use of for twenty-six weeks. In a study comparing FES use with AFOs, gait asymmetry, calculated again using swing time, showed a 15% improvement with FES (Ring et al., 2009). Finally, stride time variability, a measure of gait rhythmicity, was measured in twenty-four new users of FES at initial application, four weeks and eight weeks with reduction in variability by 23%, 27% and

33% respectively (Hausdorff and Ring, 2008) with the latter improvement being maintained after one year of use (Laufer et al., 2009).

e) Patient-reported outcomes

Roche's review (2009) noted that over thirty different outcome measures were employed in the studies included, indicating that there is not a standardised approach to assessment of FES effectiveness in research. NICE guidance (2009) recommends that 'further publication on the efficacy of FES would be useful, specifically including patient-reported outcomes'. This potential change in focus is supported by existing evidence and the following discussion reviews this evidence.

Two important studies by Taylor et al (1999, 2004) collated user opinions from patients of a clinical service. Respondents to these postal questionnaires were current users of FES and were significant in number - 78 and 69 respectively. In the former study (Taylor et al., 1999b), reduced effort, reduced risk of tripping, increased walking distance and increased confidence were each chosen by over 65% of respondents as reasons for using FES. The primary reason for use was a reduction in the effort of walking (29% of respondents), with reduced risk of tripping and increased walking distance chosen by 15% and 9.4% respectively. In the second study (Taylor, 2004), reduced effort, long term improvement in walking, increased confidence and reduced risk of tripping were each chosen by over 60% of respondents as reasons for use. The primary reason was again reduced effort (27%), followed by therapeutic effect (i.e. carryover), long term improvement in walking, increased confidence, reduced risk of tripping and increased independence.

Again in a study of patients of a clinical service, a quality of life measure (i.e. PIADS) was obtained as well as walking speed, from a group of twenty new users after eighteen weeks of use (Barrett and Taylor, 2010). The Psychosocial Impact of Assistive Devices Scale (PIADS) is a self-rating scale that is designed to evaluate the effect of assistive devices on perceived quality of life (QOL). It was developed to reflect the changing function and participation abilities as a result of an assistive device and measure psychological aspects of well-being such as self-confidence, enabling and liberating effects, impact on function, performance and productivity (Jutai, 2002). After 18 weeks of FES use, PIADS scores showed a positive effect on all aspects of well-being measured by the scale, suggesting that FES had a positive

effect on psychological well-being. There was no correlation of PIADS scores with improvements in walking speed.

A trial which provided implanted dual channel FES, following fourteen participants for twenty-six weeks and comparing outcomes with a control group, measured health-related QOL using the Short Form-36 and Disability Impact Profile (Kottink et al., 2010). A significant positive effect was found in the physical functioning and general health domain of the former and in the mobility, self-care and psychological status of the latter. When another group of twelve implanted FES users were asked if they felt the device had improved their quality of life, the majority agreed (Burridge et al., 2008).

These studies suggest that the traditional measures of walking speed and PCI on their own do not provide a complete picture of the benefits of FES to users. They support the anecdotal reports from clinicians and users that the effects of FES routinely extend beyond objective measures of walking, with reasons for use, other than increased walking speed, consistently rated by users as more important. This may also explain why some users continue to use the device despite small gains in objective measures of walking.

Further studies have used functional outcome measures to assess effectiveness. In two studies a shortened version of the Stroke Impact Scale (SIS) was applied. This is a self-reported measure of a wide range of physical functional limitations following stroke. In one study, of single channel FES after one year of normal use by sixteen participants, SIS measures showed a significant increase in both physical functioning as well as community participation (Laufer et al., 2009). In a second study, of dual channel FES used for one hour to walk over a six month period, the SIS was used to assess improvements without FES use (Embrey et al., 2010). Again in this second study there was an improvement in community participation. Evidence from qualitative studies supports these findings. In a small exploratory study of patient experiences using FES, for example, the authors concluded that the device had far-reaching effects on patient's lives, including an increase in social confidence, improved performance of activities of daily living and increased opportunities for work, social and leisure activities (Malone, 2002). A more recent study (Wilkie et al., 2012) revealed that users felt their walking was much better, they were able to

resume previous roles, regain control of their life and their independence and that use of FES had some psychological effects in terms of positive feelings and improved mood.

Several studies since those by Taylor et al (1999, 2004) have noted that the use of FES improves confidence. FES users from the Malone et al (2002) study described feeling more confident, as they felt the risk of falling was reduced. Furthermore, a study of an implanted foot drop stimulator found that one of the main reasons for satisfaction with the device was improved confidence during gait (Sinkjaer et al., 2006). The authors note that further work is needed to define 'confidence'. In the Wilkie et al (2012) study an improvement in confidence was also noted by participants. It is possible that improving confidence may in turn create a perceived increase in safety and furthermore, a perception of a reduced risk of falls. All of the participants in the study by Malone et al (2002) reported falling prior to use of FES and, as a consequence, described losing confidence with their walking.

The commonly used alternative to FES is an AFO, and as such there are some comparison studies. However, small numbers of participants have been involved and the results of comparative gait measures have been contradictory, although there has been a fairly consistent user preference for FES. In a study of fourteen participants (Sheffler et al., 2006) the effect of AFO and FES on improving functional ambulation was comparable; however participants indicated a preference for FES. In contrast, a randomised controlled trial of twenty-nine participants, comparing an implanted FES device with AFOs, walking speed improved by 23% in the FES group in comparison to 3% in the AFO group (Kottink et al., 2007). In addition, when measures of gait stability were used in another study, FES was found to improve the gait asymmetry index by 15% and to reduce swing time variability when compared with AFO use in fifteen participants (Ring et al., 2009). Participants reported feeling more stable with FES and that gait looked more normal, declaring a clear preference for FES over an AFO. Again, in a more recent study (van Swigchem et al., 2010), despite no objective difference in gait measures or levels of physical activity, twenty-six participants expressed statistically significant preferences for FES over the AFO, particularly in regard to stability and effort. Furthermore, those participants who perceived improved stability also showed improvements in obstacle avoidance ability with FES (van Swigchem et al., 2012). Finally, the perceptions of users of both FES and AFOs were

captured in a study of nine patients (Bulley et al., 2011). Users preferred FES for a variety of reasons including a reduction in the risk of tripping, improved function and independence, and a perception of walking normally.

f) Discussion and conclusions

There is growing research evidence to indicate that measures other than walking speed and PCI are more important to FES users. These 'patient-centred' outcomes, which are consistently rated above objective measures as the primary reason for use, appear to explain the preference for FES use compared with AFOs. They also potentially explain continuing use of FES when objective measures do not support a significant or clinical benefit. From the two Taylor et al (1999, 2004) studies where large groups of FES users provided an insight into this issue, a reduction in effort was consistently rated as the primary reason for use, with increased confidence, reduced risk of tripping and increased walking distance as other main reasons. Whilst the authors note this reduction in effort as being consistent with observed reductions in the PCI in other studies, there is some evidence that 'effort' may be interpreted, by some respondents, as including both the mental, as well as physical dimensions.

While it can be misleading to read too much into a dictionary definition, there is clearly a commonly accepted understanding that effort can encompass both physical and mental elements. One dictionary (1994) defines effort as 'physical or mental energy needed to do something'. In another (1984) it is defined as 'strenuous exertion, vigorous attempt, force exerted, special activity, or something accomplished involving concentration'. Thus, the interpretation of 'effort' by respondents could be one or many, and possibly not just in the physical context.

The possibility that an effect on 'effort', in the context of a positive outcome of FES use, may be due to a discernible change in the amount of concentration needed to walk whilst using FES, has some support in the research literature. In the study by Malone et al (2002), participants described, prior to using FES, having to concentrate all the time when walking, including looking at their feet and overall becoming more tired. With use of the stimulator, they reported their walking as more normal and requiring less effort, as they did not have to concentrate as much on their walking. Similarly, participants from the Bulley et al study (2011) described their walking as requiring less conscious thought when using FES. Furthermore, in the study by

Burridge et al (2007) of performance over uneven ground, the measured perception score of participants showed concordance with PCI measures rather than walking speed, suggesting that the perceived benefit of FES on improvements in the effort of walking was more important. Thus, a perception of reduced effort may also be achieved whilst walking during circumstances when a trip or fall is a higher risk.

2.5 Thesis aims

This chapter introduced and discussed the concepts of motor control, reviewing the currently accepted model based on neuromuscular function primarily driven by the interaction of motor and sensory areas of the brain. However, there is strong evidence from growing numbers of papers from brain imaging and dual-task studies that support the contribution to normal gait of areas of the brain which also serve cognitive and executive function. Apart from evidence from studies involving healthy participants, there is support also from gait study literature of neurologically impaired populations. In particular these studies highlight the interference to the motor and cognitive interactions in the presence of suboptimal neural processes especially due to damage of central origin.

As discussed in the chapter, a stroke damages brain tissue and consequently creates a large range of neurological impairments, the most common affecting motor and cognitive functions. One of the consequences of surviving a stroke is a heightened risk of falls, and although the reasons for a fall can be multifactorial, the contribution of motor and cognitive dysfunction is important. One of the outcomes of stroke, that undoubtedly contributes to fall risk, is a foot drop gait. FES is used to address this by improving dorsiflexion on swing through and foot placement on initial contact, thus reducing the potential for the toe to catch the ground when walking and a trip or fall to result.

As discussed in the chapter, FES has traditionally been assessed for effectiveness by measuring improvements in gait speed and the energy cost of walking. However, increased speed is not as highly rated by users as several other perceived effects. In particular reduced effort is consistently identified as a primary reason for FES use with a reduction in the risk of tripping and falling also highly rated. A reduction in the effort of walking may include a mental component and may be plausibly explained by the contribution of cognitive function to motor control. Furthermore, whilst there is an

obvious functional improvement in walking that should reduce the risk of tripping, FES use may also reduce the demand of gait on both motor and cognitive control thus improving the ability to maintain safe and stable gait.

The primary aim of this thesis is to explore the contribution of FES to the cognitive control of gait. Firstly, the idea that cognitive control was affected by the use of FES came from very small qualitative studies, although the two studies by Taylor et al did canvass nearly 150 users. Consequently, the first objective was to gather data to either support or refute the concept of perceived effects on the mental effort of walking. If sufficient support was collected, the second objective was to explore the concept of cognitive control further by via a gait laboratory study, based on a dual-task approach.

Chapter 3 – Study of FES user reported effects

3.1 Introduction

As described in Chapter 2 (section 2.2.3c), a review of literature established the concept of a complex relationship between higher level cognitive function and gait (Sheridan and Hausdorff, 2007, Al-Yahya et al., 2011). Furthermore, impairments to the executive function and attention systems as a result of stroke, particularly when paired with physical impairments, may lead to increased competition for limited higher level resources (Woollacott and Shumway-Cook, 2002, Springer et al., 2006, Liu-Ambrose et al., 2007, Yogev-Seligmann et al., 2008, Segev-Jacubovski et al., 2011). Building on this, there was also evidence from the literature on falls, both at the start of the thesis and since, as discussed in section 2.3.4b, that indicated the contribution of cognitive deficits, including attention and memory deficits, to fall risk amongst the stroke population (Rapport et al., 1993, Hyndman and Ashburn, 2003, Wada et al., 2007, Alemdaroglu et al., 2012). However, at the start of the thesis, there was no information on how FES may interact with such motor-cognitive deficits.

In the FES literature there were a small number of publications describing the user-perceived effects of FES for foot drop. As discussed in section 2.4.3e, two postal questionnaire studies of FES user opinion (Taylor et al., 1999b, Taylor, 2004) reported factors other than walking speed, traditionally used as an outcome measure of effectiveness, to be the most important reasons for using FES. A reduction in effort was the principal reason cited by the majority of users in both studies. Further principal reasons ranked below effort were, in the first study, reduced risk of tripping, followed by increased walking distance and finally increased confidence. These all preceded increased walking speed in the ranking of primary reasons for use by FES users. In the second study, five effects were ranked more highly as primary reasons for use, before walking speed. They were ranked behind reduced effort as follows: therapeutic effect (i.e. carryover), long term improvement in walking, increased confidence, reduced risk of tripping and increased independence. Thus, there are several effects of FES that users perceive as more important than walking speed, with reduced effort of walking consistently ranked as the primary reason.

At the time, there was a suggestion, from a small qualitative study (Malone, 2002), that effort in this context may not only relate to the physical effort, but may also include the mental effort of gait. Participants described walking prior to use of FES as requiring ‘concentration all the time’. Then, with use of FES, participants described feeling that their walking was more normal and required less effort, as they did not have to concentrate so much on their walking. Participants in this study thus suggested a link between the effort of walking and a level of required concentration when walking following a stroke that was directly improved by the use of FES.

Furthermore, the findings from Taylor et al (1999b, 2004), that trips and falls appear to be reduced when using FES, could be interpreted in a number of ways. One possible explanation is that FES has a positive effect on gait stability through the biomechanical effects of lifting the foot during the swing phase and orienting the foot correctly at heel strike. However, it is possible to hypothesise that these biomechanical effects may also indirectly impact on the cognitive demands of walking, by reducing the need to pay visual attention to the foot during walking. Further, as discussed in section 2.4.2b, there is strong evidence that FES acts to change excitability of centres of the brain which serve both motor and cognitive purposes and also a suggestion that FES acts to modulate interactions between the CNS and PNS at the spinal cord. While the implications of this are entirely speculative, it is possible that such changes in neural connectivity may manifest in changes in the performance of demanding motor-cognitive tasks, such as trip or fall avoidance. Finally, the sensory stimulation associated with FES may also have an effect on the focus of attention during walking. It is therefore possible that FES may help users to avoid a fall by improving the cognitive resources available when walking is challenged. However, there were no studies exploring these effects.

It was clear that further work was required to explore and substantiate these concepts, based on user perceptions, before experimental work with users of FES was justified. Furthermore, in order to design any subsequent experimental study, more information on the perceived effects of FES was needed. As described above there was strong evidence from the wider literature to support further investigation of these concepts.

At the beginning of the thesis there was a growing body of studies using dual-task methodologies to assess gait in the presence of gait impairments and cognitive disorders e.g. Parkinson's disease (Woollacott and Shumway-Cook, 2002). Dual-task study designs, requiring a division of attention between walking and a cognitive task, are reflective and typical of real world situations where participants are required to 'walk and talk', to take note of their surroundings and to remember and follow directions. Thus, studies available at the beginning of the thesis, using this methodology, indicated that there was a relationship between gait and higher level cognitive functions. However, despite growing numbers of dual-task studies, only two small studies of exclusively stroke patients had been published at the time. The first was a study of eleven participants, using a verbal cognitive task (i.e. a pre-determined verbal response to verbal cues) as a secondary task whilst walking (Bowen et al., 2001). Gait speed decreased with task, and double support time increased; performance of the cognitive task was not reported. The second study involved ten participants and compared stride duration whilst performing a word generation task, measured initially after their stroke and then 1-9 months later (Cockburn et al., 2003). Stride duration improved with recovery more so than cognitive performance.

At this time there were also a small number of studies that had addressed the issue of whether devices to assist walking may impact on the attentional demands during gait. For instance, a dual-task methodology was applied to examine the attentional demands of use of standard and rolling walkers by healthy young adults (Wright and Kemp, 1992). The task required a vocal response to an auditory tone and the time elapsed before the response was measured. Secondary task was significantly affected in the dual-task condition with a standard pick-up walker. In a study of unilateral transfemoral amputees the cognitive demand of two prostheses was compared (Heller et al., 2000). A simple task of reading a number that appeared on a monitor and a more demanding distracting task of the Stroop test (i.e. naming the colour in which a word is printed) were both used as secondary tasks. Body sway was compared between the conditions, finding no significant difference and thus, neither prosthesis created a greater cognitive demand. However, the Stroop test created significantly larger body sway than the simple task.

The emerging literature suggested that a dual-task based experimental study would allow for investigation of the effects reported by FES users. Specifically, it would allow for a study of the effects that FES users described from the available literature (Taylor et al., 1999b, Taylor, 2004, Malone, 2002). As there was very limited evidence to support the hypothesis that FES may have an effect on motor-cognitive performance during walking, the decision was made to use a questionnaire study to explore user reported effects amongst a group of people who had been using FES for foot drop as a result of stroke. Furthermore, the secondary cognitive tasks used in dual-task studies were various and the reasoning for choice of task was not routinely reported in the literature. Again, due to the limited evidence, it was also decided that the questionnaire study could contribute to identification of an appropriate dual-task for a group of FES users. The questionnaire study aims were to substantiate or refute the suggestion in the literature that FES for foot drop is perceived to impact on the higher level cognitive functions during gait and, if confirmed, to inform the design of subsequent experimental studies that would allow for the testing of this hypothesis.

This chapter begins by detailing the aims of the questionnaire study. The process by which the questionnaire design was formulated is then described, including pilot work and the use of expert opinion to inform questionnaire structure and content. The process by which the questionnaire was implemented is then described, followed by results. Finally, the study is discussed, including its limitations, and conclusions drawn.

3.2 Aims of the questionnaire study

The questionnaire study had three main aims:

a) To investigate FES users' perceptions of the effects of FES on walking.
b) To investigate FES users' perceptions of the effect FES may have on concentration required when walking.
c) To investigate FES users' perceptions of the specific areas in which use of FES may contribute to a change in the effort of walking.

The secondary aim of the questionnaire study was to inform choice of a dual-task methodology for a possible subsequent gait laboratory study.

3.3 Development and design

3.3.1 Choice of questionnaire study design

A questionnaire was chosen to address the primarily exploratory aims of the study. Whilst the first aim of investigating the effects of FES on walking had already been addressed by the Taylor et al (1999, 2004) studies, the current study planned to explore this concept again in a new group of FES users. The other two aims to investigate the effect of FES on the concentration and effort of walking had not been extensively explored by any previous study. The exploratory nature of this study suggested that a questionnaire-based approach would be appropriate (Wood, 2001). Furthermore, a questionnaire had been successfully used to explore the effects of FES by Taylor et al (1999, 2004).

At the time of the study in 2005 there were two large FES clinical services in the UK and only a handful of much smaller services. The nature of service provision meant that services operated as regional or tertiary centres servicing the local population as well as a scattered population of users from a large area of the UK. As such, the choice of a postal questionnaire would give the sample group an equal opportunity to respond, rather than reliance upon face-to-face methods of data collection. This approach is also less susceptible to interviewer bias and is obviously an economically pragmatic approach (Polgar and Thomas, 2000).

Access to the largest group of FES users (in Salisbury (UK)) was arranged. The FES group was recruited from a clinical service, which collected information from their patients on an on-going basis and had, in the past, used questionnaires for specific research questions. Previous response rates of 55% and 74% (Taylor et al., 1999b, Taylor, 2004) were seen as indicative of a potentially similar return rate for this study.

3.3.2 Formulation of questionnaire structure, design and content

The questionnaire structure, design and content was developed according to recognised strategies (Chesson, 1993, Stone, 1993, Bradburn et al., 2004, Bowling, 2005). The focus of the questionnaire was clearly defined by the aims and there was a clear relationship with the subsequent content (Bowling, 2005). Relevant literature

on user perceptions of FES and related devices was reviewed, and questions used in these studies were analysed for inclusion in the questionnaire.

FES users were directly engaged to review perceived effects from the literature and to ascertain any other outcomes of device use. Effects of FES as previously described in the two studies by Taylor et al (1999, 2004) were reiterated by users, thus confirming the effects already reported i.e. improved confidence, increased independence. FES users also described other effects of FES when walking such as 'I don't need to look at my feet as much', 'I can think about something and not my walking' and 'I can carry on a conversation'. Furthermore, these effects were expressed as very positive effects of FES that seemed to be in addition to improved walking and also seemed to be important to users. These effects independently expressed by FES users supported concepts noted in the small study by Malone (2002) and seem to indicate that FES gave them an ability to perform other non-motor, cognitive functions more easily whilst walking. The outcomes of these discussions were used to inform construction of questions included in the questionnaire (see sections b and c that follow).

Questions were devised that were simple, unambiguous and not too long (Stone, 1993, Bowling, 2005). The order in which the questions were asked was devised taking into consideration the filtering of respondents who may no longer be using their device, achievement of a natural flow to the topics covered and difficulty of the questions asked (Chesson, 1993). It is often recommended that demographic questions should be asked at the end of a questionnaire (Bradburn et al., 2004). In this study it was felt appropriate to ask these questions at the beginning as they were felt to be non-threatening and easy relative to the subsequent questions that addressed the aims of the questionnaire (Chesson, 1993, Bowling, 2005). The question about date of stroke, at the beginning of the questionnaire, also served to screen respondents thus excluding those who had not suffered from a stroke, and may have inadvertently received a questionnaire, from analysis of results (Peterson, 2000).

The content, design and layout of the questionnaire were reviewed, with advice sought from an experienced researcher, a psychologist and a statistician. The psychologist with expertise in dual-task methodology and the researcher, who had

previously designed and published results from questionnaires applied to FES groups, gave advice about the construction of the questions and the design and layout of the questionnaire. The statistician offered advice concerning planned analysis of data and the appropriate choice of question response structures (e.g. open vs. closed questions, scaled responses) to facilitate analysis.

Once the content was finalised, the questionnaire was piloted with people from the target population. Issues concerning language used and clarity of meaning of the questions were highlighted during this process, identifying the importance of using language and terms that would be used in everyday conversations. In particular, it was important to describe the effects of FES in the questionnaire using the same wording as FES users e.g. 'I don't have to think so much about my walking when I have the stimulator switched on'. The structure of responses to questions was also tested to ensure that users could follow the directions given about how to answer correctly. Users felt that the inclusion of a response indicating that some questions would not apply to their circumstances was important, and this concurred with advice from the statistician, as this option would potentially ensure a response rather than questions remaining unanswered. Furthermore, FES users were able to identify an appropriate response, from those questions using scaled responses, which reflected the effect of FES. Overall the content of the questionnaire seemed to capture perceived effects of FES for those who participated in the pilot. Following piloting, the questionnaire was finalised.

The questionnaire addressed three aims and Figure 3.1 illustrates the process via which each aim was developed into content. Following is a description of each of these areas and of the remaining sections of the questionnaire. It should be noted that the questionnaire was implemented in July 2005, and as such the content and design was informed by literature available at that time.

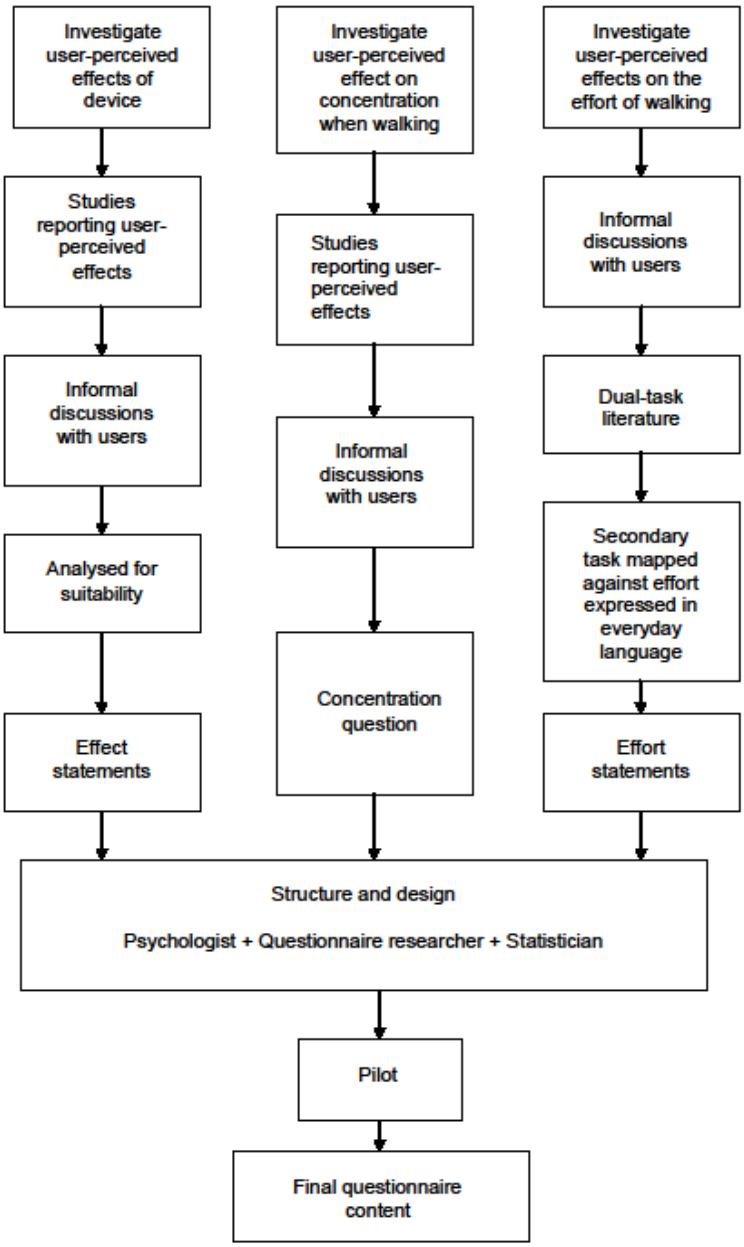


Figure 3.1: Process of development of questionnaire content

a) The effect of the device

To address the first aim of the questionnaire, the investigation of users' perceptions of the effects of their device, the relevant literature was reviewed.

FES and AFOs when used in foot drop gait both have the primary aim of enhancing dorsiflexion. AFOs apply an external brace to achieve this rather than promoting

active dorsiflexion, as is the approach applied by FES. AFOs are an alternative device to FES, thus effects perceived by AFO users may be similar to those noted in FES studies. Furthermore, as very few studies capturing FES user views were available at the time of developing the questionnaire, the decision was taken to review the closely related literature on AFO user views to inform the questionnaire design.

A systematic review (Leung et al 2003), performed to evaluate the effects of AFOs on adult hemiplegic gait, suggested that AFOs may lead to an immediate kinematic and temporal improvement in gait in selected hemiplegic patients. Only one study was included in this review that reported on the energy expenditure of AFO use, noting that oxygen consumption was lowered by the use of an AFO. Studies that included AFO user opinion as an outcome (Tyson, 1998, Tyson and Thornton, 2001, de Wit et al., 2004), canvassed a total of 49 users, seeking opinion as a secondary outcome. In the first Tyson study (1998), AFO users described being able to walk further and faster and with greater confidence and safety. More AFO users, in the Tyson et al study of 2001, agreed that the AFO improved safety and confidence when walking than those who agreed it increased speed, despite a measured statistically significant increase in speed. Furthermore, 70% of the participants in the study by de Wit et al (2004) felt their self-confidence was improved even though the measured changes in walking speed were not clinically relevant.

A review of both FES and AFO studies was used to formulate a list of possible perceived effects of devices for foot drop. From the two studies by Taylor et al (1999, 2004) the list of positive effects of FES, as perceived by users, was as follows:

- Reduction in effort
- Reduced risk of tripping
- Increased walking distance
- Increased confidence
- Increased walking speed
- Increased independence
- Improved ability to walk on uneven ground
- No longer need an AFO
- Improved fitness with exercise
- No longer need assistance to walk

- Improved walking without FES
- No longer need to use stick
- Carryover effect
- Corrects inversion of the foot

The majority of these effects were re-iterated by participants in the study by Malone et al (2002). Furthermore, 80% of patients reported an increase in confidence with FES, although this was from a mixed group of patients including those with Multiple Sclerosis (Singleton, 2004).

From the two AFO studies performed by Tyson et al (1998, 2001) the following positive effects were identified by users:

- Able to walk further
- Able to walk faster
- Increased confidence
- Increased safety
- Able to swing leg forward more easily
- Lifting toes improved
- Taking weight through foot improved

In broad agreement with these, de Wit et al (2004) asked participants to consider the difficulty and self-confidence involved in the 'timed up and go test' and using stairs, with and without an AFO. Less difficulties and greater self-confidence were reported when wearing the AFO. Although FES users highly rate a reduction in effort as an outcome, this effect was only noted in one AFO study (Geboers et al., 2002) in which a questionnaire collated user opinion of 16 AFO users with foot drop as a result of peroneal nerve lesion or L5 radiculopathy. Results indicated that AFOs had a positive effect on walking performance and walking effort in 75% of the participants.

Each possible outcome regarding the effect of FES, as derived from the FES and AFO literature as discussed above, was considered for applicability. The focus of this process was to reflect outcomes reported by users, to date reported in few studies, but potentially of importance to them in the context of this thesis. Another key point was to minimise the length of the list of included outcomes to minimise the burden to the respondents. Therefore, questions which did not clearly relate to the focus of the

thesis, or had previously been shown to be of little relevance to users were excluded. The following lists the reasoning for inclusion of outcomes in Section C (1) of the questionnaire (see Appendix A.1):

- Increased confidence, ability to walk further and faster - Common to both FES and AFO studies therefore respondents may perceive this as an effect.
- Reduction in effort - Highly rated by FES users and also in one non-stroke AFO study (Geboers et al., 2002).
- Increased independence - Highly rated by FES users.
- Reduced risk of tripping, improved ability on uneven ground, increased safety - Identified by both FES and AFO users as positive outcomes of device use.
- No longer need assistance to walk - Rated by over 30% of FES users (Taylor et al., 1999b, Taylor, 2004) as a positive effect and could be related to feeling of independence.
- Improved fitness with exercise, no longer need to use stick - Rated by the fewest number of FES users as an effect (Taylor et al., 1999b, Taylor, 2004) however potentially important effects for some users.

Two further effects were included in the questionnaire, Section C (1) (see Appendix A.1) that were derived from discussions with FES users as well as from the Malone et al (2002) study. Users noted that their posture improved with device use and that their walking became more balanced and even.

To encourage a response to each potential effect of the device and to be confident that each effect was considered by the respondents, the effects were framed as statements that required a response. Respondents were given a choice of responses and were directed to the need for a response (see Section C (1), Appendix A.1). The choice of response was related to the statement and was designed to gain agreement by using endorsement stimuli; ‘agree’, ‘disagree’ (Peterson, 2000). A third choice was also available - ‘doesn’t apply’ – thus accounting for those respondents for whom the statement was not a perceived effect. Designing the response in this way addressed issues of sensitivity and specificity (Bowling, 2005) by allowing for those not affected by the questions asked. This response structure also aided statistical analysis of data, by encouraging respondents to record an answer to each of the statements.

To obtain the most highly rated effects of FES, the Taylor et al (1999, 2004) studies asked the participants to identify, from the effects that they had noted as applicable to them, the most important effect. The questionnaire used in this current study also asked this question to collate data on the most highly rated effects of FES, in order to establish the primary reason for FES use and compare these results with the previous studies.

b) Concentration during walking

To investigate users' perceptions of the effect the device may have on concentration required when walking a single question was posed.

The Malone et al (2002) study used narrative interviews to collate data on the effect of FES. Results noted that 'participants described feeling that their walking was more normal and required less effort, as they did not have to concentrate so much on their walking.' Thus, these participants had linked the concept of effort with concentration required for walking. This recorded effect of FES from this study was re-iterated during informal discussions with FES users who indicated that they didn't have to think so much about walking with FES and that their level of concentration on or thought about walking was reduced when walking with FES. As FES users highly rated the effect of a reduction in effort in the two Taylor et al studies (1999, 2004), and this may include a mental component, a question asking specifically about concentration was clearly warranted.

In Section C (4) a single question about the concentration required to walk with and without the device was posed. A scaled response was sought rather than a yes/no response, to provide a more sensitive and precise response (Bowling, 2005). A simple verbal scale of three responses was chosen and the language and format of the scale was tested during pilot work and found to be appropriate.

The scale was a simple graded choice between 'none', 'some' and 'a lot', thus allowing respondents who did not perceive any effect on their concentration to choose 'none'. Respondents were asked to consider the amount of perceived concentration required to walk with and without their device, providing data about the change in concentration perceived to be as a result of use of the device.

c) Effort of walking

The third aim of the questionnaire was to investigate users' perceptions of the specific areas in which use of their device may contribute to a change in the effort of walking. Outcomes as a result of addressing this aim would firstly provide evidence to justify the subsequent application of a dual-task methodology in a gait laboratory to assess the effort of walking and secondly, to inform the choice of an appropriate secondary task.

Development of this section of the questionnaire (Section C (5) – see Appendix A.1) was initially driven by informal discussions with FES users. The users described effects when using the device such as; being able to think about something else, being able to talk to someone else and not having to look at the ground when walking. These descriptions of other effects seem to indicate that FES gave them an ability to perform other non-motor, cognitive functions more easily whilst walking and were supported by narratives from the Malone et al (2002) study, where participants indicated that FES use had an effect on other actions pursued whilst walking. Secondly, discussions took place with an expert on cognitive processes (Bowen, 2004, 2005) to discuss possible cognitive tasks that would be part of everyday life that device users would do whilst walking. The relevant dual-task literature that was available at the time was reviewed as part of these discussions and also as part of the questionnaire development process. The aim of the literature review was to identify the secondary tasks (i.e. walking being the primary task) used in previous studies. Studies of healthy and gait-impaired participants were included; the principle search criteria were a dual-task approach to assess gait and/or secondary task performance.

The secondary tasks used in dual-task studies were analysed for their relationship to everyday tasks and broadly grouped and mapped against statements, in everyday language, that reflected how users would potentially describe the effects of the device. Table 3.1 shows the results of this process. The largest number of studies required the participants to verbally respond to questions whilst walking e.g. answering autobiographical questions (Rochester et al., 2004) and hence mapped well against the users perception of an effect of FES on an ability to talk to someone else whilst walking. Further studies required participants to generate word lists

(Cockburn et al., 2003) or memorise digits (Ebersbach et al., 1995) thus requiring an ability to think about something else whilst walking. Finally, a handful of studies employed tasks that required participants to visually pay attention to a stimulus and respond (Heller et al., 2000), a behaviour that some users reported finding easier with FES.

The literature reviewed also highlighted studies where physical obstacles had been used as a secondary task (Said et al., 1999, van Hedel and Dietz, 2004, Schrodt et al., 2004). These secondary motor tasks involved stepping or a change in normal walking pattern, which would have created a challenge to a foot drop gait; already both physically and mentally demanding and at a higher risk of trips and falls. Informal discussions with users had also highlighted secondary physical effects of device use, concerned with an ability to avoid trips and falls. It was thus felt appropriate to include statements reflective of a secondary motor task that would occur during walking.

Finally, during clinical practice some stroke survivors described difficulty maintaining their gait when walking in a noisy environment, as the noise acted as a source of distraction. For example, one person described emergency vehicle sirens or noisy car engines as a creating a need to either stop or reduce their speed when walking in the street to be sure of maintaining a balanced, safe gait. Whilst, there were not a number of dual-task studies at the time employing secondary tasks that could be mapped against this, it was felt appropriate, due to its clinical relevance, to include this as a potential effect noted by users whilst walking.

Table 3.1 shows the effects of the device, expressed as a positive statement in everyday language, mapped against secondary cognitive and motor tasks used in reported dual-task studies. These everyday expressions of tasks were then used to devise the dual-task statements in the questionnaire (Section C (5), see Appendix A.1). The statements were also devised with the aim of informing the choice of a dual-task, appropriate for use in the gait laboratory study that followed. As such, it was important to clarify that the relationship of each statement to a potential dual-task intervention was established in the literature.

Statement	Secondary cognitive or motor task and study reference
I can think about something else whilst I walk.	Male or female name generation (Camicioli et al., 1997) Categorised word generation (Haggard et al., 2000, Cockburn et al., 2003) Memorisation of digits (Ebersbach et al., 1995) Memorisation of words (Lindenberger et al., 2000)
I can walk without thinking about it.	As above.
I can walk onto a kerb.	Obstacles of various heights (Said et al., 1999) Treadmill with obstacle (van Hedel and Dietz, 2004) Obstacle + arithmetic task (Schrodt et al., 2004)
I can walk on uneven ground.	As above.
I can avoid a trip or fall when I walk.	As above.
I can look at the things around me when I walk.	Stroop test (Heller et al., 2000) Physical response to visual stimulus (Sparrow et al., 2002)
I can walk without looking at the ground.	As above.
I can walk in a noisy environment.	Clinical observation
I can answer questions whilst I walk.	Arithmetic task (Haggard, 1998, O'Shea et al., 2002, Hausdorff et al., 2003, Sheridan et al., 2003, Schrodt et al., 2004) Stops walking while talking test (de Hoon et al., 2003) Clock hands on clock face (Haggard, 1998, Haggard et al., 2000) Targeting paired words (Haggard et al., 2000) Answering questions (Rochester et al., 2004) Verbal response to tone (Lajoie et al., 1993, Wright and Kemp, 1992, Gage et al., 2003)
I can talk to someone when I walk.	Verbal response to verbal stimulus (Bowen et al., 2001, de Visser et al., 2003) Plus as above.

Table 3.1: Device effect statements mapped against secondary task.

The statements asked if using FES when walking made a difference to the secondary task e.g. talking to someone. The statements were framed to elicit a response that completed the statement using comparison stimuli (Peterson, 2000) in a scaled response; ‘easier’, ‘same’ or ‘harder’. As in the questionnaire section about the effects of the devices, statements were used to increase responses and respondents

were directed to the need for a response. Respondents for whom the statement was not a perceived effect were able to choose 'the same' as their response. Again, by accounting for those respondents who were not affected, issues of sensitivity and specificity were addressed (Bowling, 2005). As in the previous questions about the effect of the device, this structure also aided statistical analysis of data.

Finally, to assist with narrowing down the choice of task, respondents were asked to identify, from the statements in the questionnaire, the one task that was most important to them.

d) Characteristics of respondents

The questionnaire included questions to establish the characteristics of the respondents. Section A (see Appendix A.1) requested the sex, date of birth, date of stroke, side affected by the stroke and any health problems or disabilities.

There was potential for the questionnaires to be sent to people who no longer used their FES device. As such, in Section B (see Appendix A.1) respondents who no longer used their device were not required to answer any of the questions in the following Section C; these were concerned with the effects of the device and thus the opinion of current users was felt to be more appropriate. Non-users of FES were directed to the end of the questionnaire, and no further questions were asked.

Thus, users of FES were asked in Section B of the questionnaire (see Appendix A.1) about the use of their device. The questions were broadly based on those used by Taylor et al (1999, 2004) for FES users. Therefore, data about the amount of device use and the activities pursued whilst using the device was collected. In Section C (3) of the questionnaire (see Appendix A.1) respondents were asked about their use of any other walking aids, both with and without their device. This information would allow the current study's group to be compared with previous FES groups from Taylor et al (1999, 2004) studies.

FES users were asked in Section D (see Appendix A.1) to state when they first started using the device. Furthermore, it was possible that some current FES users may also have been using an AFO device. They were asked to identify, from a series of photos, the type of AFO that they were currently using. To capture a comparison of

the two devices respondents were asked which of the FES or AFO device, if they were using the latter also, helped them walk with the least effort.

3.4 Ethical approval

Ethical approval was granted by Salford and Trafford Local Research Ethics Committee in June 2005 (Appendix A.2) and by The University of Salford Research Governance and Ethics Sub-Committee (Appendix A.2). Approval was also granted by Salford Royal Hospitals Research and Development Directorate (Appendix A.2).

3.5 Application of questionnaire

The questionnaire was posted to patients attending the Department of Medical Physics at Salisbury District Hospital, UK, identified from a database as 18 years and over, who had received their device, between and including July 2002 and June 2004, as a result of foot drop following a stroke. This group had not been involved in a questionnaire study of this nature before.

An introductory letter (Appendix A.3) and a participant information leaflet (Appendix A.4) were sent with each questionnaire. In addition, the group received a letter (Appendix A.5) from the local collaborator at Salisbury District Hospital, explaining that confidential information would not be released to the chief investigator, during the study.

The questionnaires were coded before being posted enabling non-respondents to be identified. Non-respondents were sent a second copy of the questionnaire, four weeks after the initial post, to encourage completion and return.

The questionnaires were sent to potential respondents in July 2005.

3.6 Results

3.6.1 Questionnaire response rates

A description of the number of questionnaires sent, and the number and nature of the respondents is shown by Figure 3.2. The response rate was 65%. The number of responses from respondents who were currently using their FES was 30.

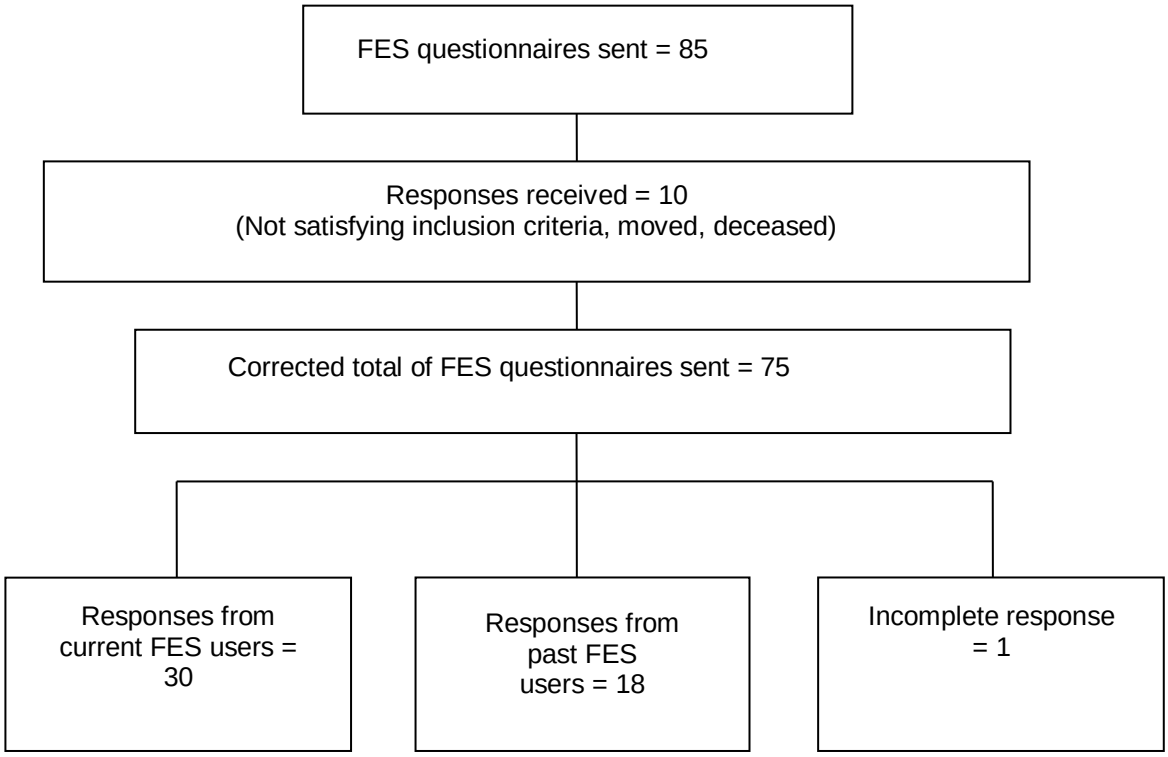


Figure 3.2: Responses to questionnaires.

3.6.2 FES users

The self-reported characteristics of respondents who were using their FES device at the time of data collection is summarised in Table 3.2. The mean age of the respondents was 64.6 years (± 13.7) and the time since stroke was 74.9 months (± 42.9).

Sex male : female (%) *n = 30*	19 : 11 (63 : 37)
Mean age years ± SD	64.6 ± 13.7
Mean time since CVA months ± SD	74.9 ± 42.9
Side of body affected left : right (%)	13 : 17 (43 : 57)
Self-reported health problems (%) Upper limb affected Speech affected Sight problems Diabetes Pulmonary disease Heart problems/High BP Back problems Arthritis	 15 (50) 5 (17) 1 (3) 4 (13) 1 (3) 6 (20) 2 (7) 3 (10)

Table 3.2: Self-reported characteristics of FES users at time of data collection (n=30).

Mean time since began use months ± SD	31.0 ± 19.8
No. of days used per week (%) **1** **2** **3** **4** **5** **6** **7** **No answer**	 7 7 3 13 17 3 50 0
Mean use per day hours ± SD	7.5 ± 4.2

Table 3.3: Self-reported usage of FES by respondents (n=30).

The usage of the devices reported by the respondents is shown in Table 3.3. The mean time since FES users had received their device was 31.0 months (± 19.8). 70% of the respondents used their device for 5 days a week or more. On the days when respondents used their device it was used for an average of 7.5 hours (± 4.2).

The activities undertaken by the respondents, either with or without FES, are illustrated by Figure 3.3. The top five activities performed with FES were longer walks, shopping, walking outdoors, day trips and social events. The top three activities performed without FES were exercising, walking indoors and walking around the home.

The use of walking aids by the FES users is shown by Figure 3.4. Each respondent could use any of the walking aids both with and without their FES, thus results for two of the aids (i.e. walking stick and assistance from another person) are in excess of 100%. A walking stick was the most frequently used aid both with (70%) and without (50%) FES, followed by assistance from another person (33%). 43% of users did not require assistance from another person when walking.

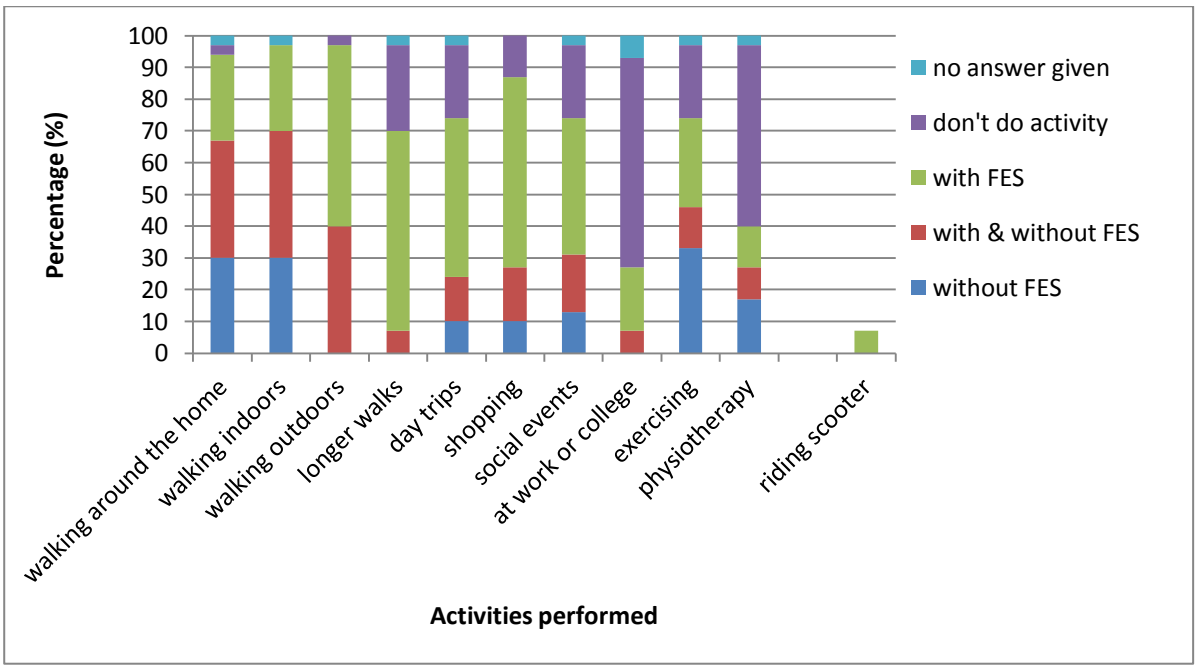


Figure 3.3: Activities undertaken by FES users, both with and without FES.

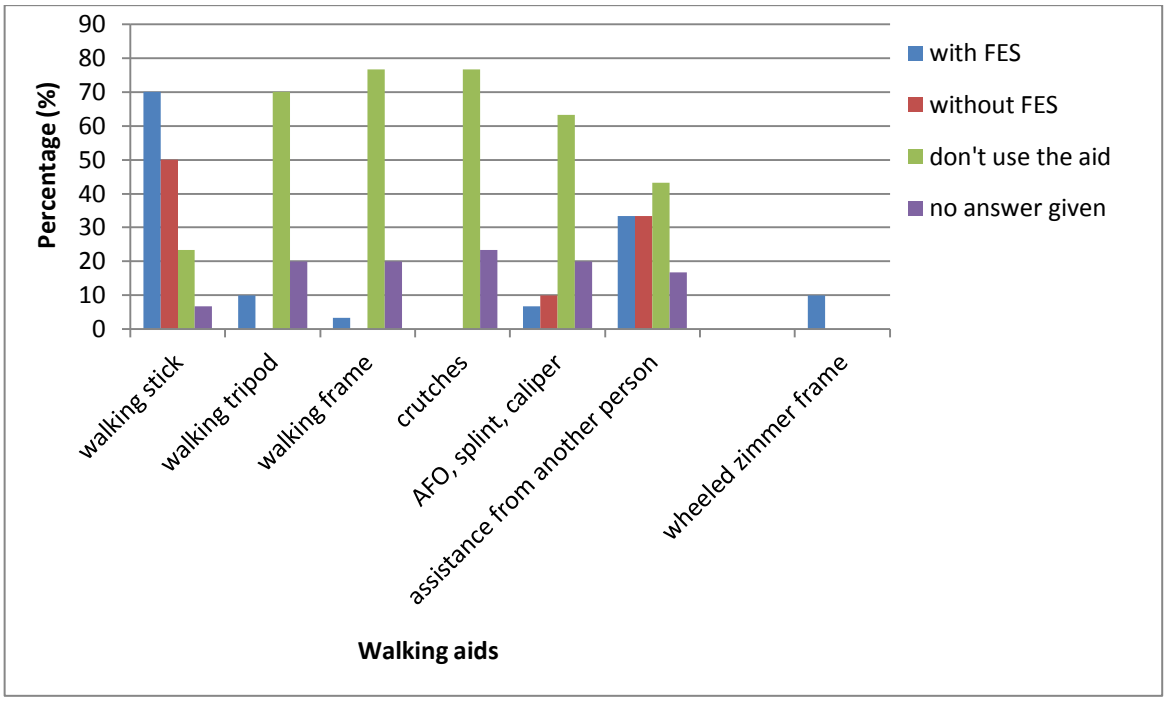


Figure 3.4: Use of walking aids by FES users, both with and without FES.

