Usability engineering in the design and evaluation of a functional electrical stimulation system for upper limb rehabilitation.

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Glossary of terms

ANRT	Advanced Neurological Rehabilitation Technologies
ATRAS	Assistive Technologies for Rehabilitation of the Arm following Stroke project
CIMT	Constraint Induced Movement Therapy
FES	Functional Electrical Stimulation
GBS	Guillain-Barré Syndrome
HCP	Health Care Professionals
ITQ	Immersive Tendencies Questionnaire
MS	Multiple Sclerosis
NIHR	National Institute for Health Research
NHS	National Health Service
OT	Occupational Therapy
P & C	Patients and Carers
PT	Physiotherapy
SALT	Speech and Language Therapy
SCI	Spinal Cord Injury
SFQ	Short Feedback Questionnaire
SUMI	Software Usability Measurement Inventory
SUS	System Usability Scale
UL	Upper limb

Abstract

Chronic physical impairment of the hemiplegic upper limb (UL) is seen in an estimated 50-70% of stroke patients, who place a high priority on regaining upper limb function. Current therapy is insufficiently intensive, often not task-oriented and hence poorly aligned with the evidence base. Functional electrical stimulation (FES) has the potential to not only increase the intensity of task-focused therapy, but also provide certain unique features, notably direct excitation of lower motor neurons. However, current FES systems are limited in their functionality and/or difficult to use. Systems are also poorly aligned to therapists' ways of working and uptake remains limited. To address these problems, a novel FES technology (UL FES Rehab Tool) has been developed. The control system design is reported in Sun, (2014). The aims of my thesis were to: 1) design a Graphical User Interface (GUI) that would enable therapists to quickly and easily set up an individually tailored library of FES tasks for each patient; 2) evaluate the usability and functionality of the UL FES Rehab Tool (software and hardware) in both laboratory (lab) and clinical settings.

An iterative, mixed methods, five-phase usability engineering approach was used to design and evaluate the UL FES Rehab Tool. Phases one to three incorporated identification of therapists' requirements, a user 'assisted walkthrough' of the software with expert and novice FES users and 'rapid prototyping' of the full system, using healthy participants. Further usability testing of the software & hardware was conducted in phase four with 1 physiotherapist and 6 patients, (total of 24 visits), in the chronic stage post-stroke. The work demonstrated in detail, for the first time, the impact of therapist involvement in the design of novel rehabilitation technology.

To address therapists' focus on setup time, using the phase four data set, a novel model to predict setup time was devised. This model was able to explain 51% of the variance in setup time based on two parameters, task complexity and patient impairment.

Finally, in phase five, a summative usability evaluation of the final prototype was carried out in 2 sub-acute stroke units. Four therapists and 1 rehabilitation assistant used the UL FES Rehab Tool with 6 patients in the acute stage post-stroke. The UL FES Rehab Tool enabled all therapists and one therapy assistant to effectively deliver FES assisted upper limb task-oriented therapy to a range of stroke patients (Fugl-

Meyer scores 8–65). The usability methods effectively captured objective and subjective feedback from therapists and patients. However the previous setup time model was unable to predict setup time, suggesting other factors were important in a clinical setting. Although participant numbers were low, the results suggested therapists' predisposition to using technology and post-training confidence in using the technology may influence their willingness to engage with novel rehabilitation technologies.

This study is the first to describe in detail the impact of a usability engineering approach on the design of a complex upper limb rehabilitation technology from early stage design to clinical evaluation. These methods can be generalised to other studies seeking to explore the usability of new forms of rehabilitation technologies.

1 Chapter One: Introduction

1.1 Overview of the thesis

Rehabilitation technologies are showing promise as interventions to promote recovery of the hemiplegic upper limb post stroke. Functional Electrical Stimulation (FES) is one of the technologies that offers the potential to support the user in varied and challenging functional task practice. Current FES devices are limited in their functionality and hence more sophisticated devices are needed. The usability of devices in challenging clinical environments such as the acute setting, are likely to influence usage (Hochstenbach-Walen & Seelen, 2012), and hence great care is needed when designing more sophisticated rehabilitation devices to ensure usability.

This study outlines a usability engineering approach to the design of a new FES system, the FES Rehab Tool, and the usability evaluation from the early design stages through to the proof of concept clinical trial, in two sub-acute stroke units.

The aim of chapter one is to outline the overall structure of the thesis chapter by chapter along with the accompanying rationale for each.

1.1.1 Chapter Two

This chapter sets the scene for the thesis by outlining the incidence and prevalence of upper limb problems following stroke, and the impact of impairments on quality of life. Non-technology based rehabilitation interventions are reviewed, starting with literature taken from basic science studies that examine the content, timing, intensity and scheduling of therapy, together with other factors that influence the success of rehabilitation, such as active participation of the learner and provision of feedback on performance. Current approaches to therapy are reviewed and compared in light of the evidence base from basic science. The limitation with current therapies is highlighted.

FES is introduced, including the underpinning science and evidence from animal and clinical studies that support its use as a means of enabling intensive task-focused practice. A review of current FES systems for upper limb rehabilitation, their functionality and limitations is also discussed, leading to the need to create the Upper Limb Functional Electrical Stimulation Tool (UL FES Rehab Tool). As usability is central to the thesis, a literature review of studies of Advanced Neurological

Rehabilitation Technologies (ANRT) that have reported on usability evaluation is included, to provide context for subsequent aspects of the thesis.

The aims and objectives that informed the thesis are then stated.

1.1.2 Chapter Three

This chapter provides an overview of the work that led to the thesis. It outlines the early work on an accelerometer controlled upper limb FES system, the Clinical Setup Tool (CST) that was the forerunner to the UL FES Rehab Tool. In order to allow the reader to better understand the UL FES Rehab Tool and the systems that it was based on, the concept of finite state-machine control is introduced. Finally, the NEAT LO30 project that much of the thesis work contributed to is described. The NEAT LO30 project was supported both by the author's work and that of a fellow PhD student, Mingxu Sun. The role of each of the authors in these complimentary pieces of work is also explained.

1.1.3 Chapter Four

This chapter describes a phased usability engineering approach to the design and evaluation of an UL FES Rehab Tool. It first outlines each of the phases of the design and usability evaluation. The authors' approach to gaining therapists' views from the advisory and focus group meetings is described and the findings presented.

1.1.4 Chapter Five

Phases two and three of the usability evaluation process are presented along with the findings from each of the phases. The chapter highlights the limited evidence base demonstrating the impact of usability engineering on ANRT design. Specifically the chapter demonstrates the impact of user involvement on the early design work on the GUI aspects of the UL FES Rehab Tool.

1.1.5 Chapter Six

The chapter begins by highlighting the importance of setup time to clinicians and identifies that there were no published methods to predict setup time for rehabilitation devices. The chapter presents the first model to predict setup time, based on the

patients' level of impairment and task complexity. Data from six participants in the chronic stage of stroke were used to create the model and the model evaluation is presented. The relationship between impairment, task complexity and setup time is discussed along with the limitations of this approach.

1.1.6 Chapter Seven

Chapter seven presents the findings from the final proof of concept study, in which therapists set up and used the UL FES Rehab Tool in a clinical setting. The usability and feasibility of version 3 of the UL FES Rehab Tool when used in two sub-acute stroke units is presented and discussed. The methods adopted, including the use of a technology acceptance measure and the therapists training, are discussed. The findings are presented and discussed along with the challenges and limitations.

1.1.7 Chapter Eight

This chapter provides a critical review of the thesis and its findings. The usability approach and resultant UL FES Rehab Tool are reviewed, in terms of its usability in a clinical setting with stroke patients. Limitations to the thesis are reviewed and discussed. The thesis concludes by re-examining the aims of the thesis and outlining the future development of the UL FES Rehab Tool.

2 Chapter 2: Literature review

2.1 The upper limb following stroke

2.1.1 Incidence and prevalence of upper limb impairments and functional limitations after stroke

There are approximately 152,000 strokes in the United Kingdom (UK) every year, with the incidence predicted to increase in the coming years (Truelsen et al., 2006). Approximately one third of people who experience a stroke die as a direct result, leaving around 1.1 million stroke survivors living in the UK (Townsend et al., 2012). The total cost of stroke to the UK economy is estimated to be between £3.7 billion and £8 billion per year (DoH, 2010)

A stroke occurs when the blood supply to the brain is disrupted leading to death of nervous tissue. Eighty percent of strokes are caused by an occlusion in a cerebral artery, such as those caused by an embolus, resulting in an ischaemic stroke. The other main pathological cause of stroke (15%) is due to haemorrhage of a cerebral artery. The remaining five percent of strokes are classified as a subarachnoid haemorrhage (Lindley, 2008).

Types of upper limb impairments exhibited post stroke include spasticity, dystonia, muscle contracture, reduced muscle power resulting in loss of strength and dexterity, (Zackowski, Dromerick, Sahrmann, Thach, & Bastian, 2004). The initial presenting impairments following stroke have traditionally been divided into 'positive' and 'negative' features of an upper motor lesion. Positive features typically comprise hyper-reflexivity or spasticity and negative features being weakness and loss of motor control (Walshe, 1961). Not untypically as a result of the primary deficits, secondary impairments arise, for example reduction in range of joint motion and changes in the mechanical properties of muscle and connective tissue, leading to adaptive muscle shortening or even contracture (Thilmann, Fellows, & Ross, 1991). In spite of a historical emphasis on spasticity and its management, numerous studies have concluded that the main contributing factor to loss of function are the negative features of weakness and loss of motor control (Burridge, Turk, Notley, Pickering, & Simpson, 2009; Ada, O'Dwyer, & O'Neill, 2006). The quality of arm movement after stroke is also disrupted. Heterogeneous studies of arm movements in stroke patients have demonstrated longer movement duration, an increased deceleration phase,

decreased movement smoothness (Alt Murphy, Willén, & Sunnerhagen, 2011), lower peak velocity, increased variability and timing of peak velocities and larger end point errors (van Vliet, Pelton, Hollands, Carey, & Wing, 2013). Poor inter-joint and intermuscular co-ordination are thought to be partially responsible for these deficits (van Kordelaar, van Wegen, & Kwakkel, 2012).

Stroke patients have been found to demonstrate a significant amount of non-use of their affected upper limb during unimanual and bimanual activities (Michielsen, Selles, Stam, Ribbers, & Bussmann, 2012). In the early stages following stroke, the patients' ability to use their hemiplegic upper limb for functional activities is often severely impaired. This inability to use the upper limb can quickly lead to a phenomenon known as 'learned non-use' (Taub, Uswatte, Mark, & Morris, 2006). Factors such as recovery of the hand (Lin, Huang, Hsieh, & Wu, 2009) and hand dominance (Darling et al., 2013) are thought to influence functional recovery. However, further studies are required to fully understand the complex relationship between motor recovery and actual amount of use in people with chronic stroke.

2.1.2 Impact on quality of life

Stroke is a major cause of disability, with over half of stroke survivors being dependent on others for assistance with activities of daily living (ISWP, May 2012). One of the most common contributors to this stark picture is chronic physical impairments of the hemiplegic upper limb, seen in an estimated 50-70% of stroke patients (Gebruers, Vanroy, Truijen, Engelborghs, & De Deyn, 2010). The upper limb is used for a wide variety of functional tasks, including contributing to balance and protecting the body from the effects of falls and external blows. The ability to reach, grasp and manipulate objects, is an essential requirement for independent performance of daily tasks, such as eating, drinking, bathing, dressing, writing and taking part in hobbies (Shumway-Cook & Woollacott, 2007; Hunter & Crome, 2002; Wolfe, 2000).

Stroke patients place a high priority on regaining upper limb function (Barker & Brauer, 2005) and an ability to participate in functional and social aspects of life has been shown to have a direct impact on quality of life (QoL) (Cameron, Cheung, Streiner, Coyte, & Stewart, 2011; Schumway-Cook & Woollacott, 2007; Hunter & Crome, 2002; Mayo, Wood-Dauphine´, & Cote, 2002; Wolfe, 2000). Previous studies have identified stroke severity as a significant predictor of stroke disability, and

health-related quality of life as long as five years post stroke (Paul et al., 2005). Indeed, following a stroke, patients with severe upper limb dysfunction are approximately twice as likely to be admitted to institutionalized care (Hunter & Crome, 2002).