The response by FES users to statements about the effect of their device is shown by Figure 3.5. Over 60% of respondents agreed with 10 of the 13 statements. 90% agreed that it was less effort to walk with their FES device. 80% and over of respondents agreed that they were able to walk further, that their walking was more balanced and even, that they were less likely to trip or fall, that they were able to walk more safely and felt more confident when they walked. 70% and over felt that they

were more able to walk on uneven ground and that they could walk faster with FES. More than 60% felt more independent and that their posture was better.

Only 20% of FES users agreed that they could use their walking aid less often whilst 50% disagreed with this statement and for 20% of respondents this statement did not apply. 36% were able to exercise more whereas 27% were not able to and a further 27% noted that this statement did not apply to them. 53% felt they could walk more often without the assistance of another person, over 27% disagreed with this statement and 20% did not feel this statement applied to them.

When respondents were asked which of these effects was the most important, the three most highly rated, each by 17%, were increased confidence when walking, increased independence and less likely to trip or fall (Figure 3.6). Less effort when walking was chosen by 13% of users as the most important effect.

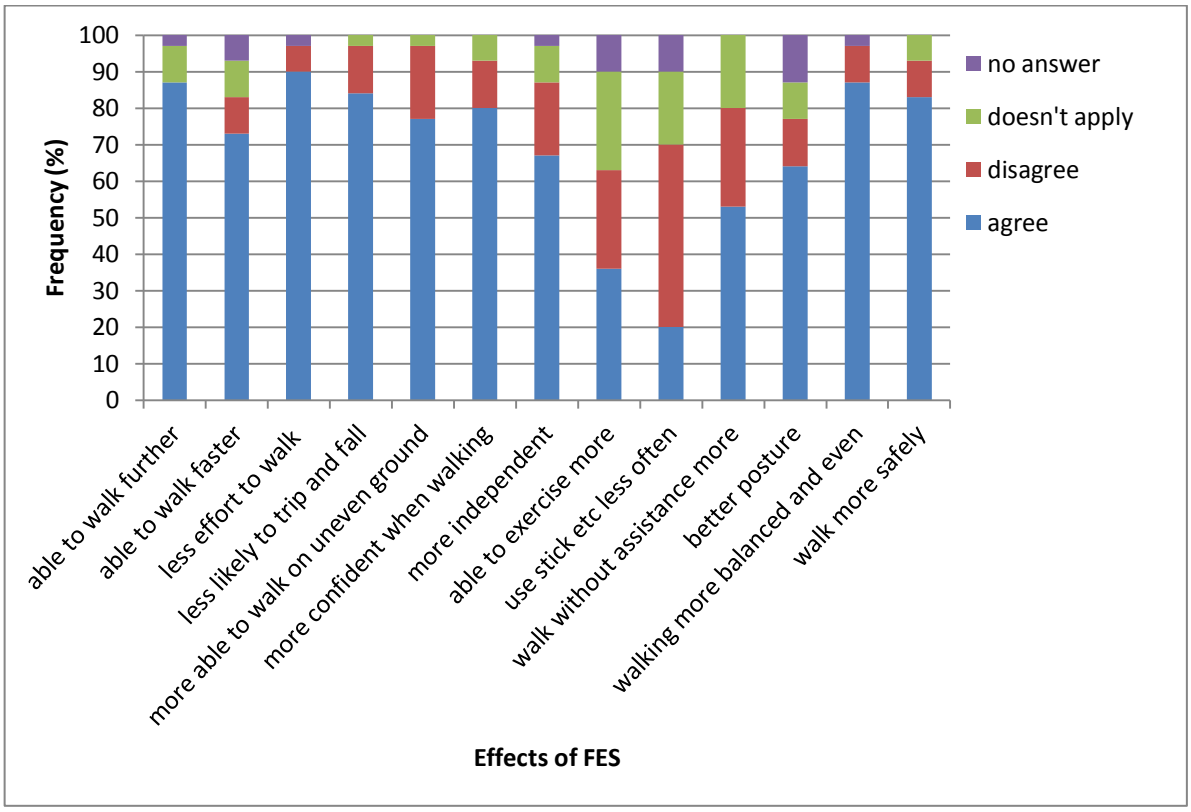


Figure 3.5: Frequency of response to effects statements by FES users.

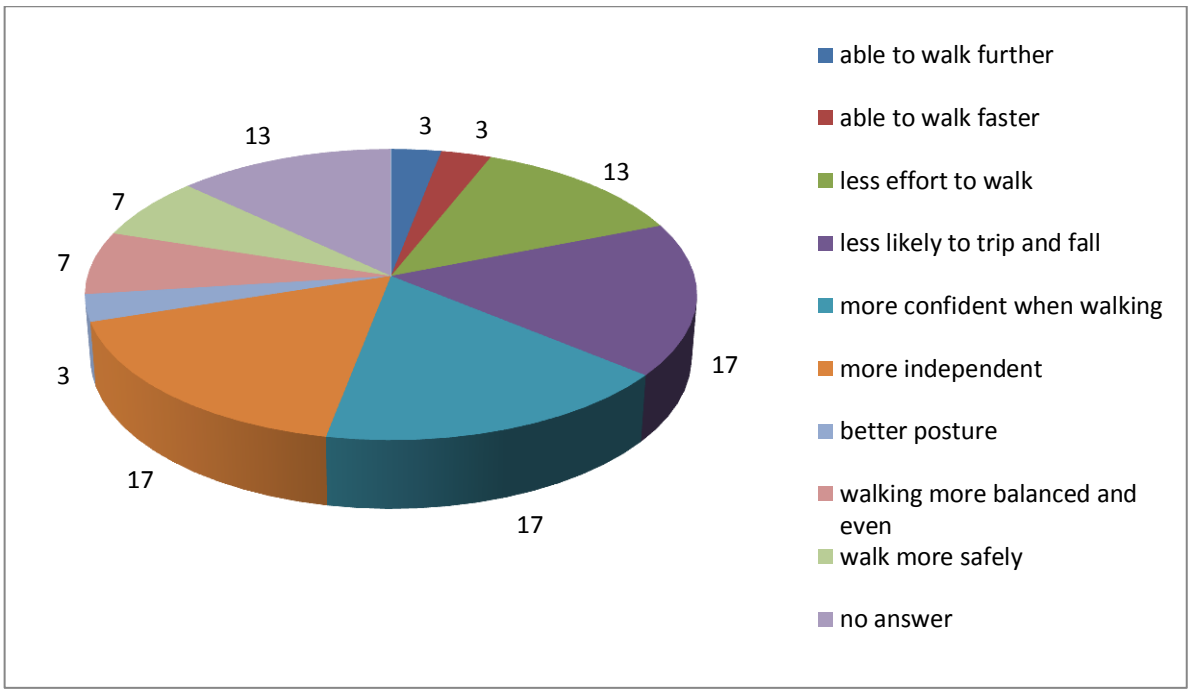


Figure 3.6: The frequency (%) of most important effect chosen by FES users.

Fourteen of the FES users also used an AFO. The AFOs used were foot-ups, Aircast ankle braces, Speed braces, Supralite AFOs, posterior leaf spring AFO and other AFOs. Twelve of these FES users felt that their FES helped them to walk with the least effort, when compared with their AFO.

When respondents were asked to rate on a three-point verbal scale, the amount of perceived concentration required to walk both with and without FES, their responses produced a significant difference between the two conditions. Figure 3.7 illustrates the frequency of responses for each condition. With FES, the amount of concentration rated as ‘some’ increased and conversely, the amount of concentration rated as ‘a lot’ decreased, when compared with walking without FES. Thus, there was a reduction in the perceived level of concentration required when walking with FES which, when statistically analysed, was significant (McNemar $x2 = 13.06$, $df=1$, $p<0.001$, 2-tailed).

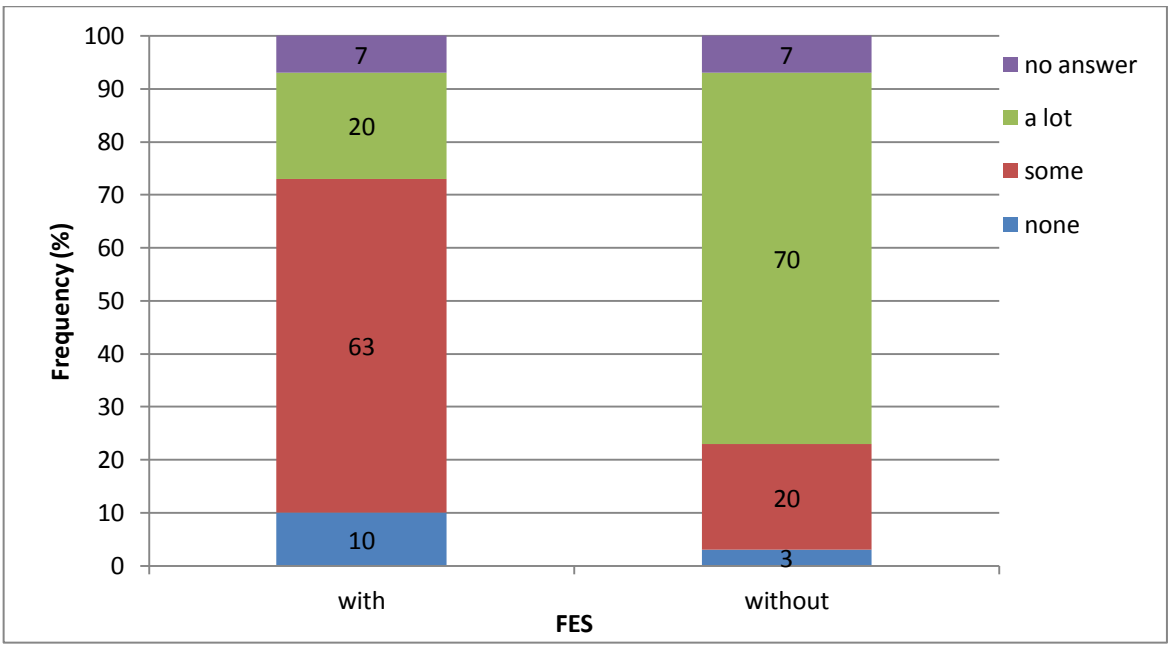


Figure 3.7: Rating by users of concentration needed to walk with and without FES.

The frequency with which respondents felt their device affected dual-tasks is detailed in Figure 3.8. Five of the ten conditions were made easier with FES for over 50% of users. In particular 70% of FES users found it easier to avoid a trip or fall and 60% found stepping up onto a kerb and walking without thinking about walking easier with FES. 57% of users found walking on uneven ground easier with FES. 54% found it easier to look around whilst walking with FES. 17% of users felt using FES made two dual-task conditions harder; walking on uneven ground and walking without thinking about walking.

When respondents were asked to identify the most important task that was easier with FES, 40% of FES users identified avoiding a trip or fall (Figure 3.9). 14% of users identified walking on uneven ground, whilst 10% chose stepping onto a kerb and looking around whilst walking.

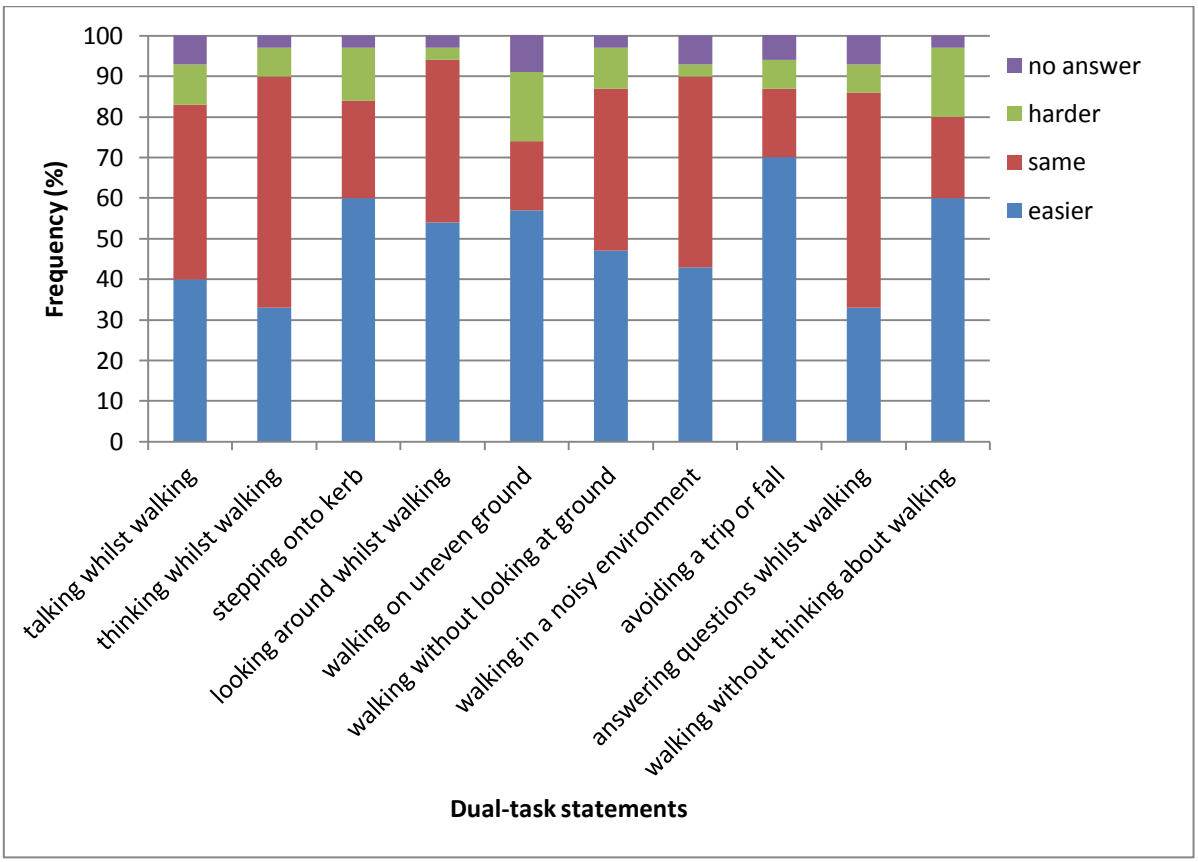


Figure 3.8: Effect of FES during dual-task conditions.

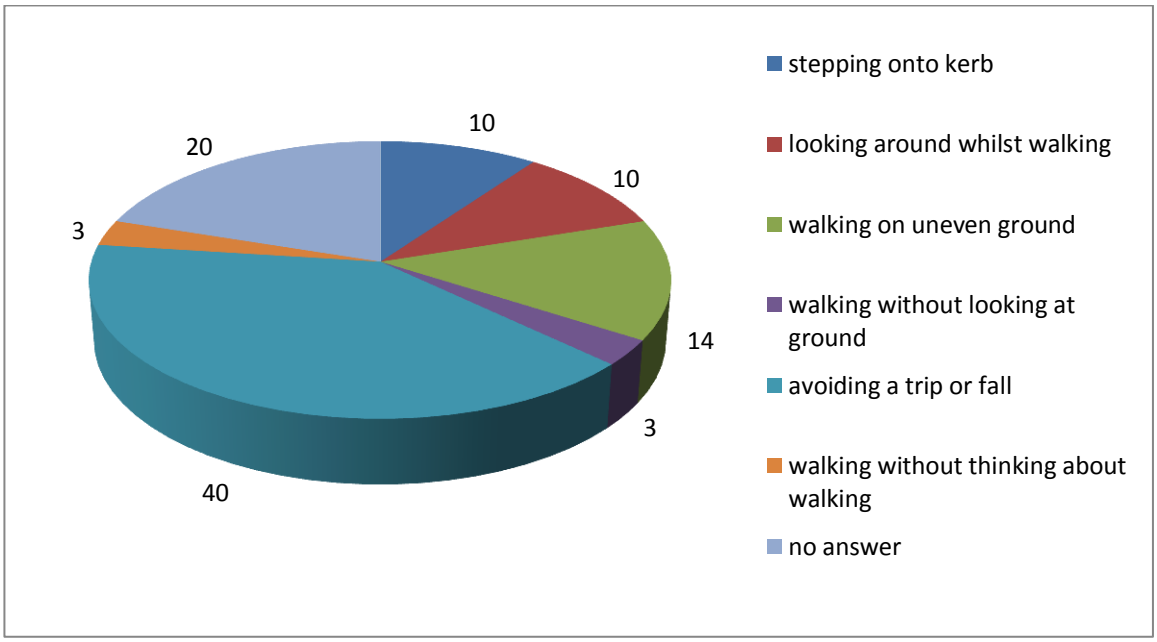


Figure 3.9: The frequency (%) of most important dual-task effect chosen by FES users.

3.7 Discussion

Interpretation of the results from this questionnaire study should be approached with some cautions. As with all self-administered questionnaires there is no guarantee that the questions were answered as requested. It is also possible that the person for whom the questionnaire was intended did not actually answer the questions. The careful ordering of the questions could have been negated by the respondents answering the questions in any order that they wished (Bowling, 2005). Even though the questions were structured to encourage completion and to allow for those respondents for whom each question did not apply, some questions were still omitted by some respondents. The results include rates of non-completion for individual items.

The questionnaires were sent from an organisation independent of the clinical service from which the respondents had received their devices. This is in contrast to the two previous FES studies by Taylor et al (1999, 2004) and it could be assumed that the possibility of positively biased responses from respondents may have been reduced.

3.7.1 Response rate

The response rate for this FES group was 65%, similar to those from the previous two postal questionnaire studies of FES groups; 55% and 74% (Taylor et al., 1999b, Taylor, 2004) but lower than reported response rates in stroke populations prior to implementation of this study; 73% (Bussin et al., 1999), 83% (O'Mahony et al., 1998), 78% (Glader et al., 2001) and 81% (Vestling et al., 2003).

There are recognised factors that experts in the field of questionnaire application cite as contributing to improved response rates (Fink, 2006). The majority of these factors were applied in this study. Potential respondents were advised that their responses would be kept confidential and anonymised and were advised how their responses would be used. Reminders were sent to non-responders. The questionnaire was piloted, checking for clarity and understanding. Broad inclusion criteria were devised resulting in a large group of over 80 FES users being identified as potential respondents. It was clear from previous studies that an FES group would probably be interested in the nature of questions asked. Other factors to improve participation

were not feasible, such as alternative options for completion of the questionnaire (e.g. web-based) and gift or cash incentives for completion.

The number of respondents who were continuing to use their FES device was 30; representing 40% of the corrected total of questionnaires sent. The number of respondents who completed the questionnaire, who no longer used their FES device was 16 (21%). These figures can only be compared with those from the two previous FES studies, which reported on data from 78 users vs. 45 non-users (Taylor et al., 1999b) and 69 users vs. 9 non-users (Taylor, 2004). As these figures do not exhibit a particular pattern it is again difficult to ascertain if the ratio of users to non-user in the current study is typical. In reality the ratios for the current and previous studies may be more a reflection of service provision and clinical practice, as well as the inherent difficulties of reliance upon the motivation of the individuals in the target population to return the questionnaire. It is not possible to speculate on the demographics or other characteristics of the non-responders.

3.7.2 FES users

The mean age of the FES group was 64.6 years (± 13.7) with 63% males and 37% females. This is reflective of a lower rate of stroke in the UK amongst women compared with men (Bhatnagar et al., 2010). The mean time since stroke was 74.9 months (± 42.9) and the amount of time since respondents began using their FES device was 31.0 months (± 19.8).

a) Usage

Respondents used their devices in a similar manner to those from previous FES studies. 70% of respondents in the current study reported using their device for 5 days or more a week (Table 3.4) which agrees well with Taylor et al (1999) where 53% of a mixed group of FES users, used their device every day, and 48% of the CVA participants from their 2004 study used their device for 7 days a week.

On the days when respondents used their device, it was used for an average by the group of 7.5 (±4.2) hours. Figure 3.10 reports the results for this question in the same categories as three other studies that have reported the daily usage of FES; the questionnaire allowed respondents to identify the amount of time FES was used

rather than providing pre-determined categories. Two of the studies are results for a mixed group of participants, including those with stroke, (Taylor et al., 1999b, Jenkins, 2012) whilst the other set of results are only for stroke participants (Taylor, 2004). Over 40% of respondents used their device for 9 hours or more, which concurred with the recent service audit by Jenkins (2012). In both studies by Taylor this amount of usage was higher at over 50%. The majority of respondents used their FES device for between 9 – 12 hours, in contrast to the other studies in which the largest percentage of participants used their FES all day. The difference in usage patterns may reflect differences in the type of service users, in terms of the severity of walking disability for example, or could be as result of the different method used to collect this data.

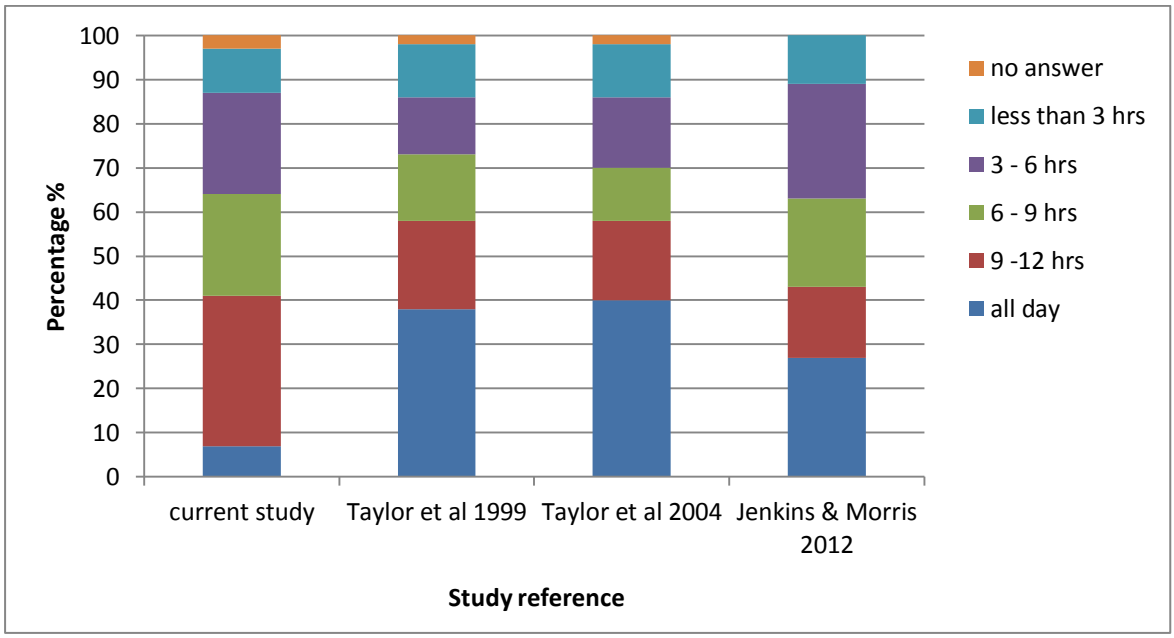


Figure 3.10: Usage of FES for current study and three published studies, as a percentage of each study group,

Respondents were quite clear about their use of FES in relation to the activities that they pursued, particularly evidenced by the high number of respondents who answered the question (Figure 3.3). Over 50% of the group reported always using their device for activities outside the home (walking outdoors, longer walks, day trips and shopping) (Figure 3.3). By contrast, less than 30% reported always using their device walking indoors or at home. From clinical experience, it is quite common for patients to discard orthoses and equipment that aids walking once they enter their home or a safe indoor environment, preferring to rely upon banisters, handrails and

strategically placed furniture to mobilise safely. The results for the FES group appear to be consistent with this clinical observation.

Most respondents also clearly felt the need to use some other form of walking assistance. By far the most common form of assistance was the use of a walking stick both with and without FES (Figure 3.4). Surprisingly, more respondents reported using a walking stick with FES (70%) than without FES (50%) and this possibly reflects that respondents used their FES more often outdoors (Figure 3.3). Over 40% of the respondents did not require assistance from another person, either with or without FES, thus indicating independence when walking.

Effect	Current study (from 13 effects)	Taylor et al 1999b (from 12 effects)	Taylor et al 2004 (from 14 effects)
Less effort to walk	1 (90)	2 (77)	1 (83)
Able to walk further	2 (87)	3 (70)	6 (58)
Walking more balanced and even	3 (87)	N/A	N/A
Less likely to trip and fall	4 (83)	4 (69)	4 (63)
Walk more safely	5 (83)	N/A	N/A
More confident when walking	6 (80)	1 (79)	3 (70)
More able to walk on uneven ground	7 (77)	7 (41)	9 (42)
Able to walk faster	8 (73)	5 (62)	5 (60)
Walking would improve in the long term	N/A	N/A	2 (73)

Table 3.4: Ranking of agreement with effect statements by frequency (% of total group).

b) Effect of FES

There were high levels of agreement with the statements in the questionnaire about the effect of the device as perceived by the FES users with over 60% of respondents agreeing with 10 of the 13 statements. The highest agreement, of 90%, was with the perceived reduction in effort when walking with their FES device. This is in agreement with previous studies, with this effect being in the two highest (Taylor et al., 1999b) and the highest most commonly perceived effects (Taylor, 2004). Table

3.4 compares the results of the current study against those for the two previous FES studies. It is worth noting that the 1999 study by Taylor provides results for a mixed group of users that includes patients with Multiple Sclerosis, although the majority of users (i.e. 79%) received FES due to stroke.

There is strong agreement with the ranking of the most often identified effects between the current study and that of Taylor et al 1999b. It would appear that the introduction of the concept of improving gait in the long-term, probably as part of clinical practice, for the 2004 group had highlighted this as a highly anticipated hope for the future amongst users and thus other effects were not chosen as often. It could be argued that this is a prospective effect rather than a currently perceived effect, and thus perhaps not appropriate to include in this type of question.

Interestingly, two effects in the current study - improved balance and increased safety when walking - which were identified from AFO studies, gained high levels of agreement. A high agreement with these statements would be expected as a high number of respondents agreed they were less likely to trip or fall.

Even though 73% of respondents in the current study felt that they could walk faster with FES, this frequency of response still placed this effect below seven other more frequently agreed with effects. In Taylor's two studies this effect was the fifth most often identified effect. Furthermore, in a study of foot drop due to both stroke and Multiple Sclerosis, the effect of FES on the effort of walking on uneven surfaces was perceived to be more important than an increase in speed (Burridge et al., 2007a). As has previously been noted in section 3.1, walking speed has traditionally been chosen as an outcome measure to assess effectiveness of FES, but is not reflective of the most important of the user-perceived outcomes. It's ranking below several other outcomes by respondents in this study, again indicates that users perceive other effects to be more apparent.

When respondents were asked to identify the most important effect of the device, again results concurred with those from the two previous studies by Taylor (Table 3.5). The perceived reduction in effort of walking was in the top two of all three studies, and was more highly ranked than an ability to walk faster.

Effect	Current study (from 13 effects)	Taylor et al 1999b (from 12 effects)	Taylor et al 2004 (from 14 effects)
More confident when walking	1 (17)	4 (6)	4 (10)
More independent	1 (17)	6 (1)	6 (7)
Less likely to trip and fall	1 (17)	2 (15)	5 (8)
Less effort to walk	2 (13)	1 (29)	1 (27)
Able to walk further	4 (3)	3 (9)	0 (0)
Able to walk faster	4 (3)	5 (3)	7 (3)
Walking would improve in the long term	N/A	N/A	3 (20)
Carryover effect	N/A	N/A	2 (22)

Table 3.5: Ranking of most important effect statements (% of total group).

Some respondents provided comments about the effect of their FES device that concurred with the responses to the questionnaire statements. Respondents felt that use of the device made them ‘less tired at the end of day’ and that they did not ‘tire so quickly’. One participant described completing 5 and 7 mile walks whilst on holiday with the use of FES. Some felt that FES use made ‘it much easier to get around’, and that it ‘slowly makes foot work’ and ‘helps me flex my ankle when walking’. One participant felt that it had ‘certainly improved my mobility the last couple of years and I would hope that I will walk normally one day’. Others generally felt the device had made a ‘great difference to my life’, ‘big difference to my everyday life’ and was ‘very beneficial’ and ‘just fantastic’. Two respondents described some difficulties with use of FES, but continued to use the device as the benefits of use outweighed the problems they experienced.

The results from the current study indicate that this group of FES users responded similarly to the effect of the device, compared with previous groups of users. This may come as no surprise as the group was obtained from the same clinical service as the two previous FES studies (Taylor et al., 1999b, Taylor, 2004) and thus it could be argued that the concurrence in results are reflective of local clinical practice. However, each study targeted different groups of users, distinguished by the date on which they began use of FES, covering over 7 years of service provision. Over this

time period the service and clinical personnel would have altered, and the service attracted patients from across the UK, rather than exclusively treating the local population.

There is now evidence from three studies of 173 FES users that clearly highlights the effects of FES that users identify most often and also as most important. Whilst results from this study cannot be generalised to all FES users, it is obvious that the FES users participating in the three studies thus far, place a high importance on effects such as a reduction in effort, the quality of their gait (i.e. less trips, improved balance, increased safety) and increased confidence and independence. These effects were in contrast to measures used in most FES studies, up to 2005, to establish the effectiveness of the device i.e. walking speed. In particular, the effect of FES on the effort of walking is consistently a highly rated effect.

It has been proposed that the effect on effort is comprised of mental as well as physical components. The results from this study support this concept, in this context, as respondents identified a statistically significant reduction in concentration required when walking with FES compared with walking without the device. This adds weight to results from Malone et al (2002) where subjective descriptions of this effect had been noted. Furthermore, since the questionnaire study was completed, in a study by Bulley et al (2011), participants described a requirement for less conscious thought when walking with FES.

When FES users, who also used an AFO, were asked to directly compare the two devices, the majority felt that their FES device allowed them to walk with less effort. This result is in agreement with a subsequent study in which participants expressed a preference for FES over their previous AFO due to a perceived improvement in the effort of walking (van Swigchem et al., 2010) as well as improved comfort, appearance, quality of gait, walking distance and stability during gait. In fact studies comparing the efficacy of AFOs and FES have consistently shown a clear preference for FES (Sheffler et al., 2006, Ring et al., 2009, Bulley et al., 2011) even though measures of gait speed (Ring et al., 2009, van Swigchem et al., 2010), activity levels (van Swigchem et al., 2010) and functional ambulation (Sheffler et al., 2006) have failed to show any significant advantage of FES. This suggests that the outcome measures used in these studies may not be capturing important information.

c) Dual-task effects of FES

The results from the dual-task effects show that respondents recognised the effect of FES on performance of secondary tasks – both non-motor and motor - whilst walking (i.e. the primary task). Interestingly, 60% of respondents found walking without thinking about walking easier with FES, in agreement with the statistically significant reduction in perceived concentration required by respondents when walking with FES and reported studies (Malone, 2002, Bulley et al., 2011). This was the most frequently non-motor task noted as easier with FES, whereas other non-motor tasks were identified as easier by just over 50% to just over 30%. Clearly thinking about walking, with a foot drop following a stroke, is a recognised phenomenon from reported studies, anecdotal evidence from FES users and now supported by the results of this study. The second most frequently rated non-motor task as easier by 54% was looking around whilst walking.

Of the five conditions that were identified by over 50% of users as easier with FES, three were secondary motor tasks that created a challenge to a foot drop gait, including stepping onto a kerb and walking on uneven ground. In fact, 70% found avoiding a trip or fall easier with the use of FES. It may be that the physical effects of FES are more frequently noted as easier because the device has primarily been provided to improve the gait of the recipient, with clinical assessment of effectiveness creating this focus as well as patient expectations driving these physical outcomes. Thus, it may not be surprising that users would identify complex physical tasks as more frequently noted to be made easier by the use of FES, than non-motor secondary tasks.

Furthermore when respondents were asked to identify the most important task that was easier with FES, the most highly rated was avoiding a trip or fall and the second was walking on uneven ground. Whilst this does concur with results in this study regarding the effects of FES and previous studies by Taylor et al (1999b, 2004) it should also be viewed with some caution. It is possible that because these two outcomes appeared in both questions about the effect of FES their importance has been highlighted inadvertently, with the earlier question having cued or primed the answer to the second question (Peterson, 2000).

3.8 Conclusion

The results from the FES group can be viewed with confidence due to a response rate and results that were similar to previous studies. Whilst results from this study cannot be generalised to all FES users, the results support those previously reported by clearly highlighting the effects of FES that users identify most often and also as most important. FES users place a high importance on effects such as a reduction in effort, the quality of their gait (i.e. fewer trips, improved balance, increased safety) and increased confidence and independence. These effects are in contrast to measures used in most FES studies to establish the effectiveness of the device such as walking speed.

In particular, the effect of FES on the effort of walking is consistently a highly rated effect and it has been proposed that the effect on effort is comprised of mental as well as physical components. The results from this study support this concept as respondents identified a statistically significant reduction in concentration required when walking with FES compared with walking without the device. Furthermore, users identified the effect of FES on secondary tasks when walking – with the majority noting walking without thinking about walking as easier with FES.

This study achieved the primary aims of investigation of users' perceptions of the effect of their device, the effect of the device on concentration required when walking and the specific areas in which use of the device contributes to a change in the effort of walking. The secondary aim of the questionnaire was to inform the choice of a secondary task to use in a dual-task methodology for the subsequent gait laboratory study. The group identified that secondary tasks were affected by device use, and the results from this FES group can be analysed with some confidence as the group responded to the questionnaire in a manner consistent with other FES groups. The two most frequently rated non-motor secondary tasks that were easier with FES were walking without thinking about walking and looking around when walking. Therefore, an appropriate secondary task for the subsequent study would be a non-motor task that distracted respondents from the primary task of walking, forcing the respondents gaze to be averted from the walking surface and/or focusing attention and concentration on the non-motor or cognitive task.

Chapter 4 - Dual-task methodology development and longitudinal study

4.1 Introduction

There is growing evidence to support the concept of a complex relationship between higher level cognitive function and gait, as discussed in the review of literature in Chapter 2 (section 2.2.3c), from emerging brain imaging (Harada et al., 2009, Suzuki et al., 2004) and dual-task gait studies (Al-Yahya et al., 2011, Segev-Jacubovski et al., 2011). Dual-task gait studies, of participants with neurological disorders, have shown that the costs to gait and cognitive task performance increase in comparison to healthy controls (Woollacott and Shumway-Cook, 2002, Yogev-Seligmann et al., 2008, Al-Yahya et al., 2011, Segev-Jacubovski et al., 2011). Studies in post-stroke gait using a dual-task design similarly found deterioration in gait speed (Bowen et al., 2001, Canning et al., 2006, Hyndman et al., 2006, Plummer-D'Amato et al., 2008, Dennis et al., 2009, Pohl et al., 2011) and a reduction in performance of the cognitive task (Plummer-D'Amato et al., 2008, Dennis et al., 2009, Pohl et al., 2011). This suggests that impairments to the brain's cognitive functions as a result of stroke, particularly when paired with physical impairments, may lead to increased competition for limited resources to control gait.

Stroke patients provided with FES consistently highly rate a reduction in the effort of walking as the most important reason for using FES. The suggestion, from a number of small qualitative studies (Malone, 2002, McAdam, 2006, Bulley et al., 2011), that effort in this context may not only relate to the physical effort, but may also include the mental effort of gait, was explored in the thesis in Chapter 3 via a questionnaire study. There was strong agreement amongst questionnaire respondents that FES reduces the concentration required whilst walking. Furthermore, respondents identified that FES use had an effect on the performance of concurrent secondary non-motor tasks i.e. those diverting their attention from the cognitive demands of walking. It was clear that the results of this study supported the suggestion from previous studies of a positive effect of FES on the cognitive processes involved in walking. These results can be interpreted as an indication of the effect of FES on the motor-cognitive interference experienced during post-stroke gait.

The results of the questionnaire study supported further exploration of the effect of FES on motor-cognitive interference. To address this, a dual-task study was

developed and implemented. A dual-task methodology is reflective and typical of real world situations, requiring participants to 'walk and talk', take note of their surroundings, and remember and follow directions, and thus requiring a division of attention between walking and a cognitive task. Application of this methodology to explore the effect of FES was novel and had previously been applied in only a handful of studies concerning other assistive devices for walking (section 3.1). As this was the first study of its kind the primary research questions to be answered were:

- Is the chosen cognitive task appropriate?
- Does FES reduce the effect of a cognitive task on gait speed?
- Does FES improve performance of a cognitive task whilst walking?
- Do any observed changes in performance of the walking and/or cognitive task change over time?

The secondary research questions were:

- Can any observed changes in gait and/or cognitive task be explained by factors other than the presence or absence of FES?
- Can observed changes in performance be related to self-reported effects?

This chapter begins by briefly describing the dual-task study. This is then followed by a detailed description of key elements of the study design. In order to justify the initial task selection a brief literature review of relevant dual-task studies is presented, focusing on the type and application of the tasks used and their relationship to cognitive processes. A critique of the literature then follows leading to a description of the task developed for use in the study. The reasons for inclusion of other secondary measures are discussed.

There then follows a description of the piloting processes used to test the suitability and feasibility of the proposed dual-task methodology and subsequent effect of these on the final study protocol. Results for the study are then presented and analysed. Limitations and problems encountered with implementation of the study are discussed and further work undertaken to solve these issues is outlined. Finally, conclusions from the study are discussed.

4.2 Protocol design

4.2.1 Study design

FES improves gait speed in the chronic stroke population (Kottink et al., 2004, Robbins et al., 2006, Roche, 2009). However, it has been noted that average speed with FES improves with increasing time since first use (Burridge et al., 1997b, Burridge et al., 2007b, Laufer et al., 2009, Stein et al., 2010). In addition, improvements in gait speed are maintained without FES indicating a therapeutic effect with some evidence to show that this also continues to improve with time (Robbins et al., 2006, Burridge et al., 2007b, Stein et al., 2010). It is possible that any effects of FES on motor-cognitive interference may also alter with increasing time spent using FES. If motor-cognitive interference effects were seen to change with time, this information could be used not only to inform future, larger study designs, it may also give insight into possible underlying mechanisms for a reduction in motor-cognitive interference. A longitudinal repeated measures study design was therefore chosen. This design allows for exploration of changes in the effects of motor-cognitive interference over time, with each participant serving as their own control.

The available gait speed data of those studies reporting changes in speed over time, both with and without FES, is plotted in Figure 4.1. The time interval between collection points varies somewhat between the studies making comparisons difficult. However, in the majority of studies the rate of change in speed increase appears to be highest within the first 3 months (Burridge et al., 1997b, Burridge et al., 2007b, Laufer et al., 2009). In support of these measured effects, a report on clinical experience of FES provision (Burridge et al., 1997a) noted that whilst “the rate at which patients adapt to a new gait pattern varies” with FES use, “by 3 months, all the patients had adapted, and the improved gait pattern was reflected in their walking speeds”. This suggests that studying the effects of FES on motor-cognitive interference during the period of adaptation and most rapid change in gait speed may provide insight into whether changes in interference show the same trend. Thus, the study was designed to collect data at 14 weeks, at which point it was hypothesised that adaptations to gait had stabilised. An interim assessment was then planned for approximately half-way through the study at 6 weeks after baseline. This reflected clinical service (Burridge et al., 1997a) and would also capture data during the adaptation period.

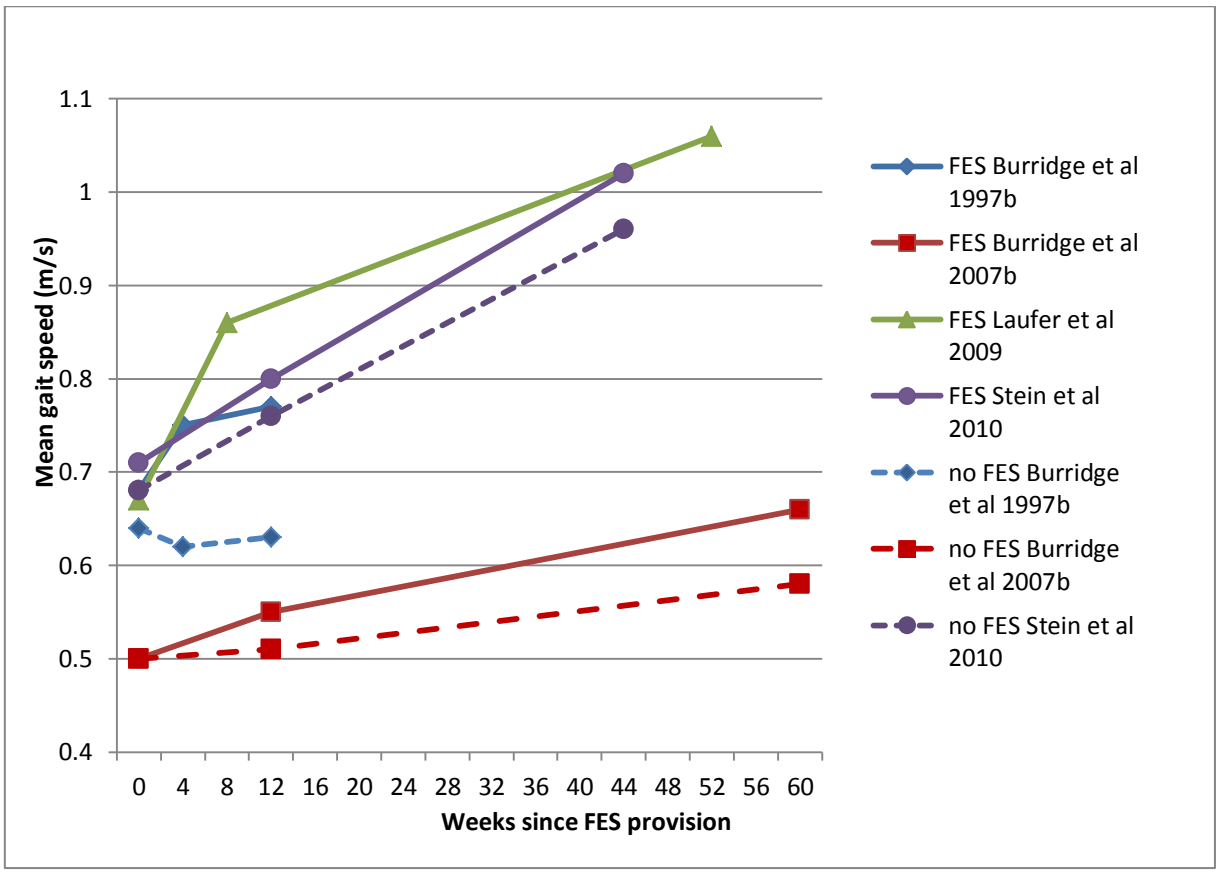


Figure 4.1: Plot of changes in gait speed over time, both with and without FES, from published studies.

The primary outcome measures were gait speed and cognitive task performance. In order to answer the question “Does FES reduce the effect of a cognitive task on gait speed?” speed of walking was measured with and without FES, under two conditions, walking with and without a cognitive task. To answer “Does FES improve performance of a cognitive task whilst walking?” cognitive task performance was measured when walking, both with and without FES. Cognitive task performance was also measured whilst seated to provide a baseline measure against which walking performance could be compared and subsequently motor-cognitive interference could be assessed.

Thus participants were observed under four walking conditions:

- no FES
- no FES with a concurrent cognitive task
- FES assisted
- FES assisted with a concurrent cognitive task

During the dual-task conditions it was expected that participants would differ in the prioritisation that they gave to walking or performing the cognitive task, with the result that, as a group there would be variation in the change in outcomes between conditions. Thus, the secondary question was formulated; “Can any observed changes in gait and/or cognitive task be explained by factors other than FES and cognitive task?” Prioritisation of task is most likely a product of the integration of factors such as the individual’s cognitive state, compensatory capabilities and personality (Yogev-Seligmann et al., 2012). As such, a number of other outcome measures were collected via validated tools to obtain data to explore potential variation of outcomes. As stroke can affect both cognitive and physical abilities (see Section 2.3.3 and 2.3.4) which can both have an effect on the ability to adjust to motor-cognitive interference, measures of cognitive ability, independence, falls and sensory neuropathy were collected.

In addition, the self-reported effects of FES were collected via a shortened version of the questionnaire (Appendix B.1) used in the study reported in Chapter 3. This allowed for a comparison between perceived and directly measured effects of FES on motor-cognitive interference.

The key elements of the design of the gait laboratory study – choice of cognitive task, gait speed and other outcome measures – are discussed in the following sections.

4.2.2 Previously used dual-task tests

To explore the cognitive control of gait for FES users, a task placing a ‘load’ on the cognitive processes during gait was required. Conclusions reached from the dual-task question of the questionnaire study (Section 3.8) indicated that users reported finding that FES made it easier to walk under certain conditions in which an additional attentional load was placed on them and reduced the amount of concentration needed to walk. The two most frequently rated non-motor secondary tasks that were easier with FES were walking without thinking about walking and looking around when walking. Therefore, an appropriate secondary task for the subsequent study would be a non-motor task that distracted participants from the primary task of walking and/or forced the participants gaze to be averted from the walking surface, and focusing attention and concentration on the non-motor or cognitive task.

Available literature at the time of designing the study was consulted and the possibility of using an existing neuropsychological test was explored. The following discusses this process, reviewing literature available at the time and published since, critiquing the tasks discussed and finally describing the tasks chosen for piloting.

a) Dual-task approaches

Development of the content of the questionnaire had included a process of mapping available dual-task studies of both healthy and gait-impaired participants (see Section 3.3.2c). The results of this process are summarised in Table 3.1 which also shows the variety of secondary tasks used.

Tasks chosen in previous studies can be broadly categorised as those involving a secondary motor task, including obstacle avoidance, and those involving a cognitive process. A review paper by Al–Yahya et al (2011) provides a classification system by which cognitive tasks can be clustered, which is applied in the following review. There are a large number of dual-task studies of which a selection, with a focus on those applied to elderly and neurologically impaired groups, including stroke, are reviewed here.

i) Motor task

Whilst several studies have included a motor task as one of a series of tasks, including cognitive tasks, only a limited number of studies have employed purely a motor task as secondary to the primary task of walking.

<u>Involving upper limb</u>

There are only a handful of studies using motor tasks that involve the upper limb. Apart from the obvious concurrent performance of a secondary motor task during the primary task of walking, these tasks would potentially require the participants to focus their gaze and attention on the functioning of the upper limb, and thus divert their gaze from the walking surface and surrounding environment.

In a study aimed at analysing ability to perform secondary motor tasks whilst walking both stroke and age-matched healthy participants were required to perform two

secondary tasks. The first involved correctly buttoning four shirt buttons; the second required the participant to carry a tray of glasses without dropping any glasses (Yang et al., 2007a). Gait parameter results indicated that stroke participants had more difficulty performing two concurrent tasks than the controls. The authors then went on to use the tray carrying task to assess the effectiveness of a dual-task based (i.e. holding and bouncing a ball whilst walking) exercise program for chronic stroke (Yang et al., 2007b). They concluded that improvement in gait parameters under dual-task conditions indicated the beneficial effects of the therapy.

Several studies have included a motor task as part of a series of secondary tasks. Carrying a glass of water has been used in several of these studies with participants instructed to avoid spilling any of the water whilst walking. In a recent study this task was used in an attempt to discriminate fallers from non-fallers in cognitively impaired older people (Taylor et al., 2013), finding no added benefit of the dual-task assessment in this group in identifying fallers. A study of a stroke group by Canning et al (2006) used the same task, as well as a cognitive task, comparing gait speed with healthy older and young adults. Whilst gait speed deteriorated with this motor task for the stroke group, gait was not slower than the group of older people, indicating that the task did not interfere with walking in the stroke group.

A cognitive task and motor task was used in a study of a group with Parkinson's Disease to identify which approach produced the greater interference with gait (O'Shea et al., 2002). Participants were asked to transfer coins, one at a time using their dominant hand, from the pocket on their dominant side to the opposite pocket. Gait was compromised by simultaneously performing this task, but no more than the cognitive task (serial subtraction) also performed in this study. The rate of coin transfer slowed whilst walking.

Walking over obstacles

Walking along pathways with obstacles has been used as a dual-task approach in several studies, comparing performance to walking over a smooth surface. The approach here is based on the assumption that the task of stepping over an obstacle is more attention-demanding (Plummer-D'Amato et al., 2012). In common with the tasks involving the upper limb, there is also an obvious additional motor component

to this secondary task and hence it is difficult to attribute outcomes to the influence of purely cognitive factors.

A study of older adults used an obstacle designed to simulate a door threshold, with an aim of determining how a concurrent cognitive task affected stepping over an obstacle (Schrodt et al., 2004). Changes in toe and heel clearance of the obstacle were noted during performance of the cognitive task (i.e. the '1-back' task which is described later). In another study of older adults, Plummer-D'Amato et al (2012) used an obstacle to increase the difficulty of the gait task whist participants walked performing a cognitive task also. Results indicated that gait task difficulty influences dual-task effects on gait speed in older adults.

Upper limb tasks would potentially divert gaze away from the walking surface, but the confounding factor of upper limb hemiplegia would affect the ability to perform the task, and thus reduce the possibility of measuring secondary task performance. Further, both upper limb tasks and, obstacle avoidance tasks, while diverting attention from the task of walking, would also greatly increase the risk of falling in the target group. These points are discussed further in the section critiquing all the dual-task approaches that follows.

ii) Cognitive tasks

Reaction time tasks

There are several versions of reaction time (RT) tasks used in the dual-task literature. The task requires the participant to respond (e.g. by pressing a button), without the need for any discriminatory decision-making, to a sensory stimulus and the elapsed time of response is measured. The task is used to measure neural processing speed and thus a slowing in RT may be an indication of an underlying attentional deficit (Lezak et al., 2004).

Both auditory and visual stimulus can be used in reaction time tasks. Both forms of stimulus were used in a study comparing the reaction time of older adults to healthy young adults (Sparrow et al., 2002), requiring the participants to press a hand-held button to acknowledge the stimulus. Walking trials used auditory (i.e. a chime) and visual (i.e. projection of an 'R' on a screen) stimulus individually and then in some trials both were used randomly. Walking trials were either along a flat unmarked

walkway (“untargeted walking”), or required the participant to walk along the same walkway, but to also target one step inside a marked area (“targeted walking”). Older group RTs were longer in visual stimuli trials, especially during targeted walking. Another study by the researcher (Sparrow et al., 2008) used only a visual stimulus, possibly as a result of the outcomes of the previous study, to assess the effect of age on gait control. During the dual-task step time increased in the older group compared with matched controls.

Other studies using RT tasks require a verbal response to an auditory stimulus (e.g. a tone), assessing verbal RT, collected via the use of a microphone headset. Using this task in a group of younger and older adults, Gage et al (2003) tested walking on walkways altered in width and height from the ground, to create walking conditions requiring differing attentional demands. RT increased for both groups when postural threat was increased. This version of a RT task was also used in a study of a group of elderly people using a variety of walking devices, reporting that changes in reaction time between conditions indicated that the devices assessed required increased attention (Wellmon et al., 2006).