2.1.3 The recovery process following a stroke

The CNS has a capacity to reorganise in response to injury, pathology or behavioural demands placed on it (Xerri, 2012; Cramer et al., 2011; Pascual-Leone, Amedi, Fregni, & Merabet, 2005). This reorganisation occurs as a result of neuroplasticity of the neuromuscular system, which if influenced early after stroke, can have a positive effect on recovery of the upper limb. However, if this reorganisation is left to its own devices, it can be detrimental to recovery. Neuroplasticity can be defined as…….

> *"the ability of the nervous system to respond to intrinsic and extrinsic stimuli by reorganizing its structure, function and connections; can be described at many levels, from molecular to cellular to systems to behaviour; and can occur during development, in response to the environment, in support of learning, in response to disease, or in relation to therapy" (Cohen et al., 1997, pg.180).*

Recovery is a broad term widely used to describe the process of reverting towards a previous (normal) state following a stroke. The International Classification of Functioning, Disability and Health (ICF) can be used to help cluster recovery (Levin, Kleim, & Wolf, 2009) into three areas; body structure and functions, activities and participation. Where recovery occurs, it is due to a combination of spontaneous changes and relearning of skills. Spontaneous recovery is thought to occur in the first few days and weeks post stroke. Changes over a longer time frame are probably due to other neuronal mechanisms, such as long-term potentiation, axonal regeneration and sprouting (Langhorne, Bernhardt, & Kwakkel, 2011). The processes contributing to recovery have been categorised as 1) '*restitution'*, restoring or repairing the functionality of the damaged area; 2) '*substitution*', reorganisation of partly spared pathways that take on the function(s) of the damaged area; and 3) '*compensation'* which is the use of other body structures, or the same body structure used in a different way, to achieve a functional goal (Langhorne et al., 2011). Only 1) and 2) are classified as 'true recovery'. 'True recovery' is associated with an increase in

dendritic branching in the relevant parts of the cortex and a resumption of the same kinematics of the movement as those utilised prior to the stroke. A 'compensatory response' is where neuroplastic changes may still take place as a result of re-learning, however the kinematics of the movement are different to those used pre-stroke (Metz, Antonow-Schlorke, & Witte, 2005). For example when stroke patients are attempting to reach for an object, they may employ compensatory forward flexion of the trunk in order to accommodate for a lack of shoulder flexion and elbow extension. Further studies are required before the relationship between 'true recovery' and 'compensation' can be fully understood. Section 2.2 outlines the factors that may influence recovery.

2.2 Basic science studies

In this section, the evidence from animal studies, together with recent clinical trials is introduced, pointing to the key features of effective therapy interventions.

2.2.1 Timing of interventions

The mechanism of neuroplasticity is thought to be influenced by the timescale post stroke and is still only partially understood. Animal studies have provided evidence that the plasticity of the brain and behavioural recovery is evident in the first month post stroke (Murphy & Corbett, 2009; Kleim & Jones, 2008). Krakauer, Carmichael, Corbett, & Wittenberg, (2012) eloquently describe the molecular, cellular and physiological changes in the peri-infarct cortex in the early stages following stroke. There appears to be mixed views regarding the optimum time to commence treatment post stroke (Allred, Young Kim, & Jones, 2014). Studies have found that early, intensive rehabilitation interventions post stroke can lead to cell damage (Schallert, Fleming, & Woodlee, 2003; Humm, Kozlowski, James, Gotts, & Schallert, 1998). However, this has to be balanced against the risk that a delay to commencing rehabilitation can result in the establishment of sub-optimal compensatory movement patterns (Biernaskie, Chernenko, & Corbett, 2004). There is also some evidence from clinical studies to suggest that there is an optimal timing for rehabilitation interventions post stroke (Farmer, Durairaj, Swain, & Pandyan, 2014; Biernaskie et al., 2004) and that efforts beyond 30 days are potentially less effective (Barbay et al., 2006). Importantly in humans, further changes in 'compensatory recovery' may take

place after 30 days. However, the mechanisms for these changes are less well documented. In addition, humans may continue to make considerable motor gains based on increases in strength or endurance of muscles, both of which are likely to impact on functional activity. In summary, more information is required regarding the variability in post-stroke injury and time-dependent neural activity before the optimum timing for rehabilitation interventions can be confirmed.

A systematic review of Randomized Controlled Trials (RCTs) that used assistive technologies (AT) for rehabilitation of the upper limb with stroke patients was undertaken by Farmer et al. (2014). The data was used to assess the effect size of the intervention across all dimensions of the ICF framework. A moderate benefit was found for AT when compared with usual care or in addition to usual care. There was a greater effect size for patients in the acute phase i.e. up to 6 weeks post stroke. There were two exceptions to this finding; 1) Neuromuscular Electrical Stimulation (NMES) to the shoulder (Church et al., 2006) and 2) Constraint induced Movement Therapy (CIMT) earlier than 6 weeks post-stroke (Dromerick, Lang, & Birkenmeier, 2009).

Constraint-Induced Movement Therapy (CIMT) is a form of treatment for the hemiplegic upper limb that consists of constraint of the unaffected upper limb, simultaneous with intensive (up to 6 hours) and progressive task-based training of the hemiplegic limb. This intensive practice is often referred to as 'shaping'. Wolf et al. (2010) delivered 2 weeks of CIMT to stroke patients randomized into either an early (3-9 months, n=106) or late (15-21 months, n=86) intervention group. Assessors who were blinded to the group allocation administered the Wolf Motor Function Test, Motor Activity Log (primary measures) and the Stroke Impact Scale (secondary measure) pre-intervention then at 2 weeks, 4, 8 and 12 months post intervention. Although both groups demonstrated significant improvements in upper limb recovery across all outcome measures, the early CIMT group showed the greatest relative improvement. This study reinforces the view that interventions targeted early after stroke are likely to advantageous.

2.2.2 Intensity and scheduling of practice

Arguably the most important ingredient for the re-learning of movement skills is for training to be sufficiently intensive to allow an improvement in performance (Kwakkel, 2006). In a study by MacLellan, (2011), rats were administered with brain

derived neurotrophic factor (BDNF), which has been found to improve sensorimotor recovery following ischemia. The rats were exposed to either an enriched or a non-enriched rehabilitation environment in order to examine the impact of varied reaching intensities and durations post brain lesion. The enriched rehabilitation environment typically contained multi-level cages with tubes, toys and ramps. Reaching interventions of 4 to 6 hours per day, 5 days per week for 8 weeks, with on average 300 reaching repetitions completed per session (MacLellan, 2011). The non-enriched environment was standard rat caging. Only rats in the enriched rehabilitation environment that reached a critical threshold of reaching activity (approximately 300) demonstrated recovery. Some rats engaged in the reaching activity but failed to reach the critical threshold of repetitions resulting in no recovery. Interestingly, the rats who did achieve recovery did not further benefit from the enriched rehabilitation environment when they were exposed to additional doses of the intervention. This study is important not only because it is the first to demonstrate that there appears to be a critical threshold of number of repetitions below which recovery will not occur, but also because it supports the use of task-specific interventions. One study by Birkenmeier, Prager, and Lang (2010) demonstrated that it is possible to achieve over 300 repetitions of an upper limb task within a 1 hour therapy session (3 tasks x 100 repetitions).

In 2008 a high quality randomised control trial (RCT) (the EXCITE trial), (Wolf et al., 2008), 106 out of 222 patients with mild to moderate impairments were randomly assigned to the CIMT intervention group. The patients who received CIMT achieved substantial improvements in the functional use of their affected arm and quality of life even two years after treatment had stopped. The EXCITE trial and other studies (Thrane, Friborg, Anke, & Indredavik, 2014; Cramer et al., 2011; Shi, Tian, Yang, & Zhao, 2011), support the findings that high doses of treatments are more effective than low doses. Two further studies based on the EXCITE trial data, (Hidaka, Han, Wolf, Winstein, & Schweighofer, 2012; Schweighofer, Han, Wolf, Arbib, & Winstein, 2009) demonstrated that if the dose of therapy can promote functional recovery beyond a critical threshold, that spontaneous use would continue beyond the period of therapy. A recent systematic review of the literature by Hayward and Brauer (2015), confirmed that the dose of arm activity training during acute and sub-acute rehabilitation post

stroke has been poorly documented, and as such further work is needed to determine the optimum dose for upper limb rehabilitation.

When looking to promote skill acquisition, due consideration needs to be paid to the type of practice that is scheduled. '*Massed practice,'* is where the amount of time spent performing repetitions of a task is greater than the amount of rest between repetitions. This can be problematic for patients where fatigue is an issue. '*Distributed practice'* is where the amount of rest between practice sessions is equal to or greater than the amount of time in practice (Shumway-Cook & Woollacott, 2007). Varying the task within sessions, *'variable practice'* has been found to be more effective at transference of skills than repeating the same task (*'constant'* practice). Whilst '*constant practice'* can achieve some re-learning within the training session, it has been found to be less effective in terms of 'carry-over' of learning into subsequent training sessions (retention), or indeed daily life (generalisation) (Schmidt and Lee, 2005). In addition to this, factors that make tasks more difficult in the short-term have been shown to enhance learning in the longer-term (Schweighofer et al., 2011). Such factors are referred to as '*contextual interference'*. Randomly varying the task within the training session *('random practice'*), as opposed to repeating the same task before moving on to the next task *('blocked practice'),* can lead to improved retention and in subsequent sessions. Although the mechanisms underlying 'contextual interference' still need further investigation, Joiner and Smith (2008) proposed that learning takes place via two simultaneous mechanisms: 1) a fast process that stimulates short-term fast learning, but longer term forgetting, and 2) a slow process whereby short-term learning and initial performance appear poor but result in a subsequent improvement in long-term learning and skill acquisition. This model has been further developed by Lee and Schweighofer (2009). Following a stroke, in order to promote skill acquisition, the practice conditions need to be carefully aligned to both the patients' stage of recovery, stage of learning and their clinical presentation e.g. level of fatigue, amount of visuospatial memory. Adjusting practice conditions so that they remain at an optimally challenging level for each patient is likely to maximise motor relearning.

2.2.3 Content and progression of training

Although the dose for therapeutic interventions is important when promoting upper limb recovery, without due consideration for the content and progression of training the picture is incomplete. The content and approach to therapy has been a matter of debate for many years (Wang, Chen, Chen, & Yang, 2005), with various authors proposing a particular approach e.g. Bobath, Orthopaedic, Motor re-learning amongst others. A recent Cochrane Review has found there to be no evidence of superiority of one method or approach over any other (Pollock, Baer, et al., 2014).

Animal studies have demonstrated that training needs to be task specific and challenging if it is to drive recovery (Nudo & Milliken, 1996). Rossi, Gianola, and Corvetti (2007) (Figure 2.1**)**, have described the neurobiological changes that occur as a result of brain reorganisation following injury, and advocate task-specific training as a means of providing the most suitable form of extrinsic stimuli.

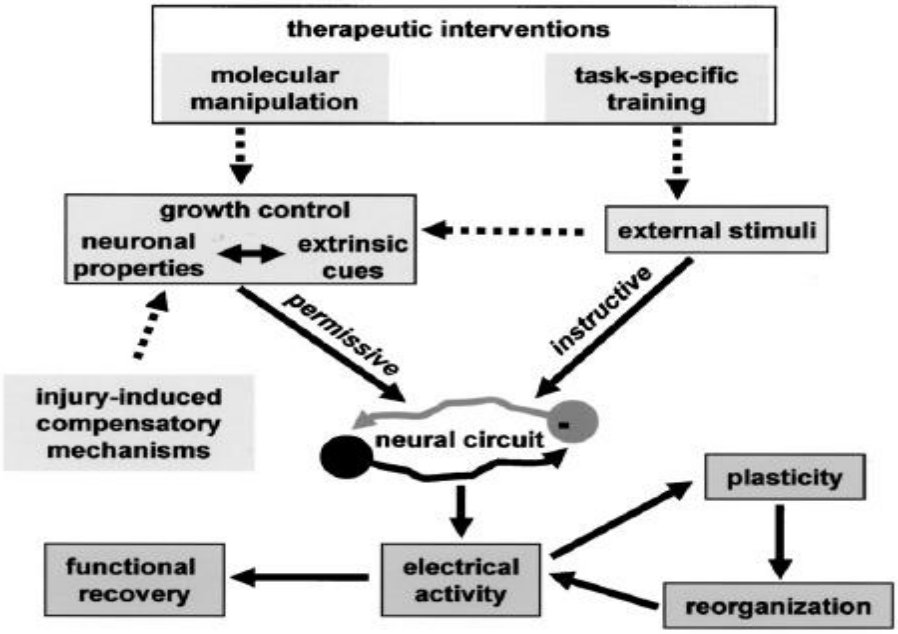


Figure 2.1: Interaction between growth control mechanisms and environmental stimuli during physiological plasticity and repair. Reproduced with permission of Rossi et al., (2007).

They suggest that after injury endogenous compensatory modifications are responsible for changes to growth control settings. These growth control changes provide a permissive trigger to the neuronal circuitry to reorganise in such a way that will drive functional recovery. However, often an external stimulus, such as task-specific training, is required in order to instruct or guide the direction of reorganisation. As a

result of the evidence from animal and human studies, task-oriented or task-specific training has been proposed as a fundamental ingredient when designing training schedules to promote skill reacquisition (French et al., 2010). A recent study has extended this concept by demonstrating that re-learned skills only generalise to similar movement sequences that occur in the same workspace, with similar joint co-ordinations as those learned during training (Panarese, Colombo, Sterpi, Pisano, & Micera, 2012). In addition, practice schedules need to progressively challenge the learner if motor learning is to take place. Guadagnoli and Lee (2004) describe this as creating 'optimal challenge points', which considers the level of skill the leaner has achieved, the task difficulty (including the environment that the task is performed in), and the amount of information available, as important variables. These variables have been taken into account when designing 'iterative learning' systems, and have been incorporated into new UL FES technologies that are currently under development (Meadmore et al., 2014).

In recent years as the evidence for a focus on reducing spasticity has waned, Progressive Resistance Training (PRT) has increased in popularity. Weakness is a dominant feature in post stroke hemiplegia, as a result of changes at a neural (supraspinal) and muscular level (Patten, Lexell, & Brown, 2004). Although a sufficiently large body of evidence remains to be collected, PRT appears to offer some merit (Porter, 2000; Hurley & Roth, 2000). However, PRT may not be beneficial for all severities of stroke patients. PRT has been shown to be most beneficial for patients with mild to moderate levels of impairment where voluntary effort can be initiated (Winstein et al., 2004; Thielman & Gentile, 2002). The transfer of improvements in strength to functional improvement remains to be fully examined.

Human studies that have used a robotic device to deliver passive rather than active movement have demonstrated that passive movements can maintain or improve range of motion at upper limb joints, but do not necessarily lead to functional motor recovery. What is clear from both of the approaches outlined above, and from previous studies, is that motor recovery is supported through active volitional effort by the patient (Hogan et al., 2006). Movements by the therapist on behalf of the patient (passive movements), whilst useful for maintaining joint and muscle range, are less effective when it comes to promoting motor recovery of the upper limb (Lynch et al., 2005).

2.2.4 Feedback on performance

One of the fundamental requirements to enhance motor relearning is provision of information or feedback, either during or following task performance. Feedback can be classified into two categories: '*intrinsic'* feedback which is provided by the body's own sensory-perceptual information, via internal sensory processes that occur as a result of movement e.g visual or proprioceptive feedback, and occur during performance of a task. '*Extrinsic'* or *'augmented'* feedback: usually arises from an external environmental source (Subramanian, Massie, Malcolm, & Levin, 2010). As intrinsic feedback is often disrupted following a stroke, provision of extrinsic feedback is crucial to supplement this deficit. Extrinsic feedback can be given verbally, manually or by using visual means such as a visual display, demonstration or video. Extrinsic feedback can be further divided into 'knowledge of results' (KR) and 'knowledge of performance' (KP). KR is "externally presented information about the outcome of performing a skill or about achieving the goal of the performance" (Magill, 2003). KP is "information about the movement characteristic that led to achievement of the goal" (Magill, 2003). For example, a patient may be instructed to straighten their elbow to more effectively reach a target object. Studies in healthy participants (Wulf & McConnel, 2002) and in stroke patients (Durham et al., 2013) have found KR to be more beneficial. Importantly for therapy that uses functional tasks, additional extrinsic feedback can be redundant if the outcome of the performance is inherent in the task (Platz et al., 2001; Beukers, Magill, & Hall, 1992), and might even be detrimental.

Timing of feedback is also important for the retention of information. Feedback can be provided concurrently (at the same time as the task is being performed) or terminally (after performance is complete). Terminal feedback can be further sub-divided into a number of sub-categories including bandwidth feedback (provided at intervals throughout training) and average feedback. When considering the timing of feedback, the patients' stage of learning also needs to be taken into account (Mount et al., 2007; Ezekiel, Lehto, Marley, Wishart, & Lee, 2001). Wherever possible, patients should be encouraged to solve the motor problem (Mulder & Hochstenbach, 2003).

This brief overview of feedback highlights the complexity of providing feedback, especially to patients where cognitive processing and memory may well be impaired.

It is therefore not surprising that a review conducted by van Vliet and Wolf (2006) on provision of extrinsic feedback for motor relearning following stroke, concluded that although there are clear benefits for provision of feedback to enhance motor learning, further studies were required before it was possible to determine the most suitable type, frequency and attentional focus for each possible patient presentation.

In summary, from a review of basic science studies in animals and humans, there are varying amounts of evidence to support upper limb training schedules being:

1) *Timely* in that they should commence early post stroke, when neuronal processes can cope with external influences; 2) s*ufficiently intensive* to support those individuals who have the potential to reach activity dependent recovery thresholds. This has been postulated to be in the region of 300 repetitions per training session. However, attention to the *scheduling of practice* is required so as to align to the patients' needs; 3) the *content* of training should be *functionally* oriented, such as the approached used within task-oriented training. Training that aims to address 'weakness' rather than 'spasticity' appears to have clear benefits. However, movement sequences and tasks need to be *progressive and optimally adapted* to meet both the patients' capability and the environment in which the skill is to be used; 4) And finally, due consideration needs to be given to the type, frequency and timing of feedback, adapted to align with the stage of learning and the patient's presentation.

Section 2.2.5 reviews current therapy provision in order to allow comparison with the evidence presented in section 2.2.4.

2.2.5 The reality of current therapy provision

Current guidelines recommend that whilst in hospital stroke patients should receive the equivalent of 45 minutes of each therapy, Physiotherapy (PT), Occupational Therapy (OT) and Speech and Language Therapy (SALT) five days per week (The Intercollegiate Stroke Working Party, 2014). The revised analysis from the National Sentinel Stroke Clinical Audit in 2010 (ISWP, May 2012), reported that although 74% (n=6578) and 67% (n=6138) of patients nationally were deemed to be suitable for 45 minutes of physiotherapy (PT) and occupational therapy (OT) respectively on at least 5 days per week, only 45% (PT, n=2944) and 47% (OT, n=2861) actually received therapy input. Out of the same group of patients who received physiotherapy, 55% received less than 45 minutes. In support of these findings, the first report from the Sentinel Stroke National Audit

Programme (SSNAP, April 2013-March 2014) (The Intercollegiate Stroke Working Party, 2014), found that out of the 85% of patients that required physiotherapy, they only received 32 minutes of therapy in just over half of their in-patient stay. Bearing in mind that these figures are based on therapy for restoration of mobility as well as upper limb function, and that previous studies have identified that therapy tends to focus on mobility rather than treatment of the upper limb (Cott, 2004), it is reasonable to assume that therapy for the upper limb falls significantly short of what is required to promote recovery (Rudd, Jenkinson, Grant, & Hoffman, 2009). In addition, the length of time that patients remain in hospital following a stroke has significantly decreased over the last decade (Figure 2.2).

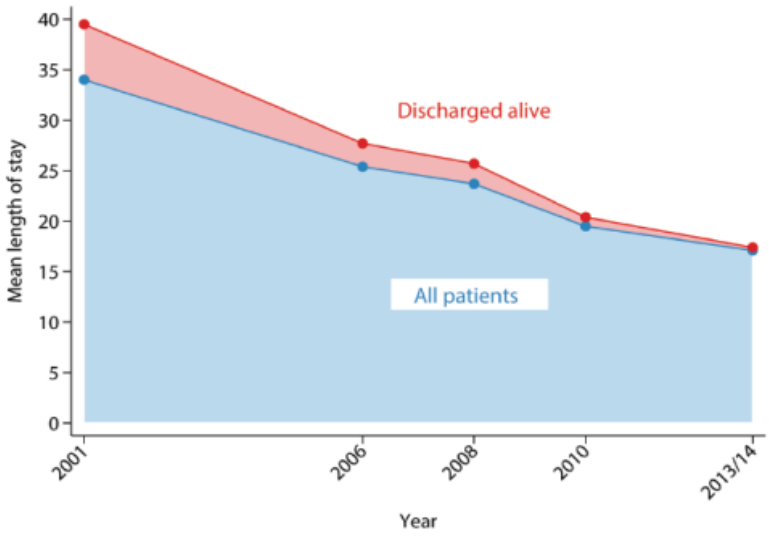


Figure 2.2: **the graph shows the mean length of stay in hospital from 2001 to 2013-14, showing that mean length of stay has decreased significantly. The top line depicts those patients who were discharged alive and the bottom line represents all patients (The Intercollegiate Stroke Working Party, 2014).**

The average length of stay is now 17 days (median 7) (The Intercollegiate Stroke Working Party, 2014). A quarter of patients stayed less than 3 days and a quarter 21 days or more. This rapid turnover of patients undoubtedly contributes to the lack of sufficiently intensive programmes of therapy in hospital environments.

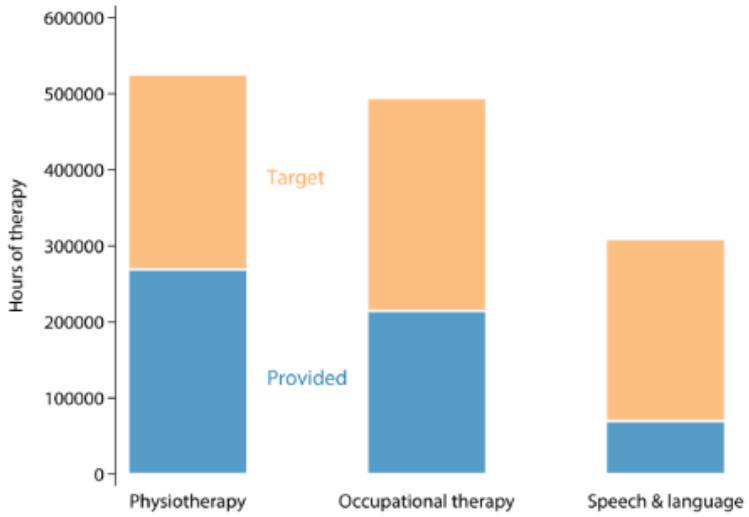


Figure 2.3: **Total hours of therapy provided for all patients across the year against the target number of hours (The Intercollegiate Stroke Working Party, 2014).**

Figures taken from the same audit report showed that the total hours of therapy fall below target numbers (Figure 2.3), and on discharge 37% of patients required assistance with activities of daily living (ADL) (The Intercollegiate Stroke Working Party, 2014). As upper limb function is crucial to carrying out ADL, this most probably demonstrates that restoration of upper limb function had not occurred, and corroborates findings from previous studies (Kong, Chua, & Lee, 2011; DoH, 2010), that promoting upper limb recovery remains a significant challenge.

A recent study by McHugh, Swain, and Jenkinson (2013) gathered information on the most frequently used interventions adopted by therapists for rehabilitation of the upper limb post stroke. Interventions were classified according to those used for mild, moderate and severe patients. One hundred and ninety two surveys were distributed to 28 geographical regions across the UK. Fifty three surveys were returned from 20 out of the 28 regions. Thirty seven in-patient settings and forty community based settings were represented. A total of 998 treatment components were identified, the majority of these (n=403) were for the moderately impaired category. Similar to other studies (Rudd et al., 2009), the survey found that the majority of therapy time was spent on treatment for patients who were moderately impaired. The total time estimated to be dedicated to physiotherapy for the entire in-patient stay was 5 hours. Similarly, for Occupational therapy (OT) 3 hours, and Speech and Language Therapy (SALT) 1.3 hours. In general, the use of rehabilitation technologies was low across all centres. However, Constraint Induced Movement Therapy was most widely used for mildly

impaired patients (21%) and Functional Electrical Stimulation (FES) for those who were moderately (36%), or severely (18%) impaired.