Finally, a study applying a RT approach in a stroke group required participants to respond to a stimulation delivered by an electrode at the back of the neck, by pressing on a pressure-sensitive pad in the mouth (Regnaux et al., 2005). A marked increase in RT was noted amongst the stroke group when compared with healthy controls.

Discrimination and decision-making tasks

Discrimination and decision-making tasks require selective attention and an appropriate response, thus are usually used to measure attention and response inhibition (MacLeod, 1991). The Stroop test is an example of such a task. In this test the name of a colour is displayed printed in a colour that is not the colour named (e.g. ‘RED’ displayed in blue). The participant is required to successfully enunciate the colour in which the word is printed whilst suppressing the tendency to read the word. This popular neuropsychological test has been used in the dual-task paradigm. For example, it was used in a dual-task study of unilateral amputees (Heller et al., 2000) to compare two prosthetic limbs. Using the ratio of sway of the forehead during

walking in dual and single task conditions ("Automation index") as an outcome, there was no difference between the devices.

An auditory stimulus can be used as an alternative to a visual stimulus in the Stroop test, thereby avoiding the need for sight of a screen or monitor during walking trials. An auditory Stroop test has been used in two studies; participants were required to respond to 'high' or 'low', spoken in either a high or low pitch, naming the pitch it was spoken in whilst repressing the tendency to repeat the spoken word. The first study investigated balance impaired older adults, combining the Stroop test with an obstacle crossing task (Siu et al., 2009). Conclusions reached indicated that this group, when compared with an older group, lacked the ability to allocate attention between a postural and cognitive task, as they were unable to adjust performance when instructed to do so for different single and dual-task conditions. The second study, of a group of people recovering from operative removal of lower limb tumours (de Visser et al., 2003), also found that gait was hindered by the dual-task condition during recovery.

Other stroke studies have used an audio-discrimination task (Al-Yahya et al., 2011). The example used by three studies required participants to respond 'yes' or 'no' to a verbal cue of either 'red' or blue' respectively. In the first study by Bowen et al (2001) performance of this task whilst walking adversely affected gait speed and balance, measured via double support time, in a stroke group. In another study, once again gait speed was reduced when performing this task, amongst a stroke group and this time in comparison with elderly and young groups (Canning et al., 2006). Finally, people identified as having unilateral spastic paresis of the lower leg, following a stroke, were studied to assess the effectiveness of a bespoke high orthopaedic boot (Eckhardt et al., 2011). Functional ability, using the 'Timed Up and Go Test', under dual-task conditions using this audio-discrimination task, was improved by use of the boot.

Several stroke dual-task studies have used the 'clock task' which is a visuospatial decision-making task. The task requires participants to respond yes or no to a given time (e.g. 1:25) based on whether the hands of the clock would both be in the target half of the clock face. Plummer-D'Amato et al (2008, 2010, 2012) used this task in a series of studies as one of several tests to analyse the interaction between different

cognitive processes and specific aspects of gait, finding that this task affected the single limb support phase and that very few errors were made in the cognitive task. In a study by Dennis et al (2009) two tasks, one of which was the clock task, were used in a stroke group and age-matched healthy group. The stroke group appeared to favour maintaining gait speed over task performance. This decision-making task was adapted from a study of a mixed group of neurologically impaired people, including those post-stroke (Haggard et al., 2000).

Discrimination and decision-making tasks have been used in several stroke studies and seem to provide sufficient motor-cognitive interference as to create reduction in measured outcomes. The performance of the task could be measured, in conjunction with gait parameter outcomes, to quantify the extent of the interference.

Verbal fluency tasks

Tasks that require the participant to spontaneously produce words on pre-specified topics are examples of verbal fluency tasks. For example, the participant may be asked to list 'things to eat'. This group of tests examine executive functions (Lezak et al., 2004) and are widely used in the dual-task literature, perhaps as the closest approximation of real-world ability to 'walk and talk'. The following discusses some of these studies to illustrate the variety of approaches employed.

A large number of studies have required participants to generate lists of words whilst walking, assessing verbal fluency and the effect of this task on gait. This approach has been used in groups assessing the effect of interference of the task on walking in healthy older people (Dubost et al., 2006, van Iersel et al., 2007), frail elderly (Beauchet et al., 2005), early Alzheimer's Disease (AD) (Camicioli et al., 1997), acquired brain injury of mixed cause (Haggard et al., 2000), essential tremor (Rao et al., 2013), and stroke (Cockburn et al., 2003).

Generation of animal names has been used in many of these studies. Dubost et al (2006) found that the older people in their study exhibited increased stride time variability with this task performance. Amongst a group of frail elderly (Beauchet et al., 2005) this same task did not affect lateral gait instability, however an alternative task of counting backwards did alter this, indicating that the choice of task is important in this group. In the study by Rao et al (2013) participants with essential

tremor were asked to generate lists of animal names beginning with a letter given to them by the researcher (e.g. B). Interference with gait parameters was greatest in those with lower cognitive scores. Directing generation of word lists by the supply of a starting letter was used as task by van Iersel et al (2007) amongst a group of healthy older adults. As in the Dubost study, stride time variability increased with task, as did stride length and body sway.

Other topics have been used to generate word lists whilst walking. Female or male names was used as the secondary task in a study of groups of healthy elderly compared with people with early AD (Camicioli et al., 1997) noting that AD participants slowed significantly during dual-task. In studies by Haggard et al (2000) of an acquired brain injury group and Cockburn et al (2003) of a post-stroke group, participants were given a category about which to generate a list of words (e.g. things in the house) with both studies noting increased stride duration and poorer task performance during dual-task.

Another approach in dual-task study designs have required participants to respond to questions whilst walking, resulting in spontaneous speech. Studies of patients groups have used this approach. In a group of people with Parkinson's Disease (PD), participants were required to respond to questions about their past whilst walking and then whilst carrying a tray with cups on it (Rochester et al., 2004). The multi-task condition resulted in significantly slower gait speed and reduced step length. Several studies of stroke groups have used spontaneous speech as a task, in particular using the approach defined by Kempner et al (2006). In this study, speech was elicited by using a variety of questions requiring participants to describe, for example, people or events influencing their lives, recent vacations, significant inventions of the 20th century or individuals they admire. Healthy older adults and those with stroke were compared using this dual-task in the study by Kempner et al (2006), finding that both gait and speech deteriorated in those with stroke. Subsequent studies of stroke groups using this task found that gait speed was reduced during the dual-task condition (Plummer-D'Amato et al., 2008, Pohl et al., 2011, Plummer-D'Amato and Altmann, 2012).

Mental tracking tasks

This group of tasks require the participant to hold information in their mind for manipulation or while performing a mental process, and are usually used to examine sustained attention and information processing speed (Lezak et al., 2004).

Serial subtraction is an example of this type of task, requiring participants to perform consecutive subtractions by a given amount from a given starting number, subtracting aloud whilst walking. This task is frequently used in dual-task designs. In a study of older adults two serial subtraction tasks were used (Srygley et al., 2009). Performance of both tasks and gait speed reduced during the dual-task condition, with subtraction of '7' resulting in slower gait.

In the study by van Iersel et al (2007), which also used a word generation task, again two serial subtraction tasks were used to assess walking balance in a group of healthy older people, finding that under dual-task balance measure deteriorated. In a study that included several dual-tasks, a serial subtraction task was also used to assess the effect of dual-tasking on gait variability in older adults and idiopathic elderly fallers (Springer et al., 2006). The authors concluded that dual-tasks destabilised the gait of idiopathic, elderly fallers.

This task has been used in several studies of patient groups. Walking stability and variability of unilateral transfemoral amputees was compared with healthy controls under a dual-task requiring serial subtraction (Lamoth et al., 2010). There were no effects of task on gait parameters measured. In studies of PD groups this task has been used to assess the effectiveness of spatiotemporal parameters and the Gait Deviation Index in quantifying gait deviations in dual-task (Speciali et al., 2013) and as a comparison with a motor task (O'Shea et al., 2002). In a study by Dennis et al (2009) two tasks were used in a stroke group and age-matched healthy group. The clock task, as previously discussed, was one of these and the other required the participants to serially subtract three, beginning at 100. Results from this study indicated that the stroke group appeared to prioritise the cognitive task over maintenance of walking speed.

Counting backwards is another example of a mental tracking task used in dual-task studies. This task requires participants to count backwards by 1 aloud from a pre-

determined starting number. This task was used in a study of frail older adults finding that slower walking speeds whilst performing the task were associated with recurrent falls in this group (Beauchet et al., 2008). Backwards counting was used in a study comparing people with dementia and healthy controls showing that stride time increased in the dementia group under the dual-task (Allali et al., 2008).

Working memory tasks

Tasks that require holding information in the mind that is then available for processing are referred to as working memory tasks, which involves short-term explicit memory (Lezak et al., 2004) (see Chapter 2, section 2.2.3a). Measures of recall of information, after completion of walking trials, and provided to participants whilst walking, have been used in several dual-task gait studies.

Examples of working memory tasks are those that require the participant to listen to a text whilst walking, followed by answering multiple choice questions about the text when the walking trial was completed. In a study by Springer et al (2006) that has previously been discussed, this approach was used as one of several tasks. The same approach was used in a PD group (Yogev et al., 2005) finding that gait variability was increased with dual-task compared with matched healthy controls. In both of these studies, another dual-task required participants to listen to text taking note of the number of times a particular word was used, and to then report this at the end of the trials. In a similar approach, PD participants were asked to listen to the number of tones sounded whilst completing a walking task, reporting their result at the end of the trial (Lord et al., 2010). Results indicated that participants adopted a strategy to maintain gait speed rather than be concerned about the accuracy of their response

The use of recall was also used in a study of a stroke group and healthy controls (Hyndman et al., 2006). Participants were required to remember a 7-item shopping list that was recited to them whilst walking, which they were then asked to recall after they had finished walking. People with stroke had reduced cognitive recall and those identified as fallers, exhibited a reduction in stride length during the dual-task condition.

In contrast to this type of list recall test, participants in another study were trained in a mnemonic memory technique prior to data collection (Lindenberger et al., 2000). The task involved recall in correct order of 16-item lists of highly imaginable and highly concrete nouns after walking on two narrow tracks of differing complexity. Results indicated that increased age resulted in a greater reduction in memory task performance and walking speed and accuracy of walking on defined pathways. This research group applied the same task again in a study introducing obstacles as a further source of difficulty to the walking task concluding that older adults prioritised walking at the expense of memory performance (Li et al., 2001).

The '1-back' task is an example of a working memory test. In contrast to those described above where the memorisation aspect of the test occurs whilst walking and the testing element of the memory takes place when walking is completed, during the '1-back' test both aspects of memorisation and testing take place whilst walking. The '1-back' test requires the participant to listen to numbers pronounced and to then respond to each presented by stating the previously presented number. This test was used in a group of older adults who were required to also walk over an obstacle whilst performing the task (Schrodt et al., 2004). Results indicated that maintenance of gait performance was given a higher priority than task performance. This test was also used in a series of studies by Plummer-D'Amato (2008, 2010, 2011) that used several cognitive tasks. The 1-back test produced less gait interference than spontaneous speech, affecting paretic single limb support.

b) Critique of dual-task methodologies

The number and variety of tasks found in the dual-task literature reviewed is indicative of a lack of standardisation and clarity about appropriate task choice. A similar picture of varied task choice is also found in studies involving people with stroke; each of the cognitive task categories discussed above included a stroke study. The following section critiques task choice in the context of the literature and review articles, leading to an argument for the development of a task as a novel approach for assessing the effect of FES on cognitive processes.

Firstly, a secondary motor task has been applied in various dual-task methodologies either requiring involvement of the upper limbs (e.g. carrying a tray of glasses) or requiring negotiation of obstacles. Results from the questionnaire study, discussed in

section 3.8, support the potential for the use of obstacles as a secondary task, as participants placed a high importance on the quality of their gait, recognising the effect of FES on complex physical tasks such as stepping up onto a kerb. The difficulty with use of a motor task, secondary to the primary task of walking, is the potential for interference between similar motor-driven cognitive processes, rather than creating a clear distinction between the cognitive processes involved in gait and those involved in other neurally-modulated behaviour. Thus, use of a secondary motor task alone would not allow for the proposed study to verify or refute FES-user reports that indicate it is easier to think and concentrate while walking with FES. There are also important safety and pragmatic considerations with the use of an obstacle avoidance task in a group of people post-stroke. The high risk of falls when testing obstacle avoidance would create a need to use a harness system to ensure safety during walking trials. This would have introduced additional practical constraints on testing (Salford has a single ceiling-mounted harness system in the most heavily used of the motion analysis laboratories). This approach was discounted and the focus was on a secondary cognitive task.

One of the most striking similarities of the majority of cognitive tasks reviewed, including those used on stroke groups, was a need for the participant to respond to the stimulus or input verbally whilst walking (Canning et al., 2006, Kemper et al., 2006, Plummer-D'Amato et al., 2008). The motor component of articulation has the potential to create an interference effect, and may explain some of the motor-cognitive interference measured in some dual-task studies. This point was made in the study by Dennis et al (2009) in discussing the limitations of their choice of serial subtraction task. The authors noted that their choice of task required continuous vocalisation and a self-generated response sequence. Hence participants may have adopted the same rhythm for walking and talking, plus the motor component of articulation may have had an interference effect. Prior to this study, this point was also made by Hyndman et al (2006) who made the choice to avoid vocalisation whilst walking by applying a working memory task, requiring the participants to recall a list, delivered verbally whilst walking, after walking was complete. This task choice elegantly removed the confounding effect of motor interference due to talking, drawing upon sustained attention to encode and maintain material in short-term memory and replicated the type of cognitive interference encountered in everyday memory.

Thus, a memory task that avoided a verbal response whilst walking would also avoid a 'second' motor task whilst walking, and was a valid and important point to consider when selecting a task. Furthermore, in the context of no clear indication of task choice from previous studies, including those of stroke groups, the results from the questionnaire study provided an initial focus to drive task choice. The following describes how this and several other factors were addressed during the process of task development.

4.2.3 Development of new task

The process of identification of a suitable secondary cognitive task for the dual-task protocol was driven by the following points, which are each discussed:

- Questionnaire results from Chapter 3
- Task that was measurable and a primary outcome
- Avoidance of interference from a secondary motor task
- Feasibility of the task application whilst walking

Importantly the focus was driven by the outcome of the questionnaire study (see section 3.8) which concluded that an appropriate task would require FES users in the planned study to walk without thinking about walking and/or look around whilst walking.

Secondly, an important point adopted for this thesis was the identification of a secondary task that could be measured and used as an outcome. The potential in adopting this approach would be to quantify the effect of FES on motor-cognitive interference, under dual-task conditions. Furthermore, from the literature reviewed there was a noted inconsistency in the outcomes of dual-task studies reported. Whilst gait parameters were reported by all studies, the performance of task was not always included as an outcome (Eckhardt et al., 2011, Canning et al., 2006). In some cases the tasks were purely utilised to create divided attention and hence there was a focus on ensuring that the task was completed correctly. In a recent review of dual-task studies of older people (Beurskens and Bock, 2012) this point was raised as a methodological issue noting that by ignoring outcomes related to either the task or gait, changes in dual-task performance cannot be distinguished from those due to task prioritisation.

Thirdly, the focus was also driven by avoidance of tasks that would require a verbal response whilst walking. Adopting this type of task would remove the potential interference of articulation on motor-cognitive processes. Thus the task could be described as 'purely' involving cognitive processes, without the inclusion of a secondary motor task to interfere with the primary motor task of walking. This type of task would require a response once walking finished, thus reliant upon neural processes involved in memory in order to execute them. This important point regarding task selection directed the choice to those tasks reliant upon memory.

Finally, as in dual-task studies, the feasibility of application of the task during walking was an important factor. This also included taking account of the environment in which the study could take place e.g. the available space within a gait laboratory. Furthermore, it was important to ensure that the creation of a cognitive load did not make the task so difficult that participants were unable to complete the task or that their walking ability was put under excessive duress as to make walking unsafe. The task also needed to be appropriate for a stroke population. These final points were addressed during piloting of the task chosen and the study protocol which is discussed later in the chapter.

These important points were taken into the process of task choice. The initial driver (i.e. questionnaire study outcomes) indicated that FES users would respond to a task that required them to look around whilst walking. By default this would avert their gaze from the walking surface and require a visual stimulus or input. From the review of the tasks used in the dual-task literature, those using visual stimulus tested reaction time (Sparrow et al., 2008) and discrimination (Heller et al., 2000) rather than memory. Thus, the decision was made to consider using an existing neuropsychological test as a task. The following describes the process by which neuropsychological tests were explored and considered, and the task was chosen.

a) Visual task

Existing visual memory tests required a visuomotor response which is typically drawing e.g. Complex Figure Test or Rey-Osterrieth Test (Lezak et al., 2004). In these tests the requirement is to replicate the figure after it is shown. Whilst this may have been appropriate to incorporate into a dual-task study, by projection of the figure onto a screen whilst walking, in a stroke group this type of testing would be

more difficult for those with upper limb effects of stroke and potentially create further participant exclusion criteria. As an alternative, visual recognition tests, which test short-term memory, negated the need for the participant to draw and also allowed figures to be projected on a screen whilst the participant walked. There are several examples of these in the literature, using variations on a format which shows the participant target figures at the beginning of the test and subsequently requires the participant to identify these from amongst a series of foils as the test progresses and further figures are shown e.g. Recurring Figures Test (Kimura, 1963), Continuous Recognition Memory Test (Hannay et al., 1979), Continuous Visual Memory Test (Trahan and Larrabee, 1988), Wechsler Memory Scale – III Faces (Wechsler, 1997).

b) Verbal task

The outcome of the questionnaire study also indicated that FES users would respond to a task that required them to walk without thinking about walking. Thus a cognitive task that diverted their attention from the task of walking would create a cognitive load suitable for a dual-task protocol. This would be achieved by a visual recognition task. But with tasks used in dual-task studies employing visual input in the minority, a decision was made to take forward two memory tasks to piloting. As the majority of tasks reviewed in the literature used a verbal input or stimulus, inclusion of a 'verbal' task was identified as appropriate in this context. Either a verbal or visual task would divert attention away from walking and thus potentially provide a measure of the degree to which participants need to think about walking. A 'common sense' assessment of both approaches indicates that tasks derived from this dual-focus would potentially be reflective of real life situations occurring whilst walking.

There were some examples from the dual-task literature of tasks requiring a response after walking was complete, drawing upon the cognitive processes involved in memory, and reliant upon verbal stimulus or input (Yogev et al., 2005, Springer et al., 2006, Hyndman et al., 2006). Alternatively, a verbal recognition test, to mirror the format of the visual task, offered a potentially more easily applied and measured verbal task. Amongst available verbal neuropsychological tests there are several recognition tests that expose the participant to target words and then require the participant to identify them when they are paired with another word e.g. Memory Test for Older Adults (Hubley and Tombaugh, 2002), Recognition Memory Test

(Warrington, 1984). Both of these examples of tests also include a visual recognition component that follows the same format of testing.

c) Task development

The format of the Memory Test for Older Adults and the Recognition Memory Test (RMT) were the most appropriate choice for the purposes of creating a cognitive load that tested short-term recognition and could be adjusted for difficulty to avoid excessive cognitive load. In fact Warrington's Recognition Memory Test (RMT) had been incorporated into The Camden Memory Tests (Warrington, 1986) as a shortened version, indicating that it was possible to develop tests of differing lengths and thus tailor the task to the time spent walking.

Thus two tests were devised, based on the format of the RMT, which tested visual and verbal recognition and taken forward to piloting. The format required participants to walk whilst listening to words spoken (verbal) or looking at figures shown (visual) at two second intervals; this frequency is taken from the Continuous Visual Memory Test. Then, when seated, the participants heard the word paired with another word or saw the figure paired with another figure, in a different order to that in which they were previously heard or shown. They were asked to identify the word or figure that they had heard or seen previously.

In order to be able to score the results in a consistent manner across participants it was important to ensure that similar cognitive processes were involved for all participants when committing the target word or figure to their short-term memory. Words can introduce a number of dimensions into a memory task that can affect test performance e.g. imagery, familiarity, emotion (Lezak et al., 2004). Thus, words of low imagery and of three syllables or less were chosen using a database of words (Wilson, 1988) which could be searched based on these criteria. Similarly, figures that are of familiar objects, flora or fauna would affect test performance. Participants could potentially translate the image into its verbal form, rather than remember it in its image form, resulting in a test of verbal rather than visual memory. Thus, figures were chosen that were abstract and indeterminable using those from the Continuous Visual Memory Test (Trahan and Larrabee, 1988) supplemented by abstract figures drawn by the researcher.

For the piloting process several visual and verbal tests were produced. The words and figures were not repeated during the course of a single gait laboratory session, neither as targets nor as paired foils. Appendices B.2 and B.3 provides examples of the word lists that were played as pre-recorded lists and the figures that were projected on a screen, both at two second intervals. Examples of the paired words and figures, that tested the participants' memory, are also included.

4.2.4 Other measures

It was expected that, when participants are asked to walk and perform the concurrent cognitive task, they would differ in the weighting they gave to walking or task performance. For example, stroke participants have been noted to adopt a strategy of altering the grammatical content of speech and adopting a slower gait speed during dual-task in order to maintain performance in both tasks (Pohl et al 2011). In contrast, when stroke participants were required to cross obstacles whilst walking and performing a cognitive task (Smulders et al 2012) results suggested that maintaining gait was prioritised. Yogev-Seligmann et al (2012) have proposed a model that explains the integration of factors such as the individual's cognitive state, compensatory capabilities and personality that may be involved in task prioritisation.

The study design therefore included collection of other measures that were chosen to describe the participants and to allow investigation of whether observed changes in gait and/or cognitive task could be explained by factors other than the presence or absence of FES. The following discusses the measures chosen.

a) Falls measures

One possible explanation for participants' choice of priorities could have been their falls history, and perceived risk and attitudes about the safety of walking and the possibility of falling. Advice was sought from the lead clinician of the local NHS falls service (Greene 2008) in the choice of measures appropriate to capture these potentially influential factors.

A widely used validated tool, at the time of designing this study, was the Falls Efficacy Scale (FES) (Appendix B.4) (Tinetti et al., 1990). This scale was designed to measure self-perceived fear of falling (Hellstrom and Lindmark, 1999) by assessing confidence in performing ten activities of daily living without falling (Yardley et al.,

2005) on a scale of one (most confident) to ten (least confident). A score out of 100 was obtained when the scale was applied, with higher scores indicating lower confidence. The scale had been used in several stroke studies (Michael et al., 2006, Fritz et al., 2007, Michael et al., 2009). Participants completed the scale at baseline and both subsequent data collection visits to examine change in confidence over time with use of their FES device and subsequent relationship to primary outcome measures.

As recommended in a study exploring fear of falling (Delbaere et al., 2010a) this measure of perceived falls risk was matched by a measure of falls risk based on external factors. A large variety of measures are cited in the research literature to assess this risk. To reduce the burden of the study on participants a quick and simple tool was chosen that was used locally in Salford by the falls team (Greene, 2008) and was designed for use in primary care. The Falls Risk Assessment Tool (FRAT) (Nandy et al., 2004) has five items (Appendix B.5). Three or more risk factors positively predict a fall within the next six months. Again, this was collected at baseline and both subsequent data collection visits, in particular to note any change in risk with time.

Finally, the participant's fall history was recorded, to match perceived risk with actual risk in this instance, via discussing fall or near fall events, using a proforma to record details of each event (Lord et al., 2007)(Appendix B.6). At the initial visit participants were asked to recall events during the previous 12 months, whilst at subsequent data collections they were asked to recall any events during the intervening period. Whilst one of the highly rated reasons for use of FES, by users, is a reduction in the risk of falling and tripping (Section 2.4.3e) only one study to date has assessed the effect of FES on the occurrence of falls (Hausdorff and Ring, 2008) noting a decrease in incidence. Results from the data from this study will potentially add to knowledge in this area.

b) Cognitive abilities

The participants were also assessed in terms of their general cognitive abilities as this would influence their performance on a cognitive task whilst walking. Thus outcomes of a cognitive assessment could be used in analysis of primary results to explain the contribution of this variable to the outcomes. The opinions of two

psychologists experienced in the field of stroke rehabilitation and research (Bowen 2007 and 2008, Kitching 2008) were sought to establish the most appropriate tests to quantify and describe this factor. Two tests were chosen to quantify this factor, both of which are well established in the field of neuropsychological assessment, and are relatively brief, in keeping with minimising the burden of the study on the participant. Both tests were applied once at the beginning of data collection.

Firstly, to estimate the participants' pre-morbid (i.e. pre-stroke) state of mental ability the National Adult Reading Test (NART) (Nelson, 1991) was used. This test is often used to estimate this ability in adults as vocabulary correlates best with overall ability level (Lezak et al., 2004). The NART is comprised of fifty words printed in order of increasing difficulty (Appendix B.7). The words are 'irregular' and thus can only be read correctly if the participant recognises them, rather than phonetically decode the word if it is unfamiliar. The test requires the participant to read aloud the list of words. The number of errors made are recorded and this is used to obtain an estimation of their predicted pre-morbid general intellectual ability (Bright et al., 2002). The score is converted to Predicted WAIS-R Full Scale IQ using the conversion scale devised by Nelson and Willison (Nelson, 1991) following re-standardisation of the NART.

Secondly, the Digit Span test from the Wechsler Memory Test (Wechsler, 1981) was used to assess the participants' level of attention (forward span) and working memory (backwards span) (Lezak et al., 2004). A series of increasingly longer digit sequences are spoken by the researcher, and the participant is requested to repeat each sequence exactly. In the case of the backwards span, the participant is required to repeat them in an exactly reversed order (Appendix B.8). For both forwards and backwards spans, the participant repeats increasingly longer series until they are no longer able to do so correctly, and each span is scored out of 14. The raw unconverted scores for both forward and backwards spans can be evaluated against a scale indicating the range of performance abilities (Lezak et al., 2004). Scores of 6 and above for the forward test are within normal limits, and scores of 4 and above are within normal limits for the latter (Lezak et al., 2004).

c) Overall independence

An overall measure of daily functioning was determined at each data collection visit to describe the cohort and to identify any changes that may have occurred over time.

The Barthel Index (Mahoney and Barthel, 1965) was used to provide an overall measure of independence in activities of daily living (ADL) (Loewen and Anderson, 1990)(Appendix B.9). This is a well-established and widely used (van der Putten et al., 1999) global measure of functional status (Loewen and Anderson, 1990) that has been included in the 'Stroke: Transfer of Care Summary' produced by the Royal College of Physicians (RCP, 2008b).

d) Sensory neuropathy

Finally, participants were assessed for peripheral neuropathy of the feet and lower legs, using a 10 gram monofilament to apply a standardised assessment (NICE, 2004). Neuropathy can affect balance when walking and contributes to a greater risk of falls (Richardson et al., 1992, DeMott et al., 2007) and hence may influence task prioritisation. As with other measures in this study, neuropathy was assessed at each data collection to assess any changes over the duration of the study.

4.3 Pilot work to finalise protocol

The use of a dual-task methodology and the decision to use cognitive tasks that were developed for this study necessitated piloting of the protocol. Feasibility and suitability of application of the protocol to a group of FES users post-stroke was assessed by piloting procedures outlined in the following sections. The specific aims of the piloting were to:

a) Selection of the most appropriate task
b) Identify the best mode of delivery for the secondary memory task
c) Establish if the protocol was feasible
d) Establish if the protocol was safe

The following describes the key issues addressed during piloting work.

4.3.1 Measuring cognitive task performance

Success in cognitive task performance was a primary outcome measure, along with gait speed, for this study. The ability to score the memory task and hence compare results across conditions was therefore important.

Due to anticipated gait speed differences, between participants, between walking conditions (i.e. with and without FES) and also over the course of the study, the time taken to walk a fixed distance would vary. The average speed at which new FES users walk, prior to provision of FES, ranges from 0.19 m/s (Bogataj et al., 1995) to 0.94 m/s (Granat et al., 1996). Furthermore, an average improvement in gait speed with FES use has been reported to be 0.13 m/s (Kottink et al., 2004). Consequently, if the slowest speed of 0.19m/s and the fastest of 1.07 m/s (i.e. 0.94 + 0.13 m/s) are used to calculate the time it would take for a range of study participants to cover a typical 10m length walkway, the range could be 9 to 53 seconds.

Assuming that gait and cognitive task performance were both to be measured in a laboratory of fixed length, the following possible design options were considered:

a) Fix the number of target words/images and vary the length of each walking trial to accommodate different walking speeds.
b) Vary the number of target words/images presented over a fixed length walking trial to accommodate different walking speeds.
c) Vary the frequency with which target words/images appear over a fixed length walking trial to accommodate different walking speeds.
d) Use a fixed number of targets or words/images for all participants and all conditions.

Solution a): To ensure the same degree of recall difficulty, each memory task should have the same number of items to be recognised either verbally or visually; leading to the use of a memory task of a fixed duration.

The restrictions of using a gait laboratory of fixed length would create a situation where faster participants would need to turn around to continue walking, whilst performing the memory task, potentially more than once. Turning, with the inherent need to decelerate and then accelerate, is considered more cognitively demanding than walking in one direction at a steady state (Herman et al., 2011) and presents significant practical challenges if using a visual task. It was agreed that turning during dual-tasking was not an acceptable option as this would contaminate the task performance results and hence varying the length of each walking trial was rejected.

An alternative was to use the largest of the University of Salford's gait laboratories in which participants could walk in a straight line over a distance of up to 25m, potentially avoiding the need for participants to turn whilst walking. Application of a visual task in this environment however, would create challenges of delivery. From a practical perspective, the lab is heavily used for teaching, and is not ideally suited for people with stroke, being rather crowded with equipment and having tripod-mounted cameras. Additionally, faster walkers (i.e. 1.07 m/s) potentially would require a 20m length walkway to see ten figures, for example, delivered at 2 second intervals. Thus the size of the projected figures would need to be sufficiently large to be viewed at the beginning of a walk, for the fastest walkers starting the furthest distance away from the screen. To ensure consistency of task difficulty, between conditions and participants, the size of figures would need to have been the same for each test. At the end of the walk, in the case of a fast walker, the figures may then be overly large, creating difficulties for those participants with hemi-neglect, who would potentially not pay attention to the entire figure, thus increasing the difficulty of the memory task. As such, the use of the walkway lengths tailored to gait speed was rejected.

Solution b): An alternative potential solution to the problem of speed variation between participants and across conditions would be to vary the number of targets, according to the time spent walking. However, it was not clear whether it would be possible to model the effects of altering the number of items to be recalled on cognitive task difficulty. If this proved impossible, this would mean analysing the results for memory task performance across conditions, as speed changed with condition and across participants, would not be possible.

Solution c): A further alternative approach was to deliver a fixed number of targets and alter the frequency with which they were delivered. This could accommodate differing gait speeds and thus ensure that the targets were seen wholly during walking. Hyndman's study (2006) had used this approach to deliver a 7-item list, closely matching the time taken to walk 5m with the time taken to deliver the entire list by altering the frequency of item delivery. Lists were prepared over durations of 5, 10, 15 and 20 seconds, thus the range in interval between items was 0.7 to 2.9 seconds. Task performance was analysed with no apparent allowance for differences within the group nor between the seated condition, presumably delivered over a standard time period, and the walking condition. The speed of the group is reported

in the dual-task condition as 0.5 ± 0.3m/s, thus the range of time spent walking 5m was approximately 5 to 50 seconds. This indicates that each of the 5 to 20 second lists were probably used in the group study, creating a variation in the task applied, and potentially confounding outcomes comparing task performance when seated with walking.

This approach would result in the gap between each target differing between walking conditions, and between participants. This inconsistency in the task would be difficult to account for when analysing the results.

Solution d): Having rejected potential options (a-c), due to the difficulty in taking account of variations in task length/frequency and consequences of varying walking length on task performance, it was decided to fix the number and frequency of targets and length of walkway. This approach would fix the difficulty of cognitive task performance across conditions and between participants and allow for comparison. As a consequence during some trials, when walking speeds were faster, some of the target items would be heard or seen whilst the participant stood still after walking the length of the walkway; during the slower trials, participants would potentially complete viewing the targets before reaching the end of the walk. This is further justified below.

The memory tasks require the participant to pay attention to the task during the acquisition phase, committing the target words and figures to short term memory, and retain the targets in short term memory between the end of the acquisition phase and testing. This is a continuous process as the memory task continues and more items are committed to and retained in memory, including whilst standing still if this were to occur (in the faster participants) and while walking, after the end of the task (in slower participants).

The number of targets chosen for the memory tasks was based on the length of walkway, the average walking speed for new FES users and the frequency at which targets would be delivered. With a 10 metre walkway and an average walking speed for FES users, as calculated from the studies included in Kottink's review (2004), of 0.5 m/s, the duration of walking was calculated as 20 seconds. Thus, with a 2 second interval for target delivery (as described in section 4.2.3c), the number of targets was defined as 10 per memory task. The length of test in the context of placing a

sufficient cognitive load was tested during piloting, with a plan to assess the scores on memory task performance as indicative of appropriate difficulty under all conditions.

4.3.2 Measuring dual-task performance

Piloting was performed firstly with healthy participants and then one post-stroke participant to establish a suitable study protocol in terms of timings of each data collection aspect and appropriate use of study apparatus. Further piloting was then performed with a group of three people – one post-stroke subject who did not use FES and two post-stroke established FES users – who all agreed to take part to assist development of the study protocol. They represented a range of people post-stroke, exhibiting variety in gait speed and cognitive ability.

Gait speed data was collected using kinematic data from waist markers, collected via a 3D video motion capture system (Qualysis). The method of analysis of this data followed published methodology (Carter et al., 2009) and utilised code written by Dr Thies, University of Salford, in Matlab software. A more detailed description of this approach is given in the study protocol that follows in this chapter.

The FES non-user participant was asked to follow the planned study protocol to assess feasibility of the dual-task protocol, with a focus of application of the memory tasks. Thus, two trials were collected for each memory task, in the absence of the two FES walking conditions i.e. with and without FES. Performance on task was recorded, but speed was not (Table 4.1). For the subsequent piloting with the two FES users, the planned protocol was followed, involving execution of both memory tasks whilst seated, collection of gait speed and task performance whilst walking and collection of other measures (e.g. Barthel score) between walking trials. Both memory tasks were piloted using ten items presented at 2 second intervals. Each FES user performed one walking trial under each condition. Tables 4.2 and 4.3 show the results for task and speed.

	Verbal task		**Visual task**	
	Seated	Walking (2 repeats)	Seated	Walking (2 repeats)
FES non-user	10	10, 7	10	6, 9

Table 4.1: Task performance success (out of 10) for FES non-user pilot participant.

	Verbal task			Visual task		
	Seated	FES	No FES	Seated	FES	No FES
FES user (1)	5	7	7	8	8	9
FES user (2)	8	8	8	9	8	7

Table 4:2: Task performance success (out of 10) for FES user pilot participants.

	Walking condition					
	FES	No FES	FES + verbal task	FES + visual task	No FES + verbal task	No FES + visual task
FES user (1)	1.04	0.96	0.87	0.88	0.90	1.05
FES user (2)	1.39	1.12	Not collected	1.14	1.09	1.09

Table 4.3: Speed (m/s) of FES user pilot participants.

As the test of memory task performance involved distinguishing a series of targets seen or heard during walking from paired foils, a score of 5 out of 10 could be attributed to pure chance. Analysis of the scores achieved by the pilot participants were all, with the exception of one score, over 5 out of 10. This suggests that attention was paid to the two memory tasks. Memory task performance results also showed a drop in performance of the memory tasks for the FES non-user on 3 out of 4 trials, when compared with their performance during sitting (Table 4.1). However, FES users showed little consistent change in task performance across conditions (Table 4.2). As expected, speed increased with FES for both participants compared with no FES. Introducing either task led to a decrease in speed when walking with FES, but less clear effects when walking without FES (Table 4.3).

One further FES user participant piloted the final protocol using the visual task exclusively, before the study proceeded to recruitment, to confirm that the protocol would run correctly and smoothly. Task performance results were collected for three walking trials, both with and without FES (Table 4.4).

Seated	FES			No FES		
10	9	10	10	9	10	10

Table 4:4: Visual task performance success (out of 10) for FES user pilot participant.

4.3.3 Discussion of results of piloting

The ability of the pilot participants to understand and follow the cognitive tasks both whilst seated and whilst walking was assessed. Both memory tasks were generally easily understood and followed. Subjective assessment of the perceived impact of the memory tasks whilst walking, by pilot participants, described them as sufficiently difficult to require their attention and concentration, and that whilst walking successful completion of the memory tasks seemed more difficult. However, the three pilot participants each found the verbal task hard to hear whilst walking on one occasion during the piloting procedure. Each time this necessitated the verbal walking trial to be repeated, thereby compounding fatigue.

It also became clear that completion of the memory tasks required some familiarity with the testing procedure and created a small amount of initial anxiety due to concerns about memory ability. This anxiety soon reduced after completion of one test. It was therefore decided to deliver this planned measure of performance of the memory tasks while seated in the screening battery, rather than as part of the main protocol. This would firstly, ensure that all participants who entered the study understood and could complete the memory tasks and secondly, potentially address any anxiety felt due to lack of familiarity with the memory task.

During walking trials whilst performing both of the memory tasks, pilot participants walked safely. No stumbles, toe catching, near misses or falls occurred and the pilot participants felt safe during the dual-task conditions, including without their FES device switched on. Pilot participants did not need to stop walking whilst concurrently performing either memory task.

The visual task was chosen to take forward to the final protocol for the following reasons. Firstly, it satisfied the effects of FES as identified by the questionnaire outcomes i.e. a task that created a distraction from the perceived thinking associated with walking and from looking at the walking surface whilst walking. Secondly, during piloting there were no problems experienced with application of the visual task whilst walking, in contrast to the verbal task.

4.3.4 Visual task

Piloting identified that the visual task was the most appropriate and hence taken forward. Secondly, piloting showed that the protocol was feasible to deliver; the results of piloting suggested that motor-cognitive interference was achieved by use of the visual task, and that this task was able to be executed. Finally, piloting established that the protocol was safe.

The visual task was finalised for the study protocol to show ten abstract figures at 2 second intervals whilst the participant was walking. The target figures, paired with foils, were then shown to the participant whilst seated after walking was completed. The participant was required to identify the target figures and a score of success was obtained. The target figures and the foils were not repeated during a testing session, allowing for six walking trials with task (i.e. three each with and without FES). The target figures were not repeated as target figures during the entire study, thus 21 different visual tests were required; 1 seated test and 6 walking trial tests for each of the three data collection visits. Furthermore, extra visual tests were devised to allow for the possibility of aborted walking trials. The order in which the target figures were shown, when paired with the foils, was different to the order in which they were shown when walking. Targets were either ‘A’ or ‘B’ when paired with the foils and this was also randomised (see Appendix B.3). The order in which the different visual tests (i.e. 21 in total) were used was randomised between participants.

4.4 Final protocol and Ethical and R&D approval

Ethical approval was granted by Stockport Research Ethics Committee (Appendix B.10) and by The University of Salford Research Governance and Ethics Sub-Committee. Approval was also granted by Greater Manchester Primary Care Research Governance Partnership (Appendix B.10) for Salford Primary Care Trust and Heywood, Middleton and Rochdale Primary Care Trust.

Difficulty recruiting to the study resulted in submission of an amendment to ethical and research and development committees, requesting a change in recruitment to a proactive approach, which had been initially proposed but was unfortunately rejected in the initial ethics applications. Furthermore, the amendment also proposed that the researcher be able to provide an FES device to participants, under the care of a practitioner, for the duration of the study. Ethical approval of the amendment was

granted by North West 8 Research Ethics Committee – Greater Manchester East (Appendix B.11), the University of Salford Research Governance and Ethics Sub-Committee and the Greater Manchester Primary Care Research Governance Partnership (Appendix B.11). Approval was also granted by Lancashire Care NHS Foundation Trust Research and Development.

Participants recruited to this study entered into the study after approval and implementation of the amendment

4.4.1 Recruitment and screening

Physiotherapists, experienced in the assessment of suitability for FES and provision of FES, based in Greater Manchester, were asked to identify potential participants from their caseload. Inclusion criteria were as follows:-

- adults 18 years and over
- hemiplegic foot drop gait resultant from stroke
- no previous use of FES
- able to understand spoken and written English
- suitable for FES following physiotherapy assessment.

Those physiotherapists able to provide an FES device, both via the NHS and privately, were asked to give potential participants an invitation letter (Appendix B.12) and participant information sheet (Appendix B.13). If their patient agreed, the practitioner forwarded the name and contact details of the potential participant to the researcher.

Some FES services in Greater Manchester provided FES on a private basis to patients. Other physiotherapy services could assess patients as suitable for FES but relied upon provision of the device via a case-by-case NHS commissioned service with neighbouring FES services. In both of these situations potential study participants were offered the opportunity to use an FES device provided by the researcher for the duration of the study. Thus, physiotherapists were asked to give these potential participants an invitation letter (Appendix B.14) and participant information sheet (Appendix B.15). If their patient agreed, the practitioner forwarded the name and contact details of the potential participant to the researcher.

Participants recruited via this process only received the FES device if they were suitable for inclusion in the study after successful completion of the screening process (described below). Further use of FES was facilitated by the researcher and the participant's physiotherapist after completion of the study. The participant accessed either private or NHS provision and the study device remained in situ until this was achieved, to enable seamless care.

Once details of potential participants were received, the researcher made contact to discuss their willingness to be considered for inclusion, to answer any questions, to establish availability for all data collections and to rule out exclusion criteria e.g. planned surgery, involvement in other studies. An appointment was then arranged to meet the potential participant.

At the first meeting informed consent was obtained (Appendix B.16), after the study was discussed with the participant to ensure that the nature of their involvement was understood. The participant was then screened for suitability by establishing past and current medical status, including medication and ongoing treatment or planned investigations. Each participant was assessed to establish that they were medically stable and had no co-morbidities that would confound the data collected in the study. If necessary, the participant's GP or named consultant was contacted, with the agreed consent of the participant, to clarify past and/or current medical history.

The participant was then asked to complete, whilst seated, the visual memory test to assess their ability to understand and follow instructions, and thus be able to participate in the study. Those participants found to be unsuitable to proceed with involvement in the study at this stage, were returned to their referring clinician for ongoing care.

If agreed via completion of the appropriate section on the consent form, the participant's GP and other appropriate health professionals were then informed of their inclusion in the study via letter (Appendix B.17).

4.4.2 Study protocol

a) Visit 1

Following successful screening, further data was collected at the initial meeting with the participant as follows:

- Participant descriptives – age, sex, height, weight, dominant foot/leg
- Stroke history – date of stroke, side affected, other effects of stroke, treatments and interventions received
- Use of walking aids/orthoses
- NART
- Digit Span – Forwards and Backwards
- Barthel Index
- Fall and near fall history – questions via proforma
- FRAT
- Falls Efficacy Scale (FES)
- Assessment of neuropathy

The participants then attended the gait laboratory for the collection of baseline gait parameter data, approximately 7-10 days after provision of their FES device. Before this collection of data, each participant completed a final screening procedure to ensure that they were able to walk safely during the test procedures. The reasoning behind this procedure was that, despite the positive results from the piloting, there would potentially be an increased risk of falling during walking without FES, whilst performing the memory task, potentially the most demanding condition. Whilst the researcher walked with the participant, they were asked to perform an example of the visual memory task. If the participant tripped, nearly fell or felt particularly unsafe during this test they were not asked to continue with their participation in the study.

b) Visits 2 and 3

Each participant attended the gait laboratory on two more occasions; 6 weeks after this initial visit and then a further 8 weeks later. At each of these subsequent visits to the gait laboratory the participant's medical status was checked to ensure continued suitability for inclusion in the study and to note any confounding conditions that may have affected study results. The following measures were taken at each of these subsequent visits, including those repeated from baseline:

- Approximate use of FES, since the last visit
- Falls or near falls since the last visit – questions via proforma
- Barthel Index
- FES questionnaire
- Falls Efficacy Scale (FES)
- Assessment of neuropathy
- Visual memory task whilst seated

c) Walking trial protocol and data analysis

The gait laboratory set-up is illustrated by Figure 4.2. The participants walked in one direction only for all trials; towards the screen upon which the figures for the task were projected. The length of walkway was approximately 10m.

Figure 4.2: Photo of gait laboratory set-up for dual-task protocol.

A wall-mounted, 12 camera 3D motion capture system (Qualysis) collected kinematic data at 100Hz. During walking trials, a cluster of four 9 mm reflective markers, mounted on a fixed plate, were attached to the participant on a flexible wide belt, and were placed to sit over the posterior aspect of the sacrum. Marker data were filtered with a fourth-order Butterworth filter with a cut off frequency of 7Hz and analysed using Matlab software. The first derivative of one of the waist marker's position data,

recorded along the direction of forward progression, was used to obtain gait speed, during the 'comfortable gait speed' interval. This interval was found by excluding the data taken when the waist velocity was less than 85% of the maximum velocity for the trial (Carter et al., 2009).

Participants were instructed to walk at a comfortable pace for each walking trial. During dual-task trials no instructions were given regarding prioritising either walking or task completion. Participants were made aware, at the beginning of the study, that they would be required to watch a series of abstract figures projected onto a screen that was positioned at the end of the walkway, whilst they walked. They also were instructed that they would be asked to recognise these figures, when paired with another figure, after they had finished walking and were seated. They were familiarised with the test format via the screening procedure.

They were instructed to begin walking from outside the data capture area and to continue walking along the entire length of the laboratory, coming to a stop in front of the screen. They were also instructed to continue watching the figures on the screen whilst walking until a blank screen appeared, and to continue looking at the screen until they stopped walking. They were also instructed, if necessary, to continue watching the screen if the figures were still being projected after coming to the end of their walk.

The order in which walking trials for the four conditions were collected was randomised between participants and between data collection visits. Furthermore, the order in which visual tests were shown was randomised between participants.

4.5 Results

4.5.1 Recruitment

Two participants were recruited to this study. The intention was to recruit up to twelve however this proved impossible primarily due to a lack of local FES service provision in Manchester. Several attempts were made to address this during the recruitment period. Firstly an amendment to the recruitment procedure, which included provision of the FES device by the researcher, was arranged. Secondly, R&D approval for several NHS services across Greater Manchester to act as patient identification centres was gained following assurances from the service clinicians that they would

be able to refer potential participants. A total of four services gave a commitment to recruit participants to the study, referring two people to the study who were subsequently recruited. Unfortunately, the study was stopped due to lack of participants. As discussed in more detail in the Discussion section of this chapter, the results from this study were used to inform a further study, which is presented in Chapter 5.

As only two participants completed the study the results are presented as two case studies.

4.5.2 Participant descriptors

Table 4.5 summarises descriptors of both participants.

Participant	A	B
Age (years)	75	46
Sex	Female	Female
Height (m)	1.52	1.72
Weight (kg)	65	102
Hemisphere affected by stroke	Left	Right
Time since stroke at study commencement (mths)	27	41
Barthel score[#] (max of 20)	14	19
NART raw score (errors of possible 50)	11	19
Predicted premorbid general intellectual ability from NART score	117[*]	107[*]
WAIS-R Digit Span forwards (max of 14)	10[†]	6[†]
WAIS-R Digit Span backwards (max of 14)	5[†]	3[¥]

NOTE: [#] Barthel score remained constant over data collection period [*]Median IQ = 100±15 SD [†]Scores are within normal limits [¥]Score borderline of cognitive defecit

Abbreviations: NART, National Adult Reading Test (Nelson, 1991); WAIS-R, Wechsler Adult Intelligence Scale – Revised (Wechsler, 1981).

Table 4.5: Participant descriptors.

4.5.3 Gait speed, task performance and other outcomes

a) Participant A

Participant A had no other health issues and there was no evidence of peripheral neuropathy. The participant reported that the stroke had resulted in a reduction in right hand function, occasional poor memory and some difficulty finding the correct words to use. During the course of the study she was actively involved in regular physiotherapy and guided cardiovascular exercise. She had previously been supplied with a double caliper to address her foot drop, which she no longer used as it did not lift the foot sufficiently to enhance gait. This participant used a tripod walking stick to aid walking.

i) Gait speed

The results for speed, measured during each condition, are summarised in Table 4.6. The participant was able to complete two walking trials for each condition at each data collection visit.

	Weeks since FES provision		
	0	**6**	**14**
No FES	0.21 (0.20, 0.21)	0.20 (0.19, 0.20)	0.22 (0.22, 0.22)
FES	0.20 (0.20, 0.20)	0.21 (0.21, 0.22)	0.22 (0.22, 0.23)
No FES + task	0.21 (0.20, 0.21)	0.19 (0.19, 0.20)	0.20 (0.20, 0.20)
FES + task	0.21 (0.21, 0.21)	0.19 (0.19, 0.19)	0.20 (0.20, 0.20)

Table 4.6: Mean speed (min, max) for each condition, over two walking trials, collected at each visit (Participant A).

Changes in average gait speed over time for each condition are illustrated by Figure 4.3. Speed increased over 14 weeks by 5% without FES and by 10% with FES. At 6 and 14 weeks concurrent performance of the visual task reduced walking speed, both with and without FES, as expected. At week 0, dual-tasking resulted in an increase in speed of 5% with FES. At 6 weeks dual-tasking resulted in reduction of speed by 10% with FES and 5% without FES. At 14 weeks dual-task performance reduced speed by 10% when walking with FES and without FES.