It can therefore be concluded from the review of current practice, that it appears to be poorly aligned with the evidence base and indeed the recommended clinical guidelines. It is clear that existing rehabilitation practice alone will not address the increase in demand for rehabilitation and that new ways of tackling this growing problem are urgently required. Numerous studies have demonstrated the potential for technology to assist with the timing, intensity, and content of therapy, particularly for the upper limb (Demain et al., 2013; Hochstenbach-Waelen & Seelen, 2012; Rosser et al., 2011; Timmermans, Seelen, Willmann, & Kingma, 2009). These interventions have the potential to free up valuable therapist time and provide a situation where patients can access rehabilitation interventions in order to practise functional movements at their own pace. However, it is important to stress that rehabilitation technologies need to be seen as an adjunct to the therapeutic process, rather than one that replaces it. Both patients and practitioners need to be persuaded that the evidence base for their implementation is strong, and that it provides an additional dimension to the 'toolbox' of practitioners. Section 2.5 examines this issue in more depth.

The next section introduces the reader to FES, which is central to this thesis.

2.3 Functional Electrical Stimulation (FES)

2.3.1 Basic science. What is FES?

Before explaining electrical stimulation, a brief introduction to recruitment of muscle fibres is provided. Muscle activity is controlled by the Central Nervous System (CNS). Communication between the CNS and the muscles occur via motor neurons. A motor unit is a single motor neuron and its associated muscles fibres. Once a motor neuron is activated, all the muscle fibres it supplies are activated (Bear, Connors, & Paradiso, 1996).

When there is no stimulation the membrane of the neuron has a negative charge in comparison to its surroundings. This is known as its 'resting potential' and the neuron can be described as 'polarised'. The resting potential is achieved through the concentration balance of four ions; potassium, K^+, sodium, Na^+ , chloride, Cl^- and carboxylate, $RCOO^-$ (from proteins). When a neuron is stimulated its resting potential

is altered or 'depolarised'. Depolarisation changes the permeability of the cell membrane causing diffusion of Na^+ into the axon. The charge inside the cell becomes more positive, causing an 'action potential'. Once this has been achieved the membrane becomes less permeable to Na^+ and begins to favour K^+ once again. K^+ leave the axon until the resting potential is achieved once again. The membrane is then 're-polarised' (RSC, 2004). This process of depolarisation and re-polarisation continues at a local level to allow transmission of the nerve impulse along the motor neuron. In a myelinated neuron, the electrical impulse jump from one 'node of Ranvier' to the next, thereby speeding up conduction (Figure 2.4).

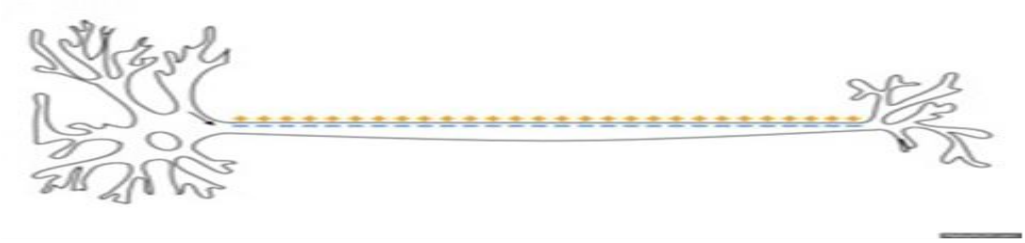


Figure 2.4: **Propagation of an electrical impulse along the axon of a motor neuron**

"Action Potential" by Laurentaylorj - Own work. Licensed under CC BY-SA 3.0 via Wikimedia Commons - https://commons.wikimedia.org/wiki/File:Action_Potential.gif#/media/File:Action_Potential.gif

FES is the use of Neuromuscular Electrical Stimulation (NMES) to activate paralysed muscles in a precise sequence and magnitude, resulting in the accomplishment of functional tasks. Lower motor neuron electrical stimulation alters the electrical field surrounding a nerve's axon, and if the field reaches sufficiently high level, action potentials are induced (Figure 2.5).

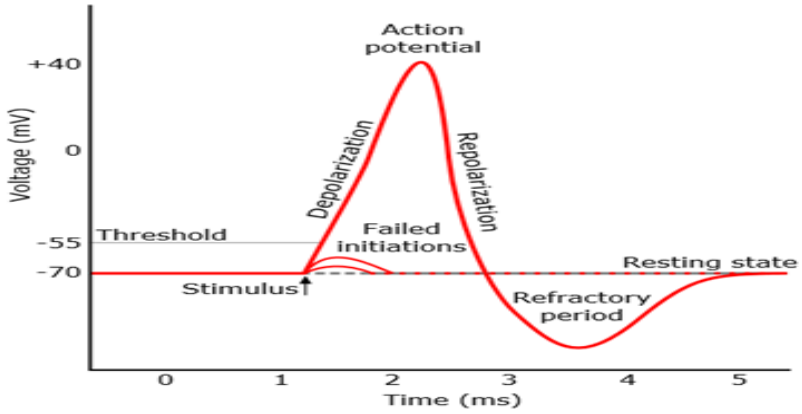


Figure 2.5: **Depolarisation of a motor neuron and generation of an action potential**

http://en.wikipedia.org/wiki/Action_potential. **Action potential" by Original by en:User:Chris 73,**

updated by en:User:Diberri, converted to SVG by tiZom - Own work. Licensed under CC BY-SA 3.0 via Wikimedia Commons.
http://commons.wikimedia.org/wiki/File:Action_potential.svg#mediaviewer/File:Action_potential.sv

The most common method of applying stimulation is via surface electrodes as in Figure 2.6. However, FES has also been administered using percutaneous or implanted systems (Peckham & Knutson, 2005).

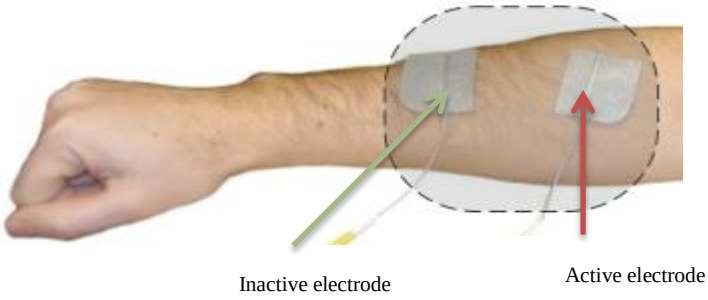


Figure 2.6: **Diagram to show the application of surface electrodes. Reproduced and adapted from:** http://spectrum.ieee.org/automaton/robotics/medical-robots/robot-controls-human-arm

Stimulation protocols in FES typically utilise a current-controlled delivery method, whereby biphasic charge balanced pulsing is used to prevent the build-up of unwanted chemical substances. The first phase (stimulation phase) elicits the action potential. The second phase (reversal phase) reverses the electrochemical processes that occur during the stimulation phase. The polarity of a bi-phasic pulse can either be cathode-first or anode-first. Figure 2.7 illustrates a cathode-first example as this can affect the threshold of activation. Peripheral, cutaneous stimulation usually employs a cathode-first method due to the lower activation threshold (Merrill, Bickson, & Jefferys, 2005).

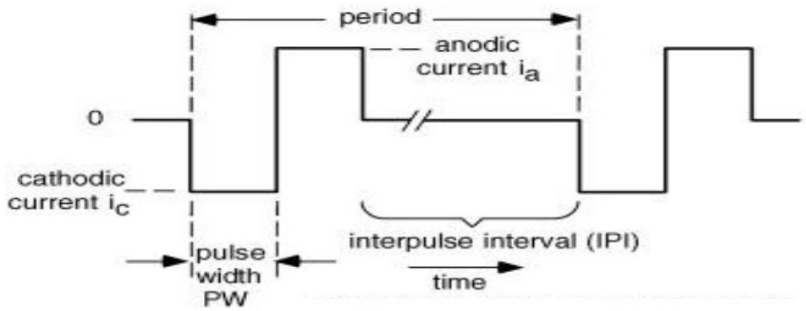


Figure 2.7: **Typical waveform for FES (Merrill et al., 2005). The narrow pulse width is indicated PW. The interpulse interval (IPI) is the time between pulses.**

In conventional electrical stimulation waveforms, the largest diameter nerve fibres are initially recruited (type IIb, fast twitch, depicted in red), followed by type IIa (green) and type 1 (slow twitch, fatigue resistant, blue) (Figure 2.8). This is the reverse order to that occurring under normal physiological conditions (Merrill et al., 2005).

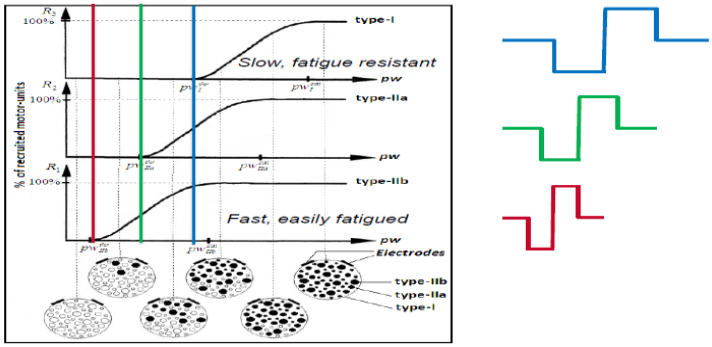


Figure 2.8: **Muscle fibre recruitment order with corresponding pulse widths (Hamouda, 2014)**

The recruitment of different motor units over time produces a physiological tetanic state (Figure 2.9).

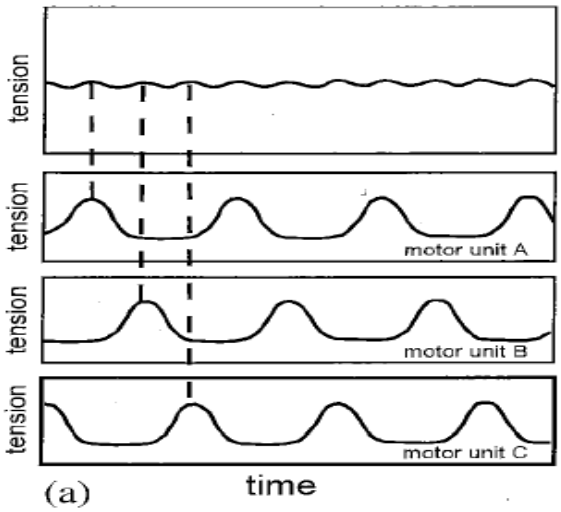


Figure 2.9: **Stimulation frequency showing recruitment of different motor units over time resulting in a physiological tetanic state (Baker, Wederich, McNeal, Newsam, & Waters, 2000).**

The frequency of stimulation is the number of stimulation pulses delivered per second. Most commercially available FES systems operate at between 20-40Hz. With FES, the frequency of stimulation is often fixed, and hence the user adjusts the pulse width or pulse amplitude to alter the force of muscle contraction.

A unique feature of FES is that is activates motor nerve fibres both orthrodromically and antidromically. The antidromic impulse is postulated to have an effect on the plastic adaptations occurring at the anterior horn cell when performed in conjunction with voluntary effort via a damaged pyramidal motor system (Rushton, 2003) (Figure 2.10).

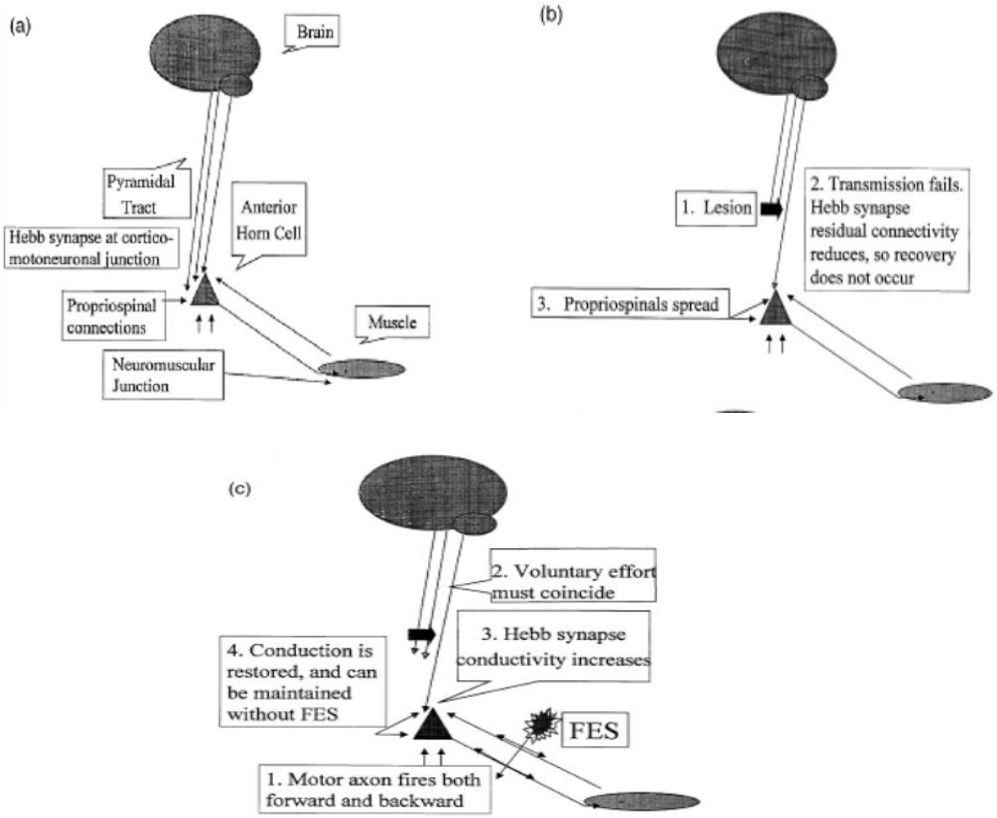


Figure 2.10: **Diagram to demonstrate the theory proposed by Rushton (2003). (a) The proposed normal physiology (b) a lesion in the system (c) the system following NMES intervention. Diagram from Rushton (2003).**

2.3.2 A review of the efficacy of upper limb FES assisted practice

Traditionally electrical stimulation for the upper limb has involved the use of stimulators that deliver repetitive stimulation using pre-set timings (cyclical stimulation). Although this form of stimulation is generally passive, it is thought to have a beneficial effect (Powell, Pandyan, Granat, & al, 1999; Pandyan, Granat, & Stott, 1997), and has therefore been defined as therapeutic electrical stimulation (TES)

(de Kroon, van de Lee, IJzerman, & Lankhorst, 2002). TES has been aimed at reducing impairment, for example by increasing muscle strength or range of movement. Although it is useful for reducing impairment, there is limited evidence to support its impact on activity or function (Chae et al., 1998).

Another category of electrical stimulation is Functional Electrical Stimulation (FES). FES is a means of stimulating muscle in order to achieve functional tasks (de Kroon et al., 2002). FES can be used either on its own, or in combination with an orthosis to act primarily as an assistive device by enabling completion of everyday tasks (neuroprosthesis), for instance in patients with spinal cord injury, and/or as a training modality with the aim of promoting recovery of function. The latter approach is the one most commonly used with stroke patients. In a recent systematic review and meta-analysis by (Howlett, Lannin, Ada, & McKinstry, 2015), subgroup analysis from 8 studies (Page, Levin, Hermann, Dunning, & Levine, 2012; Faisal & Priyabanani Neha Om, 2012; Tarkka, Pitkanen, Popovic, Vanninen, & Kononen, 2011; Hara, Ogawa, Tsujiuchi, & Muraoka, 2008; Daly et al., 2005; Mann, Burridge, Malone, & Strike, 2005; Popovic, Popovic, Sinkjaer, Stefanovic, & Schwirtlich, 2004; Popovic, Popovic, Sinkjaer, Stefanovic, & Schwirtlich, 2003) (181 participants) found that FES had a large effect on upper limb activity (SMD 0.69, 95% CI 0.33 to 1.05) compared with a control group. However the control groups were generally traditional therapy, which was often not defined. In contrast to these findings, a recent Cochrane Systematic Review (Pollock, Farmer, et al., 2014) found there to be insufficient robust evidence from RCTs to support the use of FES as an intervention for upper limb recovery. However, the small number of participants in studies, the heterogeneity of studies and often insufficient control of the effect of duration of interventions across groups, makes it difficult to draw firm conclusions.

In spite of this lack of sufficient cumulative robust evidence, a number of studies have demonstrated significant clinical benefit with systems in which the onset and termination of stimulation is patient-controlled, from EMG (Bolton, Cauraugh, & Hausenblas, 2004), or movement sensors located on the hemiplegic upper-limb (Mann, Taylor, & Lane, 2011), or by the contralateral limb (using buttons for example) (Chan, Tong, & Chung, 2009), or where a therapist triggers stimulation to assist with the movement at appropriate points (Popović, Sinkjær, & Popović, 2009;

Thrasher, Zivanovic, McIlroy, & Popovic, 2008). Even when severely affected acute stroke patients, with minimal movement in their affected arm, undertake intensive functional task practice, using therapist-triggered FES, significantly improved clinical outcomes can be achieved (Thrasher et al., 2008). The following section reviews the evidence from studies where systems were patient-controlled.

In recent years there have been a number of reviews of FES for the upper limb. Bolton (2004) carried out a meta-analysis on EMG triggered neuromuscular stimulation on stroke motor recovery for the arm and hand (up to 2003). Only 5 studies were deemed to be sufficiently robust to be included in the analysis (Cauraugh & Kim, 2002; Cauraugh, Light, Kim, Thigpen, & Behrman, 2000; Francisco, Chae, & Chawla, 1998; Hummelsheim, Amberger, & Maurtiz, 1996; Kraft, Fitts, & Hammond, 1992), and of these only 1 study (Francisco, Chae, Chawla, & al., 1998) could be categorized as being in the acute phase post stroke (just 4 patients in the intervention group). Nevertheless, they found an overall beneficial effect on hand / arm function for acute / sub-acute (16%) and chronic stages (84%) of stroke. There was a significant mean effect size of 0.82 and a 95% confidence interval of 0.10-1.55. Some caution should be exerted when considering this review as non-randomised studies were included.

A subsequent systematic review by Chan (2008) examined the literature between 2003 to 2008. Five studies met the inclusion criteria (studies which included stroke patients who were at least 3 months post stroke, and used upper limb function, range of movement, tone or muscle strength as the primary outcome measures (Ring & Rosenthal, 2005; Kimberley et al., 2004; Cauraugh & Kim, 2003; Alon & Ring, 2003; Alon, Sunnerhagen, Geurts, & Ohry, 2003). None of the patients included in the review were in the acute stage of stroke and all patients were classified as having a mild or moderate level of impairment. The findings from these studies demonstrated that FES combined with practising functional tasks can improve functional recovery.

A Cochrane review in 2009 entitled “electrical stimulation for promoting recovery of movement or functional ability after stroke” (Pomeroy, King, Pollock, Baily-Hallam, & Langhorne), examined 24 clinical trials (up to 2004) and concluded that electrical stimulation improved some aspects of functional ability post stroke when compared with no treatment or a placebo. The review did not find any advantage of electrical

stimulation over other treatment modalities, such as standard physiotherapy. However, only 10 studies focused on electrical stimulation for the upper limb. Of the 10 studies, 6 were EMG triggered systems, predominantly for the wrist and hand in order to facilitate hand opening (Kimberley et al., 2004; Cauraugh & Kim, 2003; Cauraugh & Kim, 2002; Cauraugh et al., 2000; Francisco, Chae, Chawla, et al., 1998; Heckmann et al., 1997). The remaining studies were either not triggered (Linn, Granat, & Lees, 1999; Chae et al., 1998; King, 1996) or were triggered manually (Popovic et al., 2003). The heterogeneity of studies in these reviews makes it difficult to establish the efficacy of functional electrical stimulation, and impedes the generalisation of results. In spite of the promising basic science studies reviewed in section 2.2 the application to human studies with FES requires further research. A recent review by Quandt & Hummel, (2014) concisely summarises the position to date regarding the efficacy of FES; treatment doses, optimal stimulation parameters, timing of interventions and the level of severity of stroke patients likely to benefit from FES remains inconclusive.

There appears to be a growing evidence base for the use of voluntary movement (patient triggered) triggered FES, in particular movement that is triggered via accelerometers or electro-goniometers. This method harnesses the benefits of combining the patient's voluntary effort with that of FES. A review by Popović et al. (2009) concluded that integration of electrical stimulation in combination with exercise-active movement enhanced motor re-learning following central nervous system damage. They also suggested that the therapeutic effects are likely to be more effective when treatment is applied in the acute, rather than the chronic phase of stroke. This seems to be in keeping with the basic science studies.

A recent study by Meadmore et al. (2014), using a convenience sample of 5 participants with stroke, adds to the growing evidence base for movement controlled FES. The rehabilitation system used in the study combined a Microsoft Kinect® (Microsoft, Washington, USA) and electro-goniometer (Model SG75 Biometrics Ltd, Newport, UK), in order to collect arm positon data, with an FES unit and a dynamic, mobile mechanical arm support (SaeboMAS) which acted as a de-weighting system. Stimulation levels were governed by Iterative Learning Control (ILC) (Meadmore et al., 2012; Freeman et al., 2011) based on the stroke participants performance during functional tasks. Fugl-Meyer and Action Research Arm Test (ARAT) scores

significantly improved from pre to post-intervention, alongside a reduction in arm support for unassisted FES performance.

This evidence suggests that functional improvements from FES may result from its use in supporting voluntary-triggered, task-focused practice. Clearly more evidence from larger, well designed multi-centre RCTs need to be undertaken before any firm conclusions can be drawn. However, larger studies can only be carried out if movement controlled FES devices that are sufficiently robust and flexible, in order to treat a wide range of patients, are in existence. Commercially available devices where stimulation is patient-controlled may be limited. A review of FES devices that are available commercially is reviewed in section 2.4.

2.4 FES-systems for upper limb rehabilitation

2.4.1 Review of current commercial & research systems, including limitations on functionality

Due to the growing promise of FES a number of commercial devices have made their way to market. The four most readily available FES devices will be reviewed in relation to their relative merits and shortcomings.

Bioness H200® wireless hand rehabilitation system (Figure 2.11)

This system combines FES with an orthosis, which stabilises the wrist joint into extension, thereby optimising the flexor activity of the fingers (Page et al., 2012; Schill et al., 2011; Ring & Rosenthal, 2005). The system contains a microprocessor which sends stimulation signals wirelessly to the electrodes embedded in the arm unit. Up to 5 muscles, forearm flexors and extensors, can be stimulated. The pattern of stimulation is pre-programmed by a therapist and enables the patient to perform a variety of functional tasks. However, the system is not under volitional control, in that it is not triggered by the patients' movement, and can only be used to stimulate muscles in the forearm and hand. Consequently it is not suitable for patients with more severe and diffuse upper limb paralysis.

Figure 2.11: **The Bioness H200®hand rehabilitation wireless system**

Otto Bock Stiwell Med4 system

The Stiwell med4 system (Figure 2.12) comprises of up to 4 channels of electrical stimulation combined with 2 EMG channels. The system is able to facilitate the achievement of more complex movement sequences involving multiple joints. The EMG channels allow the patient to initiate the triggering of stimulation by using muscle activity, and provides biofeedback on movement activity, including any compensatory muscle activity. The system has an integrated GUI and does not require PC support. Research studies involving patients who have used the system have commenced (Kwakkel et al., 2008; Rakos, Hahn, Uher, & Edenhofer, 2007) and although final results are yet to be released, there appear to be some promising results.

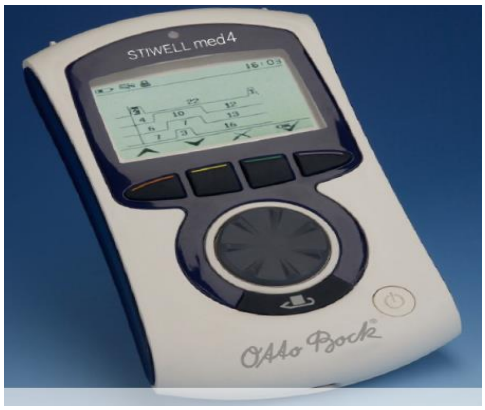


Figure 2.12: **The Stiwell med4 EMG-triggered FES system**

Zynex NeuroMove™ NM 900 (Biomation, USA).