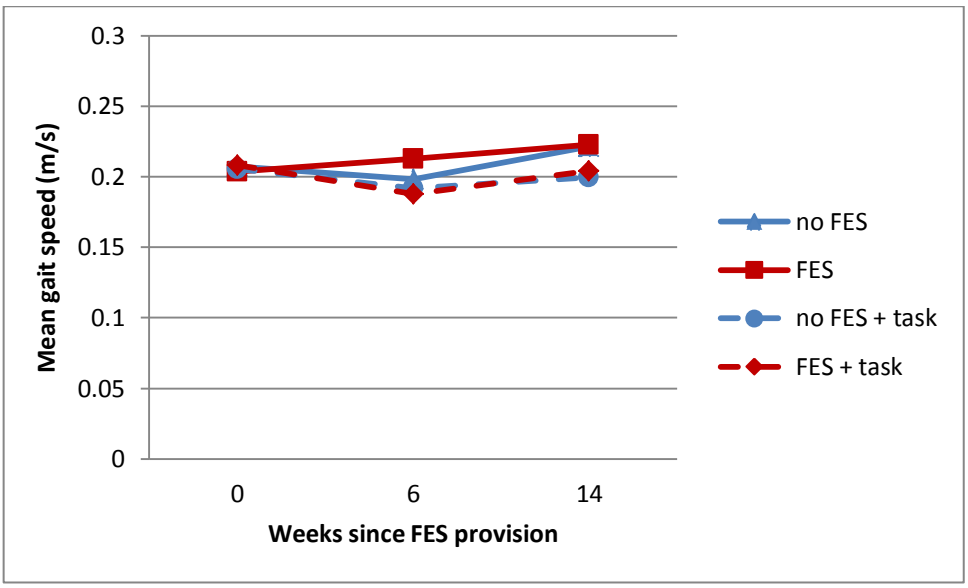


Figure 4.3: Walking speed at each visit, averaged over two trials, for each walking condition (Participant A).

ii) Visual task performance

Figure 4.4 illustrates the success with which the visual task was performed during walking trials. Success in visual task performance was reduced when walking with and without FES. At weeks 0 and 14 visual task performance was lower without FES, when compared to with FES, as was expected. At week 6 with FES resulted in lower visual task performance than without FES.

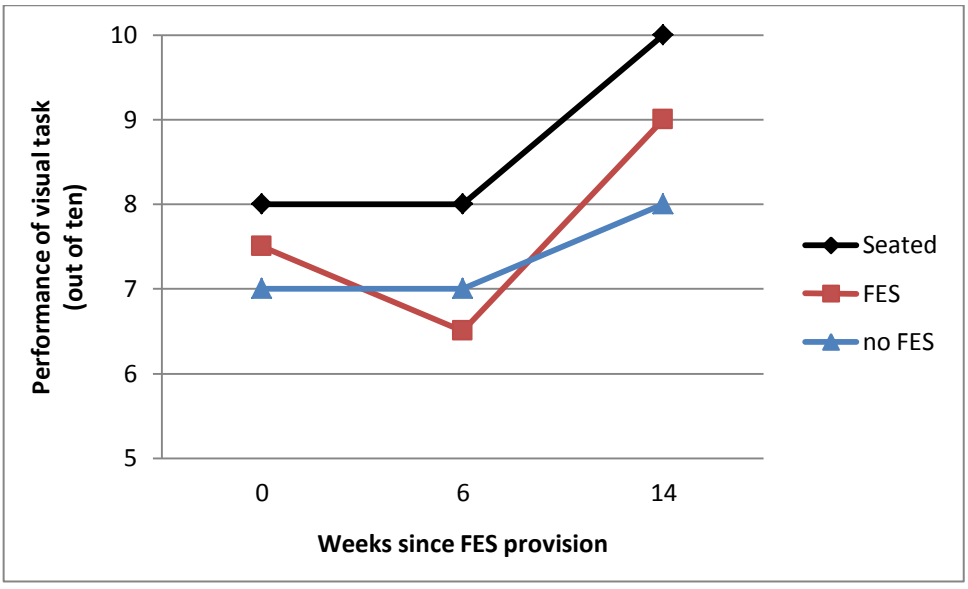


Figure 4.4: Score on visual task at each visit, averaged for two walking trials for each condition and from one seated trial (Participant A).

iii) Falls

At initial data collection the participant was assessed, using the Falls Risk Assessment Tool (FRAT), as not at high risk of a fall in the future. At this point the participant could not recall experiencing a fall or near fall in the preceding year. During the interim between first and second data collection this remained the same. At week 14 the participant described one near miss in the last 8 weeks whilst outdoors negotiating steps, suffering a loss of balance and no injuries.

Results for the Falls Efficacy Scale (FES) changed over the course of the participant's study involvement; baseline at 42, 6 weeks at 31 and 14 weeks at 48 (scores out of 100). In particular at 6 weeks there is a drop of 11 points on the scale, but then a rise above the baseline at 14 weeks despite a near miss during the interim.

iv) Questionnaire results

Over the course of involvement in the study the participant completed the questionnaire twice; at 6 and 14 weeks. Responses to the questions were predominately positive but did alter between the two collections.

Of the 13 statements about what the participant was able to do when using FES, she agreed with 9 at 6 weeks and 10 at 14 weeks, indicating an overall positive effect of FES use. The specific changes in response are as follows:

- A positive shift at 14 weeks to agreement with the three statements 'I am less likely to trip and fall', 'I am able to exercise more' and 'I am able to walk without assistance from another person more often'.
- A negative shift at 14 weeks to disagreement with the two statements 'I am more able to walk on uneven ground' and 'My posture is better'.

Her most important reason for using FES was at 6 weeks was 'I am able to walk faster' and at 14 weeks this changed to 'I am able to walk more safely'.

In the second section of the questionnaire, the participant identified the amount of perceived concentration when walking with FES as 'none' and without FES as 'some' at both data collections.

In the third and final section, from 10 statements about the difference that FES made when walking under different conditions, the participant identified 8 at 6 weeks and 6 at 14 weeks as ‘easier than without the stimulator. The specific changes in response are as follows:

- A positive shift at 14 weeks to agree that ‘thinking about something else whilst I walk’ was easier with FES
- A negative shift at 14 weeks to indicate that ‘talking whilst walking’, ‘walking on uneven ground’ and ‘answering questions whilst walking’ were the same with FES as without FES.

The most important activity that was easier with FES remained the same at both data collections as ‘stepping up onto a kerb’.

Between data collections the participant increased the number of activities pursued using FES, which concurred with increasing use of the device, as familiarity with its use improved and the amount of time worn increased to approximately 10 hours a day. At 6 weeks the participant had used the device minimally, predominately to stimulate muscle contraction rather than as an aid to walking. This was due to a misunderstanding between the treating clinician and the participant. Despite this, the participant was very positive about the device describing it as ‘smashing’ at 6 weeks and then at 14 weeks describing the positive effect of FES as ‘getting around quicker and easier’ and ‘able to go places I haven’t been before’.

b) Participant B

Participant B had several other health issues; Diabetes secondary to Polycystic ovary syndrome, Asthma, mild Angina and Hypothyroidism. There was evidence of unilateral peripheral neuropathy of the left foot. The participant reported that the stroke had resulted in a minor loss of spatial awareness which was most apparent when fatigued, and of being easily distracted in noisy environments. She had used a fixed ankle AFO until being provided with FES and occasionally used a walking stick.

i) Gait speed

The results for speed over time, measured during each condition, are summarised in Table 4.7. The participant was able to complete three walking trials for each condition at each data collection visit.

	Weeks since FES provision		
	0	6	14
No FES	0.79 (0.78, 0.79)	0.81 (0.77, 0.86)	0.86 (0.85, 0.90)
FES	0.79 (0.79, 0.80)	0.89 (0.86, 0.93)	0.94 (0.91, 0.98)
No FES + task	0.74 (0.72, 0.75)	0.76 (0.75, 0.79)	0.79 (0.76, 0.77)
FES + task	0.75 (0.74, 0.77)	0.84 (0.82, 0.87)	0.84 (0.82. 0.86)

Table 4.7: Mean speed (min, max) for each condition, over three walking trials, collected at each visit (Participant B).

Changes in speed over time for each condition are illustrated by Figure 4.5. Speed increased over 14 weeks by 9% without FES and by 19% with FES. At each visit concurrent performance of the visual task reduced walking speed, both with and without FES, as expected. At week 0, dual-tasking resulted in a reduction of speed by 5% with FES and 6% without FES. Similar percentage reductions in speed were seen at 6 weeks. At 14 weeks dual-task performance reduced speed by 10% when walking with and by 8% without FES.

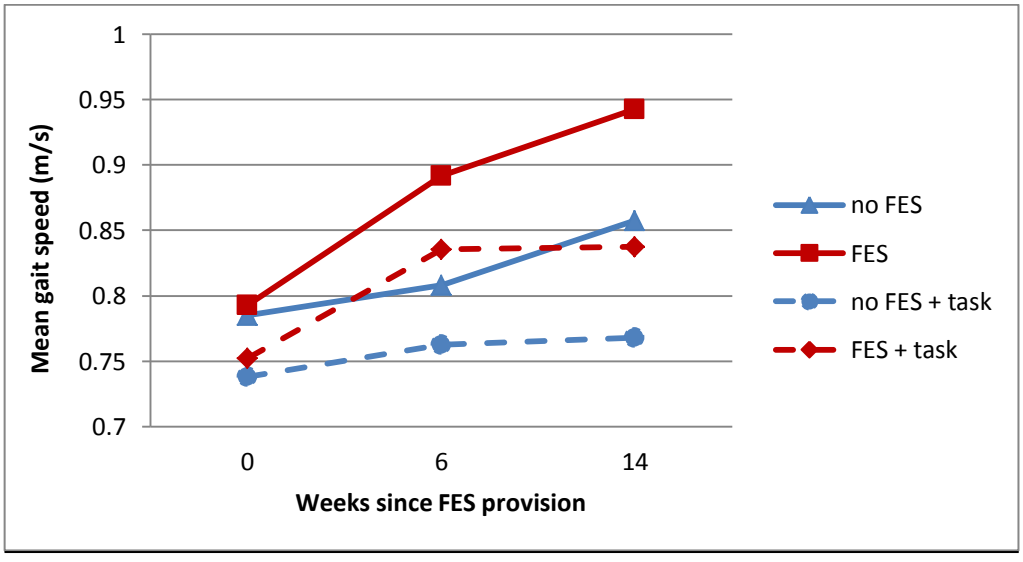


Figure 4.5: Walking speed at each visit, averaged over three trials, for each walking condition (Participant B).

ii) Visual task performance

Figure 4.6 illustrates the success with which the visual task was performed during walking trials. Success in visual task performance was consistently the lowest at

each data collection, when walking without FES. When walking with FES visual task performance varied little from seated results. At week 14 seated performance was lower than when walking with FES.

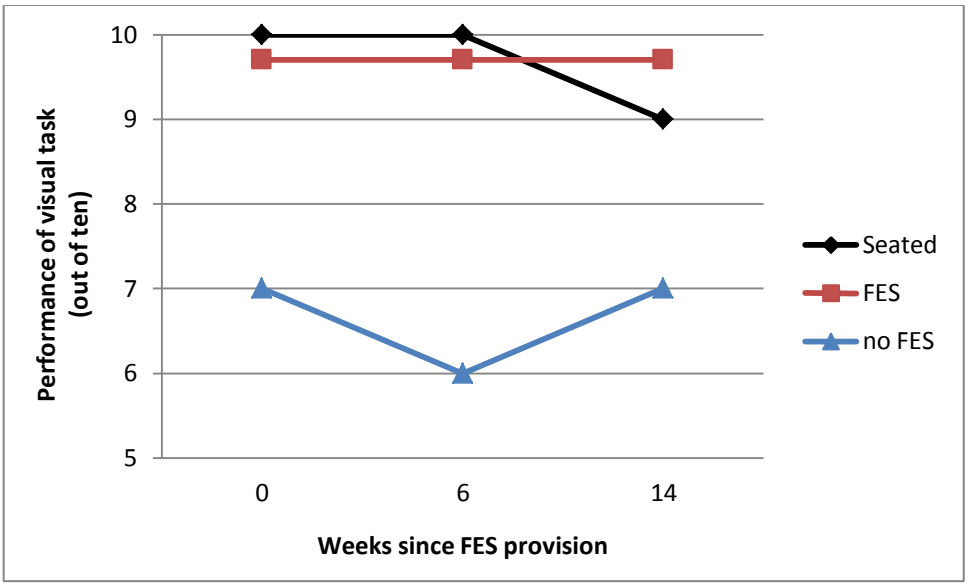


Figure 4.6: Score on visual task at each visit, averaged for three walking trials for each condition and from one seated trial (Participant B).

iii) Falls

At initial data collection the participant was assessed, using the Falls Risk Assessment Tool (FRAT), as at high risk of a fall in the future. At this point the participant could recall experiencing one fall in the preceding year whilst in the garden, due to a loss of balance, resulting in a bruised hand. She also described nearly falling as a weekly occurrence, due a loss of balance usually when multi-tasking. During the interim between first and second data collection the participant recalled one fall whilst walking up stairs at home, resulting in no harm, and two trips whilst indoors. At week 14 the participant did not report any near misses or trips during the interim, and only one fall when not using FES, which did not result in harm and was due to catching her dropped-foot on a dress.

Results for the Falls Efficacy Scale (FES) change over the course of the participant's study involvement; baseline at 26, 6 weeks at 50 and 14 weeks at 45 (scores out of 100). In particular there is a rise in scores associated with FES use at 6 weeks which

is slightly reduced at 14 weeks, perhaps due to a fall during the interim, but essentially maintained at 14 weeks.

iv) Questionnaire results

Of the 13 statements about what the participant was able to do when using FES, she agreed with 11 at 6 weeks and with 12 at 14 weeks. There were only a few changes in effects of FES over the two data collections. The specific changes in response are as follows:

- A positive shift at 14 weeks to agreement with the two statements 'I am able to walk further' and 'I am able to exercise more'.
- A negative shift at 14 weeks to disagreement with one statement 'I am able to walk faster'.

Her most important reason for using FES was consistent at both data collections as 'I am more independent'.

In the second section of the questionnaire, the participant identified the amount of perceived concentration at 6 weeks when walking with FES as 'some' and without FES as 'none'. At 14 weeks this changed, when walking without FES to 'a lot'.

In the third and final section, the participant identified, at 6 weeks, 9 of the 10 statements about the difference that FES made when walking under different conditions as 'easier than without the stimulator'. At 14 weeks the participant identified all 10 statements as easier. The specific change in response was as follows:

- A positive shift at 14 weeks to agree that 'walking in a noisy environment' was easier with FES.

The most important activity that was easier with FES remained the same at both data collections as 'avoiding a trip or fall'.

Between data collections there was a small increase in the number of activities pursued by the participant using FES. The participant used the device daily after a short initial familiarisation period, indicating at both 6 and 14 week data collection that she used it consistently for 8 hours a day, both whilst working and when at home. It is worth noting that this participant ran her own business. The participant also received Botox therapy as required to address inversion spasm of the foot due to stroke.

During the course of the study the participant noted that the Botox injection received approximately one month prior to FES provision seemed to be more effective and last longer. She especially noted that she had not needed to return for a further injection, which would have normally occurred within the timespan of her involvement in the study.

This participant had used an AFO prior to FES provision. She felt that FES allowed her to walk with least effort in direct comparison to the AFO. The participant noted that FES allowed her to 'do other things whilst walking' and 'to look around'.

4.6 Discussion

Prior to the provision of FES, Participant A walked without FES at a mean speed that placed her at the lower end of reported gait speeds for participants in other FES studies (Kottink et al., 2004, Robbins et al., 2006) and the walking speed for Participant B placed her at the higher end. Gait speed then increased for both participants with the use of FES over the study period, in a manner consistent with previous findings (Taylor et al., 1999c, Burridge et al., 1997b). Gait speed at weeks 6 and 14 was faster with FES than without FES. This, as well as an increase in speed without FES relative to baseline at 14 weeks, is in agreement with previous work (Burridge et al., 1997b, Taylor et al., 1999a) noting the evidence of a therapeutic or 'carryover' effect.

Under dual-task conditions, gait speed dropped both with and without FES, compared with the single task condition. Gait speeds with FES, under dual-task were largely faster than without FES and task. For Participant B the drop in speed during the dual-task conditions with and without FES, as compared to walking without the visual task, was the same for each condition at each visit, rising from 5% to just over 10% at 14 weeks. Thus, the reduction in gait speed due to the effect of cognitive task performance increased over time (perhaps because gait speed itself increased over time), but was no greater whether the participant walked with or without FES. Interestingly, when walking with FES and performing the cognitive task very similar walking speeds to the single walking task without FES were measured.

For Participant A at week 14, under dual-task conditions, walking with FES reduced speed by 9% and without FES was slower with a 10% reduction, when compared the

single task conditions. These percentage changes represent small reductions in speed relative to an already slow walking speed. The results at 6 weeks are confusing and are probably more likely to be a representation of a lack of FES use, as a result of a misunderstanding between the participant and her clinician. Interestingly, results for visual task performance also appear to be affected by this.

The slowing of gait with the introduction of a concurrent cognitive task is consistent with previous stroke research (Bowen et al., 2001, Canning et al., 2006, Hyndman et al., 2006, Plummer-D'Amato et al., 2008, Dennis et al., 2009, Pohl et al., 2011). The fact that a non-motor cognitive task was used in this study also supports the general theory of motor-cognitive interference (Dennis et al., 2009) and argues against this simply occurring when two motor tasks (talking and walking) draw on similar resources.

The results for visual task performance during walking were largely as expected; performance when walking without FES produced the lowest scores. Results suggest that when walking with FES, the participants were able to devote a similar degree of attention to the cognitive task, as when seated, and this did not change over time. This suggests that potential cognitive gains from FES use may cancel out cognitive costs of performing everyday dual tasks such as walking and cognitive activity. In contrast, when walking without FES, cognitive task performance dropped by up to 20% (Participant A) and 40% (Participant B) compared to when seated. Whilst not consistently the same amount this drop in performance was maintained over time. This result for Participant B indicates that without FES there was a marked motor-cognitive interference effect. The questionnaire results support this interpretation of the cognitive task results; both participants found that less concentration needed to be allocated to walking with FES at 14 weeks and that concurrent tasks became easier when walking with FES.

Participant A was very positive about the effect that FES had on improving her ability to do things and go places that, up until using FES, she had not been able to do. Participant B was able to make a direct comparison with an AFO device used, stating that FES allowed her to walk with less effort. She also was able to clearly identify that FES use had a positive effect on increasing the amount of time that Botox therapy remained effective. Furthermore, Participant B clearly felt that FES had a positive

effect on her ability to perform concurrent tasks and to avoid looking at the ground whilst walking.

The changes in the primary outcomes over time for both participants show some variation. At baseline gait speed differed very little between the four walking conditions. This then changed with increased time of use of FES, with change in gait speed between conditions increasing at both 6 and 14 weeks. Under dual-task, both with and without FES, speed was slower than single task and this was consistent at both 6 and 14 weeks. The absolute size of the reduction in speed with addition of visual task became larger with time. Visual task performance also showed some variation with time, between the two participants. At 14 weeks Participant A's performance without FES was the lowest in comparison to seated scores over the three visits. Participant B however exhibited a consistently large difference between seated scores and those without FES, across the three data collections.

4.7 Conclusion

This novel approach, applying a dual-task methodology to assess the effect of FES on motor-cognitive interference, necessitated consideration of choice of secondary task and subsequent piloting to establish appropriateness for an FES user group. Piloting clearly established that a dual–task using a visual task, which was developed for the study, was feasible. Piloting also established that the protocol was safe. Most importantly piloting confirmed that the task would impose a cognitive load and create sufficient interference to affect gait speed and some evidence that it may affect task performance under dual-task conditions. Furthermore, the other measures collected were appropriate and feasible in the context of the study, and did not create an unnecessary burden upon the participants during piloting.

The results of the piloting process were then re-iterated by the outcomes from the participants recruited to the longitudinal study. These participants showed evidence of motor-cognitive interference in a reduction in gait speed and in visual task performance under dual-task conditions. Furthermore, FES reduced the effect of this interference. In addition, responses to the questionnaire supported these primary outcome measures.

Difficulties with recruiting further participants to the study, despite several attempts to solve unforeseen issues, unfortunately resulted in a halt to further work. However, confidence in the protocol and the results obtained were the drivers to seek an alternative group of FES users, upon which to apply this novel and now tested methodology. Changes in the primary outcome measures over time indicated that, in the context of measuring the effects of a dual-task, it was more probable that consistent and clearly measurable effects occur after longer use of FES. Thus, the protocol was adopted for application in a group of FES users based in a well-established clinical service in Sheffield, UK. The overall aim remained the same – to explore the effect of FES on motor-cognitive interference - but in a larger group of established users using a cross-sectional study design. Chapter 5 describes this study.

Chapter 5 – Cross-sectional dual-task study

5.1. Introduction

At the beginning of the thesis there was very little information on how FES may impact on motor-cognitive interference. One small qualitative study had reported that FES users described use of their device being associated with a reduction in the concentration required to walk (Malone, 2002). In questionnaire studies users had consistently highly rated the effect on effort reduction as important (Taylor et al., 1999b, Taylor, 2004). These effects of FES were first explored in detail in the questionnaire study, described in Chapter 3. Respondents reported a reduction in the concentration required to walk with FES compared to walking without. Further, they supported statements suggesting performance of specific secondary tasks during walking as easier with FES than without. These results supported the first study of FES for foot drop that used a dual-task methodology to study the effects of FES on motor-cognitive interference during gait. Chapter 4 described the development of this methodology, with particular focus on development of an appropriate task and testing of feasibility of the protocol.

Whilst results varied between participants, there was some evidence to support FES user reported outcomes from the questionnaire study in Chapter 3. Visual task performance was poorer without FES, dropping by up to 20% and 40%, compared with seated performance. With FES, particularly for one participant (B), levels of visual task performance were close to those when seated, suggestive of a positive effect of FES on motor-cognitive interference. This supports a perceived reduction of concentration required to walk with FES and the positive effect of FES on secondary tasks; both reported from the questionnaire study. Gait speed results were firstly, indicative of the effect of the visual task, in that speed reduced both with and without FES with the addition of the task. Secondly, the drop in speed under dual-task changed with time; in particular rising for one participant (B) from 5% to 10% for both with and without FES. Speed with FES and task was faster than without FES and task at 14 weeks. Thus, application of the protocol with two new FES-users showed that FES appears to have a positive effect on motor cognitive interference during walking. However, participant numbers were too low to allow firm conclusions to be drawn.

Chapter 4 demonstrated the feasibility of the dual-task protocol in that reductions in both gait speed and visual task performance could be successfully measured during the dual-task condition. The protocol was effective at delivering and measuring motor-cognitive interference and the novel visual task created a sufficient cognitive load. The protocol was also shown to be safe for a group of post-stroke FES-users and achievable; the task was not overly burdensome to perform whilst walking. The practicalities of recruiting new users to this study proved difficult to overcome, and therefore recruitment was stopped. However, application of the protocol and results obtained from the longitudinal study suggested there was merit in studying a larger group to further explore the effect of FES on motor-cognitive interference.

The results from Chapter 4 showed greater and more consistent differences between conditions in gait speed and task performance at 14 weeks than at the previous data collection visits. This indicated that established users of FES may be more likely to exhibit clearly measurable effects during dual-task conditions. In addition, studying a group of established FES users would be representative both of the general FES user population and of the respondents to the questionnaire study, described in Chapter 3, who had clearly identified a positive effect of FES on concentration and dual-tasks. Finally, and most importantly, several well-established clinical services could be accessed in the UK, from which to recruit an appropriate sample of established FES-users. Thus, the dual-task protocol was applied to a group of established users of FES.

The study reported in Chapter 4 focused only on speed as the measure of motor performance. However, Chapter 3 results showed that FES-users reported other effects of FES on gait stability which are measurable in the laboratory setting e.g. over 80% agreed that walking was more balanced and even. In this study the analysis of gait is therefore extended to investigate how gait parameters that are reflective of gait stability and balance may be affected by FES and motor-cognitive interference. Stroke gait was reviewed in Chapter 2, section 2.3.4a, noting the lack of data defining the characteristics of foot drop gait, resulting in largely a description of hemiparetic gait. Post-stroke gait is typically slow as well as being characterised by abnormal temporal and spatial parameters. Of these abnormal parameters, there are those that are more closely associated with maintenance of balance and may be associated with falls risk. Due to the increased risk of falls in post-stroke populations, also discussed in Chapter 2 (section2.3.4b), the importance of these measures is

elevated when assessing the effectiveness of FES. The literature associated with the gait parameters measured in this study is discussed in the following paragraphs, in the context of the aspects of gait that have been identified by FES users as of high importance.

As previously mentioned, respondents to the questionnaire study in Chapter 3, identified that FES use had a positive effect on various aspects of walking. Over 80% of respondents agreed that FES made their walking more balanced and even. In addition, over 70% agreed that FES increased their ability to walk on uneven ground. This latter outcome is in agreement with several studies that have identified an improved ability with FES to walk on uneven ground, walk on carpet and avoid obstacles (Burridge et al., 2007a, Laufer et al., 2009). The indication from both qualitative and quantitative outcomes is that FES has an effect on improving balance during gait and on improving the ability to negotiate non-smooth walking surfaces.

The maintenance of balance whilst walking is closely linked to maintaining postural stability; the ability to maintain the position of the body's centre of mass within specific boundaries (Lord et al., 2007). For example, during double support the boundary is defined by the area of both feet, whereas during single support this is reduced to the area bounded by a single foot – an inherently more challenging task. Thus perturbations of the centre of mass outside the boundaries, defined by the base of support, challenges balance and heightens the risk of falling (Winter, 1995). Maintenance of balance during walking is a particular challenge in post-stroke gait due to the presence of weakness, cognitive impairments and often maladapted reflexes (Lord et al., 2007, Carr and Shepherd, 2011).

A balanced gait would be characterised by a normal representation of the phases of the gait cycle, both per leg but also between legs, with stance accounting for 60% and swing phase for the remaining 40% of cycle time. In post-stroke gait, the swing phase of the paretic leg is typically longer than the non-paretic leg, being measured as 39.8 ± 4.6% vs 21.5 ± 4.5% in a study by Chen et al (2005). To date there have been a few FES studies that measured gait phases to assess device effectiveness. In a study of an implantable FES device (Kottink et al., 2012) gait cycle phases were analysed reporting normalised stance phase of 60% and first double support phase of 11% of the paretic limb and single support of the non-paretic limb of 41% after 26 weeks use.

In addition, comparison of the time spent by each leg, in the phases of gait, are a measure of the symmetry of gait. A high asymmetry indicates an uneven distribution of weight-bearing; a situation that is inherently more likely to be susceptible to loss of balance via gait perturbations due to uneven walking surfaces, for example. Thus, gait asymmetry may lead to an increased risk of falls (Woolley, 2001, Yogev et al., 2007, Oken and Yavuzer, 2008). Hemiparetic gait can exhibit greater swing time asymmetry (Chen et al., 2005, Morris et al., 2010). This measure was adopted as an outcome in several studies to assess the effect of FES on balance and fall risk, reporting an improvement of up to 45% (Hausdorff and Ring, 2008, Laufer et al., 2009, Ring et al., 2009).

Respondents to the questionnaire study also indicated that FES had a positive effect on reducing the likelihood of tripping or falling. Over 80% agreed that FES had this effect, plus this was identified as one of three of the most highly rated important reasons for using FES, and 70% felt that FES made it easier to avoid a fall. Whilst there are some limitations associated with this result (see section 3.7.2c) this is an important effect of FES for users and is reflective of the effect of FES on the quality of their gait. The importance of this effect to FES users concurred with outcomes from both previous studies by Taylor et al (1999, 2004). Despite the importance of avoiding a fall, only one study has reported on the incidence of falls with FES, finding a 92% reduction with FES use over a two month period (Hausdorff and Ring, 2008). This paper also assessed change in stride time variability with FES use as an indicator of improvement in gait rhythmicity, but also due to a strong link with this gait parameter and falls risk in the literature (Hausdorff et al., 1997, Hausdorff et al., 2001). After 8 weeks use stride time variability was reduced by 33% which indicated improved stability (Montero-Odasso et al., 2012). Lower stride time variability, which is the stride-to-stride fluctuations in gait, is thought to reflect less higher cognitive control of gait and more efficient gait patterns (Hausdorff, 2005).

These FES studies suggest that some of the typical temporal abnormalities seen in post-stroke gait, affecting gait cycle phases, gait asymmetry and stride time variability, can be improved by the use of FES. By improving them the assumption is that gait is more balanced, even and rhythmical, and subsequently less susceptible to perturbation. The effect of FES on these parameters may in some part be due to a reduction in motor-cognitive interference during walking facilitated by FES.

A small number of dual-task stroke studies have reported on gait parameters that have been affected by the addition of a cognitive task. Double support time has been shown to be susceptible to dual-task interference in stroke groups by an increase in the amount of time spent in this phase of gait (Bowen et al., 2001, Plummer-D'Amato et al., 2010). Both studies note that this increase may be indicative of a disruption to balance during walking. In fact, an increase in this parameter is suggested to be an attempt to stabilise gait (Maki, 1997).

Furthermore, paretic single limb support time (i.e. non-paretic swing time), has been shown to be especially susceptible to dual-task interferences in stroke groups (Plummer-D'Amato et al., 2008, Plummer-D'Amato and Altmann, 2012). Single support in the paretic limb is a particularly vulnerable aspect of stroke gait, firstly due to the inherent challenges to balance during single support, and secondly in stroke due to loss of muscle control and power, reducing the ability to bear weight whilst in single support. Both of these studies noted a reduction in the time spent in single support on the paretic limb under dual-task conditions, suggesting adoption of a cautious gait.

Abnormal spatial gait parameters also characterise post-stroke gait. Step length can be altered, with either limb exhibiting a shorter step length (Chen et al., 2005). In a dual-task study the difference in step length between single and dual-task distinguished fallers and non-fallers in a stroke group. Fallers exhibited a larger decrement between the single and dual-task conditions in non-paretic leg step length (Baetens et al., 2012). Stride length is also typically reduced in hemiparetic gait (Morris et al., 2010). Differences in stride length, under dual-task conditions, in a post-stroke group have been found to distinguish fallers from non-fallers, with the latter exhibiting longer strides (Hyndman et al., 2006). Therefore, the small number of studies investigating the effects of cognitive tasks on post-stroke gait, indicate that in response to motor-cognitive interference, people revert to a more stable base of gait in which more time is spent with two feet in contact with ground (i.e. double support) and less time is spent on the weaker leg. Furthermore, the perceived risk to balance and the potential to fall is presumably translated into an approach that shortens stride and step length. Measuring these gait parameters, which are susceptible to dual-task interference in post-stroke gait, in the current study, may provide evidence of the effect of FES on gait that relate to user perceptions such as improved safety and increased avoidance of falls.

The primary research questions for this dual-task study of established FES users were:

- Does FES reduce the effect of a cognitive task on speed and gait parameters associated with balance and stability?
- Does FES improve performance of cognitive task whilst walking?

The secondary research question was:

- Can changes in gait and/or cognitive task be explained by factors other than the presence of absence of FES i.e. confidence of avoiding a fall, cognitive ability, overall independence or sensory neuropathy?
- Can observed changes in performance be related to self-reported effects?

This chapter begins by briefly describing the protocol used in this study, with reference to the previous study and highlighting key differences. The results are then presented and analysed, followed by discussion of results, including analysis of the results in the context of questionnaire results for this group of FES users. Finally, the chapter concludes with a discussion of limitations and conclusions drawn.

5.2 Protocol

This study recruited participants from a well-established NHS FES service based at the Northern General Hospital in Sheffield, UK. The patients from this service attended for review of their FES device, following initial set-up and issue, at 3 months then again at 6 months and continued to be seen every 12 months for review. The clinicians offered to assist in recruitment from their patient caseload of established users and also offered use of their clinical and gait laboratory facilities to collect data.

The needs of the clinical service were balanced against the requirements of the study. Thus, patients who were due for clinical review, during the period of participant recruitment, were invited to take part in the study. Those who agreed to take part and fulfilled the inclusion criteria were seen at the Sheffield clinic by the researcher for data collection and were also seen by the clinicians, on the same day, for their clinical review. Thus, participants were not required to attend the clinic for a separate data collection appointment.

The clinical service accommodated the extra appointment time required for data collection. This was restricted to a minimum to avoid a significant disruption to service provision. A maximum of three trials per walking condition was accommodated, however the number of markers used to derive kinematic data was minimised to ensure good marker visibility per trial and thus avoid poor trials and the need for replication of trials. The minimum marker set facilitated identification of gait events i.e. heel strike and toe off, allowing for subsequent calculation of spatio-temporal gait parameters. Gait speed was collected as part of the clinical review via use of light gates; this data was shared between the clinicians and the researcher.

The following describes details of the protocol, referring to similarities and differences with the protocol followed in the previous study, described in Chapter 4, as necessary.

5.2.1 Sheffield protocol

Participants' progression through the study is illustrated by Figure 5.1.

a) Participant selection criteria

Participants included in this study fulfilled all of the following inclusion criteria:

- 18 years and older
- 3 months or more use of single channel FES
- Unilateral foot drop due to CVA
- Able to understand spoken and written English

Participants included in this study had been using their FES for three months or more. As discussed in the context of the design of the previous longitudinal study (see section 4.2.1), there is a general trend of improvement in gait speed with time and an indication that this can continue for many months after first use of FES. Some studies have shown continuing improvement in gait speed at 26 weeks or more (Kottink et al., 2007, Laufer et al., 2009, Stein et al., 2010). However there is evidence to suggest that by 3 months of FES use any further changes in speed and gait patterns would be slowed (Burridge et al., 1997a, Burridge et al., 1997b). In addition, the clinicians who ran the FES service in Sheffield concluded from their own

clinical observations that by 3 months of FES use the gait of the majority of their caseload had stabilised.

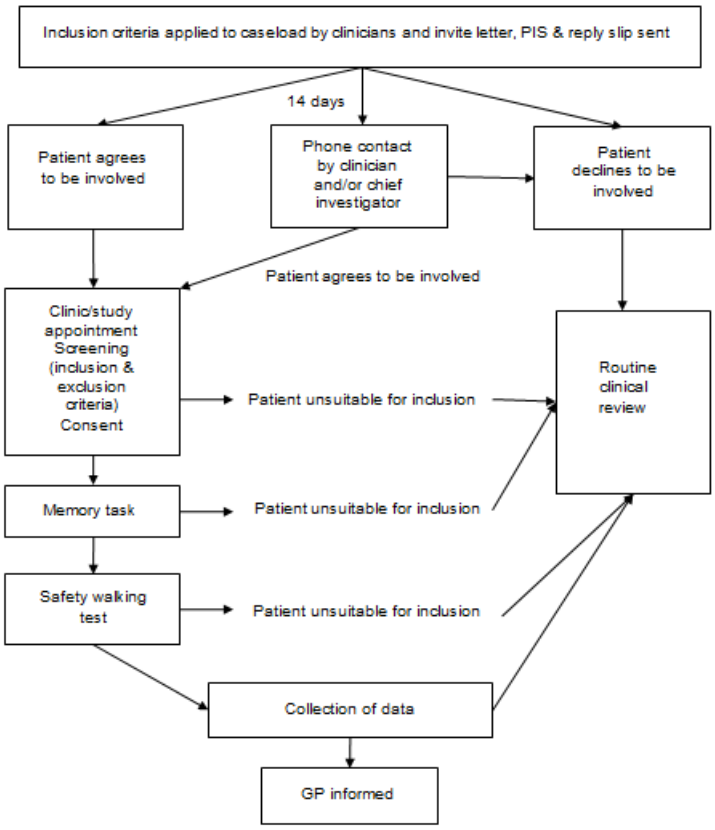


Figure 5.1: Flowchart of participant progression through the trial.

Potential participants were excluded if any of the following exclusion criteria were fulfilled:

- Past medical history or current medical status, including medication and ongoing treatment or planned investigations that contra-indicated participation e.g. Parkinson's disease, investigations for possible cancer.
- Involvement in another research study that would have confounded study results.
- Inability to follow and participate in the Visual Memory Test.
- Trip or near fall when walking without their FES whilst performing the memory test (i.e. test trial for risk of falling as part of screening process).

b) Recruitment process

Clinicians at the FES clinic at the Northern General Hospital in Sheffield identified potential participants from their patient database, who satisfied the inclusion criteria

and were due for their clinical review as part of their routine care. Participant invitation letters and information sheets were sent (Appendix C.1 and C.2) which included a reply slip (Appendix C.3) and stamped addressed envelope. In the letter, the potential participants were asked to either telephone the researcher or return the response slip, indicating either that they would like to be considered for the study, or that they would not. Those who were interested in being involved in the study voluntarily provided the researcher with their preferred contact details by contacting the researcher either by phone or by using the reply slip. Potential participants were asked to contact the researcher, rather than the clinicians at Sheffield, to reduce the time spent by the clinicians supporting this study.

Those who advised that they did not wish to be contacted by the researcher had their name forwarded to the Sheffield clinicians to be appointed for their review. Those who indicated that they were interested in becoming involved were contacted by the researcher and screened for suitability. Their names were then forwarded to the clinicians to be appointed either to the data collection sessions or for a normal review if they were screened as not suitable.

After 14 days the clinicians followed-up by phone those patients who had not been in touch with the researcher, to address the appointment scheduling issue. Those who expressed an interest in participating in the study (and hence who required a longer appointment slot) were asked if they agreed to the researcher contacting them and for their contact details being forwarded to the researcher. If they agreed, the researcher then contacted these remaining potential participants to screen them for suitability and the outcome of this was forwarded to the clinicians.

c) Screening

The participants attended the FES clinic at the Northern General Hospital in Sheffield. Their partner, family member or friend was present during data collection at their request. An initial discussion occurred during which the inclusion criteria were checked as fulfilled and the exclusion criteria were ruled out. Informed consent was obtained and the consent form was signed by the participant (Appendix C.4). The participant then completed, whilst seated, the memory test that was used i.e. visual recognition memory test. This assessed their ability to understand and follow instructions, and thus their ability to participate in the study. Those participants found

to be unsuitable to proceed with involvement in the study at this stage, were then seen by the clinical staff for their normal clinical review, and no further study data was collected.

Those participants assessed as suitable to proceed with their involvement at this point were then assessed for risk of falling during their participation. As in the previous study, they performed the visual memory test whilst walking without FES, whilst a member of the research team walked with them. If the participant tripped, nearly fell or felt unsafe during this test trial they did not continue with their participation in the study, and were seen by the clinical staff for their normal clinical review.

Those participants assessed as suitable to proceed with their involvement were then asked further questions and also asked to complete further tests. These are described in the following sections.

If agreed via completion of the appropriate section on the consent form, the participant's GP and other appropriate health professionals were informed of their inclusion in the study via letter (Appendix C.5).

d) Gait parameter and task performance collection

Measures of gait and task performance were collected following the protocol described in Section 4.4.2c. Thus, gait parameters were collected under the same four walking conditions and a baseline measure of task was collected whilst seated.

The gait laboratory set-up is illustrated by Figure 5.2. The participants walked in one direction only for all trials; towards the monitor upon which the figures for the task were projected. The total length of walkway was approximately 10m; 7.9 m of which was defined by light gates at each end, with approximately 1m at either end to allow acceleration before passing the gate and deceleration of gait after passing the other gate. The light gates were used to calculate gait speed.

A wall-mounted 8 camera Vicon MX motion analysis system, collected kinematic data at 100Hz. During walking trials, 9mm reflective markers were placed on the shoes and lateral malleolus as illustrated by Figure 5.3. One marker was placed on the heel at the most posterior point of the midline of the shoe (labelled 'heel marker' in

subsequent sections), and this was used to identify heel strike in analysis. Three markers were placed across the metatarsophalangeal joints; dorso-medially on the first, dorsally between the second and third and dorso-laterally on the fifth. The marker placed between the second and third metatarsophalangeal joints was used to identify toe-off during analysis (labelled 'toe marker' in subsequent sections). The other two markers were used to identify last point of foot contact if the participant's foot did not leave the ground through the most distal part of the foot, but alternatively through the medial or lateral part of the foot. Similarly, the medial and lateral toe markers were also used to identify the first point of foot contact in those participants who did not initially strike with the heel; striking with midfoot or forefoot. A final marker was placed on the lateral malleolus, to facilitate construction of a foot model to aid analysis in Visual 3D. Video cameras, synchronised with the Vicon motion analysis system, were placed at the far end and midway along the walkway and captured video footage of each gait trial.

Figure 5.2: Gait laboratory set-up showing monitor for projection of visual task, Vicon cameras and video cameras.

Kinematic data was reconstructed using Nexus 1.5.2 and then analysed using Visual 3D. No filtering of marker data was performed; plots of marker positions were visually assessed finding minimal noise (i.e. randomised digitising errors) (see Figure 5.4 for

an example plot). Visual identification of gait events using kinematic data and visual inspection of video and model data was used. As explained below, video footage also aided identification of gait events in this study, which has been found to be reliable in the identification of heel strike and toe-off (Wall, 1996).

Figure 5.3: Reflective marker placement.

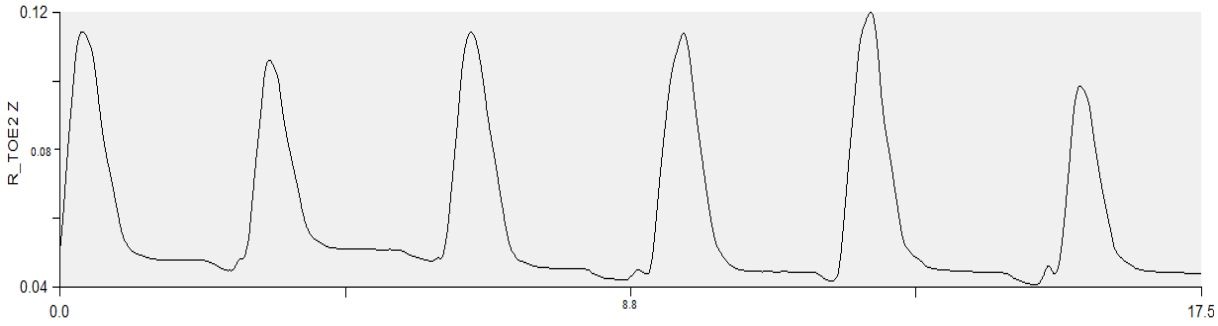


Figure 5.4: Example plot of marker position; toe marker plot, x-axis time in seconds, y-axis vertical displacement in metres.

Video footage, together with inspection of the foot model created in Visual 3D was used to identify the point of initial foot contact in participants who did not strike with their heel. In these trials, the first point of foot contact was labelled as heel strike. Video footage and inspection of the foot model created in Visual 3D was also used to identify lift-off in those trials where participants did not transfer weight through the distal foot e.g. lift-off medially through the hallux due to an abducted foot position. In the remaining cases, the vertical component of heel and toe marker position data, expressed in the global lab coordinate frame, were plotted against time and used to visually identify each individual initial contact and lift-off. Heel strike and lift-off

(termed toe-off throughout the subsequent parts of the thesis) times were recorded and these were subsequently used to calculate spatiotemporal gait parameters via the report function of Visual 3D (described in Section f that follows).

e) Other measures

The other measures collected in this study were included, as in the previous study, as measures to describe the population and to address the secondary research question. These measures are the same (with the exception of the FES-I) as those collected in the previous study, as described in section 4.2.4, and are listed below:

- NART
- Digit Span – Forwards and Backwards
- Barthel Index
- Fall and near fall history – questions via proforma
- FRAT
- Falls Efficacy Scale – International (FES - I)
- Assessment of neuropathy
- FES questionnaire

The only exception was replacement of the FES (Falls Efficacy Scale) with the Falls Efficacy Scale – International (FES-I) (Appendix C.6). This scale is a revised and updated version - that is also valid and reliable - of the original Falls Efficacy Scale developed by Tinetti et al (1990). The FES-I measures confidence for avoiding a fall and level of concern about falling (Yardley et al., 2005, Moore et al., 2011). The FES-I is successful in detecting concerns about social activities and more demanding outdoor activities, and is thus useful in evaluating community populations (Yardley et al., 2005). The FES-I has become a widely accepted tool for assessing concern about falling (Delbaere et al., 2010b) and has been analysed as appropriate for assessment of older adults at risk of falling (Helbostad et al., 2010, Greenberg, 2012). Notably the FES-I has been used in an assessment of an AFO (Hung et al., 2011).

Participant descriptors were also collected as follows:

- Participant descriptives – age, sex
- CVA history – date of CVA, hemisphere affected, other effects of CVA
- Use of walking aids/orthoses
- Approximate use of FES i.e. on a daily/weekly basis

f) Data analysis

i) Sample size

Data collected from the previous longitudinal gait laboratory study and pilot work to inform development of the study protocol was analysed to estimate a sample size for this study. Following statistical advice, changes in speed and performance of cognitive task across conditions were compared. Analysis of gait speed results for seven trials of each condition from four participants to calculate sample size is detailed in Table 5.1. Decrements in gait speeds between conditions were calculated to obtain a percentage change in gait speed, from which the standard deviation (SD) was calculated. As each participant was measured under all conditions the results could be compared using the paired t-test and hence the notation for use of Altman's nomogram (Petrie and Sabin, 2009) of $(2 \times \delta) \div \sigma_d$ to obtain the standardised difference could be applied to obtain the sample size for each comparison.

Condition compared to without FES, with task to obtain decrement	With FES, without task	With FES, with task	Without FES, without task
σ_d[1]	10.1%	12.3%	9.1%
δ[2]	7.9%	7.9%	7.9%
Standardised difference	1.56	1.28	1.74
Sample size[3]	13	19	10

1. SD of difference between decrements.
2. Smallest mean difference. This is the smallest change in gait speed that indicates a clinical improvement in hemiparetic gait (Flansbjer et al., 2005).
3. Calculated at 80% power, 0.05 significance.

Table 5.1: Calculation of sample size based on gait speed results.

Cognitive task performance results for ten trials from five participants was also analysed to calculate sample size in relation to the primary research question of FES improving cognitive performance whilst walking. As each participant was measured under each condition of seated, walking with FES and walking without FES the results could be compared using the paired t-test – i.e. comparison between decrements when two walking condition scores are compared with seated score. In this calculation the smallest mean difference in cognitive task score between conditions was defined as a change in score of 1 (i.e. smallest difference in an individual's score between conditions). Therefore, applying the same notation for use of Altman's nomogram the following was obtained:-

σ_d = 1.36 (SD of difference between decrements without and with FES)

δ = 1 (smallest mean difference nb. the cognitive task is scored out of 10)

Standardised difference = $(2 \times \delta) \div \sigma_d$ = 1.47

A sample size of 15 was required to have an 80% chance of detecting a difference in means of 1 on the cognitive score (SD of difference = 1.36) at the 5% level of significance using the paired t-test.

Therefore the largest sample size (i.e. 19 for gait speed) from all four calculations was sought to ensure that all desired minimal effects are detected. The sample size was increased to 21 to allow for the unlikely event of a possible 10% of participants withdrawing from the study during data collection.

ii) Analysis of data

The participants completed up to three walking trials per walking condition dependent upon their ability. Gait speed was calculated per trial by calculating time taken to walk between light gates placed 7.9 m apart at both ends of the walkway.

The report function of Visual3D was utilised to calculate temporal and distance parameters from heel strike and toe-off events for both feet. Stance time was computed using time between heel strike and toe-off and conversely, swing time used time between toe-off and heel strike. Stride time was calculated as the time between consecutive heel strikes of the same leg. Double support time was computed using time between right heel strike to left heel toe off and left heel strike to right toe-off. Stride length was calculated using the distance between consecutive

heel strikes of the same leg. Step length was calculated using the distance between heel strikes of contralateral legs.

Measures of gait rhythmicity and variability were then calculated using these measures. Stride time variability was characterised as the coefficient of variation (CV), calculated as SD/Mean x 100 (Lord et al., 2011). The gait asymmetry index was calculated using swing time, as follows; 100 x [(swing time paretic – swing time nonparetic)/(swing time paretic + swing time nonparetic)] (Hausdorff and Ring, 2008).

Statistical analysis of differences between the walking and task conditions was performed using SPSS 20, applying repeated measures ANOVAs, with Greenhouse-Geisser correction as appropriate, to gait and task outcome measures. Post hoc testing, using the Bonferroni correction, was applied to reveal significant differences between conditions.

5.2.2 Ethical and R&D approval

Ethical approval was granted by NRES Committee South Central - Southampton A (Appendix C.7), approving an approach to recruitment that differed from the one eventually followed. An application to The University of Salford Research, Innovation and Academic Engagement Ethical Approval Panel was not initially accepted due to concerns with the proposed recruitment process. The application was subsequently approved (Appendix C.8), following a change to the recruitment approach, as described in Section 5.2.1b above. This change necessitated submission of an amendment to the NRES committee which was subsequently approved (Appendix C.9). Approval was also granted by Sheffield Teaching Hospitals NHS Foundation Trust Research and Development Department (Appendix C.10).

5.3 Results

5.3.1 Recruitment

Forty-three potential participants were identified by the clinicians and sent study invitation packs. Of these, 21 expressed an interest in being involved in the study, either by sending a reply slip to the researcher, contacting the researcher by phone or agreeing to being contacted by the researcher after the clinician had followed them up after no response to the initial posting. Of these, 16 attended for data collection

and were all screened as suitable on the day for inclusion in the study. The number of participants recruited to the study represented 37% of the total number contacted.

The remaining 5 did not attend for data collection for the following reasons:-

- 2 people booked appointments but cancelled on the day due to sudden illness and were unable to re-appoint
- 1 person could not attend on the available appointment dates
- 1 person was suffering from heel ulcerations and was not able to use his FES device for the duration of the data collection period
- 1 person was unwell when initially contacted and was then unable to be contacted

5.3.2 Participant descriptors

The characteristics of participants is summarised in Table 5.2. The mean age of participants was 59.6 years (± 17.2) and the time since stroke was 90.7 months (± 87.6). Participants self-reported a range of both stroke-related and other health problems. None of the participants tested positive for sensory neuropathy of the feet.

The mean Barthel Index score for participants was 18.5 (± 1.3). There was little difference in scores between participants and the mean score indicates that they had high levels of independence in their activities of daily living.

The number of errors made during performance of the NART by each participant was used to obtain an estimation of their predicted pre-morbid general intellectual ability (see Chapter 4, 4.2.2b). The mean predicted premorbid IQ for the group was 114 (± 11). The mean IQ for UK residents is 100 (± 15) (Lynn and Vanhanen, 2002). Therefore the group mean was above that for UK residents and the minimum IQ for the group (i.e. 90) was not below the lowest range of the UK average.

Performance on the digit span tests, both forward and backward, were assessed using the raw unconverted scores, against a scale indicating the range of performance abilities (see Section 4.2.2b). For both tests, with exception of two participants, all participants' scores were within normal limits.

Sex male : female *n = 16*	9 : 7	
Mean age years ± SD (range)	59.6 ± 17.2 (22, 81)	
Mean time since CVA months ± SD (range)	90.7 ± 87.6 (12, 348)	
Hemisphere affected by CVA left : right *n = 16*	9 : 7	
Self-reported CVA related problems Upper limb affected Face affected Sight problems Speech affected Memory problems Hearing problems Fatigue **Self-reported health problems** Heart problems/High BP Diabetes Hypothyroidism Lower limb osteoarthritis Back problems Fibromyalgia Osteoporosis **Negative test for sensory neuropathy**	 15 3 10 8 4 1 1 5 1 1 2 2 1 2 16	
Barthel Index score out of 20 ± SD (range)	18.5 ± 1.3 (16, 20)	
Mean predicted premorbid full scale IQ ± SD (range)	114 ± 11 (90, 128)	
Digit span scale *n = 16* Within normal limits Borderline of cognitive deficit Indicative of cognitive deficit	Forward 14 1 1	Backward 14 1 1

Table 5.2: Characteristics of participants (n= 16)

a) Use of FES

The usage of FES by the participants is summarised in Table 5.3. The mean time since participants began using FES was 30.9 months (± 24.0). Participants reported using their device on average for 4.5 days (± 2.0) days a week. On the days when participants used their device they reported using it for an average of 6.0 hours (± 2.4).

Mean time since began use months ± SD (range)	30.9 ± 24.0 (3, 97)
Mean use per week (self-reported) days ± SD	4.5 ± 2.0
Mean use per day (self-reported) hours ± SD	6.0 ± 2.4

Table 5.3: Usage of FES by participants (n=16).

b) Falls descriptors

Tables 5.4 and 5.5 summarise the results of measures taken to assess falls risk, level of concern about falling and falls history. The FRAT results show that the majority of participants were assessed as at risk of falling in the next 6 months. A positive response to three of the five items on the tool identified the participant at risk. One of the items is a diagnosis of stroke hence it is not surprising that the majority of participants were deemed to be at risk. This result is supported by the fall history information, based on recall, from 15 of the participants; one participant did not recall any fall events.

The FES-I scores were categorised, using cut-off points determined in a validation study of the scale (Delbaere et al., 2010b), as low 16 – 19, moderate 20 – 27, and high 28 – 64. Three of the participants had moderate levels of concern, with the majority having high levels of concern. This result concurs with that for risk of falls and the fall history for the group.

FRAT **At risk of a fall** Y:N *n = 16*	**FES-I** **Level of concern** High : Moderate : Low *n = 16*
12 : 4	13 : 3 :0

Table 5.4: FRAT and FES-I scores for the group.

No. of falls	No. of participants	No. of near misses	No. of participants
0	11	0	4
1	3	1	3
2	1	2	7
3	1	3	0
4	0	4	2

Table 5.5: Self-reported falls and near misses by participants (n=16).

5.3.3 Gait speed and visual task performance

a) Gait speed

Results for gait speed for the group, under each condition, are illustrated by Figure 5.5. The Shapiro-Wilk test of normality was applied to gait speed data, using the 'FES off' data as a representation of baseline gait speed, assessing the distribution as normal (df=16, p=0.14).

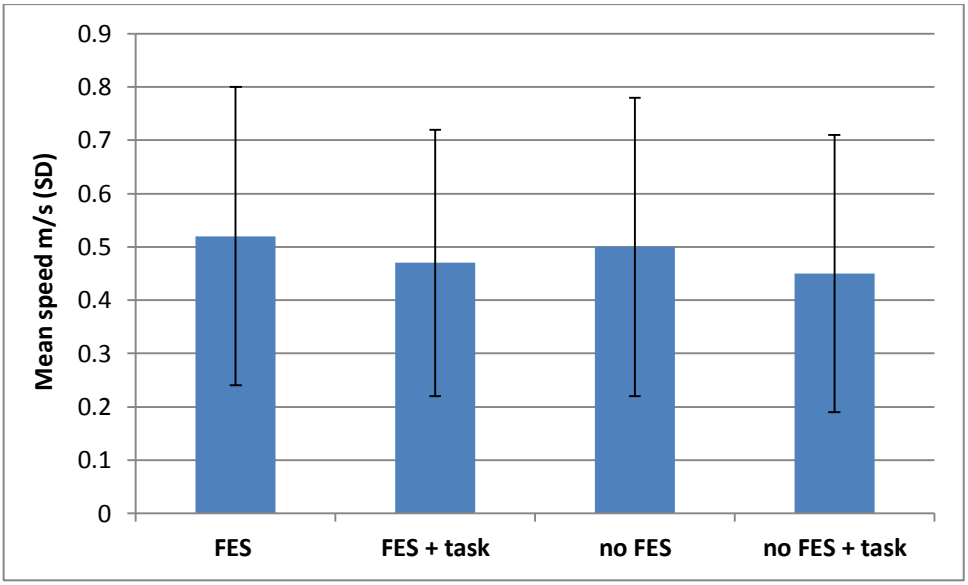


Figure 5.5: Walking speed for the group, for each condition (Mean ± SD).

Fourteen participants completed three walking trials per condition, whilst the remaining two participants were unable to achieve this due to fatigue, completing two walking trials per condition.

There was a statistically significant difference between mean gait speed over the four walking conditions ($F(2.18,45)=15.17, p=0.00001$). Post hoc testing revealed three statistically significant differences in mean gait speed (Table 5.6). Speed showed a statistically significant reduction with addition of task for FES (0.52 ± 0.28 m/s vs 0.47 ± 0.25 m/s, p=0.003) and for no FES (0.50 ± 0.28 m/s vs 0.45 ± 0.26 m/s, p=0.002). This change in speed with addition of task, for both FES and no FES, represents approximately a 10% reduction in speed. It is interesting to note the similarities in differences in speed between these two comparisons and the similar confidence intervals calculated.

Speed with FES was faster than speed without FES plus task, representing an approximate increase in speed of 15%, which was also statistically significant (p=0.0002). There was a 4% increase in speed between FES and no FES, but this did not show statistical significance at p<0.05. There was no statistically significant difference between speed attained with task when walking with or without FES (p=0.256).

Speed (a)	Speed (b)	Mean difference (a-b)	p value	95% CI for difference	
				Lower Bound	Upper Bound
FES	FES + task	0.052*	0.003	0.017	0.087
	No FES	0.026	0.065	-0.001	0.053
	No FES + task	0.077*	0.0002	0.037	0.117
No FES	No FES + task	0.051*	0.002	0.017	0.085
	FES + task	0.026	0.633	-0.072	0.020
FES + task	No FES + task	0.025	0.256	-0.009	0.059

*The mean difference is significant at the 0.05 level.

Table 5.6: Pairwise comparisons results of repeated measure ANOVA, analysing differences between mean speed for each condition.

b) Visual task performance

Results for success of visual task performance are illustrated in Figure 5.6 and shown in Table 5.7. There was a statistically significant difference in task performance between the three task conditions ($F(2,30)=18.29$, p=0.000006). During both dual-task conditions, task success statistically significantly reduced, compared with the seated measure; FES p=0.0003, no FES p=0.0001. There was no significant statistical difference between task performance with and without FES (p=0.405).

Task performance (a)	Task performance (b)	Mean difference (a-b)	p value	95% CI for difference	
				Lower Bound	Upper Bound
Seated	FES	1.325*	0.0003	0.638	2.012
	No FES	1.925*	0.0001	1.036	2.814
FES	No FES	0.6	0.405	-0.423	1.623

*The mean difference is significant at the 0.05 level.

Table 5.7: Pairwise comparisons results of repeated measure ANOVA, analysing differences between task performance for each condition.

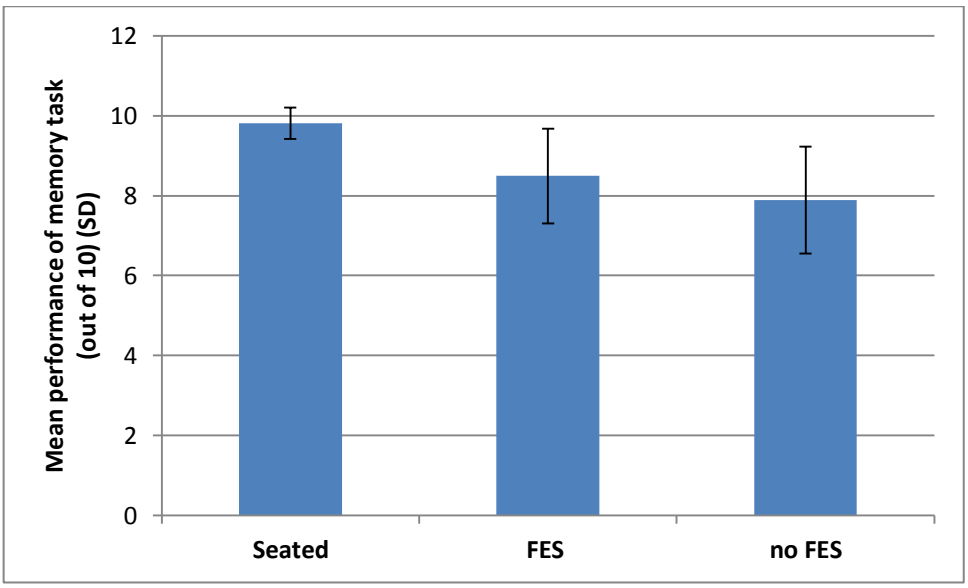


Figure 5.6: Visual task performance for each condition (Mean ± SD).

c) Regression of speed and task

Linear regression was performed of speed during task conditions (i.e. with and without FES) on task results whilst walking (i.e. with and without FES). Scatterplot of values is shown by Figure 5.7. Regression of speed on task found no linear relationship (B= 0.038, p=0.285, 95% CI [-0.033, 0.109]).

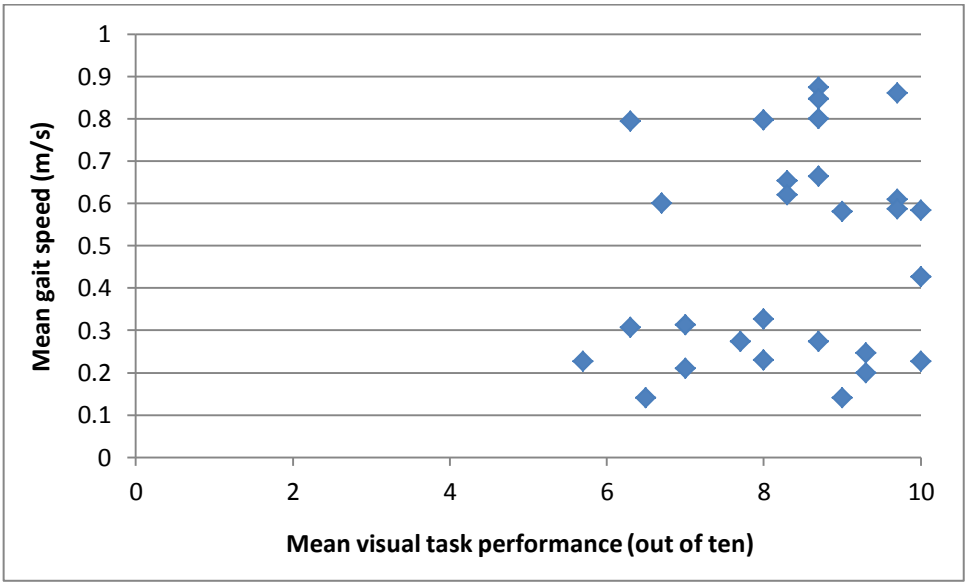


Figure 5.7: Scatterplot of speed vs visual task performance during dual-task conditions, with and without FES.

5.3.4 Gait parameters

Results for temporal and spatial gait parameters are reported, including statistical analysis of differences between results for each condition.

a) Temporal and spatial gait parameters

i) Stride time

Mean stride time (Figure 5.8) statistically significantly differed between the four walking conditions ($F(3,45)=9.86$, p=0.00004). Differences in stride time agreed with those found for gait speed, as would be expected. Stride time statistically significantly increased with addition of task for FES (1.83 ± 0.61s vs 1.91 ± 0.65s, p=0.001) and for no FES (1.95 ± 0.71s vs 2.05 ± 0.79s, p=0.011). Stride time without FES plus task was statistically significantly longer than with FES (1.83 ± 0.61s vs 2.05 ± 0.79s, p=0.009).

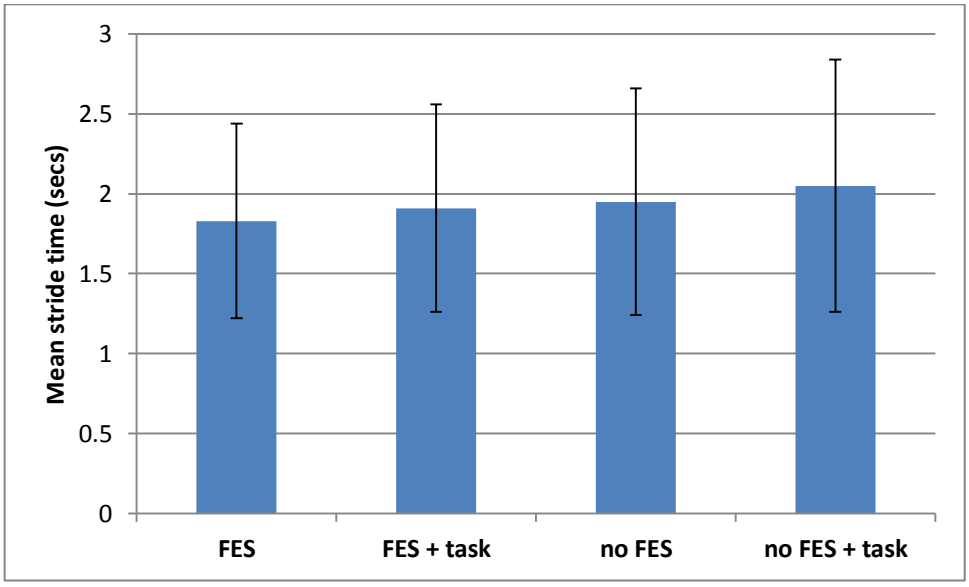


Figure 5.8: Stride time for each condition (Mean ± SD).

ii) Stance time

Stance time under each condition, for both paretic and non-paretic legs is represented by Figures 5.9 and 5.10 These measures of mean time represent a percentage of stride time (i.e. cycle time) for the paretic leg as follows; 67% FES, 69% FES with task, 70% no FES and 72% no FES with task. The percentage of

stride time that these measures represent for the non-paretic leg are as follows; 79% FES, 80% FES with task, 81% no FES, 81% no FES with task.

Stance time, for both paretic and non-paretic legs, statistically significantly differed between the four walking conditions; paretic ($F(1.39,45)=11.80$, $p=0.001$), non-paretic ($F(1.37,45)=9.59$, $p=0.003$). Post hoc test using the Bonferroni correction revealed five statistically significant differences in mean stance time for the paretic leg and four for the non-paretic leg.

Stance time for the paretic leg statistically significantly increased when walking without FES, compared to with FES (1.23 ± 0.53s vs 1.37 ± 0.64s, p= 0.031). The addition of task statistically significantly increased stance time for both FES (1.23 ± 0.53s vs 1.32 ± 0.59s, p=0.001) and no FES (1.37 ± 0.64s vs 1.47 ± 0.73s, p=0.016). FES had the lowest stance time on the paretic leg whilst no FES with task had the highest, with a statistically significant difference between the two (p=0.005). The difference in stance time between the two task conditions was statistically significant; no FES with task had a longer stance time than FES with task (1.32 ± 0.59s vs 1.47 ± 0.73s, p=0.044).

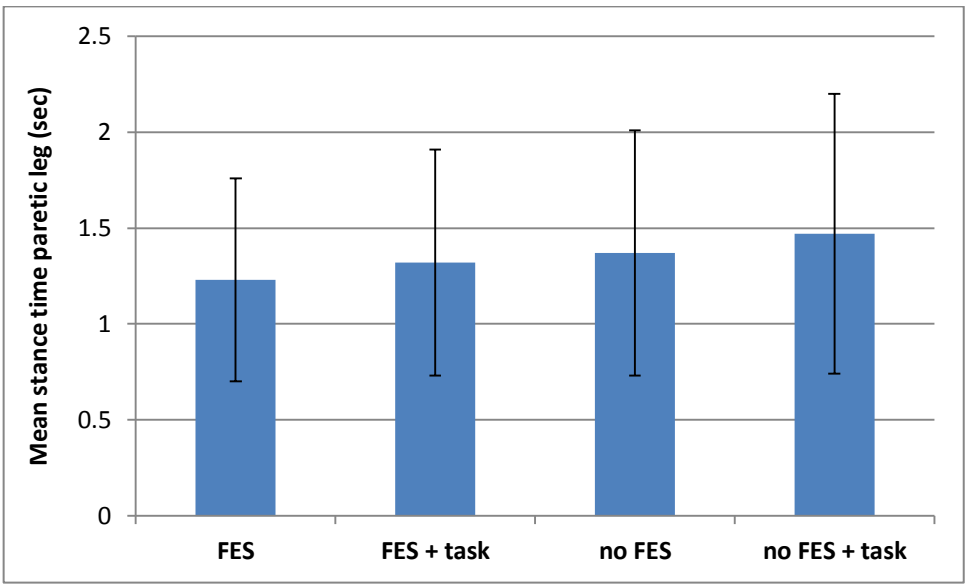


Figure 5.9: Stance time of the paretic leg for all conditions (Mean ± SD).

Stance time for the non-paretic leg statistically significantly increased when walking without FES, compared to with FES (1.44 ± 0.58s vs 1.57 ± 0.68s, p= 0.05). The addition of task increased stance time for both FES (1.44 ± 0.58s vs 1.52 ± 0.62s,

p=0.005) and no FES (1.57 ± 0.68s vs 1.67 ± 0.75s, p=0.02), and both of these were statistically significant increases. FES had the lowest stance time on the non-paretic leg and no FES with task the highest, with a statistically significant difference between the two (p=0.011). The difference in stance time between the two task conditions was not statistically significant (p=0.097).

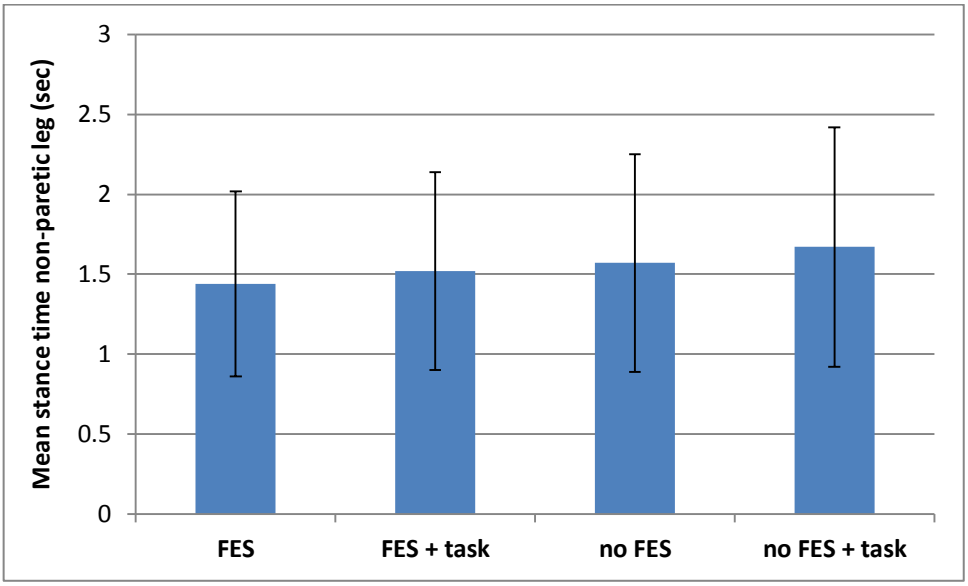


Figure 5.10: Stance time of the non-paretic leg for all conditions (Mean ± SD).

iii) Swing time

Mean swing time, for both paretic and non-paretic legs, under each condition is represented by Figures 5.11 and 5.12. Swing time did not statistically significantly differ between conditions for both paretic leg swing time ($F(1.87,45)=1.04, p=0.36$) and non-paretic leg swing time ($F(2.04,45)=0.27, p=0.77$).

These measures of mean swing time represent a percentage of stride time (i.e. cycle time) for the paretic leg as follows; 33% FES, 31% FES with task, 30% no FES and 28% no FES with task. Swing time on the paretic leg is equivalent to single support time on the non-paretic leg. The percentage of stride time that these measures of swing time represent for the non-paretic leg are as follows; 21% FES, 20% FES with task, 19% no FES, 19% no FES with task. Swing time on the non-paretic leg is equivalent to single support time on the paretic leg.

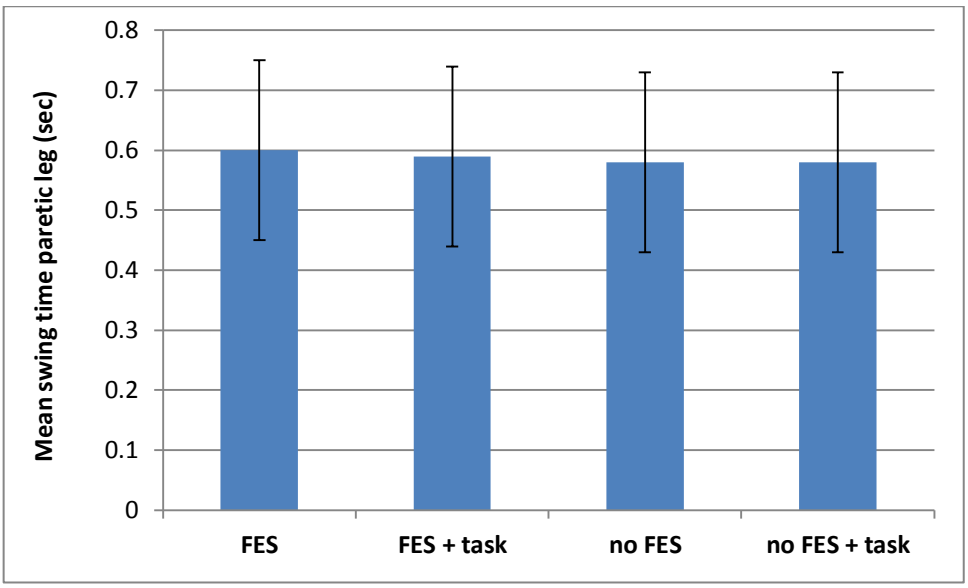


Figure 5.11: Swing time of the paretic leg for all conditions (Mean ± SD).

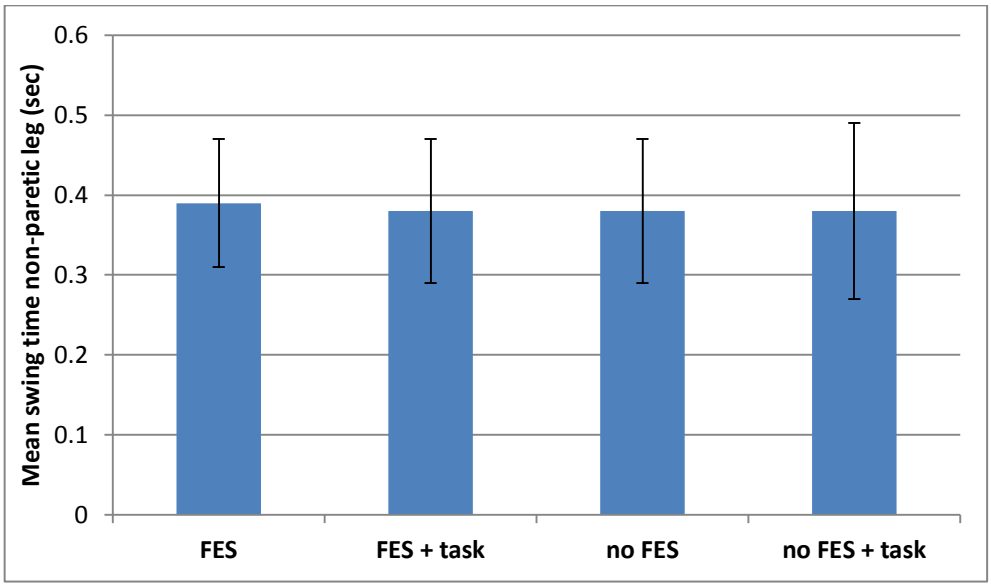


Figure 5.12: Swing time of the non-paretic leg for all conditions (Mean ± SD).

iv) Double support time

Double support time under each condition is illustrated by Figure 5.13. These represent a percentage of stride time (i.e. cycle time) as follows; 46% FES, 49% FES with task, 51% no FES and 53% no FES with task. Mean double support time statistically significantly differed between the four conditions ($F(1.36,45)=11.76$, p=0.001). It statistically significantly increased when walking without FES, compared to with FES (0.85 ± 0.52s vs 0.99 ± 0.63s, p= 0.025). The addition of task increased double support time for both FES (0.85 ± 0.52s vs 0.94 ± 0.58s, p=0.001) and no

FES (0.99 ± 0.63s vs 1.09 ± 0.71s, p=0.018); both of these increases being statistically significant. FES had the lowest double support time and no FES with task the highest, with a statistically significant difference between the two (p=0.006). The p value for the difference in double support time between the two task conditions was just above the significance level, set at 0.05, at 0.051; with FES and task had a smaller double support time than without FES and task.

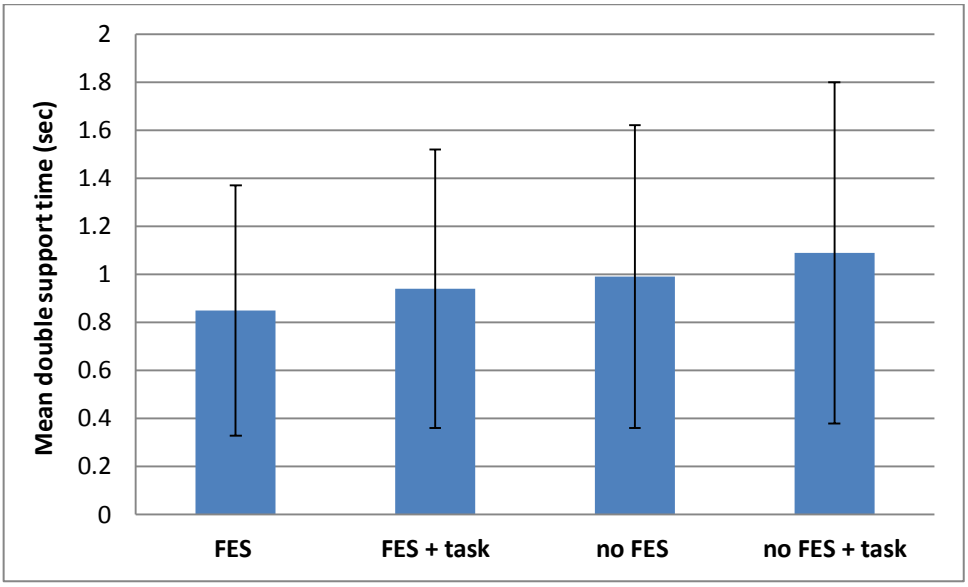


Figure 5.13: Double support time for all conditions (Mean ± SD).

b) Spatial gait parameters

i) Step length

Step lengths for both the paretic and non-paretic legs are illustrated by Figures 5.14 and 5.15. Mean step length, for both paretic and non-paretic legs, statistically significantly differed between the four walking conditions; paretic (F(2.26,45)=8.20, p=0.001), non-paretic (F(1.49,45)=5.29, p=0.02). Post hoc test using the Bonferroni correction revealed three statistically significant differences in mean step length for the paretic leg and the non-paretic leg.

Step length for the paretic leg statistically significantly decreased with the addition of task for both FES (0.44 ± 0.14m vs 0.42 ± 0.14m, p=0.02) and no FES (0.44 ± 0.15m vs 0.41 ± 0.1m, p=0.006). There was also a statistically significant difference between FES and no FES with task (p=0.03).

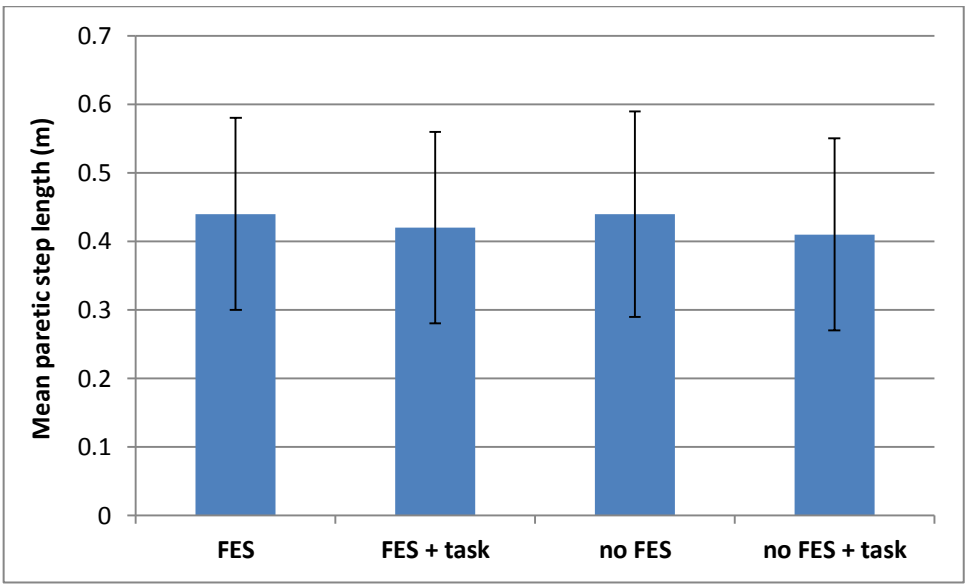


Figure 5.14: Step length of the paretic leg for all conditions (Mean ± SD).

Step length for the non-paretic leg statistically significantly decreased with the addition of task for both FES (0.39 ± 0.18m vs 0.37 ± 0.18m, p=0.004) and no FES (0.38 ± 0.18m vs 0.36 ± 0.18m, p=0.013). There was also a statistically significant difference between FES and no FES with task (p=0.006).

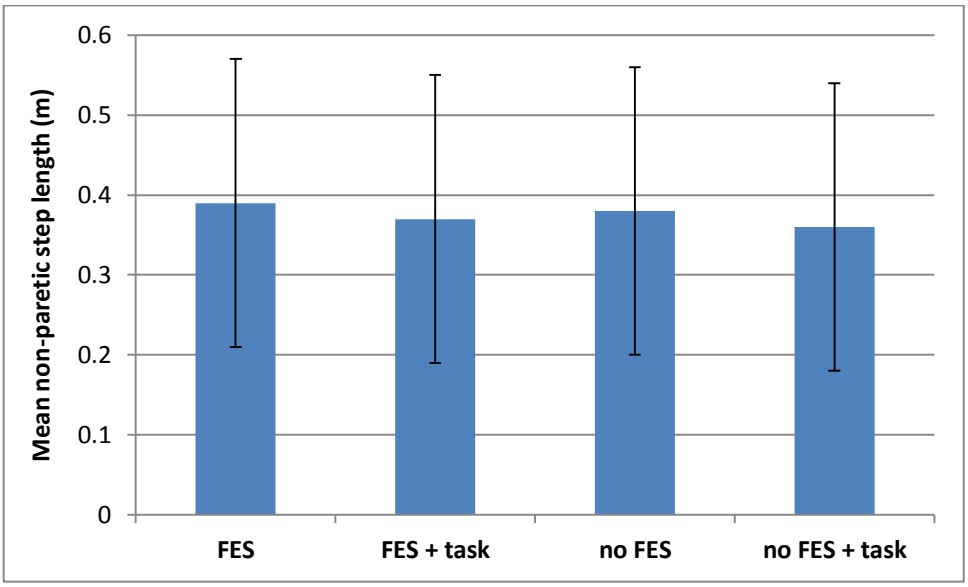


Figure 5.15: Step length of the non-paretic leg for all conditions (Mean ± SD).

ii) Stride length

Mean stride length (Figure 5.16) statistically significantly differed between the four conditions ($F(3,45)=16.87$, p=0.000000). There was a statistically significant

decrease in stride length with the addition of task for both FES (0.84 ± 0.31m vs 0.79 ± 0.3m, p=0.001) and no FES (0.81 ± 0.32m vs 0.77 ± 0.3m, p=0.002). FES had the longest stride length and no FES with task the shortest, with a statistically significant difference between the two (p=0.00003).

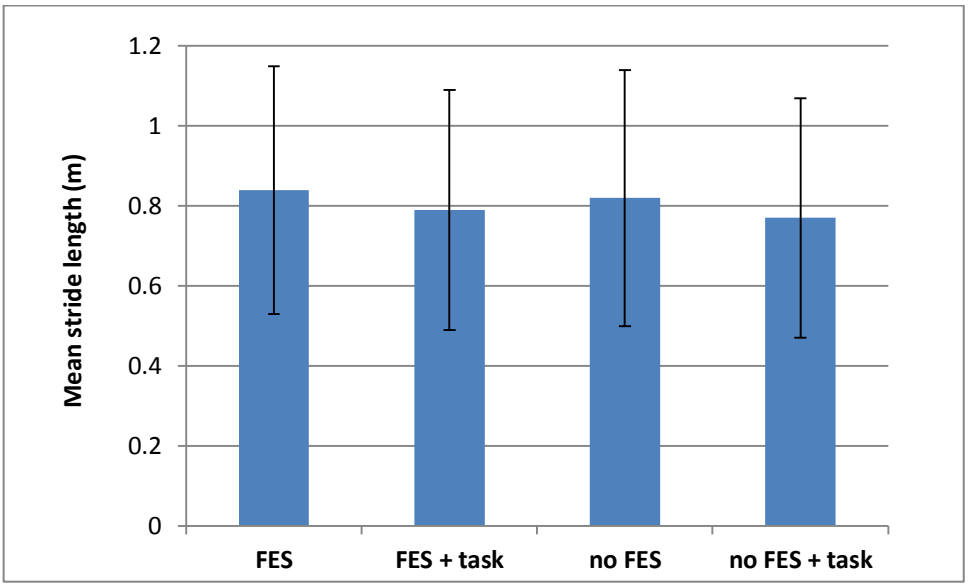


Figure 5.16: Stride length for all conditions (Mean ± SD).

c) Gait stability and balance

i) Stride time variability

The number of steps for both the paretic and non-paretic leg was collected for walking trials. The results for trials with FES for each participant, which produced the least number of steps over the capture area, as a result of fastest walking speeds were analysed for total number of steps of all the trials. Those trials that collected less than 12 steps per leg were removed from the analysis of stride time variability. This is in agreement with suggested recommendations from a recent review paper (Lord et al., 2011). The average number of steps for the remaining 11 participants, for each walking condition was 18.6 ± 4.9.

Mean stride time variability under each condition is represented by Figure 5.17. Repeated measures ANOVA determined that stride time variability did not statistically significantly differ between conditions ($F(1.8,30)=0.77, p=0.47$).

The difference between stride time variability measures for FES and no FES represents a 29% reduction with FES. There was also a 29% reduction in stride time variability with FES when task was removed.

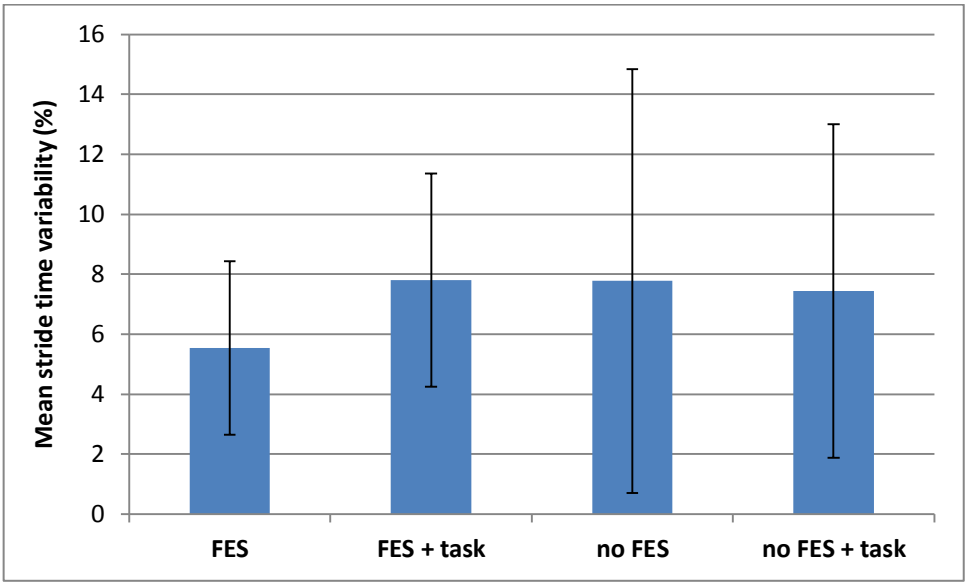


Figure 5.17: Stride time variability for all conditions (n=11, Mean ± SD).

ii) Gait asymmetry

Gait asymmetry, calculated using swing time, under each condition is represented by Figure 5.18. For gait to be symmetrical the index value should be close to 0. The results for each walking condition show that gait was not symmetrical for each condition for the group. Mean gait asymmetry did not statistically significantly differ between the four conditions ($F(1.78,45)=0.49$, $p=0.59$).

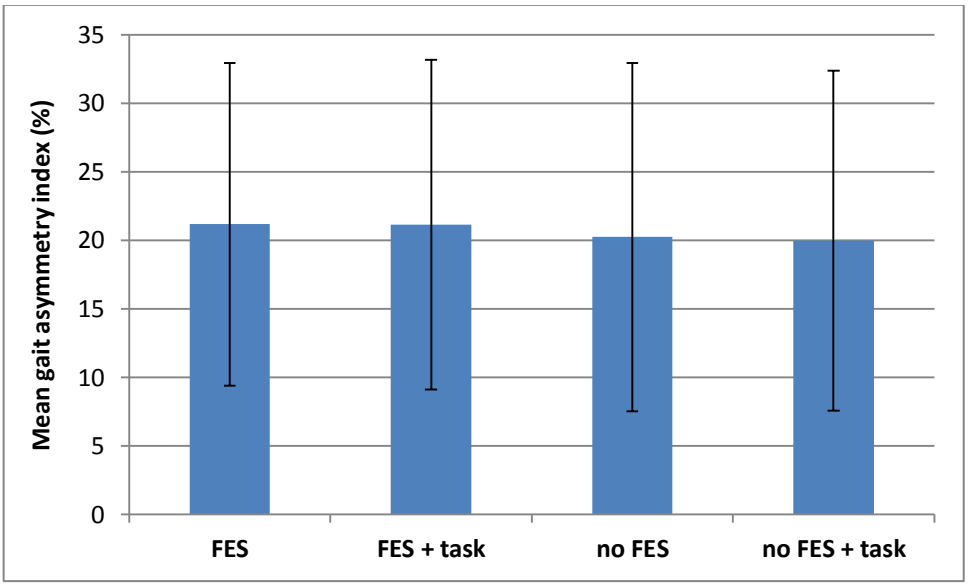


Figure 5.18: Gait asymmetry index for all conditions (Mean ± SD).

5.3.5 Questionnaire results

The results for the questionnaire completed by the participants follow.

a) Activities and walking aid use

The activities undertaken by the participants, either with or without FES, are illustrated by Figure 5.19. The top five activities performed with FES were longer walks, shopping, walking outdoors, day trips and social events. The top three activities performed without FES were exercising, walking indoors and walking around the home.

The use of walking aids by the participants is shown by Figure 5.20. Each participant could use any of the walking aids both with and without their FES, thus results for the aids are in excess of the total number of participants. A walking stick was the most frequently used aid both with and without FES. The other aids were used infrequently by participants.

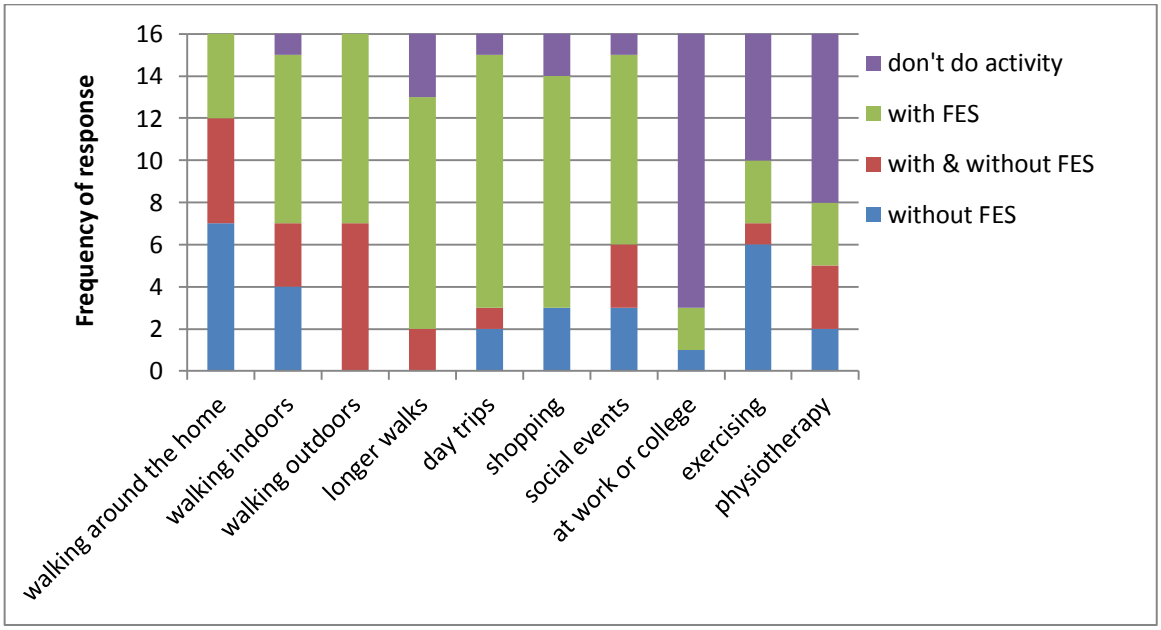


Figure 5.19: Activities undertaken by participants, both with and without FES.

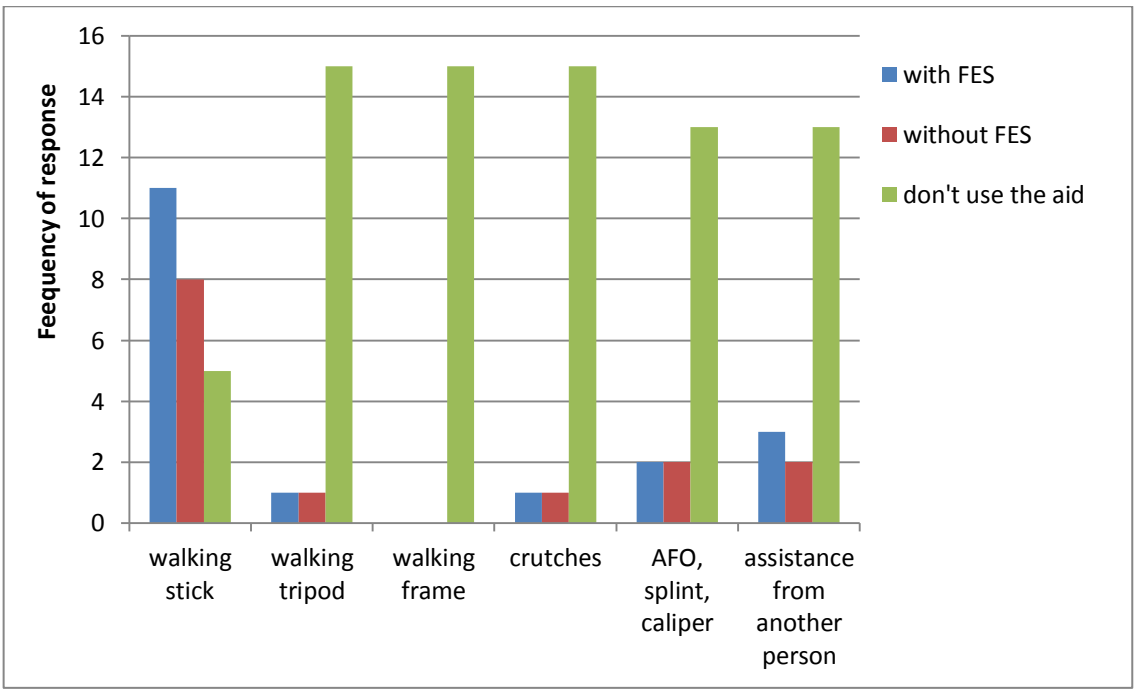


Figure 5.20: Use of walking aids by participants, both with and without FES.

b) The effect of FES

The response by participants to statements about the effect of their device is shown by Figure 5.21. Over 50% or more of participants agreed with 10 of the 13 statements. 15 agreed that they were able to walk more safely with their FES device. Furthermore, 14 participants agreed that they were less likely to trip or fall and that their walking was more balanced and even. 13 felt that they were able to walk further and faster, that they were more confident when they walked and that they were more independent with FES. 12 participants felt that they were able to walk with less effort and 10 felt that they were more able to walk on uneven ground. 9 participants felt that their posture was better with FES.

11 participants disagreed with the statement that they could use their walking aid less often, with the remaining 5 participants responding that this statement did not apply to them. Furthermore, 6 participants disagreed that they were more able to walk on uneven ground with FES. 6 participants felt that with FES they were able to walk without the assistance of another person, 4 disagreed with this statement and 6 did not feel that this statement applied to them. 5 were able to exercise more whereas 4 were not able to and a further 7 noted that this statement did not apply to them.

When participants were asked which of these effects was the most important, the most highly rated by 4 participants was increased confidence when walking (Figure 5.22). The next most highly rated by 3 participants was an ability to walk more safely, followed by less effort to walk and less likely to trip or fall, which were both chosen by 2 participants.

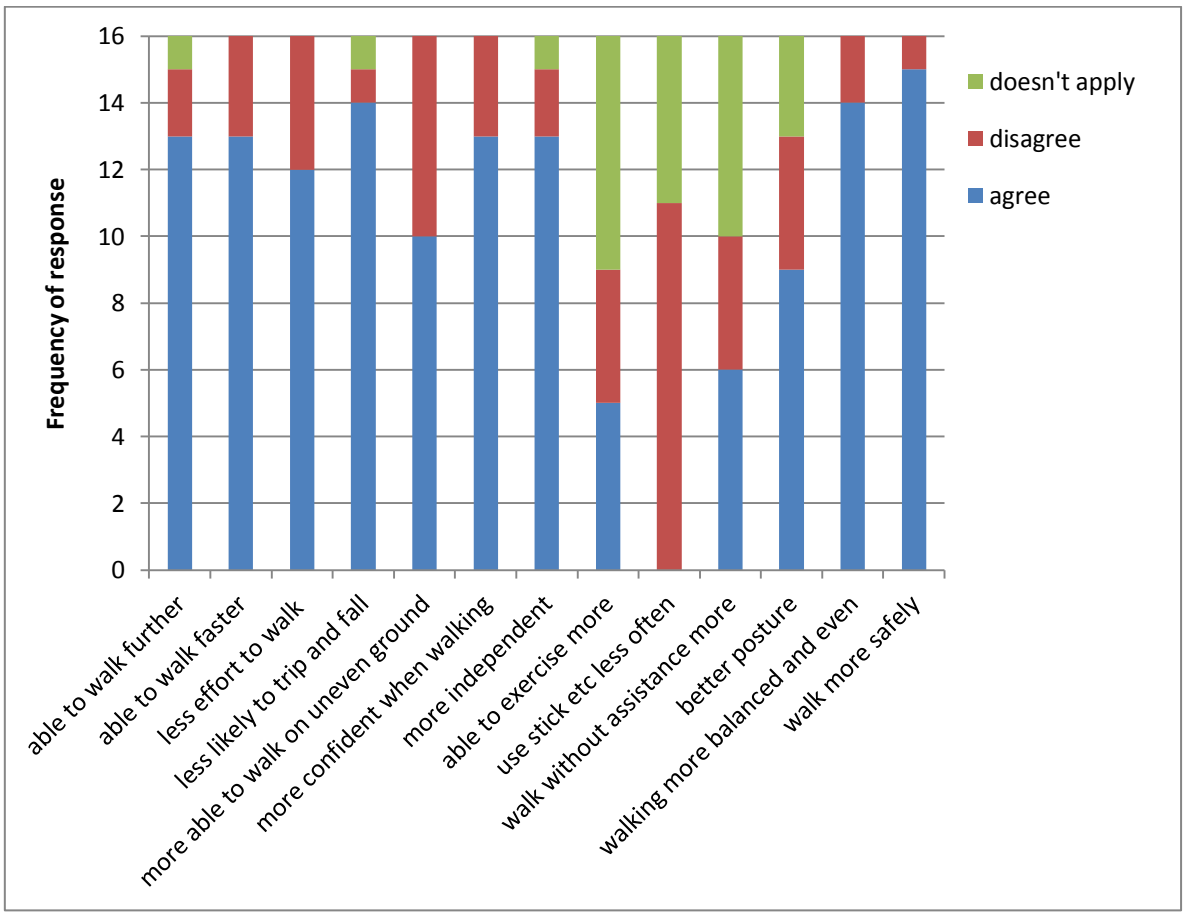


Figure 5.21: Frequency of response to effects statements by participants.