Figure 2.13: **NeuroMove™ NM900**

The 'NeuroMove' (formerly the AM800) (Figure 2.13) is a surface EMG triggered neuromuscular electrical stimulation device. It measures peak values in the EMG signal to detect when a patient is attempting to move. It is marketed for use in stroke or spinal cord injury patients. It is recommended for use of no more than 30 minutes at a time. However, only one stimulation channel is available, greatly limiting its functionality.

MyoTrac Infiniti

Figure 2.14: **The MyoTrac Infiniti, produced by Saebo, USA.**

Saebo Myotrac Infinite (Figure 2.14) is an EMG triggered stimulation system. It has 2 channels of stimulation and incorporates biofeedback from the EMG signals. Pulse width, pulse rate, ramps times and stimulation time periods are adjustable to some extent degree. However, beyond these parameters it is limited in its programmability.

2.4.2 Limitations with existing FES systems

Section 2.4.1 highlighted that a remaining problem with the majority of FES systems is that the triggering of the burst of stimulation often has to be triggered manually by the therapist carrying out the treatment session or is not controlled by movement of the limb, but instead by EMG. Devices that are triggered by therapists are not a practical solution if patients are to perform highly intensive practice. Although EMG triggered systems hold some promise, detecting the patients' muscle activity amongst machine generated stimulation activity can be problematic. In addition, more severe patients can have minimal upper limb muscle activity for effective triggering of stimulation. By contrast, devices that where stimulation is triggered directly from other types of sensors e.g. accelerometers have the potential advantage of not requiring constant therapist support for their use. Accelerometer-triggered FES devices use the change in limb or hand-located accelerometer signal that results from voluntary movement to initiate or terminate stimulation. Although studies that have used accelerometer triggered stimulation show significant promise (Mann et al., 2011), the devices used to deliver the stimulation can be difficult and time consuming to set-up. Complex upper limb tasks usually require multiple stimulation channels which compounds the problem of long set-up times. In addition, such devices have often required specialist engineering support to setup (Tresadern, Thies, Kenney, & Howard, 2008). These issues, among others may limit the future uptake of FES devices into healthcare settings and provides the rationale for the development of a new advanced UL FES Rehabilitation Tool (UL FES Rehab Tool).

2.5 Use of health technology within clinical practice

Health technologies aim to promote health, prevent and treat disease, and improve rehabilitation and long-term care (NIHR, 2015). The use of health technologies within health care has been reported to be generally low, particularly within the National Health Service (NHS), in spite of their potential to be cost-effective (Tomlin, Peirce, Elwyn, & Faulkner, 2012). The NHS has been 'a late and slow adopter of technology', with only 4.5% of the NHS budget spent on health technologies, as compared with the remainder of Europe where the average spend is 6.3% (MTG, 2009; Force, 2004). Commercially led market analysis has identified significant potential for rehabilitation devices over the next few years with stroke rehabilitation

technologies highlighted as the primary growth area (Cavuoto, Cornett, Grill, & Pope, 2009). The NHS Next Stage Review interim report highlighted the importance of technology in the NHS (DoH., 2007), and the availability of funding (for example from the Preventative Technology Grant, (http://www.ict-ageing.eu/?page_id=1617). In spite of this promise, uptake remains relatively low.

Therapists' uptake of even very simple to use technology has traditionally been poor. From a survey of physiotherapists in the Republic of Ireland, even exercise equipment was not widely used, in spite of its wide spread availability, with less than 50% of therapists allowing patients to exercise on their own (Coote & Stokes, 2003). The focus of this thesis is on more sophisticated technologies than those addressed by Coote. In this thesis, a new term, advanced neurological rehabilitation technologies (ANRT) has been used, defined as software-controlled, electrical, mechanical or electro-mechanical devices or immersive multimedia designed to encourage sensory-motor recovery post neurological injury. This definition includes robotics, virtual reality and functional electrical stimulation (FES) systems.

Burridge and Hughes (2010) conducted a review of the most commonly used ANRT's in clinical practice. They concluded that in spite of some of the technology having a growing body of evidence to support its use e.g. CIMT, uptake remained poor. This was in stark contrast to other less evidenced technologies such as the Saeboflex dynamic hand orthosis, where the company reported sales to 55 out of 320 NHS Acute and Primary Care Trusts. In 2010 O2 developed and launched the "Wii fit' for use by people with stroke as part of their global e-health strategy (EHI, 2010). Interestingly, in 2013 O2 decided to withdraw its health products due to poor uptake of the devices. A subsequent UK wide survey of stroke teams carried out as part of the Assistive Technologies for Rehabilitation of the Arm following Stroke (ATRAS) project, (McHugh et al., 2013) confirmed these findings in that assistive or rehabilitation technologies[1] were not widely used. CIMT was the most widely used for mildly impaired patients and electrical stimulation for moderate and severe patients. A recent large survey of Health Care Professionals (HCP) (n=292) and Patients and Carers (P & C) (n=123) by Hughes, Burridge, Holtum Demain, et al. (2014) examined the translation of evidence-based assistive technologies into clinical practice. It reported

[1] The terms assistive device and rehabilitation technology are often used interchangeably (Chau, 2013).

that 41% of health care professions (HCP) and 64% of patients and carers (P & C) had never used assistive technologies. FES was the most used by both HCP (34%) and P & C (47%) whilst robotics and biofeedback were the least used. Uptake of rehabilitation devices remains low for a variety of reasons, which will be discussed in section 2.6.

2.6 Adoption of rehabilitation technology

Successful adoption or uptake of ANRT into clinical practice is dependent upon a multitude of factors. The views of policy makers, service providers and service users is critical to adoption (Demain et al., 2013). The following section will examine the main barriers to adoption and use, by key stakeholders.

2.6.1 Perceived barriers to adoption and use in practice

The barriers to adoption of ANRT are complex and include user acceptance (clinicians and patients), cost, availability and flexibility of devices, insufficient robust evidence to convince health care commissioners of the value of rehabilitation devices, and often an insufficiently large effect size to drive organisational change (Cheeran, Cohen, & Dobkin, 2009). Although ANRT appear to offer promise, before this potential can be realised the barriers to uptake need to be addressed. Even when considering technology where efficacy has been demonstrated to some extent e.g. CIMT, robotics and virtual reality, uptake remains low (Arya, Pandian, Verma, & Garg, 2011; Brewer, McDowell, & Worthen-Chaudhari, 2007; Lum, Reinkensmeyer, Mahoney, Rymer, & Burgar, 2002).

A review by Hochstenbach-Waelen and Seelen (2012) provided important insights into factors that should be considered when seeking to implement technology for rehabilitation of the upper limb into daily clinical practice. They reviewed the literature on the use of technology in upper limb rehabilitation and conducted semi-structured interviews with therapist working in stroke rehabilitation. The criteria fell into two main categories: a) therapy related and b) software and hardware related. The therapy related criteria stressed the importance of alignment with the patients' goals, consideration of cognitive impairments, be task-oriented and progressive in nature, take into account effective training principles related to intensity and frequency of therapy and finally to provide feedback and help to motivate patients. The software

and hardware requirements were extensive and highlighted that setup needed to be quick and easy and for the technology to be user-friendly. Therapists stressed the importance of short setup times, stating that therapy sessions were usually only 30 minutes, consequently lengthy setup times would severely hamper adoption. This reinforces the need to align new rehabilitation technology to the practices of therapists, and the needs of patients.

Even for FES devices, such as for foot-drop where NICE guidelines recommend its use, device reliability, inability to use in certain contexts e.g. near water, difficulty donning and doffing and allergic reaction to the electrodes have been cited by patients as barriers to uptake (Bulley, Shiels, Wilkie, & Salisbury, 2011). In the survey by Hughes, Burridge, Holtum Demain, et al. (2014), the top five factors that influence adoption were reported as: an evidence-base supporting use, ease of setup, safety, comfort and durability. The results from this survey and from Hochstenbach-Waelen and Seelen (2012) clearly highlight the importance of usability of ANRT to adoption and use within clinical practice.

2.7 Usability

2.7.1 Usability and usability engineering

In this thesis usability is defined in accordance with the International Standards Organisation (ISO) 9421-11 standard, part 11, as "the effectiveness, efficiency, and satisfaction with which specified users achieve specified goals in particular environments" (ISO, 1997, pg. 1). Users in the context of the thesis are either professional users, i.e. therapists, or end-users (patients).

Usability engineering originates from human factors science and ergonomics and has been developed most widely in the field of human-computer interaction (Shneiderman, 2004; Cooper & Riemann, 2003). It refers to research and design methods for improving ease-of-use of new products and devices. Although usability engineering methods are well established in other domains, they remain relatively new in the field of rehabilitation technologies. Figure 2.15 illustrates the key components of a usability engineering process and highlights its iterative nature.

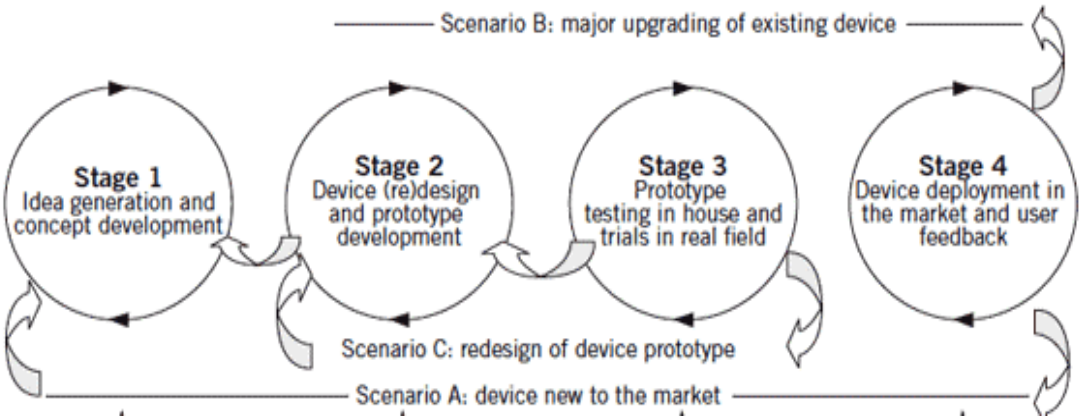


Figure 2.15: **Key components of a usability engineering process adapted from Shah, Robinson, and AlShawi (2009).**

2.7.2 Usability evaluation methods

A systematic approach to the development of ANRT requires robust usability methods. Methods used mainly in the early stage of the usability engineering process to gather user requirements are termed "inquiry methods" and include focus groups, interviews and surveys; inspection methods lend themselves to the development stage at which point prototypes are available. Usability testing methods are most appropriately used towards the final stages of the design process, when summative feedback from users is required (Robinson et al., 2005).

Section 2.8 reviews the literature to identify ANRT that have reported on usability evaluation. In order to guide the reader, some of the more frequently used methods are outlined below.

Cognitive Walkthrough (Lewis, Polson, Wharton, & Rieman, 1990) and Heuristic Walkthrough (Nielsen, 1994) are both usability inspection methods. With 'Cognitive Walkthrough' the expert is asked to use the device, placing themselves in the position of the user and answer four questions: (1) will the user try to achieve the correct effect, (2) will the user notice that the correct action is available, (3) will the user associate the correct action with the desired effect, and, if the user performed the right action, (4) will the user notice that progress is being made toward accomplishment of his goal. 'Heuristic Walkthrough' assesses the device based on a pre-defined set of criteria termed 'usability heuristics, such as error prevention and match between the system and the real world. Both approaches are highly structured.

User based testing methods or 'assisted walkthroughs' allow end users to participate in the evaluation of a user interface by working through task based scenarios. The purpose is to identify the majority of usability problems. Usability problem can be defined as "the parts of a system that cause users trouble, slow them down, or fit badly with their preferred ways of working" (Hertzum & Jacobsen, 2003). Users are asked to explain their actions and choices by 'thinking-aloud' (Nielsen, 1994). This method has the advantage of providing an insight into the reasons behind usability problems rather than merely identifying the problem (Jaspers, 2009). Where necessary, the researcher offers prompts to encourage the user to keep verbalizing their thoughts. It has been widely used to identify design problems during usability testing of interactive computer systems (Hertzum, Hansen, & Anderson, 2009).