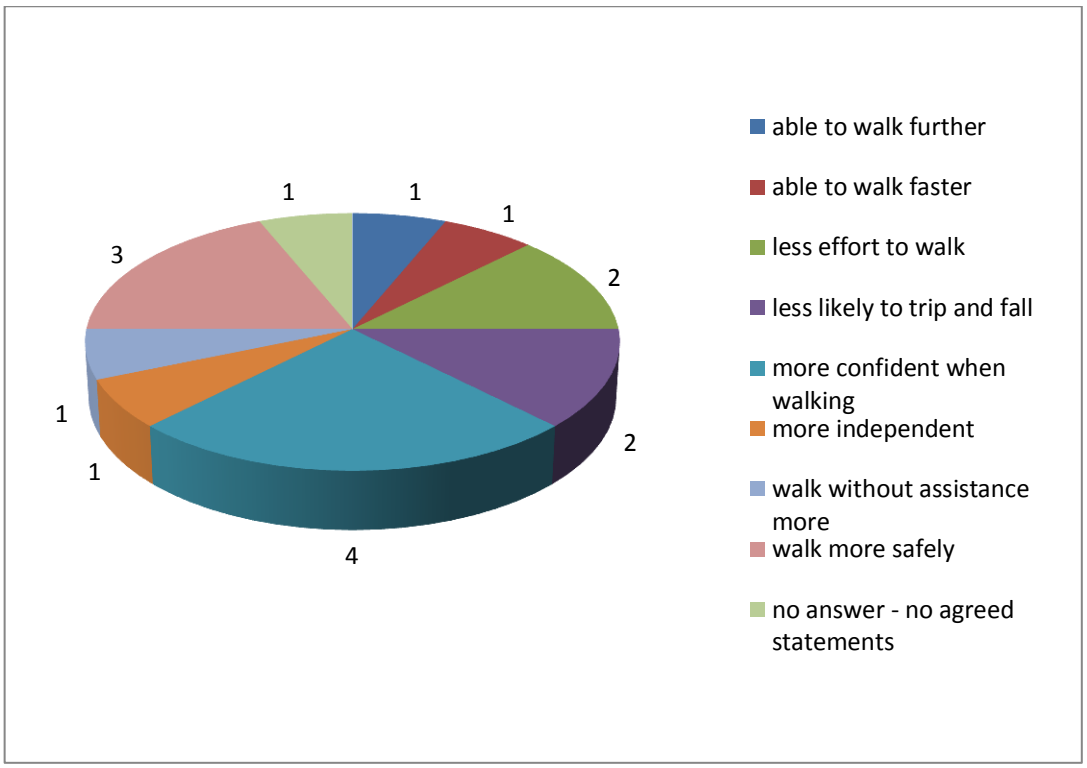


Figure 5.22: The frequency of the most important effect chosen by participants.

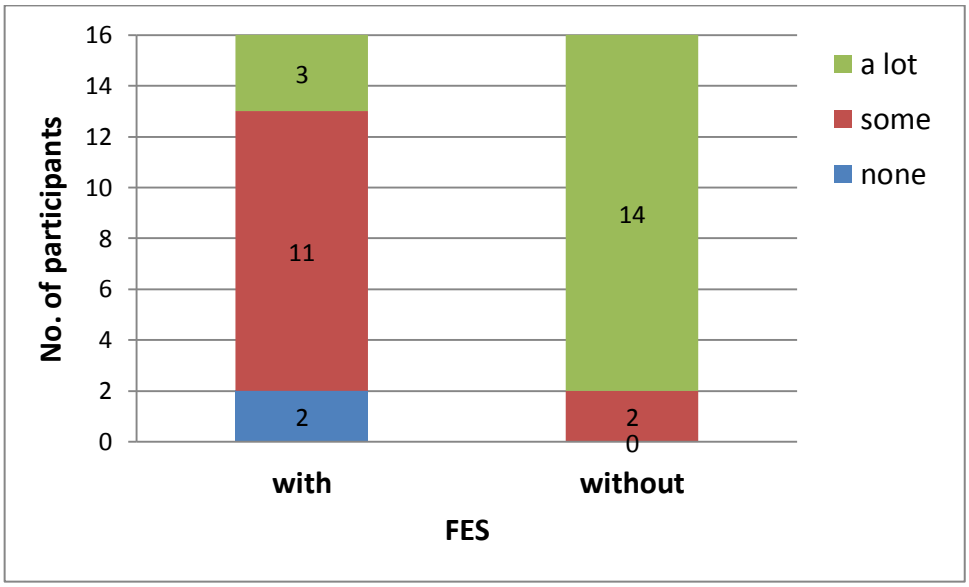


Figure 5.23: Frequency of scaled responses to rating by participants of concentration needed to walk with and without FES.

c) Perceived level of concentration

When participants were asked to rate on a three-point verbal scale, the amount of perceived concentration required to walk both with and without FES, their responses produced a significant difference between the two conditions. Figure 5.23 illustrates the frequency of responses for each condition. With FES, the amount of

concentration rated as ‘some’ increased and conversely, the amount of concentration rated as ‘a lot’ decreased, compared with walking without FES. Thus, there was a reduction in the perceived level of concentration required when walking with FES which, when statistically analysed was significant (McNemar $x2 = 7.69$, $df=1$, $p<0.01$, 2-tailed).

d) Dual-task effects

The frequency with which participants felt their device affected dual-tasks is detailed in Figure 5.24. Seven of the ten conditions were made easier with FES for 50% and over of the participants. In particular 12 participants found it easier to avoid a trip or fall and walking without thinking about walking easier with FES. 11 participants found it easier to talk whilst walking with FES. 10 found it easier to step up onto a kerb. Furthermore, 9 found FES made it easier to look around and answer questions whilst walking. 8 found walking without looking at the ground easier with FES. 7 participants felt using FES did not make a difference to walking on uneven ground, walking in a noisy environment or thinking whilst walking.

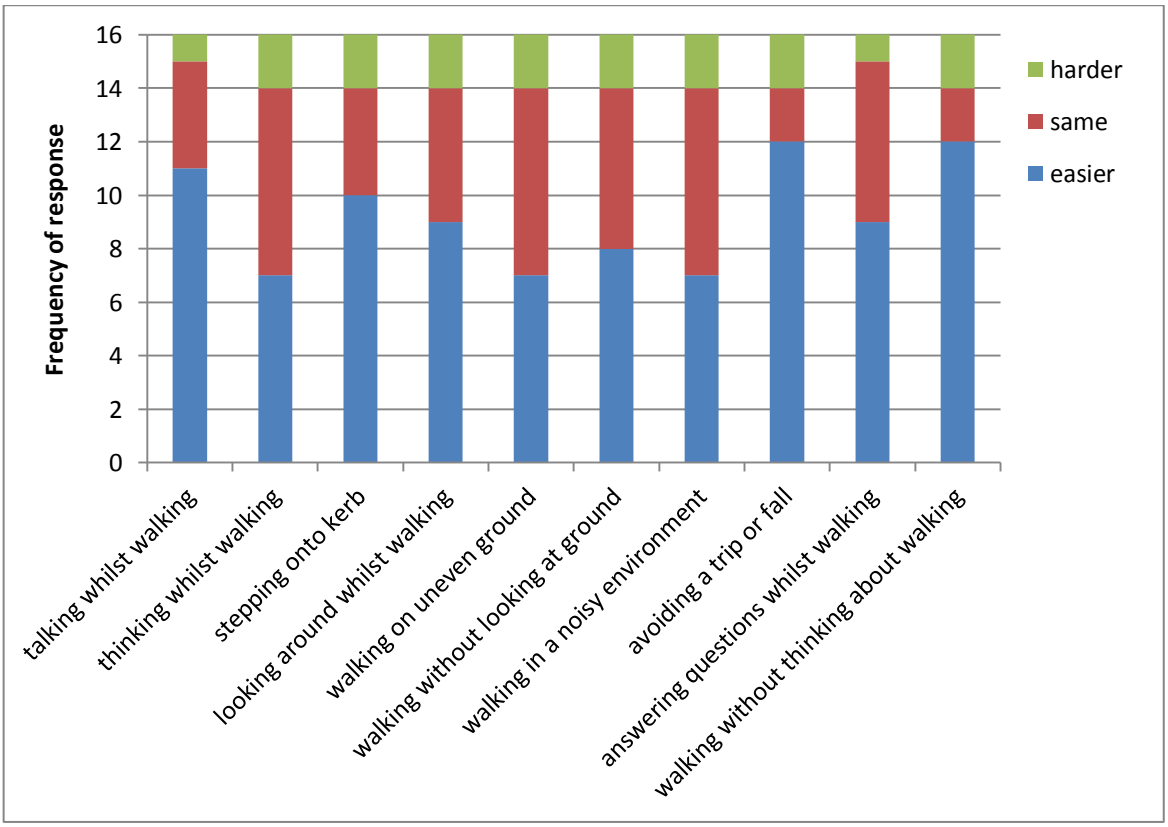


Figure 5.24: Effect of FES during dual-task conditions perceived by participants.

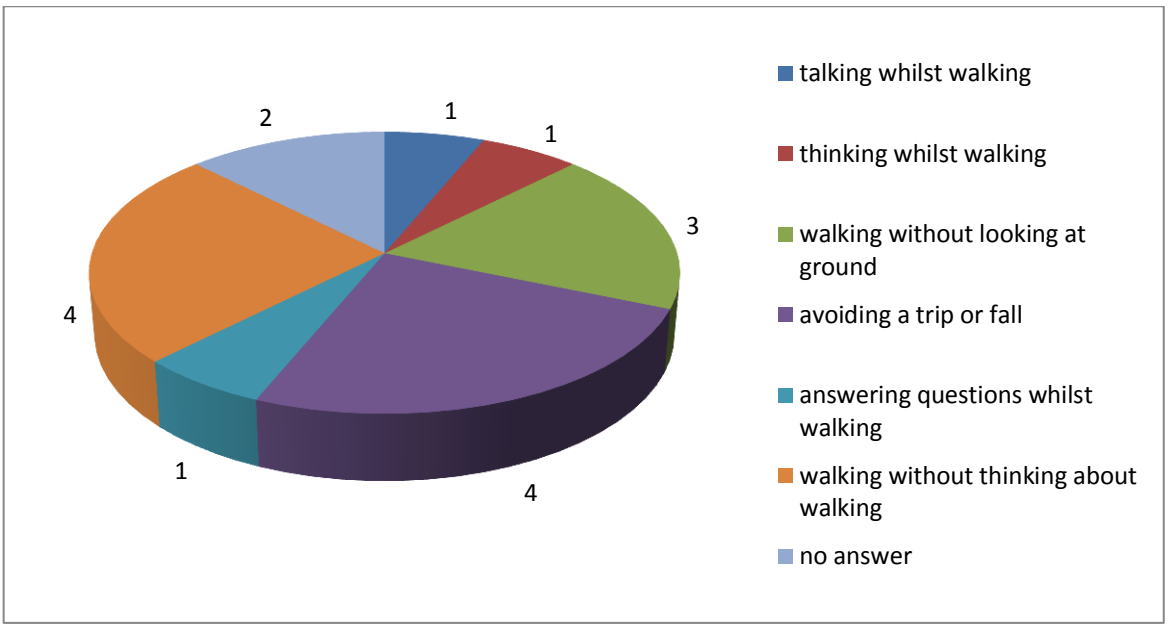


Figure 5.25: The frequency of most important dual-task effect chosen by participants.

When participants were asked to identify the most important task that was easier with FES, 4 identified walking without thinking about walking and avoiding a trip or fall (Figure 5.25). The next most important task was identified by 3 participants as walking without looking at the ground.

e) Participant comments

Participants also provided an interesting insight into how the use of FES affected their lives. Several expressed the effect of FES as an overall summation describing FES as 'brilliant', making a 'huge difference' to their life and 'improving the quality of my life'. One participant 'wouldn't be without' their FES device and said that they often recommended it to other people who have had a stroke. In the case of one participant, they described a shopping trip without their FES device, due to a lost wire, during which they found they forgot to buy items and rushed decisions, finding the experience a lot harder, more fatiguing and that they were more concerned about falling than usual. Another participant felt that using FES gave them the confidence to attend university and that without FES they would not have gone.

Four of the participants had used or were currently using an AFO. When asked which device helped them walk with the least effort, three participants chose FES. Furthermore, these participants stated that the AFO 'didn't work' and that FES was 'more comfortable'. Although the remaining participant chose the AFO, they did feel

that FES was a better option as it made their leg actually move, and that an AFO would never make their leg improve, however they felt an AFO was easier to use.

5.4 Discussion

5.4.1 Participant descriptors

There was almost equal representation of left and right hemisphere affected by stroke and sex in the sample of FES users participating in this study. The mean age of the group was 56.6 ± 17.2 years. With 75% of stroke cases occurring in people over 65 years of age (DOH, 2005), this group were younger than typical for people post-stroke, and also represented a wide range of ages – minimum of 22 years and a maximum of 81 years. When compared with other FES studies of people post-stroke, the age of participants in this study is similar. In the study by Ring et al (2009) the mean age was 52.2 ± 3.6 years, in the study by Laufer et al (2009) it was 55.0 ± 14.6 years and in the study by Hausdorff et al (2008) it was 54.0 ± 13.5 years.

The mean time since stroke was 90.7 ± 87.6 months. The range of time since stroke was large amongst participants; minimum of 12 and a maximum of 348 months. There was also a large range of time since commencement of FES use; mean 30.9 ± 24.0 months, minimum of 3 and maximum of 97 months. The sample also exhibited a diverse range of both stroke related problems and other health issues. It is interesting to note that ten of the participants self-reported that their sight was affected by their stroke, however they were able to clearly see the visual task whilst walking and did not identify that their sight impeded their task performance.

The participants self-reported use of their FES in terms of days per week and also hours per day basis. In comparison to previously reported usage, discussed in Section 3.7.2a, this group used their device less often during the week at 4.5 ± 2.0 days per week and less per day at 6.0 ± 2.4 hours per day.

5.4.2 The effect of FES on gait speed and gait parameters

The effect of FES on gait speed and other gait parameters, when compared with walking without FES, is discussed in the context of the FES literature.

a) Gait speed

Gait speed is routinely used as an outcome measure to assess the effect of FES both clinically and in research studies. Mean gait speed with FES in this study was faster

than walking without FES, as expected and evidenced in the FES literature (Kottink et al., 2004, Robbins et al., 2006, Roche, 2009). However, in this sample the difference was not statistically significant. In fact the change in gait speed with FES represents approximately a 4% increase which is much lower than the pooled improvement reported by Kottink et al (2004) of 38%.

Speed both with and without FES for each participant is plotted in Figure 5.25. Only one participant slowed with the addition of FES and four maintained the same speed both with and without FES. Thus, the remaining 11 participants exhibited an increase in speed with the addition of FES, although as can be seen from Figure 5.26, this was small in some cases. It is possible that the number of walks requested of participants, to collect data across all conditions, together with the attentional effort required in 2 of the 4 test conditions, led to greater fatigue than in previous, less complex studies. This may have resulted in a slowing of gait during data collection.

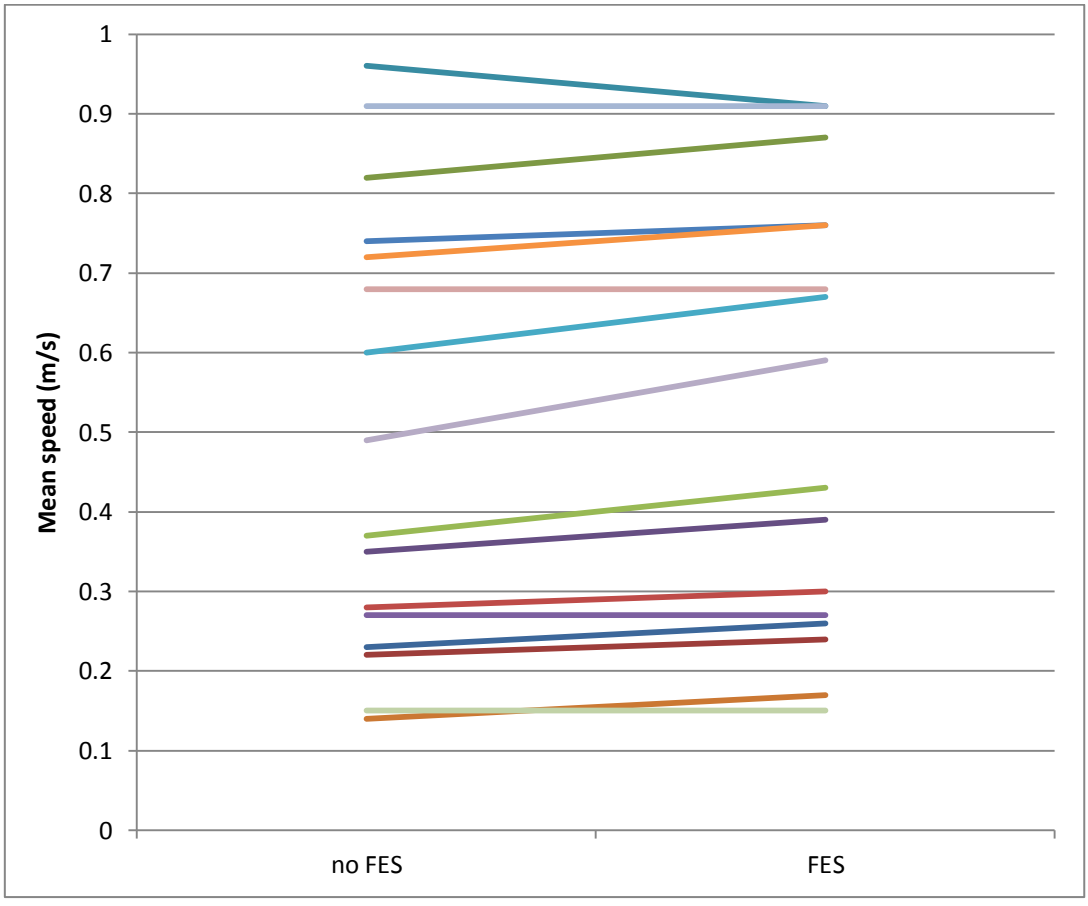


Figure 5.26: Plot of gait speed of each participant showing change in mean gait speed with addition of FES.

b) Gait parameters

i) Stance time

Stance time for the paretic leg reduced with FES, compared to without FES, from 1.37 ± 0.64s to 1.23 ± 0.53s. This represented a small reduction in the mean percentage of the gait cycle spent in stance, reducing from 70% to 67%, which was statistically significant (p= 0.031). Stance time for the non-paretic leg also reduced when walking with FES, from 1.57 ± 0.68s to 1.44 ± 0.58s. Again this represented a small reduction in the mean percentage of the gait cycle, reducing from 81% to 79%, which was statistically significant (p= 0.05).

A study of an implantable FES device (Kottink et al., 2012) showed, after 26 weeks use, stance phase duration reduced to 60 % on the paretic leg and 71% on the non-paretic compared to baseline. Thus, the reduction in stance phase of both legs with FES in the current study agree with Kottink's outcomes, including the difference between the legs, with the paretic stance time closer to the normal value of 60%, than that for the non-paretic leg.

ii) Double support time

When walking with and without FES were compared, double support time reduced with FES; 0.99 ± 0.63s without FES to 0.85 ± 0.52s with FES. This represents a 5% reduction in the mean percentage of the gait cycle, reducing from 51% to 46%, and is statistically significant (p= 0.025). This is more than double the percentage of the gait cycle spent in double support of 20%, reported in healthy walking (Whittle, 2003) and agrees again with Kottink's study (2012), which noted that the double support phase was reduced, when compared with baseline after 26 weeks use of FES, on both paretic and non-paretic legs to 11% and 19% respectively. Thus, in the current study FES improved the time spent in double-support, although the effect was limited and did not approach normal.

iii) Swing time

Swing time, for both paretic and non-paretic legs, increased by a small amount with FES which was not statistically significant, when analysed across all conditions using ANOVA. When expressed as a percentage of the gait cycle, mean swing time on the paretic leg increased with FES to 33% from 30% without FES. For the non-paretic leg a similar increase occurred; from 19% without FES to 21% with FES. Thus, FES

enhanced the percentage of the gait cycle both legs were in swing, bringing them both slightly closer to the normal percentage of cycle time of 40%, with the paretic leg closer to normal than the non-paretic leg.

Swing time on the paretic leg is equivalent to single support time on the non-paretic leg and swing time on the non-paretic leg is equivalent to single support time on the paretic leg. Single support phase was measured in Kottink's study also. Although this was reported as the first single support phase, FES use of 26 weeks increased the percentage of the gait cycle spent in single support for both legs; the paretic increasing from 25% to 29% and the non-paretic increasing from 36% to 41%. Thus, in both Kottink's and the current study, FES had the effect of increasing the percentage of the gait cycle spent in swing phase for both legs, which also increased the percentage of the gait cycle each leg spent in single support. Although, the percentage of the gait cycle spent in this phase of gait was improved in the current study, the difference between the values for each leg and their difference from normal show that participants still walked with non-symmetrical gait.

iv) Stride time variability

Mean stride time variability reduced by 29% with FES, compared to walking without FES. Even though this was a large reduction this was not statistically significant when the difference between the four walking conditions was analysed with ANOVA. A study by Hausdorff et al (2008) reported stride time variability as indicative of the effect of FES on gait rhythmicity. Due to the strong links between this measure and fall risk, a measure of fall occurrence was also collected. These new FES users obtained an immediate 23% reduction when FES was first used, followed by a 33% reduction after 8 weeks of FES use, which was maintained after one year of use (Laufer et al., 2009). Furthermore, after 8 weeks FES use fall frequency was calculated to have reduced by 92%, with 14 of the study's 24 participants falling in the two months prior to the study and only 2 falling during the study.

The findings from the current study show good agreement with Hausdorff's and Laufer's outcomes at 8 weeks and 12 months. It is interesting that with prolonged use of FES, as in the current study group, there is still approximately a 30% difference in this measure when compared with walking without FES. Furthermore, 5 participants from the current study self-reported falling in the last year, which represents

approximately 30% of the group. This can be compared to fall rates of 43-70% reported by studies of groups 1 year post-stroke (see section 2.3.4b) as lower than perhaps expected. However this group are greater than one year following stroke.

v) Gait asymmetry

Gait asymmetry, calculated using swing time, did not statistically significantly differ between walking with and without FES, when analysed using ANOVA for all conditions. In fact, the index increased by a small amount of 4% with addition of FES in this group. However, asymmetry with FES of 21 ± 12% was close to outcomes for a group of users after 12 months use of 26 ± 13%, also calculated using swing time (Laufer et al., 2009). In this reported study, at 12 months asymmetry was 38 ± 20% without FES which is higher than 20 ± 13% for the current group of users. It is possible that this result represents asymmetry without FES for longer-term users, although it should be noted that the range of time of FES use was 3 to 97 months amongst the participants in this study.

5.4.3 The dual-task effect when walking without FES

The dual-task effect on task, gait speed and other gait parameters, when walking without FES, is discussed in the context of the dual-task stroke literature.

a) Task performance

Task performance, when walking without FES, reduced in comparison to baseline seated scores from 9.81 ± 0.40 to 7.78 ± 1.34. This was equivalent to a large reduction in performance of 20% which was also statistically significant ($p = 0.0001$).

The task used in this study was novel in design, testing visual recognition short-term memory of participants, requiring articulation of response after walking. Hyndman et al (2006) used a similar approach, testing short-term memory recall of a shopping list, in their dual-task study of people with stroke compared with healthy controls. The stroke group recalled fewer items than the controls and their task performance deteriorated significantly under the dual-task condition compared to seated measures by 17%. Although there are obvious differences in the task used, the difference between seated and dual-task performance is similar between Hyndman's study and this study. However, whilst the number of items remained the same for each trial in both Hyndman's and this study, the length of time over which the 7-item list used in

the former was delivered, was altered to match the length of time during which each participant walked 5 metres. Thus, the gap between each item differed between seated and walking conditions, and between walking trials for each participant. In contrast, the interval between the projection of each figure was kept constant in the current study, lending greater confidence in comparisons between conditions, due to consistency in task. Secondly, the dual-task condition in Hyndman's study was measured only once, compared with 2-3 walking trials per condition in the current study. Again, this limits comparison of results.

b) Gait speed

There was a reduction in mean gait speed under the dual-task condition when walking without FES, from 0.50 ± 0.28 m/s to 0.45 ± 0.26 m/s, which was statistically significant ($p = 0.017$) and represented a 10% reduction in speed. Previous studies suggest this represents a clinically relevant change in gait speed (Flansbjer et al., 2005). This also suggests that the effect of the task was sufficient to reduce gait speed to level that would affect function, when walking without FES, indicating that there was significant motor-cognitive interference.

Other reported dual-task studies of stroke groups, also found reductions in gait speed with addition of task (see Chapter 2, section 2.3.5). Direct comparison of gait speed reduction with these studies is limited due to the novel design of task used in the current study. The exception is Hyndman's study, as described in the previous section, which recorded a reduction in speed of 29%, which is almost three times that of the current study, using a task that similarly did not require articulation during walking and tested memory. Apart from differences in the task, the stroke group in Hyndman's trial was older at 66.5 ± 11.8 years vs 59.6 ± 17.2 years, and had suffered their stroke more recently 16 (7, 56) months vs 90.7 (12, 346) months. Secondly, gait speed measures under dual task were taken for only one walking trial. The effect of increased age may explain greater motor-cognitive interference (Al-Yahya et al., 2011) but basing the outcome on one trial suggests caution in comparison of results.

c) Gait parameters

i) Double support time

Double support time statistically significantly (p=0.018) increased under the dual-task condition when walking without FES, from 0.99 ± 0.63s to 1.09 ± 0.71s. This is equivalent to a 10% increase in time spent in double support during the gait cycle.

Two dual-task studies of stroke groups have measured this parameter as an indicator of the effect of task on balance when walking. In the study by Bowen et al (2001) the first of the two double support phases of gait were measured and a significant increase under the dual-task condition was noted. In a study using several tasks, Plummer-D'Amato et al (2010) found a significant increase in the amount of time spent in double support under dual-task with the '1-back' task and a spontaneous speech task, and although there was a measured difference for the clock task, it was not statistically significant. Thus, the results from the current study are in agreement with outcomes from other stroke groups indicating that balance under dual-task was similarly affected when walking without FES. The motor-cognitive interference due to addition of task is evident in this disruption to gait cycle phases in an attempt to stabilise gait.

ii) Swing time

Swing time of the non-paretic leg did not change under the dual-task condition when walking without FES (i.e. from 0.38 ± 0.09s to 0.38 ± 0.11s). This measure is equivalent to single support time of the paretic leg. Swing time of the paretic leg also did not change under the dual-task condition when walking without FES (i.e.0.58 ± 0.15s for both conditions). This measure is equivalent to single support time of the non-paretic leg.

These outcomes are in contrast to a pilot study which used three different tasks to explore their effect on different aspects of gait (Plummer-D'Amato and Altmann, 2012). Their interpretation of results concluded that as task difficulty increased, from a memory task ('1-back' task) to a visuospatial task (clock face) and finally to a spontaneous speech task, discreet components of gait were effected until finally gait overall was slowed. Thus, the memory task was associated with a decrement in paretic single leg support, the visuospatial task created interference in both the

paretic and non-paretic single leg support phases and finally the speech task interfered with overall gait speed. Using this interpretation, it could be concluded that the visual recognition task used in the current study, which did test memory, was not difficult enough to create changes in swing time and hence single support time for either leg. However, gait speed did decrease by 10% with task, which is a statistically significant and clinically relevant change. Applying the conclusions from Plummer D'Amato's study, the visual memory task could be described as placed at the more difficult end of the continuum due to the effect on speed.

5.4.4 Dual-task effect with FES

The effect of FES on dual-task is discussed by analysis of results for visual task performance, gait speed and other gait parameters, compared with dual-task results without FES. The analysis is made in the context of the dual-task literature and measures associated with gait stability and fall risk.

a) Visual task performance

The difference between performance of the visual task between walking with and without FES was not statistically significant (p=0.405), despite poorer performance without FES. However, during both dual-task conditions task success statistically significantly reduced, compared with the seated measure; FES p=0.0003, no FES p=0.0001. Thus, in this case using this visual task, FES did not have a significant effect upon task performance whilst walking.

b) Gait speed

The difference between gait speed under dual-task between with and without FES was not statistically significant (p=0.256), despite a slower speed without FES of approximately 4%. However, speed did significantly reduce with addition of task for FES (p=0.003) and for no FES (p=0.002). This change in speed with addition of task, for both FES and no FES, represents approximately a 10% reduction in speed, which is clinically relevant (Flansbjer et al., 2005). Therefore, in this group of FES users, FES did not significantly reduce the effect of the visual task on gait speed.

c) Gait parameters

i) Gait cycle phases

Whilst there was no statistically significant difference between stance time on the non-paretic leg between the two dual-task conditions (p=0.097), stance time for the paretic leg statistically significantly increased by 3% when walking without FES under the dual-task condition from 69% of cycle time to 72% (p=0.044).

Double support time statistically significantly increased with the addition of task both with and without FES and represented a percentage of cycle time as follows; 46% FES, 49% FES with task, 51% no FES and 53% no FES with task. There was a 4% reduction in the percentage of the gait cycle spent in double support time with FES and task compared with without FES and task. The p value for the difference between these two task conditions was calculated at just above the significance level, set at 0.05, at 0.051.

Results indicate that FES was successful at reducing the amount of time spent in double support, and stance for the paretic leg, under cognitive load. Whilst both phases were longer than normal, FES brought these phases closer to normal values. Thus, FES could be described as having a positive effect on normalising this gait phase under dual-task conditions, and these measures indicate the positive effect of FES on motor-cognitive interference.

ii) Step length

There was no statistically significant difference between step length for both the paretic and non-paretic legs, between the dual-task conditions. The study by Baetens et al (2013) identified that fallers amongst a stroke group would exhibit a greater decrement in non-paretic step length between single and dual-task conditions than non-fallers, suggesting a larger decrement in non-paretic step length may be associated with greater instability. Using their formula to calculate dual-task related decrement – i.e. (single-task step length – dual-task step length) ÷ single-task step length x 100% - the difference between step length, under dual-task, with and without FES was analysed, from the results of the current study. Interestingly, the decrement between single and dual-task with FES was 10.6 ± 12.9% and without FES the decrement was 5.4 ± 11.6%. It is also worth noting that in the study by Chen et al

(2005) of post-stroke gait, whilst differences in step length were found, the direction was not consistent, as either leg could exhibit a shorter step length.

iii) Stride length

Stride length statistically significantly decreased with addition of task both with and without FES. However, there was no statistical significant difference between stride length under both dual-task conditions. Hyndman et al (2006) distinguished fallers in a stroke group by a greater reduction in stride length, under dual-task, again suggesting a link between risk of falling and robustness of gait parameters to the introduction of a secondary task. Thus, assessing the effect of FES on gait under dual-task using stride length, did not suggest that walking with FES would reduce the likelihood of a fall.

iv) Gait rhythmicity and symmetry

Repeated measures ANOVAs were used to analyse stride time variability and gait asymmetry across the four walking conditions. For both of these gait measures there were no statistical significant differences between conditions. Thus, there was no statistical significant difference between dual-task conditions with and without FES. FES did not affect these measures of gait during task performance.

5.4.5 Questionnaire

There is agreement between the results from the questionnaire, when compared with outcomes of the questionnaire study discussed in Chapter 3. The activities undertaken both with and without FES broadly agree with Chapter 3 results; the top five activities undertaken with and FES and the top three without FES are the same in both groups. Furthermore, a walking stick was most frequently used both with and without FES by both groups.

Amongst the participants, there was a high level of agreement with the statements about the effect of FES with over 50% of participants agreeing with 10 of the 13 statements. The pattern of response to this question agreed with the questionnaire study, again supporting the importance of the effects of FES, other than gait speed, amongst users. The effects that were most highly rated by participants i.e. increased confidence, ability to walk more safely, less effort to walk and less likely to trip or fall, are in agreement with those identified in the questionnaire study (Chapter 3) and two previous studies by Taylor et al (1999b, 2004). Thus, apart from improving the quality

of gait, participants felt that the effect of FES on confidence and effort were important.

The perceived level of concentration required to walk with FES was statistically significantly less than that required to walk without FES. This agreed with the results from the questionnaire study. Furthermore, agreement with the dual-task statements was high, as 50% and over of participants agreed with seven of the ten statements. This is higher than in the questionnaire study in which 50 % and over agreed with five of the statements. This outcome may have been influenced by asking this question in the context of a dual-task study, and thus raising the participants' awareness of the effect of FES on dual-task conditions. This may have also influenced their high rating of the most important dual-tasks as 'walking without thinking about walking' and 'walking without looking at the ground'. Avoiding a trip or fall was also highly rated, as in the questionnaire study, again reflecting the importance of the physical effect of FES on the quality of gait.

These questionnaire results generally agree with those reported in Chapter 3, indicating that the effect of FES on outcomes other than gait speed are firstly, perceived by FES users, including those in this study and, secondly, are important to FES users. Despite this, the quantitative outcomes, using this dual-task approach, measuring the perceived effect of FES on other aspects of walking, and in particular the perceived reduction in concentration required to walk with FES, are in contrast to these FES user reported outcomes. That is, the interference in gait performance under a dual-task condition is not affected by the use of FES. This contradiction is explored in the next section which analyses in more detail the relationship between the questionnaire results and the primary outcomes of gait speed and task performance.

5.4.6 Analysis of primary outcomes in the context of questionnaire results

Analysis of questionnaire results for individual participants was performed to explore their relationship with the primary outcomes of gait speed and task performance. To address this, three sub-groups of participants were defined, based on their response to questions 4 and 5 (see Appendix B.1); a) those who did not perceive FES to have a positive effect on the concentration required to walk, b) those who identified dual-tasks as 'harder' with FES than without; and c) those who agreed that both concentration reduced and dual-tasks were made easier with FES. The results of the

questionnaire and primary outcomes are discussed for each of these groups to highlight any individual differences in responses and evidence of outliers. Participant descriptors are also included in the analysis to explore individual variances.

a) Group reporting no effect of FES on concentration whilst walking

Thirteen participants perceived that FES reduced the amount of concentration required to walk, returning a statistically significant difference between the amount needed whilst walking with and without FES (see question 4, Appendix B.1). Three of the participants, labelled A, B and C to aid discussion, responded in a different way. Two (A and B) felt that both with and without FES the levels of concentration were unchanged and were both 'a lot'. One participant (C) felt that the concentration required increased from 'some', without FES, to 'a lot' with FES. Interestingly, the two who felt that FES had no effect, responded in the same manner to the dual-task questions as most of the other participants, agreeing that FES made tasks 'easier' or 'the same', but nothing was 'harder'. The participant (C) who perceived FES required more concentration to walk also felt that it made every task 'harder'.

The task and gait speed results were explored for these three participants. Figure 5.27 illustrates their task performance over the three conditions. Participant A did not perceive that FES reduced the amount of concentration required to walk, however their ability to successfully identify correct task responses was better with FES. Furthermore their gait speed (see Figure 5.28), under dual-task conditions, was better with FES. Both these results indicate that FES had a positive effect on motor-cognitive interference for this participant. Finally, when reviewing their response to the dual-task question they responded that the majority (i.e. 8 out of 10) were easier with FES. This participant's perception that FES did not have an effect on concentration required to walk, was not supported by the other results.

For the other two of the participants (B and C) task performance without FES was either the same or higher than with FES (see Figure 5.27). When speed is compared between the two task conditions (see Figure 5.28), speed increased when walking without FES and task, which is in contrast to group results. Thus, under dual-task conditions FES did not have a positive effect on speed or task performance, which supports the perception of these two participants i.e. FES does not have a positive effect on the level of concentration required to walk. Interestingly these three participants all made comments about the positive benefits of FES use.

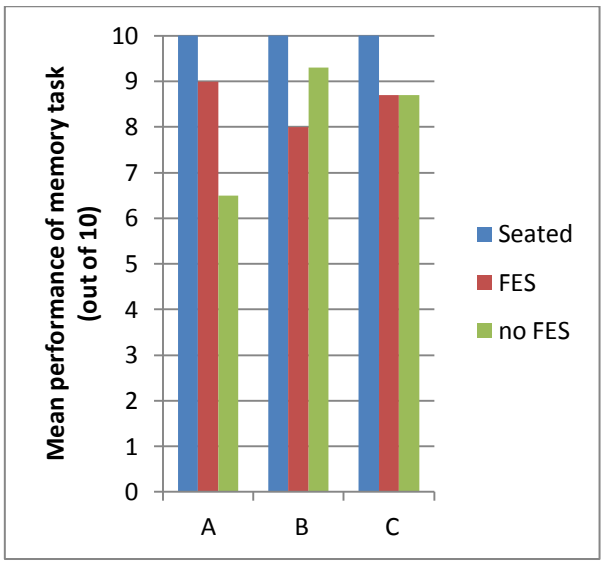


Figure 5.27: Task performance for each participant for each condition.

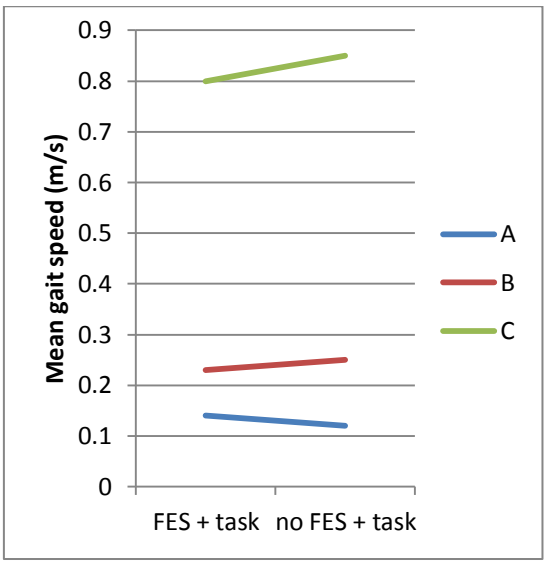


Figure 5.28: Change in gait speed for each participant with task for both FES and no FES.

The other measures collected for these participants do not distinguish them as a group from the other participants. Barthel scores indicated that they had attained high levels of independence. Predicted pre-morbid IQ and digit span backwards scores were within normal limits. Whilst the other two participants had forward digit span scores within normal limits, one participant had a score that was indicative of cognitive deficit. This was participant B whose speed and task performance under dual-task were not improved by FES.

Scores on the FES-I placed them all as having high levels of concern for falling. Participant descriptors and FES usage did not distinguish them from the other participants. The only exception being that they had been using FES for less than 10 months, in contrast to the remaining participants who had been using FES for 14 months or more. A shorter time of use, in comparison to the rest of the participants may be an explanatory factor; the effect of FES when performing concurrent tasks may be associated with increased use.

b) Group reporting some dual-tasks as harder with FES

The members of this sub-group, labelled participants D, E, F and G, were defined by their responses to question 5 (see Appendix B.1). The majority of all participants felt that FES made performing all dual-tasks either ‘easier’ or ‘the same’. However, the four participants of this sub-group felt that FES made some tasks ‘harder’; three each

identifying one task as harder, ('stepping up onto a kerb', thinking about something else' and ' walking in a noisy environment') and one participant stating that nothing was easier with FES, with tasks either being 'the same' or 'harder' with FES. Interestingly, all four participants perceived that FES reduced the amount of concentration required to walk.

The task and gait speed results were also explored for these four participants. Figure 5.29 illustrates their task performance over the three conditions. For two of these participants (D and E) task performance during walking with FES was improved, and (see Figure 5.30) gait speed was improved with FES under the dual-task condition. Both of these participants identified one dual-task each in the questionnaire as harder and, one of these participants only agreed that three of the dual-task statements were 'easier' with the remainder being 'the same'. This suggests that for these two participants, despite finding some tasks harder their primary outcomes indicate that FES had a positive effect on motor-cognitive interference.

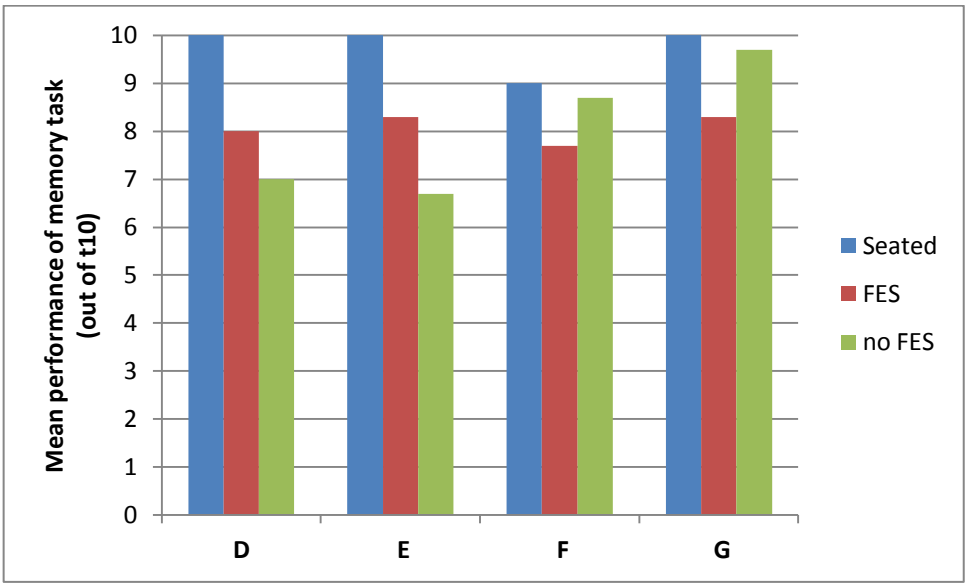


Figure 5.29: Task performance for each participant for each condition.

In contrast task performance without FES was less successful than with FES for two of these participants (F and G) (see Figure 5.29), one of which was the participant who had found that nothing was 'easier' with FES and for whom gait speed did not change between the two dual-task conditions (i.e. F). For this participant their response to this dual-task question agrees with task and gait speed outcomes, indicating that FES did not improve performance in the dual-task condition.

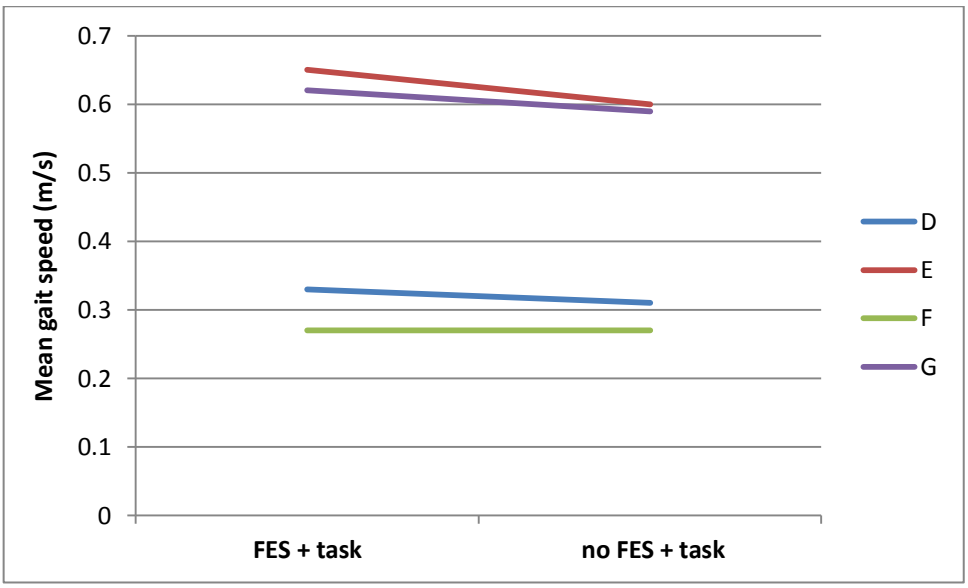


Fig 5.30: Change in gait speed for each participant with task for both FES and no FES.

The other measures collected for these participants do not distinguish them as a group from the other participants. Barthel scores indicated that they had attained high levels of independence. Predicted pre-morbid IQ scores were within the average range. Whilst the others had digit span scores that were within normal limits, participant E had a forward digit span that was borderline for cognitive deficit, and a backward digit span that was indicative of cognitive deficit. The results for this participant exhibited an 'expected' dual-task interference of speed and task, with both reducing in the dual-task conditions and FES reducing the dual-task effect and hence the motor-cognitive interference. As backward digit span is a measure of working memory, evidence of interference during dual-tasks could be expected.

Scores on the FES-I placed three participants as having high levels of concern for falling and one as having moderate concern. For this participant (i.e. F), discussed previously, FES did not improve dual-task performance and did not make any of the dual-tasks 'easier'. It is possible that this participant's level of concern influenced their approach to the effect of FES, with dual-task measures not perceived or perhaps not of high importance. If this were the case then the dual-task measures of speed and task agree with the participants perceptions. Interestingly, this participant did comment that 'if I used it more I would get more benefit from it' which perhaps indicates an understanding of the potential benefits of FES, but not necessarily the dual-task benefits. This comment may also indicate that the participant is gaining

some benefit from FES use; in this case the focus of the study (i.e. dual-task) did not align with the benefits that this particular participant receives by using FES.

Participant descriptors and FES usage did not distinguish these participants from the other participants. The only exception being that three of this group were male.

c) Self-reported responders

Nine participants (labelled H to P) felt that FES made performing dual-tasks either 'easier' or 'the same' and perceived that FES reduced the amount of concentration required to walk. The gait speed and task results were explored for this sub-group.

When speed is compared between the two task conditions (see Figure 5.31), speed reduced for seven of the participants, remained constant for one and increased for another when walking without FES and task, which is broadly in agreement with group results. Furthermore, task performance without FES was higher than with FES for only two participants (see Figure 5.32) with the remaining participants' task performance at its lowest without FES.

The two participants who performed the task better without FES (I and M) walked slower under the dual-task condition without FES. Conversely, the participant whose speed increased without FES under the dual-task condition (i.e. K) had less success with task performance without FES than with FES. For these three participants there is evidence of a positive effect of FES upon motor-cognitive interference, but both task and speed do not concurrently improve with FES. Other measures for these participants do not distinguish them from the others in this sub-group, with the exception of one (i.e. K) having moderate levels of concern about falling. There was one other participant in this sub-group of nine, who scored the same on the FES-I (all others had high concern). Interestingly, this participant's (i.e. N) task performance dropped only without FES during dual-task conditions, and gait speed was not affected by FES under dual-task. It is possible that concern for falling influenced their approach to the dual-task; that is, they may not have perceived the dual-task as threatening to walking safety and felt they could maintain gait speed whilst achieving good task performance. This is of course only an assumption as data concerning the approach to the task that participants took was not collected.

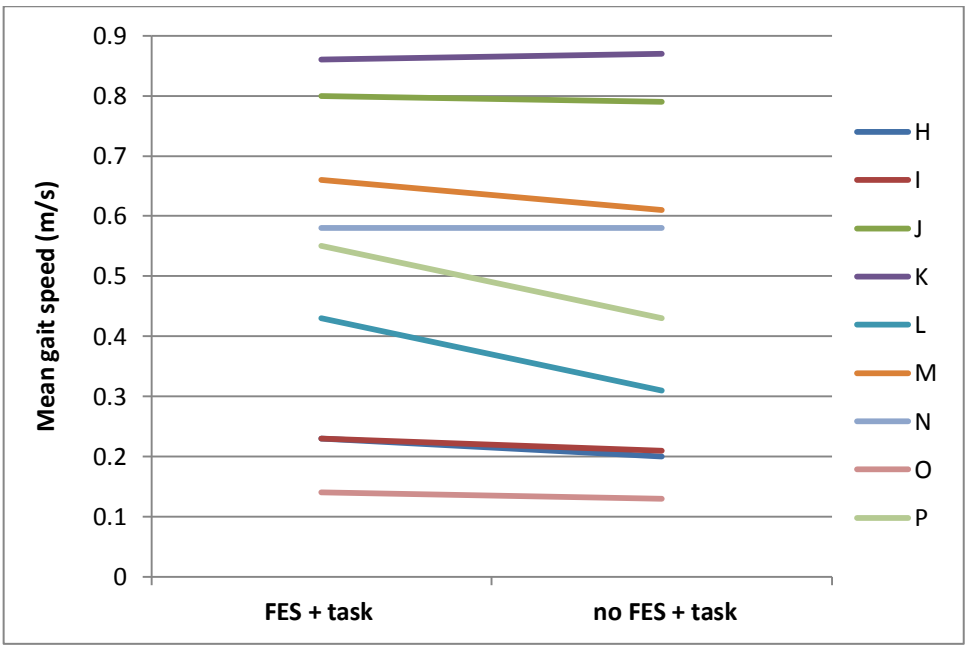


Fig 5.31: Change in gait speed for each participant with task for both FES and no FES.

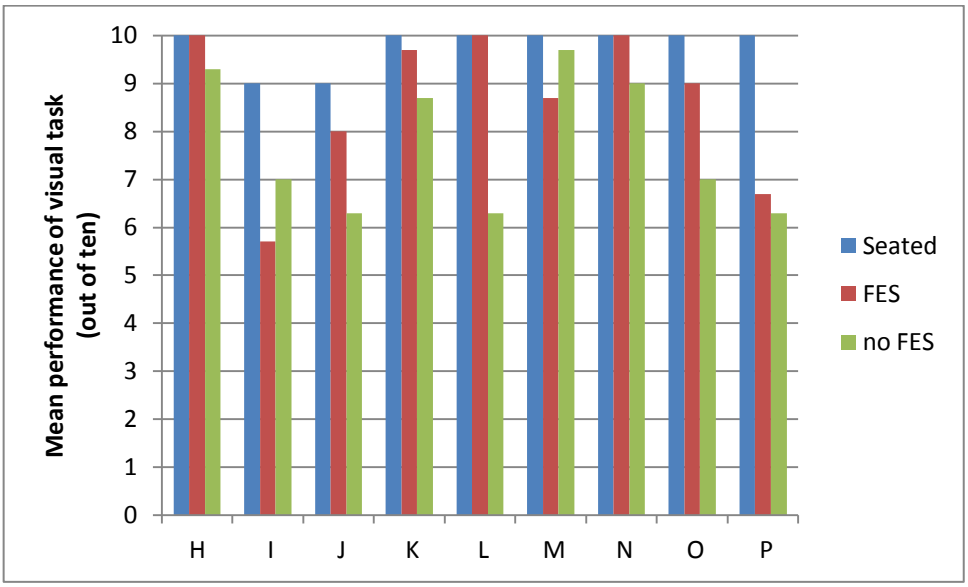


Figure 5.32: Task performance for each participant for each condition.

The other measures collected for these participants do not distinguish them as a group from the other participants. Barthel scores indicated that they had attained high levels of independence. One participant had the lowest score of all the study participants. Their gait speed was slow and with addition of task reduced by only a small amount without FES (see participant O), whilst they had more difficulty maintaining task score without FES. In this case it possible that the participant's reduced level of overall independence, in comparison to the rest of the group, meant

that gait speed only showed small amounts of change whilst the dual-task effect was shown by a drop in task performance without FES.

Predicted pre-morbid IQ scores were within the average range and above, and forward digit span scores were within normal limits. Whilst the others had backward digit scores within normal limits, one participant was borderline for cognitive deficit. This test is a measure of working memory, therefore it is not surprising that this particular participant (i.e. P) exhibited a drop in speed, which was one of the largest for this group, and a reduction in task performance under both dual-task conditions, with both outcomes lower without FES than with FES. These results indicate that the expected motor-cognitive interference experienced by this participant was reduced by FES.

Participant descriptors and FES usage did not distinguish this group of participants from the other participants.

d) Actual responders

Finally, the results for all of the participants were analysed to identify those for whom, when walking with FES, both gait speed and visual task performance increased when compared with walking without FES. From the Figures 5.27 to 5.32 results for participants A, D, E, J, O and P show that FES reduced the effect of task on gait speed and visual task performance whilst walking.

The other data collected for this sub-group was collated. The average age was higher than that of the study group at 65.5 ± 20.4 (25, 81) years. In addition the time since stroke was longer at 128.0 ± 122.3 (14, 348) months and the time of FES use was also longer 42.3 ± 33.9 (3, 97) months. Even though these descriptors were higher than for the study group they exhibited a similar large range of values. Females were more numerous at 4:2.

The ratio of hemisphere affected by the stroke was 5:1 (left:right) which was in contrast to the group ratio of 9:7. Thus there was a disproportionate representation of left hemisphere affected participants compared with the study group. When stroke-related health issues were reviewed the sub-group exhibited the same range as the study group with none that were common to all in the group.

The Barthel score approximated that of the group at 17.8 ± 1.5 and the predicted premorbid IQ score was 108 ± 10, indicative that this sub-group were not below the

UK average. Scores for the forward and backward digit span identified one participant as below normal limits for both and another one participant was borderline for cognitive deficit for the backwards span only. All of the sub-group had high concern for falls and all except one participant were at high risk of falls; both of these outcomes were in agreement with group results.

Finally, questionnaire results for this group were reviewed. All except for one participant identified FES as reducing the amount of concentration required to walk. Four participants felt that FES made performing all dual-tasks 'easier' or 'the same' whilst two participants both identified one as being 'harder' with FES compared to without FES.

Participants, who measured an improvement in both speed and visual task with FES under dual-task, did not appear to have any traits exhibited by the variables collected to distinguish them from the group as a whole, apart from a disproportionate representation of left hemisphere stroke.

5.5 Conclusion

The primary outcomes of this study indicate that the visual memory task produced motor-cognitive interference during gait; both gait speed and success of visual task performance were reduced during the dual-task conditions. FES did not reduce the effect of the task on gait speed, as there was no significant difference between gait speed with task when walking with FES compared to without FES.

Visual task performance did not significantly differ between walking with and without FES, indicating that FES does not improve performance of this cognitive task whilst walking. This finding is in contrast to effects of FES perceived by users. In particular users, both in this study and in the previous questionnaire study, have noted their ability to perform concurrent cognitive functions improved when walking with FES. This finding is also in contrast to the positive effect that FES has on reducing the perceived levels of concentration required to walk with a foot drop, expressed by the participants in this study and again by the respondents to the previous questionnaire study. In addition, prior qualitative studies, although of small numbers of FES users, had reported that their participants perceived a reduction in the amount of concentration required to walk with FES (Malone, 2002, Bulley et al., 2011). Finally, FES users have perceived that FES reduces the effort of walking over three questionnaire studies (Taylor et al., 1999b, Taylor, 2004, McAdam, 2006), which has

been suggested as including a cognitive component. The results for visual task performance do not support this concept in this case.

The other gait parameters analysed to assess the effect of FES on a reduction in motor-cognitive interference did not yield much insight into this research question. Only stance time of the paretic leg under dual-task conditions statistically significantly reduced with FES, even though this represented a small change in the percentage of the gait cycle of 3%. Thus, FES did alter the effect of the cognitive task on this gait parameter. Furthermore, the subsequent reduction in double support time of 4% facilitated by FES under a dual-task condition, although not strictly statistically significant, suggested that FES has a positive effect on balance during gait when circumstances create motor-cognitive interference.

Sub-analysis of the questionnaire results, when compared with gait speed and visual task performance outcomes indicated an inconsistency in agreement between qualitative and quantitative outcomes for some participants. There were some participants who recognised the positive effect of FES on dual-tasks and concentration but did not always provide a measure of this perceived effect in reduced speed and poorer cognitive performance without FES. The converse was also true, in that some participants did not perceive FES to have an effect on indicators of motor-cognitive interference however, their speed and task results showed clear evidence of the effect. The overall suggestion is that variation in results for the primary outcomes masked the group effect, and sub-analysis using the questionnaire results provides evidence of this variation. In addition, analysis of the sub-group of participants, who exhibited a positive effect of FES on both gait speed and visual task performance, did not provide a common group variable to explain their response.

The lack of measured effects of FES on motor-cognitive interference could be due to a few points about the design of the study. It is possible that a different cognitive task would show the effects of FES on cognitive performance more clearly. It is also possible that gait speed, whilst commonly used as an outcome measure in dual-task studies, is not the most appropriate measure of the effect of FES in these circumstances, as it is not reflective of patient-centred outcomes for FES users. This study was designed to collect speed as a primary outcome; choice of other gait

parameters as primary outcomes (e.g. variability measures) would require an alternative study protocol.

The number of participants recruited was below the sample size of 19, to capture all differences in performance. This was calculated based on a small number of trials with largely new users for gait speed, as 7 trials were used in the calculation with 5 of these by FES users after 14 weeks of device use and the remaining two from long-term users. More trials were used to calculate sample size for task performance; 10 walking trials with 5 from both new and long-term users. In particular, based on the sample size calculation of 19, the study was under-powered in relation to the comparison between the speed with and without FES under dual-task, whilst the other comparisons were calculated as able to be made with 16 participants. It is possible then, that the results from piloting the protocol did not reflect the behaviour of a larger group of FES users, and this may be due to using data from both new and experienced FES users, with the majority of the data obtained from the new users. If so, the conclusion is that the study outcomes were affected by the number of participants. It must also be remembered that the study was exploratory. Subsequently there was a potential for the results to be inconclusive, but to positively add to knowledge of the effects perceived by FES users.

Stride time variability was analysed using data from 11 of the participants, following removal of data for those where insufficient steps had been collected. This removed data for participants who walked at faster speeds, as the length of data capture area was fixed and the number of trials was restricted due to the inherent limitations of the hosting clinical service. There were no significant differences for this measure across the four walking conditions. It may be that analysis of stride time variability was compromised by the reduction in the number of participants included. Further dual-task studies with an aim of analysing these gait parameters would need to address the issue of collection of a sufficient data for all participants, in the study design.

Although the results of this study are not conclusive of an effect of FES on motor-cognitive interference, from the primary outcomes, there is a suggestion that FES may improve speed and task performance under dual-task conditions. There is also a suggestion that gait stability and rhythmicity measures are improved by FES under dual-task conditions. Furthermore, this group of FES users clearly recognised that

FES affected their ability to perform other tasks whilst walking and reduced the amount of concentration required to walk.

Chapter 6 – Summary and future work

This final chapter presents an overview of the thesis, describing the work presented with a focus on the key novel aspects and the results obtained. Conclusions are drawn, within the context of the limitations of the studies, and future approaches to research in this field of work are suggested and discussed.

6.1 Summary

6.1.1 Overview of the thesis

The primary aim of the work presented in this thesis was to explore the contribution of FES to the cognitive control of gait. This concept, upon which this body of work was based, was initially driven by outcomes reported in the FES literature indicating that patients perceived the effects of FES to be broader and more numerous than an improvement in gait speed. There had been little focus on patient-centred outcomes in the literature, but one study that did report these suggested that patients felt their walking 'required less effort, as they did not have to concentrate so much on their walking'. The idea that effort was affected by FES use had also been noted in two large questionnaire studies of patient perceptions, reporting that the most highly rated effect of FES use was a reduction in effort.

Taking the view that 'effort' can be indicative of both physical and mental effort, the latter was subsequently explored within the framework of the interaction between the motor and cognitive neural processes involved in the control of gait. Through the process of exploration three studies were designed and implemented. The focus throughout was to keep the FES user at the centre of the process and explore effects expressed by the users. With this focus, the first study explored and gathered data concerning the effects of FES on concentration and secondary tasks when walking, via a questionnaire completed by established FES users. Outcomes from this study clearly indicated that FES users perceived walking with their device to require less concentration and that FES had a positive effect on the execution of other tasks whilst walking e.g. talking.

These results supported the concept of a contribution of FES to the cognitive control of gait and provided sufficient confidence to implement further exploration of this main aim of the thesis via a dual-task study. This novel approach proved to be the first reported dual-task study of FES for foot drop following stroke, and was applied in

both a longitudinal and cross-sectional study design. Outcomes of these studies, whilst not conclusive, suggest that FES can reduce the motor-cognitive interference experienced during a dual-task situation. In addition, they indicate that the effects perceived by FES users can be quantified and there is merit in further studies to define this effect and broaden the outcome measures used to assess FES to reflect effects that are important to patients.

6.1.2 Summary of each chapter

Chapter 1 provided a brief introduction to the thesis. It presented a background to the work of the thesis, introducing the key issues. The limited FES literature focusing on patient-reported outcomes was introduced briefly, highlighting the possibility of an effect on motor-cognitive interference during gait. The small number of studies reporting this effect formed the basis of the main thesis aim which is explained. Finally, at the end of Chapter 1 an overview of the thesis was provided.

A detailed literature review of the background to the thesis was provided in **Chapter 2.** It began with an overview of the neuromuscular system, in the context of neural processes involved in the production and control of gait. The functional anatomy of the neuromuscular system was described, leading to a description of normal gait. Key current concepts concerning the contribution of higher level cognitive processes to the control of gait were then reviewed, with evidence from brain imaging studies and gait studies provided as support. There then followed an overview of stroke, covering incidence and the clinical features, with a focus on motor, sensory and cognitive effects. In particular, the effect of stroke on gait was described in detail, highlighting the subsequent high rate of falls post-stroke by a review of the relevant falls literature. The interaction between physical and cognitive impairments following stroke that affect gait were then discussed, concluding with a brief review of the growing literature on dual-task studies which focus on outcomes assessing this interaction. FES was then introduced in the chapter, initially describing the device, including its mode of action at a local level to produce functional movement. The effect of FES at a central level on spinal mechanisms and cortical neuroplasticity is also reviewed based on emerging evidence. A detailed review of the FES literature that reports the effects of FES on gait and other outcomes was then presented, with a focus on gait measures associated with stability and linked with fall risk and on patient-reported outcomes. The chapter concluded with a critique of the mismatch

between patient-reported outcomes and those chosen by researchers when assessing the effect of FES, highlighting those most important to users from the small number of qualitative studies reported. This led finally to a discussion of the aim of the thesis; to explore the contribution of FES to the cognitive control of gait

Chapter 3 focused on the first study undertaken to explore the thesis aim. It began with a brief review of the FES literature and the growing dual-task literature that was reported at the time of initiation of the thesis, in order to provide a context for development of the questionnaire study. At this time there were a limited number of FES studies reporting patient perceptions and there were a small number of dual-task studies of stroke groups. Furthermore there were just a handful of studies using a dual-task approach to assess devices. Thus, there was a suggestion from the literature that a dual-task design would facilitate investigation of patient-reported FES effects on concentration and effort. The limited evidence initiated a decision to firstly use a questionnaire to explore these reported effects of FES and to provide some evidence to support a subsequent dual-task study. The process of formulation of the questionnaire content and design was explained. Whilst existing FES and AFO literature was used, informal discussions with FES users in particular initiated formulation of the question concerning the effect of FES on secondary tasks associated with effort of walking. A secondary aim of this study was to inform the choice of task in the subsequent dual-task study. Thus, the available dual-task literature was mapped against statements, expressed in everyday language, used in the questionnaire content. Attention was paid to the structure and design of the questionnaire, to encourage responses and to facilitate statistical analysis. In addition, the questions devised were simple, unambiguous and not too long. The questionnaire was piloted and then finalised before being posted to a group of FES users attending an FES clinical service in Salisbury, UK.

Results from the questionnaire study were reported in Chapter 3 with confidence due to a response rate and results that were in agreement with previous studies. The FES users in this study placed a high importance on the effect FES had on reducing effort, improving the quality of their gait and their increased confidence and independence. The reduction in the perceived amount of concentration required to walk with FES was statistically significant. Furthermore, the respondents recognised that FES had an effect on the execution of secondary tasks whilst walking. In agreement with the result for perceived concentration, the majority of respondents felt that FES made it

easier to ‘walk without thinking about walking’. Thus, the study provided patient-reported evidence of the effect of FES on reducing the cognitive load of gait in this post-stroke group, which was sufficient to support further exploration of this effect in the thesis. In addition, the study results gave an indication of the type of task that would be appropriate for use in a dual-task study of FES users. This was taken forward to the process of task selection that was a key factor in the design of the study.

The first dual-task study is reported in this thesis in **Chapter 4**. The study design and subsequent piloting work were key issues covered in this chapter. The study was conceptualised as a longitudinal repeated measures design, recruiting new FES users, with the aim of exploring motor-cognitive interference over time. Choice of cognitive task was a key factor in this study, leading to a review of the dual-task literature which revealed a lack of standardisation of task amongst reported studies, including those of stroke groups. The majority of tasks previously used in dual-task methodologies have required the participant to verbally respond whilst walking, thus introducing a further motor component to the motor-cognitive interference assessed. This important point had been addressed in one study of a stroke group by application of a memory task that required a response after walking was complete (Hyndman et al., 2006). This point was one of the drivers for choice of a suitable task. Further points that informed this process were the outcome of the Chapter 3 study which concluded that FES users would respond to a task that required them to walk without thinking about walking and/or look around whilst walking, the ability to measure the outcomes of the cognitive task as a primary outcome concurrently with gait speed and the feasibility of application of the task whilst walking. These points led to an exploration of existing neuropsychological tests to inform the development of two new tasks, which had their basis in validated recognition memory tests and used verbal and visual input. The tasks tested short-term recognition memory and were used in pilot work to finalise the protocol, focusing on the best mode of delivery for the cognitive task, feasibility of the protocol and safety of the participants. After considering several options for delivery of the memory tasks, a format that fixed the duration and number of targets delivered was chosen for use in a laboratory of fixed length. Pilot work showed that the protocol, including the collection of other measures, was safe and feasible. Issues raised during this work concerning participant fatigue identified that using one task would be less burdensome. The

visual task was chosen to take forward to the final protocol as it satisfied the effects of FES as identified by the questionnaire outcomes (i.e. a task that created a distraction from the perceived thinking associated with walking and from looking at the walking surface whilst walking) and during piloting there were no problems experienced with application of the visual task whilst walking, in contrast to the verbal task.

The study conducted in Chapter 4 suffered from recruitment difficulties, despite several attempts to address the issue. The results for the participants recruited were analysed showing that under dual-task conditions, using the visual task, FES users showed evidence of motor-cognitive interference in a reduction in gait speed and visual task performance. Furthermore, FES appeared to have reduced the effect of this interference and the responses to the questionnaire used in the study supported these primary outcome measures. Confidence in the protocol and the results obtained were key outcomes from this study that instigated further work to implement a further study to apply this novel and now tested methodology. This work was discussed in Chapter 5.

In **Chapter 5** a cross-sectional dual-task study was conducted of established users of FES. This group was both representative of the general FES user population and the respondents to the questionnaire study, reported in Chapter 3, who had clearly identified a positive effect of FES on concentration and dual-tasks. The study protocol was followed as in Chapter 4, with the primary aim of exploring the effect of FES on motor-cognitive interference, by collecting measures of gait speed and visual task performance. In addition, in this study the analysis of gait performance was extended to investigate how gait parameters that are reflective of gait stability and balance may be affected by FES and motor-cognitive interference. This further analysis was based on Chapter 3 results showing that FES users reported other effects of FES linked to the quality of their gait e.g. 80% agreed that their walking was more balanced and even. The primary outcomes of this study indicated that the visual task produced motor-cognitive interference during gait as both gait speed and task performance were reduced during the dual-task condition. FES did not have a measured effect on motor-cognitive interference; the effect of visual task on gait speed was not reduced by FES and visual task performance did not improve when walking with FES. This latter finding is in contrast to the effect of FES perceived by users, as evidenced by the questionnaire results from this study and those reported in Chapter 3.

Analysis of other gait parameters in Chapter 5 revealed that FES reduced stance time on the paretic leg under dual-task. Even though this was a small change of 3% of the percentage of the gait cycle it was statistically significant (p=0.044), providing evidence that FES reduced the effect of motor-cognitive interference for this gait parameter. In addition, although not statistically significant (p=0.51), FES also reduced double support time during dual-task by 4% of the gait cycle, thus suggesting that FES had a positive effect on balance under circumstances of motor-cognitive interference. Sub-analysis of the questionnaire results when compared with the primary outcome measures, indicated inconsistency in agreement between these outcomes for some participants. Conclusions drawn from this analysis suggests that variation in the primary outcome results masked the group effect.

6.2 Limitations and future work

In this section the limitations of the thesis work are discussed and proposals to address them are offered to build on the outcomes of this exploratory work.

Interpretation of the results from the questionnaire study, reported in Chapter 3, should be approached with some cautions. Firstly, as with all self-administered questionnaires there was no guarantee that the questions were answered as requested. The careful ordering of the questions could have been negated by the respondent answering the questions in any order that they wished (Bowling, 2005). It is also possible that the person for whom the questionnaire was intended did not actually answer the questions. Secondly, some questions were omitted by respondents, even though the questions were structured to encourage completion and to allow for those respondents for whom each question did not apply. The results did include rates of non-completion for individual questions. Finally, there is the possibility of positively biased responses from respondents as the study had the co-operation of the clinical service from which they received their care. However, in contrast to the two previous FES studies by Taylor et al (1999, 2004) the study was implemented by an organisation independent of this clinical service. It could be assumed that the possibility of positively biased responses may have been reduced.

The longitudinal study reported in Chapter 4 suffered from recruitment difficulties and in hindsight may have been overly ambitious in the context of the absence of a well-established local FES service. Future work to investigate the effect of FES on motor-

cognitive with increasing use of FES would need to address this issue, perhaps via a recruitment from large well-established multiple clinical services over several years. It was concluded that the cross-sectional study outcomes, reported in Chapter 5, were affected by the number of participants. Even though the thesis aim was exploratory, the conclusions drawn could have been strengthened by a larger number of participants. For future work the results from the cross-sectional study could now be used to calculate sample size.

The improvement in gait speed, in the cross-sectional study, with FES compared with walking without FES was lower than in reported studies. It is difficult to define why this might have been the case as the inclusion and exclusion criteria were not restrictive. This result may limit the generalisation of the results to the broader FES user population.

Future work with an aim of capturing gait parameters dependent upon number of steps (i.e. measures of variability) would need to take into consideration participants with faster gait speeds and the choice of length of walkway. In this study, the minimum number of steps required to calculate stride time variability resulted in inclusion of a smaller sub-group of the entire study group. It is possible that this may have compromised analysis of the data. Thus, to represent all FES users, including those with faster gait speeds, future dual-task studies would need to address the issue of capturing sufficient number of steps to calculate step-dependent parameters.

Measures of changes in toe clearance and ankle joint angles were not collected in this thesis. It is of course possible that this data may have helped to identify the effect of FES on motor-cognitive interference and variation in responses to the dual-task. Future work could include these measures, and those associated with compensatory strategies for foot drop involving knee and hip motion, to explore the effect of FES under dual-task. Furthermore, the studies relied upon self-reported fall events data. Further work could include strengthening this aspect by inclusion of more robust measures of falls both retrospectively and prospectively, utilising validated methods from the falls literature.

Whilst the visual task used in the dual-task studies was developed in the context of a critique of reported studies, outcomes from the questionnaire and existing

neuropsychological tests, it is possible that those participants who did not show evidence of motor-cognitive interference did not find that the task created a sufficient cognitive load. There is some indication of this from results for the task whilst seated, as there appeared to be a ceiling effect. To address this and reduce variation in group results there may be some merit in further work using an alternative task or a battery of several tasks to further explore and define the dual-task effect that is evident for a sub-group of FES users. The type and difficulty of task has been suggested as affecting different aspects of gait in stroke populations (Plummer-D'Amato et al., 2008, Plummer-D'Amato and Altmann, 2012) and this could also be true of FES user groups. Thus, use of different tasks could be incorporated into a dual-task design to define these potential effects. It is recommended that tasks chosen for future work have a link with perceived effects reported by FES users.

Finally, it is possible that a dual-task approach may provide a measurable difference between the effect of FES and AFOs that reflects user preference for FES. However, before this type of study is pursued the effect of FES on motor-cognitive interference needs to be more clearly defined.

6.3 Conclusion

The primary aim of the work presented in this thesis was to explore the contribution of FES to the cognitive control of gait. This was achieved initially via a questionnaire study of established FES users. Evidence of a positive effect of FES was provided by a significant reduction in the amount of concentration required when walking with FES and recognition of an effect on secondary tasks whilst walking. These results informed and provided confidence in the pursuit of a dual-task study to explore the effect of FES further.

This thesis reports on the first dual-task study of FES users. This approach was established as feasible and safe for FES users via piloting work. Application of a dual-task study, to assess the effect of FES, was novel in several aspects. Firstly, whilst there have been a large number of dual-task studies reported, there are a much smaller number involving stroke groups and only a handful involving the assessment of device effects. Secondly, this study reported on both gait speed and visual task performance as primary outcome measures, in the context of the dual-task literature where both are not consistently analysed. This required that the task be measurable as an indicator of motor-cognitive interference, bringing complexity to

the study design that was addressed. Finally, the visual recognition memory task which was developed for this thesis represents a task not requiring a verbal response whilst walking and thus avoiding the motor interference of articulation whilst walking. The use of a purely cognitive task was rare in the dual-task literature, as was the use of visual input. Thus, this visual task was novel in its design and application.

The thesis achieved the overall aim of exploring the contribution of FES to the cognitive control of gait. Whilst not conclusive, results suggest that FES can reduce the motor-cognitive interference experienced during a dual-task situation and indicate that there is merit in further studies to define this effect.

Appendix A

Contents

A.1 FES Questionnaire

A.2 Ethical and Research and Development Approvals

A.3 Participant invitation letter

A.4 Participant information sheet

A.5 Letter from Salisbury FES service

Appendix Section A.1

FES Questionnaire

Questionnaire

Section A : A few questions about you

1) What is your sex? *Please circle.*

Male	Female

2) What is your date of birth? ……

3) When did you have your stroke? *An approximate date or month and year is sufficient if you do not know an exact date e.g. May 2003.*

……

4) Does your stroke affect one side of your body more than the other side? *Please circle.*

Yes, the right	Yes, the left	No

5) Please list in the space below any problems with your health or any disabilities?

Please go to the section overleaf.

Section B : About your use of the stimulator (ODFS)

1) Do you continue to use the stimulator? *Please circle*

Yes **Please continue**	No **Please go to page 7. You are not required to answer any further questions**

2) How many days a week do you use the stimulator?……...

3) On the days that you use the stimulator, for how many hours do you usually wear it?

……..……

4) When do you use your stimulator? *For **each** of the following activities, please tell us which answer applies to you, by placing a tick in **one** of the four columns.*

	I always do this **with** the stimulator	I always do this **without** the stimulator	I do this **with and without** the stimulator	I don't do this
Walking around the home				
Walking indoors				
Walking outdoors				
Longer walks				
Day trips				
Shopping				
Social events				
At work or college				
Exercising				
Physiotherapy				
Please specify any other activities that you do with the stimulator.				

Please go to the next page.

Section C : About the effect of the stimulator

1) What are you able to do when you use your stimulator? *For **each** of the following statements, please answer by placing a tick in **one** column*.

	Agree	Disagree	Doesn't apply
I am able to walk further			
I am able to walk faster			
It is less effort for me to walk			
I am less likely to trip and fall			
I am more able to walk on uneven ground			
I feel more confident when I walk			
I am more independent			
I am able to exercise more			
I need to use my stick, crutches or frame less often			
I am able to walk without assistance from another person more often			
My posture is better			
My walking is more balanced and even			
I am able to walk more safely			
Please specify any other effects of using the stimulator			

2) Of the statements that you have just **agreed** with, which **one is the most important** reason for using the stimulator?

Please circle the statement on the above list.

Please go to the questions overleaf.

3) Do you use other walking aids when walking **with and without** the stimulator? *For **each** item, please answer by placing a tick in the columns that apply to you.*

	With the stimulator	**Without** the stimulator	Don't use at all
Walking stick			
Walking tripod			
Walking frame			
Crutches			
AFO, leg splint or calliper			
Assistance from another person			
Please specify any other walking aids that you use			

4) How much concentration do you have to use when walking? *For **each** situation, please place a tick in the **one** column that corresponds to your experience.*

	None	**Some**	**A lot**
With the stimulator			
Without the stimulator			

Please go to the next page.

5) Is there a difference to your walking when you use the stimulator? *Please complete **each** of the following statements, by placing a tick in **one** column.*

	easier than without the stimulator	**the same** as without the stimulator	**harder** than without the stimulator
When I use the stimulator, I find talking to someone whilst I walk……..			
When I use the stimulator, I find thinking about something else whilst I walk…..			
When I use the stimulator, I find stepping up onto a kerb……			
When I use the stimulator, I find looking at the things around me when I walk….			
When I use the stimulator, I find walking on uneven ground…….			
When I use the stimulator, I find walking without looking at the ground…..			
When I use the stimulator, I find walking in a noisy environment……			
When I use the stimulator, I find avoiding a trip or a fall whilst I walk ……			
When I use the stimulator, I find answering questions whilst I walk……			
When I use the stimulator, I find walking without thinking about walking……..			

6) Which of the statements, that you have just agreed are **easier with the stimulator,** is the **one that is most important** to you?

*Please circle **one** statement on the above list.*

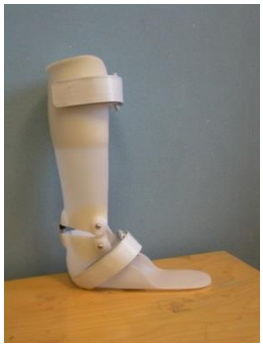
Please go to the section overleaf.

Section D : About your stimulator

1) When did you first start to use the stimulator? *An approximate date or month and year is sufficient if you do not know an exact date e.g. May 2003.*

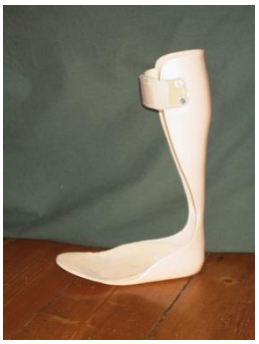
……

2) If you also use a splint, what type of splint do you use? *Please circle the photo or description that most closely resembles your splint.*

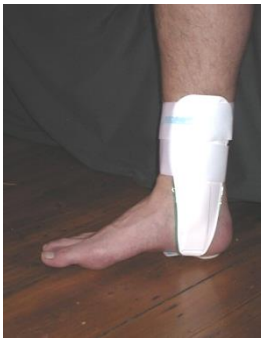


Hinged AFO

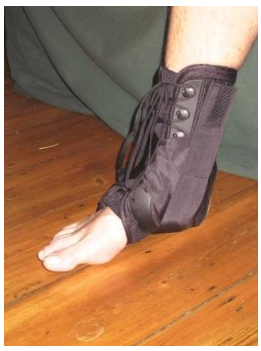
Supralite AFO



AFO



Aircast ankle brace



Speed brace

Foot-up

2.1 **None of these**

3) If you also use a splint, which of the following has helped you to walk with the **least** effort? *Please circle*

Stimulator	Splint

Please go to the next page.

Thank you for taking the time to complete this questionnaire.

Please use the space below to tell us about any further thoughts or comments.

Please use the stamped, addressed envelope to return to :-

Jane McAdam – PhD Student
C/- Dr. L.P.J. Kenney
Research Fellow
Centre for Rehabilitation and Human Performance Research
Brian Blatchford Building
University of Salford
Salford M6 6PU

Appendix Section A.2

Ethical and Research and Development Approvals

Salford & Trafford Local Research Ethics Committee
Room 181
Gateway House
Piccadilly South
Manchester
M60 7LP

Telephone: 0161 237 2438
Facsimile: 0161 237 2383

16 June 2005

Ms Jane McAdam
PhD student - Podiatric Medicine
175 Urmston Lane
Manchester M32 9EH

Dear Ms McAdam

Full title of study: **An investigation into two orthotic devices, their usage patterns, user perceptions and their effects on effort.**
REC reference number: **05/Q1404/112**

The Research Ethics Committee reviewed the above application at the meeting held on 14 June 2005.

Ethical opinion

The Committee found the study to be well presented and had no ethical objections. The Committee having requested that the consent form was withdrawn from the protocol, (as completion of the questionnaire signifies consent) note your confirmation from your email dated 15th June 2005.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Application	1	25 May 2005
Investigator CV	Jane McAdam	24 May 2005
Investigator CV	Dr Laurence Kenny - Supervisor	24 May 2005
Protocol	1	24 May 2005
Covering Letter		24 May 2005
Interview Schedules/Topic Guides	FES group to Salisbury District Hospital	24 May 2005
Copy of Questionnaire	Section A; FES;Effort	24 May 2005

	statements	
Letters of Invitation to Participants	1AFO group	24 May 2005
Letters of Invitation to Participants	1 FES group	25 May 2005
Participant Information Sheet	1 AFO group	24 May 2005

Management approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final management approval from the R&D Department for the relevant NHS care organisation.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Notification of other bodies

The Committee Administrator will notify the research that the study has a favourable ethical opinion.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

05/Q1404/112	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project,

Yours sincerely

Dr Mike Addison
Chairman, Salford and Trafford LREC

Email: Maggie.Twiney@gmsha.nhs.uk

Enclosures:

Attendance at Committee meeting on 14 June 2005
Standard approval conditions
Site approval form (SF1)

Ms Jane McAdam
Centre for Rehabilitation
& Human Peforamance
Research
Brian Blatchford Building
University of Salford
Salford
M6 6PU

Salford Royal Hospitals NHS
NHS Trust
Research and Development Directorate
Ground Floor C.S.B.
Hope Hospital
Salford M6 8HD

Director Dr. Martin Gibson

R & D Manager Mrs Julia O`Toole
JO'Toole@hope
Tel: 0161 206 5583

PA to Dr. M Gibson Ann Lundy
alundy@hope.man.ac.uk
Tel: 0161 206 5584

14th July

Dear Ms McAdam

Study Title: An investigation into two orthotic devises, their usage patterns, userperceptions and their effects on effort Rec Ref: 05/Q1404/112
Thank you for forwarding all the required documentation for your study as above. We are pleased to inform you that your study has been given Trust approval, and registered with the R&D office.

Please note that it is a requirement of the approval given by the Trust that all research, including, "clinical and non-clinical research, research undertaken by NHS staff using NHS resources, and research undertaken by industry, the charities, the research councils and Universities within the health and social care systems" must comply with the Department of Health Research Governance Framework for Health and Social Care and Good Clinical Research Practice. Clinical trials of medicinal products must comply with EU Directive 2001/20/EC & Medicines for Human Use Regulations (Clinical Trials) 2004. www.dh.org.uk

All clinical research must comply with the Health and Safety at Work Act. www.hse.gov.uk and the Data Protection Act. http://www.hmso.gov.uk/acts

Where Salford Royal Hospitals NHS Trust is registered on the notification form as the research 'sponsor' as described in the DH Research Governance Framework for Health & Social Care, please sign the attached Principle Investigator checklist and return to R&D (retaining a copy for your files).

Yours sincerely

Julia O'Toole
Research & Development Manager

Research Committee

Research Governance and Ethics Sub-Committee (RGEC)

MEMORANDUM

To	**Jane McAdam**
cc:	Professor K Holland
From	M Pilotti, Contracts Officer
Date	**19 July 2005**

Subject: **Approval of your Project by RGEC**

Project Title: **An investigation into two orthotic devices, their usage patterns, user perceptions and their effects on effort**

RGEC Project code: **RGEC04/50**

I can confirm that based on the information you have provided, the RGEC has no objections to the study on ethical grounds.

Regards,

Max Pilotti
(Contracts Officer)

For enquiries please contact
M U Pilotti, Contracts Officer
Contracts Office for Research and Enterprise
Research and Graduate College
Faraday Building
Telephone 0161 295 52654 Facsimile 0161 295 5526
E-mail m.u.pilotti@salford.ac.uk

Appendix Section A.3

Participant Invitation Letter

Centre for Rehabilitation and Human Performance Research
The University of Salford
Brian Blatchford Building
Salford. M6 6PU

July 2005

Dear Sir/Madam

RE : Study Title : An investigation into usage patterns, user perceptions and effects on effort of two orthotic devices.

I believe that you have received a drop foot stimulator from the Department of Medical Physics and Biomedical Engineering at Salisbury Hospital. My name is Jane McAdam and I work in collaboration with Dr Paul Taylor from the Salisbury department.

I would like to invite you to take part in a research study. This study fulfils part of the requirements for completion of my PhD.

Before you decide to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the enclosed information leaflet carefully and discuss it with others if you wish.

You are welcome to contact myself or Paul Taylor if anything is not clear or if you would like more information. Our contact details are at the end of this letter. Please take some time to decide whether or not you wish to take part.

Thanking you.

Jane McAdam – PhD Student
Clinical Specialist Podiatrist
C/- Dr. L.P.J. Kenney
Research Fellow
Centre for Rehabilitation and
Human Performance Research
Brian Blatchford Building
University of Salford
Salford
Manchester M6 PU

Ph : c/- 0161 206 4710
Mobile :07715 005 843
Email : Jane.McAdam@salford-pct.nhs.uk

Dr Paul Taylor
Principle Clinical Engineer
Department of Medical Physics and
Biomedical Engineering
Salisbury District Hospital
Wiltshire SP2 8BJ

Ph : 01722 429 065
Email : p.taylor@mpbe-sdh.demon.co.uk

Appendix Section A.4

Participant Information Sheet

Centre for Rehabilitation and Human Performance Research
The University of Salford
Brian Blatchford Building
Salford. M6 6PU

July 2005

INFORMATION LEAFLET

Name of Researcher : Jane McAdam

Study Title : An investigation into usage patterns, user perceptions and effects on effort of two orthotic devices.

What is the purpose of the study?

This study is being conducted to clarify our understanding of the effectiveness of orthoses for patients like yourself. In particular, we would like to find out about your views on your orthosis and the ways in which you feel that it affects your function. In the longer term, we hope that the results from this study will help to inform clinical practice

Why have I been chosen?

I am sending this letter to all patients who have problems with walking as a result of a stroke, and received a single channel Odstock Dropped Foot Stimulator from the Department of Medical Physics and Biomedical Engineering at Salisbury District Hospital, between and including July 2002 to June 2004. This letter is being sent to approximately 120 patients.

Do I have to take part?

It is up to you to decide whether or not to take part. You do not have to give a reason for not taking part. A decision not to take part will not affect the standard of care that you receive.

What do I have to do?

To take part in the study, you are asked to complete the enclosed consent form and questionnaire and return it in the enclosed addressed envelope. If a reply has not been received from you after 4 weeks, another questionnaire will be sent to you, to give you another opportunity to take part.

Please read the information over the page.

What are the benefits of taking part?

The information that is obtained from this study may help to provide better treatment for stroke patients in the future.

Will my taking part in this study be kept confidential?

All information that is collected about you will be kept strictly confidential. The questionnaire is anonymous and will be separated from the consent form upon receipt.

What will happen to the results of the research study?

I hope to present the results of this study at a conference in September 2005. The results of this study will help to inform a further study for completion of my PhD.

You are welcome to contact me if you would like a copy of the results of this study when they are available.

Who is organising the research?

This research is organised through the University of Salford.

Who has reviewed this study?

Salford University and the Salford and Trafford Research Ethics Committee have reviewed this study.

Thank you for taking the time to read this.

If you are willing to take part in this study please complete the enclosed consent form and questionnaire and use the addressed envelope to return it to me.

You are welcome to keep this information sheet.

Appendix Section A.5

Letter from Salisbury FES service

Salisbury Health Care NHS
NHS Trust

Department of Medical Physics and Biomedical Engineering
Salisbury District Hospital
Salisbury
Wiltshire
SP2 8BJ
Tel: 01722 429 065
E-mail: p.taylor@mpbe-sdh.demon.co.uk

July 2005

Dear Sir/Madam

The Department of Medical Physics and Biomedical Engineering has been asked to assist researchers at the University of Salford with a research project. The project aims to find out how the ODFS is used and how it affects the way users of the device live their life. This information will be used to help future developments.

Please read the enclosed information carefully. If you wish to take part in the study, please complete the enclosed questionnaire and consent form, and return it in the stamped addressed envelope. Participation is entirely voluntary and if you do not take part it will not affect in any way the treatment you receive from Salisbury District Hospital.

Please be assured that no confidential information about you has been released to researchers outside Salisbury District Hospital. All questionnaires are anonymous.

If you have any questions please feel free to contact myself or Jane McAdam at Salford University.

Thank you.

Yours sincerely

Paul Taylor
Clinical Engineer
Co-ordinator of FES research and clinical service

Appendix B

Contents

B.1 FES Questionnaire

B.2 Verbal recognition memory test

B.3 Visual recognition memory test

B.4 Falls Efficacy Scale (FES)

B.5 Falls Risk Assessment Tool (FRAT)

B.6 Fall and near fall history

B.7 National Adult Reading Test (NART)

B.8 Digit Span Test

B.9 Barthel Score

B.10 Ethical and Research and Development Approvals

B.11 Ethical and Research and Development Approvals – Amendment

B.12 Participant invitation letter

B.13 Participant information sheet

B.14 Participant invitation letter (FES provided by CI)

B.15 Participant information sheet (FES provided by CI)

B.16 Consent Form

B.17 GP/Health professional Letter

Appendix Section B.1

FES Questionnaire

Questionnaire

Section A : About your use of the stimulator (ODFS)

1) When do you use your stimulator? *For **each** of the following activities, please tell us which answer applies to you, by placing a tick in **one** of the four columns.*

	I always do this **with** the stimulator	I always do this **without** the stimulator	I do this **with and without** the stimulator	I don't do this
Walking around the home				
Walking indoors				
Walking outdoors				
Longer walks				
Day trips				
Shopping				
Social events				
At work or college				
Exercising				
Physiotherapy				
Please specify any other activities that you do with the stimulator.				

Please go to the next page.

Section B : About the effect of the stimulator

1) What are you able to do when you use your stimulator? *For **each** of the following statements, please answer by placing a tick in **one** column*.

	Agree	Disagree	Doesn't apply
I am able to walk further			
I am able to walk faster			
It is less effort for me to walk			
I am less likely to trip and fall			
I am more able to walk on uneven ground			
I feel more confident when I walk			
I am more independent			
I am able to exercise more			
I need to use my stick, crutches or frame less often			
I am able to walk without assistance from another person more often			
My posture is better			
My walking is more balanced and even			
I am able to walk more safely			
Please specify any other effects of using the stimulator			

2) Of the statements that you have just **agreed** with, which **one is the most important** reason for using the stimulator?
*Please circle **one** statement on the above list.*

Please go to the next page.

3) Do you use other walking aids when walking **with and without** the stimulator? *For **each** item, please answer by placing a tick in the columns that apply to you.*

	With the stimulator	**Without** the stimulator	Don't use at all
Walking stick			
Walking tripod			
Walking frame			
Crutches			
AFO, leg splint or calliper			
Assistance from another person			
Please specify any other walking aids that you use			

4) How much concentration do you have to use when walking? *For **each** situation, please place a tick in the **one** column that corresponds to your experience.*

	None	**Some**	**A lot**
With the stimulator			
Without the stimulator			

Please go to the next page.

5) Is there a difference to your walking when you use the stimulator? *Please complete **each** of the following statements, by placing a tick in **one** column.*

	easier than without the stimulator	**the same** as without the stimulator	**harder** than without the stimulator
When I use the stimulator, I find talking to someone whilst I walk……..			
When I use the stimulator, I find thinking about something else whilst I walk…..			
When I use the stimulator, I find stepping up onto a kerb……			
When I use the stimulator, I find looking at the things around me when I walk….			
When I use the stimulator, I find walking on uneven ground…….			
When I use the stimulator, I find walking without looking at the ground…..			
When I use the stimulator, I find walking in a noisy environment……			
When I use the stimulator, I find avoiding a trip or a fall whilst I walk ……			
When I use the stimulator, I find answering questions whilst I walk……			
When I use the stimulator, I find walking without thinking about walking……..			

6) Which of the statements, that you have just agreed are **easier with the stimulator,** is the **one that is most important** to you?

*Please circle **one** statement on the above list.*

Please go to the next page.

7) If you also use a splint, which of the following has helped you to walk with the **least** effort? *Please circle*

Stimulator	Splint

Thank you for taking the time to complete this questionnaire.

Please use the space below to tell us about any further thoughts or comments.

Appendix Section B.2

Verbal recognition memory test

Example of target words

Event
Does
Ease
Since
Were
Below
Why
Anyone
Less
Affirm

Example of target words paired with foils

Get	Does
Gone	Below
Plea	Why
Ease	Once
Known	Less
Were	Useful
Anyone	Best
Event	Same
Affirm	Hardly
Audit	Since

Appendix Section B.3

Visual recognition memory test

Example of paired figures

A

B

Appendix Section B.4

Falls Efficacy Scale (FES)

Participant ID _____

TINETTI`S FALLS EFFICACY SCALE

On a scale of 1 to 10 how confident are you?

1 = extremely confident
10 = having no confidence at all (or don't even try)

Questions	**Circle the best answer** **Most Confident ---------- Least confident**									
Taking a bath or shower?	1	2	3	4	5	6	7	8	9	10
Reaching into cupboards?	1	2	3	4	5	6	7	8	9	10
Preparing a meal (not requiring carrying heavy or hot objects)	1	2	3	4	5	6	7	8	9	10
Walking around the house?	1	2	3	4	5	6	7	8	9	10
Getting in/ out of bed?	1	2	3	4	5	6	7	8	9	10
Answering the door or telephone?	1	2	3	4	5	6	7	8	9	10
Getting in/out of a chair?	1	2	3	4	5	6	7	8	9	10
Getting dressed or undressed?	1	2	3	4	5	6	7	8	9	10
Doing light housekeeping?	1	2	3	4	5	6	7	8	9	10
Doing simple shopping?	1	2	3	4	5	6	7	8	9	10
Score /100	3									

Completed by _____ _____
(printed name) (signature)

Date _____

Appendix Section B.5

Falls Risk Assessment Tool (FRAT)

Participant ID _____

FALLS RISK ASSESSMENT TOOL - FRAT

A fall is **"an event which results in a person coming to rest unintentionally on the ground or other lower level, not as a result of a major intrinsic event (such as a stroke) or overwhelming hazard".**

If there is a positive response to **three or more** of the questions on the form, then the person should be considered as being at **high risk of falling** in the future.

		YES	NO
1	Is there a history of any fall in the previous year? **How assessed?** Ask the person.		
2	Is the participant on four or more medications per day? **How assessed?** Identify number of prescribed medications		
3	Does the participant have a diagnosis of stroke or Parkinson's Disease? **How assessed?** Ask the person.		
4	Does the participant report any problems with their balance? **How assessed?** Ask the person.		
5	Is the participant unable to rise from a chair of knee height? **How assessed?** Ask the person to stand up, from a chair of knee height, without using their arms.		

(Nandy et al 2004,2005)

Completed by _____ Date_____
(printed name)

Completed by _____
(signature)

Appendix Section B.6

Fall and near fall history

Participant ID _____

FALL and NEAR FALL HISTORY

During the last year has the participant experienced any falls or near falls? (record approximate date)

For each event record the following (tick the appropriate box)

Where did you fall/nearly fall?	**EVENT**	1	2	3	4
Inside	On the one level				
	Getting out of bed				
	Getting out of a chair				
	Using the shower/bath				
	Using the toilet				
	Walking up/down stairs				
Home entrances or garden	On the one level				
	Walking up/down steps/stairs				
	In the garden				
Away from home	On the footpath				
	On a kerb/gutter				
	In a public building				
	Getting out of a vehicle				
	In another person's home				
Other					
How did you fall/nearly fall?	Trip				
	Slip				
	Loss of balance				
	Legs gave way				
	Faint/dizzy				
	Lost concentration				
	Not sure				
Did you suffer any injuries?	NO				
	Bruises				
	Cuts/grazes				
	Fracture (specify)				
	Other				

(adapted from Lord et al 2001)

Completed by _____ _____
(printed name) (signature)

Date _____

Appendix Section B.7

National Adult Reading Test (NART)

SECOND EDITION

Word Card

CHORD	SUPERFLUOUS
ACHE	SIMILE
DEPOT	BANAL
AISLE	QUADRUPED
BOUQUET	CELLIST
PSALM	FACADE
CAPON	ZEALOT
DENY	DRACHM
NAUSEA	AEON
DEBT	PLACEBO
COURTEOUS	ABSTEMIOUS
RAREFY	DETENTE
EQUIVOCAL	IDYLL
NAÏVE	PUERPERAL
CATACOMB	AVER
GAOLED	GAUCHE
THYME	TOPIARY
HEIR	LEVIATHAN
RADIX	BEATIFY
ASSIGNATE	PRELATE
HIATUS	SIDEREAL
SUBTLE	DEMESNE
PROCREATE	SYNCOPE
GIST	LABILE
GOUGE	CAMPANILE

Appendix Section B.8

Digit Span Test

Participant ID _____

DIGIT SPAN — Discontinue after failure on BOTH TRIALS of any item. Administer BOTH TRIALS of each item, even if subject passes first trial

DIGITS FORWARD		Pass/ Fail	Score 2,1 or 0	DIGITS BACKWARD		Pass/ Fail	Score 2,1 or 0
1	5 – 8 – 2 6 – 9 – 4			1	2 – 4 5 – 8		
2	6 – 4 – 3 – 9 7 – 2 – 8 – 6			2	6 – 2 – 9 4 – 1 – 5		
3	4 – 2 – 7 – 3 – 1 7 – 5 – 8 – 3 – 6			3	3 – 2 – 7 – 9 4 – 9 – 6 – 8		
4	6 – 1 – 9 – 4 – 7 – 3 3 – 9 – 2 – 4 – 8 – 7			4	1 – 5 – 2 – 8 – 6 6 – 1 – 8 – 4 – 3		
5	5 – 9 – 1 – 7 – 4 – 2 – 8 4 – 1 – 7 – 9 – 3 – 8 – 6			5	5 – 3 – 9 – 4 – 1 – 8 7 – 2 – 4 – 8 – 5 – 6		
6	5 – 8 – 1 – 9 – 2 – 6 – 4 – 7 3 – 8 – 2 – 9 – 5 – 1 – 7 – 4			6	8 – 1 – 2 – 9 – 3 – 6 – 5 4 – 7 – 3 – 9 – 1 – 2 – 8		
7	2 – 7 – 5 – 8 – 6 – 2 – 5 – 8 – 4 7 – 1 – 3 – 9 – 4 – 2 – 5 – 6 – 8			7	9 – 4 – 3 – 7 – 6 – 2 – 5 – 8 7 – 2 – 8 – 1 – 9 – 6 – 5 – 3		
	Total Forward		Max=14		*Total Backward*		Max=14

Completed by _____ _____ Date _____
(printed name) (signature)

Appendix Section B.9

Barthel Score

Participant ID _____

Barthel score

The Barthel score consists of 10 measures of daily functioning. The person receives a score depending on how much help they need to do a task – the higher the total score (maximum = 20), the more independent the person.

Bowels	0	Incontinent
	1	Occasional accident
	2	Continent
Bladder	0	Incontinent/catheterised and unable to manage
	1	Occasional accident
	2	Continent
Grooming	0	Needs help
	1	Independent for face/hair/teeth/shaving
Toilet use	0	Dependent
	1	Needs some help
	2	Independent
Feeding	0	Dependent
	1	Needs help, e.g. cutting food, spreading butter
	2	Independent in all actions
Transfer (bed-chair)	0	Unable
	1	Major help, can sit
	2	Minor help (verbal or physical)
	3	Independent
Walking	0	Unable
	1	Independent in wheelchair
	2	Walks with help of person (verbal or physical)
	3	Independent (may use aid)
Dressing	0	Dependent
	1	Needs help but does half
	2	Independent
Stairs	0	Unable
	1	Needs help (verbal/physical)
	2	Independent
Bathing	0	Dependent
	1	Independent
Total		

Mahoney FT, Barthel DW. Functional evaluation : Barthel index. Md State Med J 1965; 14; 61-65.

Completed by _____ _____
(printed name) (signature)

Date _____

Appendix Section B.10

Ethical and Research and Development Approvals

National Research Ethics Service
Stockport Research Ethics Committee
Room 181, Gateway House
Piccadilly South
Manchester
M60 7LP

Telephone: 0161 237 2585
Facsimile: 0161 237 2383

20 November 2008

Private & Confidential
Ms J McAdam, PhD Student (part-time)
Centre for Rehabilitation and Human Performance Research
C/o Dr. L. Kenney (Senior Research Fellow)
Brian Blatchford Building
University of Salford
Salford
M6 6PU

Dear Ms McAdam

Full title of study: **The effect of FES on gait variability under dual-task conditions, in post-stroke drop foot subjects**
REC reference number: **08/H1012/80**

Thank you for your response to the Committee's request for further information on the above research and for submitting revised documentation. The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). The favourable opinion for the study applies to all sites involved in the research. There is no requirement for other Local Research Ethics Committees to be informed or SSA to be carried out at each site.