Questionnaires, focus groups and usability scales are further examples of qualitative usability methods. Focus groups are generally used to gather user requirements in the early stages of device development. Questionnaires are frequently used to gauge users' satisfaction with a device and examples include the Short Feedback Questionnaire (SFQ) (Kizony, Raz, Katz, Weingarden, & Weiss, 2005) and the Usefulness, Satisfaction and Ease of Use Questionnaire (Lund, 2001). For virtual reality systems where measures of presence are important, the Immersive Tendencies Questionnaire (ITQ) (Witmer & Singer, 1998) is frequently used. Usability scales have been developed as a means of quantifying users overall impression of the usability of a device. Examples of these are the System Usability Scale (SUS) (Brooke, 1996), VRUSEĐ a computerised diagnostic tool for usability evaluation of virtual environment systems and the Software Usability Measurement Inventory (SUMI) (Kirakowski, 2000; Kirakowski & Corbett, 1993).

2.8 A literature review of studies of ANRT that have reported on usability evaluation

A literature review was undertaken to identify studies that reported on the design and evaluation of ANRT, with a specific focus on usability issues. The databases of Web of Science and PUBMED were used, with a limit of English language. Search terms were mapped to their MESH sub-headings. Key words and psynonyms were used in all cases. Rehabilitation technologies were combined using the Boolean operator OR with the specific ANRT's of electrical stimulation, robotics and virtual reality and

gaming devices. This was combined using AND with the search results for computer interfaces, including psynonyms which identified 14,493 results. These results were combined with neurological condition AND usability, including their synonyms, which identified 349 results. These results were combined with the keyword users and synonyms to find 237 articles. Citations from these articles were used to track further articles for inclusion.

Of the studies found, titles and abstracts were first reviewed for eligibility. Full-text articles were then examined. Studies were included if the technology was used for rehabilitation purposes and included evaluation of usability or user feedback. Articles were excluded if the study's focus was assistive technology i.e. the purpose was only to assist the end-user to compensate for their deficit, with no focus on promoting recovery (e.g. wheelchairs), studies aimed at children rather than adults, as different methods to gather user feedback were required, or if a computer interface was not part of the rehabilitation device. Studies examining brain-computer interface were also excluded as generally these are not as yet intended to be used in practice by therapists. Data were extracted into an Excel spreadsheet.

Thirty seven studies were included in the final review (refer to Appendix 1). These were classified as: robotics, (n=12); robotics and electrical stimulation (Iterative Learning Device), (n=1); functional electrical stimulation devices (n=1); virtual reality (VR) and gaming units, (n=19), tele-rehab systems (n=3) and UniTherapy, a rehabilitation user interface (n=1).

With the exception of Dijkers et al., (1991), most of the studies in the review were relatively recent, with 31 out of the 37 studies conducted since 2007. This is perhaps unsurprising, given that many innovations in this area have arisen from recent advances in neuroscience, computing and sensing. However, it may also indicate an increasing realisation of the importance of incorporating usability methods into the development of new ANRT. Indeed user-centred design of medical devices in general has grown over the last decade (Martin, Clark, Morgan, Crowe, & Murphy, 2012; Grocott, Weir, & Ram, 2007; Shah & Robinson, 2007).

2.8.1 Types and numbers of users.

Many authors have stressed the importance of user involvement in technology design, to avoid problems arising with adoption of the technology further downstream (Martin et al., 2012; Lehoux, 2008; Shah & Robinson, 2007). The type of users involved in usability evaluations is crucial to the effective identification of usability problems (Turner, Lewis, & Nielsen, 2006). Indeed research suggests that each type of user is likely to have their own priorities when it comes to design requirements (Demain et al., 2013; Shah & Robinson, 2007). Despite a growing evidence base of user involvement in technology development and assessment, there remains a lack of clarity in the literature about how to define the users of this technology.

The extent to which different types of end users contributed to the usability evaluation in the reviewed studies varied across the identified studies. Therapists are, the 'gate-keepers' for ANRT (Demain et al., 2013) and are frequently, if not always, involved to a greater or lesser extent in setting up ANRT. However, as discussed below, relatively few of the identified studies included them.

Eleven studies out of 37 used health care professionals (HCP) as part of the evaluation and design process (refer to table 1). Interestingly Holt et al. (2007) found a significant difference in the priority of design requirements for Occupational Therapists when compared with Physiotherapists. Whitworth et al. (2003) was the only study to include a therapy assistant in the testing protocol. The almost universal absence of assistant practitioners in the usability work stands in contrast to the current trends in the workforce, of which an increasing proportion is made up of therapy assistants. The remaining studies recruited either stroke participants, healthy participants or a combination of both. The nature of usability evaluation tends to result in the recruitment of small numbers of users to test the device. Other than in the international survey by Lu et al., (2011), (n=233), which only focused on design requirements, the maximum number of professional users included was 11 (Dijkers et al., 1991). End-users, primarily stroke survivors, were recruited in larger numbers, ranging from 2 (Whitworth et al., 2003) to 22 (Meldrum, Glennon, Herdman, Murray, & McConn-Walsh, 2012). When considering usability testing rather than eliciting design requirements, none of the studies in the review provided a robust rationale for the number of users recruited. This is perhaps unsurprising as there remains a wider

debate with regards to the number of users that should be utilized during usability testing (Turner, Lewis, & Nielsen, 2006; Nielsen, 2000).

Table 2.1: **Studies from the literature review that included Health Care Professions as part of the design and usability process.**

Author(s)	Year	Device	Number & type of user
Lu E.C, Wang R.H, Herbert D, Boger J, Galea M.P, Mihailidis A.	2011	Portable 2D haptic robotic system for upper limb therapy	233 PT & OT with minimum of 1 year experience in neuro rehabilitation
Lam P, Herbert D, Boger J et al.	2008	Portable 2D haptic robotic system for upper limb therapy	8 experienced PT & OT from local hospitals. Inclusion criteria 1 year experience, practicing clinician, not involved with development of device.
Huq R, Lu E, Wang R, Mihailidis A.	2012	Portable 2D haptic robotic system for upper limb therapy	3 OT & 4 PT
Fitzgerald D, Kelly D, Ward T, Markham C, Caulfield B.	2008	E-motion: A virtual rehabilitation system that demonstrates, instructs and monitors a therapeutic exercise programme.	6 experts - ergonomist, psychologist, exercise scientist, physiotherapist, computer scientist, yoga teacher. Twelve healthy participants took part in the user evaluation study.
Gil-Gómez J, Lloréns R, Alcañiz M and Colomer C.	2011	eBaViR (Easy Balance Virtual Rehabilitation): A system based on the Nintendo Wii Balance Board (WBB)	17 stroke patients - 9 patients in the intervention, 8 control. Informal therapist feedback.
Whitworth E, Lewis J.A, Boian R, Tremaine M, Burdea G, Deutch J.E.	2003	The Rutgers Ankle Rehabilitation System (RARS) and its' telerehabilitation sub-system.	System developed collaboratively between engineers and clinical scientist. Stroke patient, therapist using the system locally, remote therapist, patient and therapy assistant.
Mawson S, Nasr N, Parker J, Zheng H, Davies R, Mountain G.	2013	The Personalised self-managed Rehabilitation System (PSMrS)	First focus group - 7 professionals. Second focus group - 7 stroke patietns and their families. Home visit - 8 patients.
Anacleto J, Silvestre R, Filho C.S, Santana B.	2012	Natural User Interface (NUI) technology	5 health professionals - 1Pt, 2 nurses, 1 OT, 1 social scientist.
Pedrocchi A, Ferrante S, Ambrosini E, Gandolla M, et al.	2013	MUNDUS modularly combines an antigravity lightweight and non-cumbersome exoskeleton, closed-loop controlled NMES system for arm and hand motion, and potentially a motorized hand orthosis, for grasping interactive objects.	Focus group - 7 doctors, 1 psychologist, 1 PT, 1 engineer, 1 patient affected by Amyotrophic Lateral Sclerosis. 36 potential users interviewed. 1 caregiver, and 2 social enterprise representatives employing disabled people. Five patients - 3SCI and 2 MS.
Dijkers M.P, deBear P.C, Erlandson R.F, Kristy K, Geer D.M, Nichols A.	1991	UL robotic device	Designed by research team - OT's & engineers. 11 therapists & 22 patients (stroke, GBS, MS, TBI) used the system.
Kyoungwon S, Kim J, Lee J, Jang S, Ryu H.	2011	Gaming intervention - high fidelity prototype RehabMaster.	16 stroke patients, 7 PT, 3 OT

Key to abbreviations: MS = Multiple Sclerosis; OT = occupational therapy; PT – physiotherapy; SCI = Spinal Cord Injury; TBI = Traumatic Brain Injury; UL= upper limb.

2.8.2 Usability methods and tools

Medical device manufacturers and researchers have previously raised concerns over the cost/benefit ratio of employing usability engineering methods in the development process, with a particular focus on the appropriateness of the tools used (Money et al., 2011). Of the 37 studies identified, questionnaires were frequently used as a method of evaluating users' satisfaction with devices. Six studies utilised study-generated questionnaires that were not previously validated (Meldrum et al., 2012; Cameirao, Badia, Oller, & Verschure, 2010; Hughes et al., 2009; Holt et al., 2007; Jackson et al., 2007). Lewis, Woods, Rosie, and McPherson (2011) and Lu et al. (2011) used a questionnaire based on a previous study. In the latter case this was from 1994. Studies that evaluated virtual environment often employed technology specific questionnaires such as VRUSE (Fitzgerald, Trakarnratanakul, Dunne, Smyth, & Caulfield, 2008; Fitzgerald, Kelly, Ward, Markham, & Caulfield, 2008) or the Immersive Tendencies questionnaire (ITQ), (Crosbie, McNeill, Burk, & McDonough, 2009). In studies where more formal methods of usability were used (Mawson et al., 2013; Fitzgerald, Kelly, et al., 2008; Whitworth et al., 2003), 'cognitive walk-through' and 'think-aloud' were the usability testing method of choice. As ANRT typically include both software and hardware, used by therapists with patients, use of conventional software usability tools on their own have frequently proven inadequate. As a consequence, researchers have experimented with or adapted existing methods, or devised new ones.

The use of multiple tools to measure the usability of a device was common place across all studies. Although the use of multiple evaluation tools allows for the triangulation of data (Ram, Campling, & Weir, 2008; Garmer, Ylvén, & Karlsson, 2004), relatively few of the studies explicitly mention triangulation. Mawson et al. (2013) made use of triangulation in a mixed-methods, user-centred design approach, to develop a home use, post stroke information and communication technology (ICT) self-management rehabilitation system. The research methods were taken from health and social sciences and user-centred design. Focus groups, in-depth interviews, cultural probes, technology biographies and 'cognitive walk-throughs' were used at different stages of the design process. Another example of a well-designed study was the Rutgers Ankle Rehabilitation System (RARS) and its' telerehabilitation sub-system (Whitworth et al., 2003), which incorporated testing observations whilst using

'think-aloud'. Sessions were videotaped and therapist-user questionnaires were also administered. The group triangulated data from each of these sources in order to identify the main usability problems. Usability evaluation of this system was particularly challenging due to its multi-users, multi- interface and remote testing issues. Additional unique approaches employed were the use of true-false questionnaires to assess how much the therapist had understood about the systems operation and requiring the therapist to explain the operation of the system to both the therapy assistant and the patient.

During usability testing, all studies exposed the same users to the device on only one occasion, thereby largely ignoring the issue of learnability. One study (Kizony, Weiss, & Shahar, 2006) reported on the development of a VR based system, TheraGame, evaluated the device after two and a half weeks, with one user. How quickly users learn to operate the device, '*learnability'*, is another important outcome that can not only shed light on a devices ease of use, but can also inform the amount of training that users may require. Only one study, Whitworth et al. (2003) examined knowledge retention as part of the usability evaluation.