Conditions of the favourable opinion

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	2008 *Date*
GP/Consultant Information Sheets	2	25 October 2008
Questionnaire: FES questionnaire	2	25 October 2008
Questionnaire: Falls efficacy scale	2	25 October 2008
Questionnaire: Fall and near fall history	2	25 October 2008
Questionnaire: Falls Risk Assessment Tool (FRAT)	2	25 October 2008
Application	5.6	05 August 2008
Investigator CV	Jane McAdam - 1	07 August 2008
Investigator CV	Laurence Kenny - 1	07 August 2008
Investigator CV	Sibylle Thies - 1	07 August 2008
Response to Request for Further Information	1	26 October 2008
Participant Consent Form	2	25 October 2008
Participant Information Sheet	2	25 October 2008
Participant Information Sheet – FES provision by CI	2	25 October 2008
Letter of invitation to participant	2	25 October 2008
Application	5.6 (2)	25 October 2008
Response to Request for Further Information	2	
Protocol	2	23 October 2008

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

08/H1012/80	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

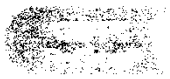
Yours sincerely

Mr Simon Jones
Chair

Email: elaine.hutchings@northwest.nhs.uk

Enclosure: "After ethical review – guidance for researchers"

Copy to: Dr Max Pilotti, Research Office
University of Salford
Faraday House
Salford
M5 4WT



Greater Manchester NHS

SalfoR+D
Acute & Primary Care Research

Acting NHS SalfoR+D Director: Dr Stephen Waldek
Associate NHS SalfoR+D Director: Dr Lloyd Gregory
ReGrouP Manager: Mrs. Linda Dack

Enquiries: Email: Salford-ReGroup-RD&[illegible]
Tele: 0161 206 8343
Fax: 0161 206 4205
Web address: http://www.gmregroup.nhs.uk/index.htm

02 June 2009

Ms Jane McAdam
Centre for Rehabilitation and Human Performance Research
C/O- Dr. L. Kenney (Senior Research Fellow)
Brian Blatchford Building
University of Salford
Salford
M6 6PU

Dear Ms McAdam

Study Title: **The effect of FES on gait variability under dual-task conditions, in post-stroke drop foot subjects.**
REC Ref No: **08/H1012/80**
R&D Ref No: **RMG 09 027**

Thank you for forwarding all the required documentation for your study as above. I am pleased to inform you that your study has been registered with ReGrouP and has gained NHS R&D approval from the following NHS Trusts:

- **NHS Heywood, Middleton & Rochdale (PCT)**
- **NHS Salford (PCT)**

All clinical research must comply with the Health and Safety at Work Act, www.hse.gov.uk and the Data Protection Act. http://www.hmso.gov.uk/acts

It is a legal requirement for Principal Investigators involved in Clinical Trials to have completed accredited ICH GCP training within the last 2 years. Please ensure that you provide the R&D Department with evidence of this (certificate for completing the course). A list of GCP training courses can be obtained from the R&D Office.

All researchers who do not hold a substantive contract with the Trust must hold an honorary research contract before commencing any study activities related to this approval. The 'Research Passport Application Form'.

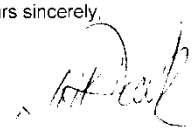
This can be obtained from web addresses: http://www.gmregroup.nhs.uk/researchers/passports.htm and http://www.hope.academic.org.uk/academic.salford/rd/Research%20Passports.htm. This form should be completed and returned, with a summary C.V and recent (within 6 months) CRB to the address shown above.

It is a condition of both NRES and NHS R&D approval that participant recruitment data should be forwarded on a regular basis. Therefore, progress reports must be submitted annually to the main REC and copied to the R&D office until the end of the study.
http://www.nres.npsa.nhs.uk/applications/review-after-progress-reports/.

Any amendments to the study should also be notified and approval sought by Ethics Committee and R&D Department. On completion of the study you are required to submit a 'Declaration of End of Study' form to the main REC, which should also be copied and forwarded to the R&D office at the address shown above.

Any serious adverse events or governance issues related to the research must be notified to the R&D office.

Yours sincerely,



Linda Dack (Mrs)
ReGrouP Manager

Cc Dr Max Pilotti (Sponsor's representative)
File

Appendix Section B.11

Ethical and Research and Development Approvals – Amendment 1

National Research Ethics Service

North West 8 Research Ethics Committee - Greater Manchester East
3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7820

26 February 2010

Private & Confidential
Ms J McAdam
PhD Student (part-time)
Centre for Rehabilitation and Human Performance Research
The University of Salford
Brain Blatchford Building
Salford
M6 6PU

Dear Ms McAdam

Study title:	**The effect of FES on gait variability under dual-task conditions, in post-stroke drop foot subjects**
REC reference:	**08/H1012/80**
Amendment number:	**1**
Amendment date:	**08 February 2010**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Letter of invitation to participant - FES provided by physiotherapist	3	08 February 2010
Participant Information Sheet: FES provided by the CI	3	08 February 2010
Participant Information Sheet: FES provided by physiotherapist	3	08 February 2010
Notice of Substantial Amendment (non-CTIMPs)	1	08 February 2010
Letter of invitation to participant - FES provided by the CI	3	08 February 2010

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

08/H1012/80:	**Please quote this number on all correspondence**

Yours sincerely

Ms Elaine Hutchings
Committee Co-ordinator Email: elaine.hutchings@northwest.nhs.uk

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr Max Pilotti, University of Salford

Greater Manchester

SalfoR+D
Acute & Primary Care Research

SalfoR+D Director: Professor Bill Ollier
NHS SalfoR+D Associate Director: Dr Lloyd Gregory
ReGrouP Manager: Rachel Georgiou
Enquiries: Email: [redacted]
Tele: 0161 206 8343
Fax: 0161 206 4205
SalfoR+D web address: http://www.nhssalfordrd.org.uk
ReGrouP web address: http://www.gmtdgroup.nhs.uk/index.htm

Our ref: **RMG/09/027**

Friday 26 March 2010

Ms Jane McAdam
Centre for Rehabilitation and Human Performance Research
C/0 Dr L.P.J. Kenney – Senior Research Fellow
Brian Blatchford Building
University of Salford
Salford M6 6PU

Dear Ms McAdam

Study Title: **The effect of FES on gait variability under dual-task conditions, in post-stroke drop foot subjects**
REC No: **08/H1012/80**

Thank you for sending details/documents of the following amendment to the R&D Office.

Document	Version	Date
Favourable REC approval letter	Amendment 1	26/02/10
Notice of substantial amendment (non CTIMPS)	Amendment 1	08/02/10
Patient invite letter – FES provided by NHS physio	3	08/02/2010
Patient info leaflet – FES provided by NHS physio	3	08/02/2010
Patient invite letter – FES provided by CI	3	08/02/2010
Patient info leaflet – FES provided by CI	3	08/02/2010

I am pleased to confirm that the amendment has been noted and approved by the R&D Department for Heywood, Middleton and Rochdale PCT and Salford PCT. Please keep us informed of any future amendments.

If you are a University employee, please check with the University Research Office whether this amendment will affect the insurance cover of your study.

Please ensure that you forward to the R&D department the necessary progress reports when submitting these to the Ethics Committee. On completion of the study you are required to submit a 'Declaration of End of Study' form and Final Report to the main REC, which should also be copied and forwarded to the R&D office at the address shown above

Yours sincerely

Rachel Georgiou
RMG and ReGrouP Manager

CC File

Appendix Section B.12

Participant Invitation Letter

Centre for Rehabilitation &
Human Performance Research
The University of Salford
Brian Blatchford Building
Salford. M6 6PU

February 2010

Dear Sir/Madam

Study Title: The effect of FES on gait variability under dual-task conditions, in post-stroke drop foot subjects.

Your physiotherapist has identified you as someone who will shortly be receiving a Functional Electrical Stimulation (FES) device to help with your walking. As such I would like to invite you to take part in a research study. My name is Jane McAdam. I am a Podiatrist, working for Salford Community Health NHS Trust. I am also studying part-time to complete a PhD, at the University of Salford. This study will help me to complete my PhD.

You have agreed with your physiotherapist, that your contact details can be forwarded to myself. I shall be contacting you within the next week to ask if you would be willing to participate. If, at this point, you decide not to take part in the study, I will not contact you again. This decision will have no impact on your ongoing care.

To take part in the study, I would like to see you four times over the next 3-4 months, for a total of up to 9 hours. Before you decide to take part, it is important for you to understand why the research is being done and what would happen at each visit. Please take time to read the attached information leaflet carefully and discuss it with others if you wish.

When we first speak to each other, I will ask you a few questions about your availability, discuss any questions that you may have and arrange a convenient time to visit you at home. If you would prefer, you can attend the University of Salford for this first visit. Your partner, family member or a friend can be present.

You are welcome to contact me, before deciding to take part, if anything is not clear or if you would like more information. Please take some time to decide whether or not you wish to take part.

Thanking you.

Jane McAdam – Principal Podiatrist and PhD Student
C/- Dr. L.P.J. Kenney, Senior Research Fellow
Centre for Rehabilitation and Human Performance Research
Brian Blatchford Building, University of Salford, Salford M6 6PU
Ph: c/- 0161 206 4710 (Podiatry Department - Hope Hospital)
c/- 0161 212 5500 (Podiatry Department – Salford Community Health NHS Trust)
Mobile: 07715 005 843
Email: Jane.McAdam@salford.nhs.uk

Appendix Section B.13

Participant Information Sheet

Centre for Rehabilitation &
Human Performance Research
The University of Salford
Brian Blatchford Building
Salford. M6 6PU

February 2010

PARTICIPANT INFORMATION LEAFLET

Study Title: The effect of FES on gait variability under dual-task conditions, in post-stroke drop foot subjects.

What is the purpose of the study?

This study is being conducted to improve our understanding of the effectiveness of Functional Electrical Stimulation (FES) for people like you. In particular, we would like to find out how it affects your ability to do other things whilst you walk. We would also like to know its affect on your daily life and activities. In the longer term, we hope that the results from this study will help to improve clinical practice.

Why have I been chosen?

All people, who your physiotherapist provides with FES because of a drop foot following a stroke, are being invited to take part in this study. We hope to have about 12 people in the study.

Do I have to take part?

You will receive the FES device, whether you take part in this study or not.

It is up to you to decide to take part. I will describe the study and go through this information leaflet when we meet. I will ask you to sign a consent form to show that you have agreed to take part. You are free to withdraw at any time, during the study, without giving a reason and without any affect upon your normal care.

You do not have to give a reason for not taking part. A decision not to take part will not affect the care that you receive.

What do I have to do?

If you take part in this study, in addition to the normal appointments with your physiotherapist, you will be seen four times by myself. These additional sessions will be spaced over the course of 3-4 months. Each of these sessions will be for approximately 2½ hours.

First session : As this study requires a time commitment from yourself, we wish to ensure that your time is not wasted. We will use this first session to make sure that the particular tests that we will use in the study are appropriate for you. In order to do this, you will be asked to carry out a memory test and to answer questions about your

health, medications and any current treatment. If you find it very difficult to follow the memory test, or if there is a particular issue with your health, your involvement with the study will stop at this point. Your physiotherapist will be advised and will continue to provide your care. This part of the session should take approximately 40 minutes.

Alternatively, if you are able to follow the memory test and there are no issues with your health, you can continue with the study. You will then be asked questions about your stroke and some further tests will be performed. During these tests you will be asked to recognise words, repeat numbers and answer questions about the things that you are able to do. You will also be asked about any falls that you may have had during the past year. The sensation in your feet and legs will also be tested with a tuning fork and a flexible filament. This part of the session should take approximately 30 minutes.

Second session : Will be at the University of Salford and within a week of receiving your FES device. You will be asked to repeat the memory test from the first session, whilst sitting and when walking with and without the FES device. For the walking trials you will be asked to bring a pair of shorts or three-quarter length trousers to wear. A private changing area will be provided and help whilst changing can be provided. Small reflective markers will be placed on your feet, ankles and torso with hypoallergenic tape. You will walk in front of cameras that will collect the movement of the markers but no video image from which you can be recognised will be recorded. You will be asked to walk several times and be given as much time as needed to rest in between walks. This session should take up to 2½ hours.

Third session : Will be approximately 6 weeks after the second session, and again will be at the University. You will be asked to perform the same walking tests as before. You will also be asked to repeat the questionnaires about your activities, from the first session, and to repeat the test of your sensation. You will be asked about the effect of FES during your normal daily activities and if you have had any falls since the last session. This session should take up to 2½ hours.

Fourth session : Will be approximately 8 weeks after the third session and, again, will be at the University. You will be asked to do the same tests that were done during the previous session and asked the same questions. This visit should take up to 2½ hours. At the end of this session, your involvement in the study will be complete.

Will the cost of my travel be paid?

The cost of travel to and from the University for yourself and a companion can be reimbursed. If you wish to travel by taxi, this can be arranged for you.

What are the possible disadvantages and risks of taking part?

It is possible that, whilst performing the walking tasks in the gait laboratory at Salford University, you may have an increased risk of falling. This may occur when walking without the FES switched on or during walking whilst performing the memory tasks. To minimise the risk of falling we will assess your ability to walk safely whilst performing the walking tasks. A member of the research team will walk with you whilst we assess your safety. If it is not safe for you to do these tests, we will not ask you to continue to be involved in the study.

It is possible that you may feel concerned about how well you do in some of the tests. You are welcome to discuss these concerns with myself and to talk about ways of coping with your feelings.

At the end of a visit to the University it is possible that you may feel physically and mentally tired. You may wish to make sure that a companion travels home with you, or drives you home or that a taxi is organised for you, to ensure that you arrive home safely.

What are the benefits of taking part?

The information that is obtained from this study may help to provide better treatment for stroke patients in the future.

What happens when the research study stops?

You will continue to be cared for by your physiotherapist. He/she will be advised of when your involvement in the study is complete.

What will happen if I don't want to carry on with the study?

You are free to withdraw at any time, without giving a reason and without any affect upon your normal care. The information that has been collected about you, up until the point that you withdraw, will be kept and used.

What circumstances will stop my involvement in the study?

At each visit you will be asked if there have been any changes in your health. There may be some changes that would stop you from taking any further part in the study. If this does occur, the reasons will be explained to you.

If you are unable to attend the visits, they can be re-scheduled within a reasonable time period. If this is not possible, your involvement in the study may have to be stopped.

If your participation in the study is stopped, the information that has been collected about you, up until this point, will be kept and used

Will my taking part in this study be kept confidential?

All information that is collected about you will be kept confidential. It will be stored securely and separated from your personal information. The information will be used for this study. It will be kept for 5 years, after completion of the study, for use in future studies, for which ethical approval would be sought. I would also like to keep your personal details for this time, to be able to contact you for further research studies. Again, any further research would be subject to ethical approval. When you are asked to agree to take part in this study, by signing the consent form, you will be asked if you agree to your contact details being retained for this purpose.

My supervisors will have access to the data collected but will not have access to your names and personal details. I will be the only person, involved in the study, who will have access to your personal details.

When the results of this study are presented or published, your identity will remain confidential. Five years after completion of the study your personal details and data collected will be disposed of safely and securely.

Involvement of other health care professionals.

Your physiotherapist will be informed of your involvement in the study, and of when this is complete.

I would wish to inform your GP of your participation in this study. When you are asked to agree to take part in this study, by signing the consent form, you will also be asked if you agree to your GP being informed.

It may be necessary to contact your GP or consultant to clarify medical details of your stroke and of your current health, if it is difficult for you to provide this information. You will be asked to agree to this contact being made, when you are asked to sign the consent form. This information is used to describe you and compare you with other participants.

If any problems with your health are highlighted during the course of the study, I will discuss this with you and agree how you would like it to be addressed.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to myself (details following). If you remain unhappy and wish to complain formally, you can do this by contacting my supervisor – Dr Laurence Kenney (details following).

You are also able to contact the following people at Salford Primary Care Trust, St. James House, Pendleton Way, Salford, M6 5FW.
Kath Ainsworth - Patient Advice and Liaison Service (PALS) - 0161-212 4832
Kath Lever - Customer Care Manager – 0161 212 4862.

In the event that something goes wrong and you are harmed during the study, there are no special compensation arrangements. If this harm is due to someone's negligence, then you may have grounds for a legal action for compensation against the University of Salford, but you may have to pay your legal costs.

What will happen to the results of the research study?

A summary of the results of this study can be sent to you. I would also be happy to discuss these with you if you wish.

The results of this study will be used to complete my PhD. I also hope to present them at appropriate conferences, as well as publish the results in peer reviewed journals. The results will be forwarded to voluntary and charity stroke organisations.

Who is organising the research?

This research is organised through the University of Salford.

Who has reviewed this study?

The University of Salford has reviewed this study. It has also been reviewed by an independent group of people, called a Research Ethics Committee, who protect your safety, rights, wellbeing and dignity. This study has been given a favourable opinion by Stockport Research Ethics Committee.

Further information

You are welcome to discuss this study with your physiotherapist.

You are welcome to contact my PhD supervisor if you have any further questions about this study, any concerns or are unhappy with any aspect of the study. His details are as follows:-

Dr. L.P.J. Kenney, Senior Research Fellow
Centre for Rehabilitation and Human Performance Research
Brian Blatchford Building
University of Salford ph : 0161 295 2289
Salford M6 6PU email : L.P.J.Kenney@salford.ac.uk

Thank you for taking the time to read this.

Please keep this information sheet. You will be given a signed copy of the consent form.

Chief Investigator
Jane McAdam – Principal Podiatrist and PhD Student
C/- Dr. L.P.J. Kenney, Senior Research Fellow
Centre for Rehabilitation and Human Performance Research
Brian Blatchford Building, University of Salford
Salford M6 6PU

Ph: c/- 0161 206 4710 (Podiatry Department - Hope Hospital)
c/- 0161 212 5500 (Podiatry Department – Salford Community Health NHS Trust)
Mobile: 07715 005 843
Email: Jane.McAdam@salford.nhs.uk

Appendix Section B.14

Participant Invite Letter

(FES provided by CI)

Centre for Rehabilitation &
Human Performance Research
The University of Salford
Brian Blatchford Building
Salford. M6 6PU

February 2010

Dear Sir/Madam

Study Title: The effect of FES on gait variability under dual-task conditions, in post-stroke drop foot subjects.

Your physiotherapist has identified you as someone who is suitable for a Functional Electrical Stimulation (FES) device to help with your walking. The device will be provided for the duration of the study by the University of Salford as part of my research study. My name is Jane McAdam. I am a Podiatrist, working for Salford Community Health NHS Trust. I am also studying part-time to complete a PhD at the University of Salford. This study will help me to complete my PhD.

If you are interested in receiving the FES device and taking part in this study, I will be contacting you, within a week to ten days of seeing your physiotherapist.

To take part in the study, I will need to see you four times over the next 3-4 months, for a total of up to 9 hours. Before you decide to take part in this study, it is important for you to understand why the research is being done and what would happen at each visit. Please take time to read the attached information leaflet carefully and discuss it with others if you wish.

When we first speak to each other, I will ask you a few questions about your availability, discuss any questions that you may have and arrange a convenient time to visit you at home. If you would prefer, you can attend the University of Salford for this first visit. Your partner, family member or a friend can be present.

You are welcome to contact me, before deciding to take part, if anything is not clear or if you would like more information. Please take some time to decide whether or not you wish to take part.

Thanking you.

Jane McAdam – Principal Podiatrist and PhD Student
C/- Dr. L.P.J. Kenney, Senior Research Fellow
Centre for Rehabilitation and Human Performance Research
Brian Blatchford Building, University of Salford
Salford M6 6PU
Ph: c/- 0161 206 4710 (Podiatry Department - Hope Hospital)
c/- 0161 212 5500 (Podiatry Department – Salford Community Health NHS Trust)
Mobile: 07715 005 843
Email: Jane.McAdam@salford.nhs.uk

Appendix Section B.15

Participant Information Sheet

(FES provided by CI)

Centre for Rehabilitation &
Human Performance Research
The University of Salford
Brian Blatchford Building
Salford. M6 6PU

February 2010

PARTICIPANT INFORMATION LEAFLET

Study Title: The effect of FES on gait variability under dual-task conditions, in post-stroke drop foot subjects.

What is the purpose of the study?

This study is being conducted to improve our understanding of the effectiveness of Functional Electrical Stimulation (FES) for people like you. In particular, we would like to find out how it affects your ability to do other things whilst you walk. We would also like to know its effect on your daily life and activities. In the longer term, we hope that the results from this study will help to improve clinical practice.

Why have I been chosen?

All people, who your physiotherapist assesses as suitable to use an FES because of a drop foot following a stroke, will be invited to take part in this study. We hope to have about 12 people in the study.

Do I have to take part?

You will receive the FES device for the duration of your participation in this study.

It is up to you to decide to take part. I will describe the study and go through this information leaflet when we meet. I will ask you to sign a consent form to show that you have agreed to take part. You are free to withdraw at any time, during the study, without giving a reason and without any affect upon your normal care.

You do not have to give a reason for not taking part. A decision not to take part will not affect the care that you receive.

What do I have to do?

If you take part in this study, in addition to the normal appointments with your physiotherapist, you will be seen four times by myself. These additional sessions will be spaced over the course of 3-4 months. Each of these sessions will be for approximately 2½ hours.

First session : As this study requires a time commitment from yourself, we wish to ensure that your time is not wasted. We will use this first session to make sure that the particular tests that we will use in the study are appropriate for you. In order to do this, you will be asked to carry out a memory test and to answer questions about your

health, medications and any current treatment. If you find it very difficult to follow the memory test, or if there is a particular issue with your health, your involvement with the study will stop at this point. Your physiotherapist will be advised and will continue to provide your care. This part of the session should take approximately 40 minutes.

Alternatively, if you are able to follow the memory test and there are no issues with your health, you can continue with the study. You will then be asked questions about your stroke and some further tests will be performed. During these tests you will be asked to recognise words, repeat numbers and answer questions about the things that you are able to do. You will also be asked about any falls that you may have had during the past year. The sensation in your feet and legs will also be tested with a tuning fork and a flexible filament. This part of the session should take approximately 30 minutes.

Second session : Will be at the University of Salford and within a week of receiving your FES device. You will be asked to repeat the memory test from the first session, whilst sitting and when walking with and without the FES device. For the walking trials you will be asked to bring a pair of shorts or three-quarter length trousers to wear. A private changing area will be provided and help whilst changing can be provided. Small reflective markers will be placed on your feet, ankles and torso with hypoallergenic tape. You will walk in front of cameras that will collect the movement of the markers but no video image from which you can be recognised will be recorded. You will be asked to walk several times and be given as much time as needed to rest in between walks. This session should take up to 2½ hours.

Third session : Will be approximately 6 weeks after the second session, and again will be at the University. You will be asked to perform the same walking tests as before. You will also be asked to repeat the questionnaires about your activities, from the first session, and to repeat the test of your sensation. You will be asked about the effect of FES during your normal daily activities and if you have had any falls since the last session. This session should take up to 2½ hours.

Fourth session : Will be approximately 8 weeks after the third session and, again, will be at the University. You will be asked to do the same tests that were done during the previous session and asked the same questions. This visit should take up to 2½ hours. At the end of this session, your involvement in the study will be complete and you will be required to return your FES device to the researcher.

Will the cost of my travel be paid?

The cost of travel to and from the University for yourself and a companion can be reimbursed. If you wish to travel by taxi, this can be arranged for you.

What are the possible disadvantages and risks of taking part?

It is possible that, whilst performing the walking tasks in the gait laboratory at Salford University, you may have an increased risk of falling. This may occur when walking without the FES switched on or during walking whilst performing the memory tasks. To minimise the risk of falling we will assess your ability to walk safely whilst performing the walking tasks. A member of the research team will walk with you whilst we assess your safety. If it is not safe for you to do these tests, we will not ask you to continue to be involved in the study.

It is possible that you may feel concerned about how well you do in some of the tests. You are welcome to discuss these concerns with myself and to talk about ways of coping with your feelings.

At the end of a visit to the University it is possible that you may feel physically and mentally tired. You may wish to make sure that a companion travels home with you, or drives you home or that a taxi is organised for you, to ensure that you arrive home safely.

What are the benefits of taking part?

The information that is obtained from this study may help to provide better treatment for stroke patients in the future.

What happens when the research study stops?

You will continue to be cared for by your physiotherapist. He/she will be advised of when your involvement in the study is complete.

You will be contacted by your physiotherapist to discuss further use of the device on a private or NHS- funded basis. As the device used in the study is owned by the University, not the NHS, you will be required to return the FES device supplied by the chief investigator at the completion of the study.

What will happen if I don't want to carry on with the study?

You are free to withdraw at any time, without giving a reason and without any affect upon your normal care. The information that has been collected about you, up until the point that you withdraw, will be kept and used. You will be required to return the FES device.

What circumstances will stop my involvement in the study?

At each visit you will be asked if there have been any changes in your health. There may be some changes that would stop you from taking any further part in the study. If this does occur, the reasons will be explained to you.

If you are unable to attend the visits, they can be re-scheduled within a reasonable time period. If this is not possible, your involvement in the study may have to be stopped.

If your participation in the study is stopped, the information that has been collected about you, up until this point, will be kept and used. As the FES device is owned by the University, not the NHS, you will be required to return the FES device.

Will my taking part in this study be kept confidential?

All information that is collected about you will be kept confidential. It will be stored securely and separated from your personal information. The information will be used for this study. It will be kept for 5 years, after completion of the study, for use in future studies, for which ethical approval would be sought. I would also like to keep your personal details for this time, to be able to contact you for further research studies.

Again, any further research would be subject to ethical approval. When you are asked to agree to take part in this study, by signing the consent form, you will be asked if you agree to your contact details being retained for this purpose.

My supervisors will have access to the data collected but will not have access to your names and personal details. I will be the only person, involved in the study, who will have access to your personal details.

When the results of this study are presented or published, your identity will remain confidential. Five years after completion of the study your personal details and data collected will be disposed of safely and securely.

Involvement of other health care professionals.

Your physiotherapist will be informed of your involvement in the study, and of when this is complete.

I would wish to inform your GP of your participation in this study. When you are asked to agree to take part in this study, by signing the consent form, you will also be asked if you agree to your GP being informed.

It may be necessary to contact your GP or consultant to clarify medical details of your stroke and of your current health, if it is difficult for you to provide this information. You will be asked to agree to this contact being made, when you are asked to sign the consent form. This information is used to describe you and compare you with other participants.

If any problems with your health are highlighted during the course of the study, I will discuss this with you and agree how you would like it to be addressed.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to myself (details following). If you remain unhappy and wish to complain formally, you can do this by contacting my supervisor – Dr Laurence Kenney (details following).

You are also able to contact the following people at Salford Primary Care Trust, St. James House, Pendleton Way, Salford, M6 5FW.
Kath Ainsworth - Patient Advice and Liaison Service (PALS) - 0161-212 4832
Kath Lever - Customer Care Manager – 0161 212 4862.

In the event that something goes wrong and you are harmed during the study, there are no special compensation arrangements. If this harm is due to someone's negligence, then you may have grounds for a legal action for compensation against the University of Salford, but you may have to pay your legal costs.

What will happen to the results of the research study?

A summary of the results of this study can be sent to you. I would also be happy to discuss these with you if you wish.

The results of this study will be used to complete my PhD. I also hope to present them at appropriate conferences, as well as publish the results in peer reviewed journals. The results will be forwarded to voluntary and charity stroke organisations.

Who is organising the research?

This research is organised through the University of Salford.

Who has reviewed this study?

The University of Salford has reviewed this study. It has also been reviewed by an independent group of people, called a Research Ethics Committee, who protect your safety, rights, wellbeing and dignity. This study has been given a favourable opinion by Stockport Research Ethics Committee.

Further information

You are welcome to discuss this study with your physiotherapist.

You are welcome to contact my PhD supervisor if you have any further questions about this study, any concerns or are unhappy with any aspect of the study. His details are as follows:-

Dr. L.P.J. Kenney, Senior Research Fellow
Centre for Rehabilitation and Human Performance Research
Brian Blatchford Building
University of Salford ph : 0161 295 2289
Salford M6 6PU email : L.P.J.Kenney@salford.ac.uk

Thank you for taking the time to read this.

Please keep this information sheet. You will be given a signed copy of the consent form.

Chief Investigator
Jane McAdam – Principal Podiatrist and PhD Student
C/- Dr. L.P.J. Kenney, Senior Research Fellow
Centre for Rehabilitation and Human Performance Research
Brian Blatchford Building, University of Salford
Salford M6 6PU

Ph: c/- 0161 206 4710 (Podiatry Department - Hope Hospital)
c/- 0161 212 5500 (Podiatry Department – Salford Community Health NHS Trust)
Mobile: 07715 005 843
Email: Jane.McAdam@salford.nhs.uk

Appendix Section B.16

Consent Form

Centre for Rehabilitation &
Human Performance Research
The University of Salford
Brian Blatchford Building
Salford. M6 6PU

CONSENT FORM

Study Title: The effect of FES on gait variability under dual-task conditions, in post-stroke drop foot subjects.

Name of Chief Investigator: Jane McAdam

Please read each of these statements. Please initial in the box at the end of the statements with which you agree.

1. I confirm that I have read and understand the information leaflet dated October 2008 (Version 2) for the above study and have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that if I withdraw from the study or if my involvement is stopped by the researcher, the information that has been collected about me, up until my point of withdrawal, will be kept and used in the analysis of the study. ☐

4. I agree to my GP being informed of my participation in the study. ☐

5. I agree to my GP or named consultant being contacted for further information about my health and past medical history. ☐

6. I agree to take part in the above study. ☐

7. I agree to my personal contact details being retained by the chief investigator, for a period of 5 years after completion of this study, for use in future studies that would be subject to ethical approval. ☐

……	……	…….……..
Name of participant	Date	Signature
……..……	……..……...	……..
Name of person taking consent	Date	Signature

(1 copy for participant and 1 copy for chief investigator's file)

Appendix Section B.17

GP/Health Professional Letter

Centre for Rehabilitation &
Human Performance Research
The University of Salford
Brian Blatchford Building
Salford. M6 6PU

Date

GP/Health professional

Dear

RE : ……

As you may know, the above mentioned patient has recently been assessed for provision of FES to improve their gait following a stroke. Their treating physiotherapist has forwarded their contact details to me, as a possible participant in a study. Upon recent successful screening for inclusion in the study, your patient has agreed to take part.

The study will assess the effectiveness of FES using a dual-task methodology during gait laboratory studies to measure gait parameters. The measures will be taken on three occasions – at baseline, at six weeks and at a further eight weeks. The study will not require the patient to change any aspect of their current care.

The study has been approved by Stockport Research Ethics Committee – REC Ref No. 08/H1012/80.
Study title: The effect of FES on gait variability under dual-task conditions, in post-stroke drop foot subjects.

I hope that this information is of benefit to you.

Yours sincerely,

Jane McAdam
PhD Student
Principal Podiatrist – Salford Community Health

Appendix C

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Appendix Section C.1

Participant invitation letter

FES Clinic
Mobility and Specialised Rehabilitation Centre
Northern General Hospital, Herries Rd, Sheffield S5 7AU
Tel: 0114 271 5577
Fax: 0114 243 1646

Date:

Dear

The clinical staff, at the FES Clinic, have been asked to assist the University of Salford with a research study. The study is being conducted to improve understanding of the benefits of Functional Electrical Stimulation (FES) for people like you.

We have identified you as someone who may be suitable to take part in the study and we would like to invite you to take part. The information that is needed for the study would be collected from you at the same time as your clinical review, which is due soon. Please take time to read the enclosed information leaflet carefully and discuss the study with others if you wish. Before you decide to take part, it is important for you to understand why the research is being done and what would happen at the clinic visit.

If you are interested in taking part in the study please complete the enclosed reply slip and send it in the stamped addressed envelope to the researcher. Alternatively you can ring the researcher. Her name is Jane McAdam and her phone number is 07715 005 843. She will contact you to ask a few simple questions about your health and she will be able to answer any questions you may have about the study. If you can take part in the study an appointment will be made for you to attend the FES clinic for your clinical review and collection of information.

If you are not able or do not wish to take part in the study please complete the enclosed reply slip or ring the researcher. An appointment will be made for your clinical review only. Your name will not be retained by the researcher, you will not be contacted again about the study and your decision will have no impact on your ongoing care.

If we do not hear from you, after two weeks, we will ring you to ask if you are interested in taking part in the study. If you are interested we will ask if you are happy for your contact details to be forwarded to the researcher. If you are not able or do not wish to take part we will book your clinical review.

You are welcome to contact ourselves or the researcher (contact details in the information sheet) before deciding to take part, if anything is not clear or if you would like more information. Please take some time to decide whether or not you wish to take part.

Many thanks.

Alison Clarke
Clinical Specialist Physiotherapist

Jill van der Meulen
Lead Clinical Scientist

Appendix Section C.2

Participant Information Sheet

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

University of Salford MANCHESTER

Centre for Health, Sport & Rehabilitation Sciences Research
The University of Salford
Brian
Blatchford Building
Salford. M6 6PU

August 2012

PARTICIPANT INFORMATION SHEET

Study Title: The effect of Functional Electrical Stimulation (FES) on gait and cognitive task, in post-stroke drop foot.

We would like to invite you to take part in our research study. Before you decide if you wish to take part, we would like to explain why the research is being done and what it would involve for you.

This information sheet explains the study. Please read this information carefully and discuss it with others if you wish. You are welcome to contact us if anything is unclear or if you would like more information. Our contact details are at the end of this sheet.

Please take your time in deciding whether or not to take part.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Part 1

What is the purpose of the study?

This study is being conducted to improve our understanding of the effectiveness of Functional Electrical Stimulation (FES) for people like you. In particular, we would like to find out how it affects your ability to do other things whilst you walk. We would also like to know how it affects your daily life and activities. In the longer term, we hope that the results from this study will help to improve clinical practice.

The study is also being conducted to complete the PhD of the chief investigator, Jane McAdam.

Why have I been invited?

All people who attend the Sheffield clinic and have been using FES for three months or more, because of a drop foot following a stroke, are being invited to take part in this study. We hope to have about 21 people in the study.

Do I have to take part?
It is up to you to decide to take part in the study. We will describe the study and go through this information leaflet before you make your final decision. We will ask you to sign a consent form to show that you have agreed to take part. You are free to withdraw at any time, during the study, without giving a reason and without any affect upon your normal care.

You do not have to give a reason for not taking part. A decision not to take part will not affect the care that you receive.

What will happen to me if I take part?
If you take part in this study, at your normal review appointment at the FES clinic, where you will be seen by the clinical staff at Sheffield, you will also be seen by the chief investigator, Jane McAdam. As well as the time that it takes to complete your clinical review, you will be in the clinic for an additional hour to complete the measurements needed for the study.

Firstly, we will make sure that the particular tests that are used in the study are appropriate for you. In order to do this, you will be asked to carry out a memory test and to answer questions about your health, medications and any current treatment. If you find it very difficult to follow the memory test, or if there is a particular issue with your health, your involvement with the study will stop at this point.

Alternatively, if you are able to follow the memory test and there are no issues with your health, you can continue with the study. You will then be asked questions about your stroke and some further tests will be performed. During these tests you will be asked to recognise words, repeat numbers and answer questions about the things that you are able to do. You will also be asked about any falls that you may have had during the past year and the effect of FES during your normal daily activities. The sensation in your feet and legs will also be tested.

You will be asked to repeat the memory test when walking with and without your FES device. For the walking trials you will be asked to bring a pair of shorts or three-quarter length trousers to wear. There will be a private changing area and help whilst changing can be provided. Small removable reflective markers will be placed on your shoes. You will walk in front of cameras that will collect the movement of the markers and video images of you walking. No recordings will be taken from which you can be recognised. You will be asked to walk several times.

What are the possible disadvantages and risks of taking part?

It is possible that, whilst performing the walking tasks in the clinic, you may have an increased risk of falling. This may occur when walking without your FES switched on or whilst performing the memory task. To minimise the risk of falling we will assess your ability to walk safely whilst performing the walking tasks. We will walk with you whilst we assess your safety. If it is not safe for you to do these tests, we will not ask you to continue to be involved in the study.

It is possible that you may feel concerned about how well you do in some of the tests. You are welcome to discuss these concerns with us and to talk about ways of coping with your feelings.

At the end of your visit to the clinic it is possible that you may feel physically and mentally tired. You may wish to make sure that a companion travels home with you, or drives you home, to ensure that you arrive home safely.

What are the possible benefits of taking part?

The information that is obtained from this study may help to provide better treatment for stroke patients in the future.

What happens when the research study stops?
At the end of the collection of measurements you will remain in the care of the clinical staff at Sheffield.

Will my taking part in the study be kept confidential?

If you decide to take part in the study, the information that is collected about you will be handled in confidence, following ethical and legal practice. Please refer to Part 2 for further details.

This completes Part 1 of the information sheet. If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

You are free to withdraw at any time, without giving a reason and without any affect upon your normal care. The information that has been collected about you, up until the point that you withdraw, will be kept and included in the study report.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the chief investigator, Jane McAdam (details at the end of this sheet). If you remain unhappy and wish to complain formally, you can do this by contacting the study co-investigator, Dr Laurence Kenney (details at the end of this sheet).

What if something goes wrong?
In the event that something does go wrong and you are harmed during the study, and this harm is due to someone's negligence then you may have grounds for a legal action. The University of Salford has insurance in place to cover indemnity and compensation for a claim. You may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?
All information that is collected about you will be handled in accordance with the consent that you have given and will be kept strictly confidential and securely stored.

Your consent form will be part of the study information and leave the clinic. This will only include your full name. All other information about you that leaves the clinic will be identified by a number and will have your name removed from it.

The co-investigator will have access to the information collected but will not have access to your name. The chief investigator will be the only person, involved in the study, who will have access to your personal details.

Information collected during the study, may be looked at by responsible individuals from the University of Salford, from regulatory authorities or from Sheffield Teaching Hospitals NHS Trust. This would be done to check that the study is being carried out correctly.

When the results of this study are presented or published, your identity will remain confidential. We would like to use any quotes that are made by you in the results. We will ask you to agree to this when we ask you to consent to taking part in the study. The quotes will be anonymised and thus will not able to be identified as made by you.

Five years after completion of the study information collected will be disposed of safely and securely.

Involvement of the other health care professionals.
We would wish to inform your GP of your participation in this study. When you are asked to agree to take part in this study, by signing the consent form, you will also be asked if you agree to your GP being informed.

It may be necessary to contact your GP or consultant to clarify medical details of your stroke and of your current health, if it is difficult for you to provide this information. You will be asked to agree to this contact being made, when you are asked to sign the consent form. This information is used to describe you and compare you with other participants.

If any problems with your health are highlighted during the course of the study, we will discuss this with you and agree how you would like it to be addressed.

What will happen to the results of the research study?
The results of this study will be used to complete the chief investigator's PhD. They may be presented at appropriate conferences, as well as published in medical or clinical journals. The results will be forwarded to voluntary and charity stroke organisations. Your name will not be published.

A summary of the results of this study can be sent to you or discussed with you if you wish.

Who is organising the research?
This research is organised through the University of Salford.

Who has reviewed this study?
The University of Salford and Sheffield Teaching Hospitals NHS Trust Research and Development Department have both reviewed this study. It has also been reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been given a favourable opinion by Southampton A Research Ethics Committee.

Further information and contact details
If you have any questions about the study please contact the chief investigator as follows:-

Jane McAdam – Principal Podiatrist and PhD Student
Salford Royal Foundation NHS Trust, Department of Podiatry, Hope Hospital, Stott Lane, Salford M6 8HD.
Ph: c/- 0161 206 4710 Mobile: 07715 005 843 Email: Jane.McAdam@srft.nhs.uk

If you have any further questions about this study, any concerns or are unhappy with any aspect of the study, please contact the co-investigator and PhD supervisor as follows:-

Dr Laurence Kenney – Reader in Rehabilitation Technologies
Centre for Health, Sport & Rehabilitation Sciences Research, Brian Blatchford Building, University of Salford, Salford M6 6PU.
Ph : 0161 295 2289 Email : L.P.J.Kenney@salford.ac.uk

If you would like further information about clinical research, The UK Clinical Research Collaboration has published a booklet entitled 'Understanding Clinical Trials'. Contact UKCRC ph: 0207 670 5452 website: www.ukcrc.org.

Thank you for taking the time to read this information sheet and considering taking part in this study.

Please keep this information sheet. You will be given a signed copy of the consent form.

Appendix Section C.3

Reply slip

REPLY SLIP

Study Title: The effect of Functional Electrical Stimulation (FES) on gait and cognitive task, in post-stroke drop foot.

Your name:……

Please tick one of the boxes

☐ **YES**, I am interested in taking part in this study.

Please contact me on this phone number ……..

The best times to ring me are ……

☐ **NO**, I am not able nor interested in taking part in this study.

Please arrange an appointment at the FES clinic in Sheffield for my routine clinical review.

Please note, if you would rather ring the researcher with your response, her phone number is 07715 005 843 and her name is Jane McAdam.

Please put this reply slip in the enclosed stamped addressed envelope.

Appendix Section C.4

Consent Form

Centre for Health, Sport &
Rehabilitation Sciences Research
The University of Salford
Brian Blatchford Building
Salford M6 6PU

CONSENT FORM

Title of Project: The effect of Functional Electrical Stimulation (FES) on gait and cognitive task, in post-stroke drop foot.

Name of Researcher: Jane McAdam

Participant ID:

Please read each of these statements. Please initial in the box at the end of the statements with which you agree.

1. I confirm that I have read and understand the information leaflet dated May 2012 (Version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that if I withdraw from the study or if my involvement is stopped by the researcher, the information that has been collected about me, up until my point of withdrawal, will be kept and used in the analysis of the study. ☐
4. I agree that any quotes I may give can be used and that my identity will be anonymised. ☐
5. I agree to my GP being informed of my participation in the study. ☐
6. I agree to my GP or named consultant being contacted for further information about my health and past medical history, if necessary. ☐
7. I understand that data collected during the study, may be looked at by responsible individuals from the University of Salford, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data. ☐
8. I agree to take part in the above study. ☐

……	……	……...
Name of participant	Date	Signature
……..	…….	……...
Name of person taking consent	Date	Signature

(1 copy for participant, 1 copy for medical notes and 1 copy for chief investigator's file)

Appendix Section C.5

GP/Health professional Letter

Centre for Health, Sport &
Rehabilitation Sciences Research
The University of Salford
Brian Blatchford Building
Salford. M6 6PU

Health Professional Name
And Address

Date :

Dear ……..

RE : Participant's name, d.o.b., address

As you will know, the above mentioned patient is currently using a Functional Electrical Stimulation (FES) device supplied by the FES clinic at the Northern General Hospital in Sheffield.

Your patient has very kindly taken part in a study, during which collection of data was performed at their …….. month review at the FES clinic.

The study assesses the effectiveness of FES using a dual-task methodology designed to assess performance of both gait and cognitive task. The measures were taken on only one occasion. The study does not require the patient to change any aspect of their current care.

The study has been approved by the Southampton A Research Ethics Committee – REC Ref No 12/SC/0253.
Study title: The effect of Functional Electrical Stimulation (FES) on gait and cognitive task, in post-stroke drop foot.

I hope that this information is of benefit to you.

Yours sincerely,

Jane McAdam
PhD Student
Principal Podiatrist – Salford Royal Foundation NHS Trust

Appendix Section C.6

Falls Efficacy Scale – International (FES-I)

Participant ID _____

FALLS EFFICACY SCALE - INTERNATIONAL

	Not at all concerned	**Somewhat concerned**	**Fairly concerned**	**Very concerned**
Cleaning the house (e.g. sweep, vacuum or dust)				
Getting dressed or undressed				
Preparing simple meals				
Taking a bath or shower				
Going to the shop				
Getting in or out of a chair				
Going up or down stairs				
Walking around in the neighbourhood				
Reaching for something above your head or on the ground				
Going to answer the telephone before it stops ringing				
Walking slippery surface (e.g. wet or icy)				
Visiting a friend or relative				
Walking in a place with crowds				
Walking on an uneven surface (e.g. rocky ground, poorly maintained pavement)				
Walking up or down a slope				
Going out to a social event (e.g. religious service, family gathering or club meeting)				
Score /64				

Completed by _____ _____
(printed name) (signature)

Date _____

Appendix Section C.7

NHS Ethical Approval

NHS
Health Research Authority
NRES Committee South Central - Southampton A
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 0117 342 1381
Facsimile: 0117 342 0445

18 May 2012

Ms Jane McAdam
175 Urmston Lane
Stretford
Manchester
M32 9EH

Dear Ms McAdam

Study title:	**The effect of Functional Electrical Stimulation (FES) on gait and cognitive task, in post-stroke drop foot.**
REC reference:	**12/SC/0253**
Protocol number:	**N/A**

Thank you for your letter of 15 May 2012, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation.

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Covering Letter		16 April 2012
Evidence of insurance or indemnity		01 August 2011
GP/Consultant Information Sheets	1	16 April 2012
Investigator CV	Jane McAdam	
Investigator CV	Dr LPJ Kenney	
Letter of invitation to participant	1	16 April 2012
Participant Consent Form: Participant Consent Form - Appendix 13	1	16 April 2012
Participant Consent Form	2	03 May 2012
Participant Information Sheet: Participant Information Sheet Appendix 12	1	16 April 2012
Participant Information Sheet	2	03 May 2012
Protocol	1	16 April 2012
Questionnaire: NART Appendix 8	1	16 April 2012
Questionnaire: Digit Span Appendix 9	1	16 April 2012
Questionnaire: Barthel Index Appendix 10	1	16 April 2012
Questionnaire: FRAT Appendix 6	1	16 April 2012
Questionnaire: FES-1 Appendix 3	1	16 April 2012
Questionnaire: FES Questionnaire Appendix 5	1	16 April 2012
Questionnaire: Visual Recognition Memory Test Appendix 4	1	16 April 2012
Questionnaire: Fall & Near History Fall Appendix 7	1	16 April 2012
REC application		
Response to Request for Further Information		03 May 2012

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

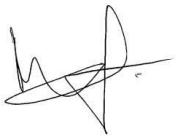
You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/SC/0253	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely



pp

Dr Paul Diprose
Alternate Vice Chair

Email: scsha.SWHRECA@nhs.net

Enclosures: *"After ethical review – guidance for researchers"*

Copy to: *Mrs Sue Braid*
Ms Jeannie Dowen McKie, Sheffield Teaching Hospitals NHS Foundation Trust

Appendix Section B.8

University of Salford Ethical Approval

University of Salford MANCHESTER

Research, Innovation and Academic Engagement Ethical Approval Panel

College of Health & Social Care
AD 101 Allerton Building
University of Salford
M6 6PU

T +44(0)161 295 7016
r.shuttleworth@salford.ac.uk

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20 July 2012

Dear Jane,

RE: ETHICS APPLICATION HSCR12/32 – The effect of Functional Electrical Stimulation (FES) on gait and cognitive task, in post-stroke foot drop

Following your responses to the Panel's queries, based on the information you provided, I am pleased to inform you that application HSCR12/32 has now been approved. I would be grateful if you could provide the Panel with a copy of the approved NRES amendment when you receive it.

If there are any changes to the project and/ or its methodology, please inform the Panel as soon as possible.

Yours sincerely,

Rachel Shuttleworth

Rachel Shuttleworth
College Support Officer (R&I)

Appendix Section C.9

NHS Ethical Approval - Amendment

NHS
Health Research Authority

NRES Committee South Central - Southampton A
Bristol Research Ethics Committee Centre
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Tel: 0117 342 1381
Fax: 0117 342 0445

20 August 2012

Ms Jane McAdam
175 Urmston Lane
Stretford
Manchester
M32 9EH

Dear Ms McAdam

Study title:	**The effect of Functional Electrical Stimulation (FES) on gait and cognitive task, in post-stroke drop foot.**
REC reference:	**12/SC/0253**
Protocol number:	**N/A**
Amendment number:	**1**
Amendment date:	

The above amendment was reviewed at the meeting of the Sub-Committee held on 14 August 2012.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Health professional letter	2	18 June 2012
Reply Slip	1	09 July 2012
Summary of protocol changes	1	20 July 2012
Letter of invitation to participant	3	16 July 2012
Participant Consent Form	3	16 July 2012
Participant Information Sheet	3	18 June 2012
Notice of Substantial Amendment (non-CTIMPs)	1	

Covering Letter		20 July 2012

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

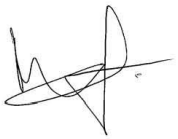
All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

12/SC/0253:	**Please quote this number on all correspondence**

Yours sincerely



pp

Dr Simon Kolstoe
Vice Chair

E-mail: scsha.SWHRECA@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Ms Jeannie Dowen McKie, Sheffield Teaching Hospitals NHS Foundation Trust*
Mrs Sue Braid

Appendix Section C.10

Research and Development Approval

11th September 2012

Ms Jane McAdam
175 Urmston Lane
Stetford
Manchester
M32 9EH

Dear Ms Adams

Authorisation of Project

STH ref: STH16529
Study title: The effect of Functional Electrical Stimulation (FES) on gait and cognitive task, in post stroke drop foot.

Chief Investigator: Jane McAdam, Salford Royal Foundation Trust
Principal Investigator: Alison Clarke, Sheffield Teaching Hospitals

Sponsor: University of Salford
Funder:

The Research Department has received the required documentation for the study as listed below:

1.	**Sponsorship IMP studies (non-commercial)** **Sponsorship responsibilities between institutions** **Responsibilities of investigators** **Monitoring Arrangements**	Not applicable Not applicable Not applicable Not applicable
2.	**STH registration document: completed and signed**	SSI form A Clarke 04 Jul 12
3.	**Evidence of favourable scientific review**	University of Salford Undated
4.	**Protocol – final version**	Version 1 16 Apr 12
5.	**Participant Information sheet – final version**	Version 3 18 Jun 12
6.	**Consent form – final version**	Version 3 16 Jul 12
7.	**Signed letters of indemnity**	UMAL 01 Aug 11
8.	**ARSAC / IRMER certificate**	Not applicable
9.	**Evidence of hosting approval from STH directorate**	Directorate Approval Form K Mathew 17 Aug 12
10.	**Evidence of approval from STH Data Protection Officer**	STH Finance Form P Wilson 03 Sep 12
11.	**Letter of approval from REC**	Southampton A REC 12/SC/0253 18 May 12 20 Aug 12 University of Salford REC HSCR12/32 20 Jul 12

Ref: STH16529/AL

12.	**Proof of locality approval**	STH R&D 09 Aug 12
13.	**Clinical Trial Authorisation from MHRA**	Not applicable
14.	**Honorary Contract**	Not applicable
15.	**Associated documents**	
	HP letter	Version 2 18 Jun 12
	Participant Information letter	Version 3 16 Jul 12
	Reply slip	Version 1 16 Jul 12
	Questionnaire NART	Version 1 16 Apr 12
	Questionnaire Digit span	Version 1 16 Apr 12
	Questionnaire Barthel Index	Version 1 16 Apr 12
	Questionnaire FRAT	Version 1 16 Apr 12
	Questionnaire FES-1	Version 1 16 Apr 12
	Questionnaire FES	Version 1 16 Apr 12
	Questionnaire Visual Recognition Memory Test	Version 1 16 Apr 12
	Questionnaire Fall & Near History Fall	Version 1 16 Apr 12
16.	**Signed financial agreement/contract**	STH Finance Form D Patel 06 Sep 12

The project has been reviewed by the Research Department and authorised by the Director of R&D on behalf of STH NHS Foundation Trust to begin.

Yours sincerely

Professor S Heller
Director of R&D, Sheffield Teaching Hospitals NHS Foundation Trust
Telephone +44 (0) 114 2265934
Fax +44 (0) 114 2265937

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