Generally speaking, the final usability evaluation phase was less well defined across studies, with studies relying on users to rate their satisfaction with the device (Llorénsa, Colomer-Fontb, Alca˜niza, & Noé-Sebastiánc, 2013; Meldrum et al., 2012; Weiss et al., 2012; Arya et al., 2011; Burdea, Cioi, Martin, Fensterheim, & Holenski, 2010; Cameirao et al., 2010), rather than observing how they interacted with the system. Whilst subjective feedback regarding the usefulness and ease of use of the device has a place, it may be influenced by users' desire to please the research team, particularly if the evaluation is carried out in the final stages of the design process when changes to the device would be costly. In addition, users may not always be sufficiently conversant with the device to identify all likely usability problems (Martin, 2008).

Usability tasks should relate closely to the tasks that users have to perform in order to achieve the intended goal of the device. Task selection has been described as a critical aspect of usability testing (Wilson, 2007). For example, problem solving tasks can reveal major usability problems, whereas tasks that are overly structured can

sometimes only uncover minor and superficial usability problems (Alshamari & Mayhew, 2009).

2.8.3 Exploitation of usability analysis to inform the design of an ANRT

Correct interpretation of usability problems is crucial to finding suitable and acceptable design solutions. Objective measures of the functionality of devices such as task completion times, error rates and task performance combined with rating the severity of problems found can help designers to make more informed decisions about where to target their resources (Khajouei, Peute, Hasman, & Jaspers, 2011; Travis, 2009). Of the studies reviewed, only Pedrocchi et al., (2013), utilised any form of rating system to prioritise the identified problems. In this case therapist rated how well the users executed the chosen tasks on a scale of 0 to 2 (0= not able to execute, 2=fully executed). Choi, Gordon, Park, and Schweighofer (2011) attempted to quantify usability problems by recording the number of adverse events that occurred whilst using the system. A Mobile Usability Lab (MU-Lab) that collected video data whilst users interacted with the device was used in the studies by Feng and Winters (2007), Johnson, Feng, Johnson, and Winters (2007) and Johnson and Winters (2004). However, neither the data analysis nor how this process influenced the design was reported.

2.8.4 Setup time for ANRT

A factor highlighted through the literature and in the early study focus groups (discussed in chapter 4), is the small amount of time available for rehabilitation of the upper limb. This situation only serves to reinforce the need for devices to be easy to administer and use. In spite of the importance of rapid setup time (Demain et al., 2013; Hochstenbach-Waelen & Seelen, 2012), only three studies in the literature review examined setup as part of the process (Pedrocchi et al., 2013; Fitzgerald, Kelly, et al., 2008; Dijkers et al., 1991), and only two of these (Pedrocchi et al., 2013; Dijkers et al., 1991) reported on setup time. Fitzgerald, Kelly, et al. (2008)) examined setup in order to identify usability problems. However they did not measure setup time as part of this process.

Further studies that fell outside of the usability literature review for ANRT, due to their lack of a computer interface, which examined usability and setup time,

were Burridge et al. (2008), van Swigchem, Vloothuis, den Boer, (2010) and Prenton et al. (2014). These studies compared FES for foot-drop either with an ankle-foot orthosis (van Swigchem, Vloothuis, den Boer, 2010) or with an implanted device (Burridge et al., 2008). Both studies highlighted the continued difficulty patients experience with surface stimulators when donning and doffing the device, positioning electrodes and the inconvenience of external wires (where systems are not wireless). Time to apply the device was examined in only one study (Burridge et al., 2008). Time taken to put the device on (whether help was given or not), was approximately 10 minutes for the Odstock Drop Foot Stimulator (ODFS). By comparison, 8 ActiGait implanted drop-foot stimulator users at 90 days and 10 at the final assessment said they were able to put the device on in less than 3 minutes and only one user reported that it took longer than 10 minutes (at 90 days). These differences are most likely due to not having to apply surface electrodes, particularly as positioning electrodes was cited by 43% of ODFS users as a problem. In this example users clearly preferred the shorter application times for the ActiGait. One potential solution for the difficulty of electrode placement for FES foot drop devices, is the development of an electrode array for foot drop (Prenton et al., 2014; Heller et al., 2013). Electrode arrays have been developed to assist with finding the optimal site for stimulation, which can vary between patients and from day to day. Heller et al. (2013) developed an electrode array for a 64 channel electrode prototype stimulator. Patients were asked to estimate setup times for their own conventional FES device when at home. The mean setup time was 11 min (range 2-30 min; n=21). The mean setup time for the lab based automated setup was significantly quicker with a mean setup time of 5.9 min (n=17). However, clinician and patients setup times, which could have been significantly greater, were not measured. In addition, the automated setup times did not include donning the stimulator and sensors. Building on these findings and further refinements of the system, Prenton et al. (2014) carried out a study to investigate whether the array-based automated setup foot drop FES system (ShefStim) could be used unsupervised over a 2 week period, by people with stroke, based in the community. Total setup time (defined as time from donning the device to satisfaction with foot alignment outcome and ability to walk) and automated setup times were recorded. In addition, community usage patterns; user satisfaction (measured using the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST)

(Demers, Monette, Lapierre, Arnold, & Wolfson, 2002), version 2.0; and usability i.e. user-reported problem (via a paper diary). User-reported problems were classified as those pertaining to setup and those unrelated to setup (external). Walking speed, ankle angles and foot clearance during swing phase of gait were also recorded. Data from 7 users, (4 stroke and 3 MS). Total setup time for the ShefStim was significantly longer at 14 min compared with 3 min 24s for the users' conventional stimulator. Although the number of problems decreased over the 2 week period, a significant number of usability problems were self-reported and recorded (n=75). Of these 48 problems were related to setup and 27 to external use. Ease of use and ease of adjustment were highlighted by users as priorities. Both of the above studies rely to some extent on self-reported measures of setup time and usability, which although useful, can be at odds with results from directly observed measures.

In summary, studies that accurately record setup time for ANRT are limited and tend to focus on patient setup times rather than clinician setup times of the device. The authors' experience, combined with examples taken from the literature, reinforce the importance, to clinicians and patients of short setup times for rehabilitation devices. In spite of the critical nature of setup time, there are currently no methods available to therapists to predict setup time.

2.9 Chapter summary and thesis aims

Chapter 2 has discussed the challenges faced by patients and therapist in the UK aiming to promote functional recovery of the upper limb following a stroke. Although there is a reasonable amount of evidence within the basic science literature to guide the delivery of rehabilitation interventions, in practice implementing sufficiently intensive treatment schedules which are underpinned by evidence is problematic. FES systems that are under the patients' control are adaptable for each patient, and that offer flexibility of training schedules have the potential to contribute towards upper limb recovery. However, as highlighted in section 2.4.1 the commercial systems currently available have too few channels of stimulation for treatment of more patients with more complex impairments; do not offer a choice of sensors for triggering stimulation and have limited options for fine tuning stimulation parameters to produce smooth, coordinated multi-joint movement sequences. There is a clear challenge in making such a flexible system quick and easy

for the therapist to use. Hochstenbach-Waelen and Seelen (2012) in their paper highlighted that setup of rehabilitation technologies should be easy and quick, not only for therapist, but also for therapy assistants. In addition, the system needs to be sufficiently flexible to adapt to a range of patient impairments and allow for their progression across therapy sessions. Finally, due to the rapid turn-over of patients through in-patient services, the systems design needs to be such that it can be used by practitioners in both hospital and community settings.

As usability of the UL Rehab Tool was likely to be critical to its successful uptake in practice, an overview of usability, usability evaluation methods and tools has been provided. The number of studies that have reported on the usability methods for ANRT is limited. Of those that have, few have extensively used an extensive range of usability engineering methods. None have directly measured setup time by therapists, particularly in real world settings and to the authors' knowledge, a method to predict setup has yet to be developed. This thesis proposes a usability engineering approach to the design and evaluation of an UL FES system that would guide therapist, quickly and easily, through the setup process.

The aims of the thesis were to:

1) Design a Graphical user Interface (GUI), that would enable therapists with no software skills, to quickly and easily set up an individually tailored library of FES tasks for each patient, together with the corresponding bespoke FES controllers;

2) Develop appropriate methods and carry out a usability and functionality evaluation of the UL FES Rehab Tool (software and hardware) in both laboratory (lab) and clinical settings.

Chapter 3 outlines the earlier research by the rehabilitation technologies group at the University of Salford, (including the author), that was a forerunner to the current project. The author's PhD work ran in parallel with that of a fellow PhD student (Sun, 2014), both of which were aligned with a New and Emerging Assistive Technology (NEAT LO30) grant, in which the author was a co-applicant. Throughout the thesis there will be cross referencing to where the author's work complimented that of (Sun, 2014). A clear distinction will be made between these parallel research projects, and the authors' respective roles. Sun's role was to write the software and develop

engineering techniques for robust triggering of the FES system. The author's role was the usability engineering work that informed the design of the GUI, and the laboratory and hospital based usability evaluation of the UL FES Rehab Tool.

3 Chapter 3: Research that led to inception of the current project

3.1 Healthy Aims and the Clinical Setup Tool (CST)

In a European Union Framework VI funded project, Healthy AIMS, the aim was to create a 2-channel implanted FES system to restore functional use of the wrist and finger extensors in patients with reasonable use of the proximal arm (Hodgins et al., 2008). Stimulation onset and termination were determined by a state-machine controller using signals from an accelerometer located on the affected arm. In this way, voluntary initiation of functional grasping tasks was possible. A serious problem with this approach is that every patient has different arm movement patterns on the affected side and, therefore, needed a bespoke controller. Consequently, medical engineers would be routinely involved with every patient, reprogramming the FES controller. As a partial solution, the Salford group, which included the author, developed a Clinical Setup Tool (CST) to set the transition parameters which sequence the stimulator's state-machine controller (Tresadern et al., 2008) (Figure 3.1). The CST was the fore-runner to the proposed UL FES Rehab Tool under design in the current thesis and LO30 NEAT project. Although this was a step forward in solving the setup problem, the CST only partially removed the need for software skills to create individualised FES state-machine controllers to suit each patient. State-machine control will be explained in more depth in section 3.3.1.

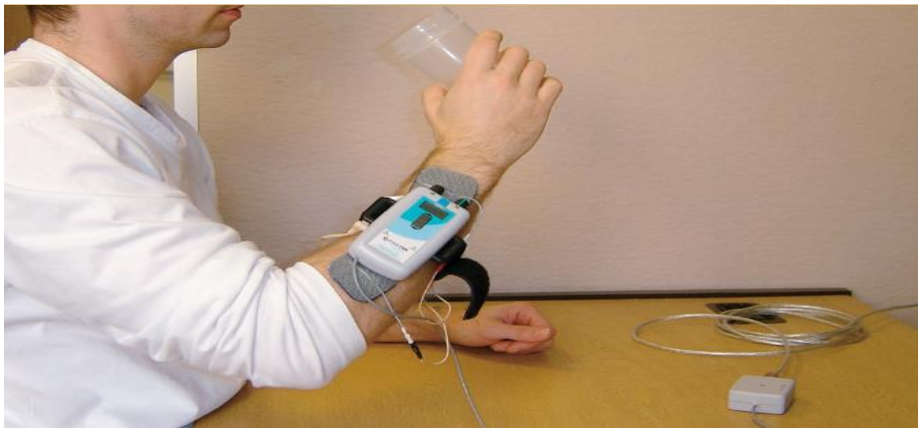


Figure 3.1: **The 2 channel stimulator used with the CST. The forearm worn stimulator assists the patient to drink from a glass.**

There were several limitations to the functionality of the CST. Firstly, it only encompassed two channels of stimulation, which limited stimulation to a maximum of two muscles groups. Whilst this was useful for mildly impaired patients, it was significantly restricted for the treatment of stroke patients with moderate to severe levels of impairment. Secondly, the movement sensors were housed within the stimulator which resulted in a lack of flexibility of sensor placement, sensor type and setup. Thirdly, the CST had limited options when programming the parameters required for functional practice. For example, stimulation levels for respective muscle groups were limited to the operator adjusting pulse width via a knob on the stimulator. It was not possible to stipulate ramps, minimum or maximum thresholds for stimulation. In addition, it was only possible to practise one functional task at a time, thereby limiting the option of multiple tasks, which has been advocated as an ingredient of random, upper limb task-oriented practice (Schweighofer et al., 2011). Finally, the user interface did not guide the user through the setup process. Software or medical engineers were required to programme stimulation and transition parameters. The following screenshot (Figure 3.2) demonstrates the technical nature of the user interface for a drinking from a glass task.

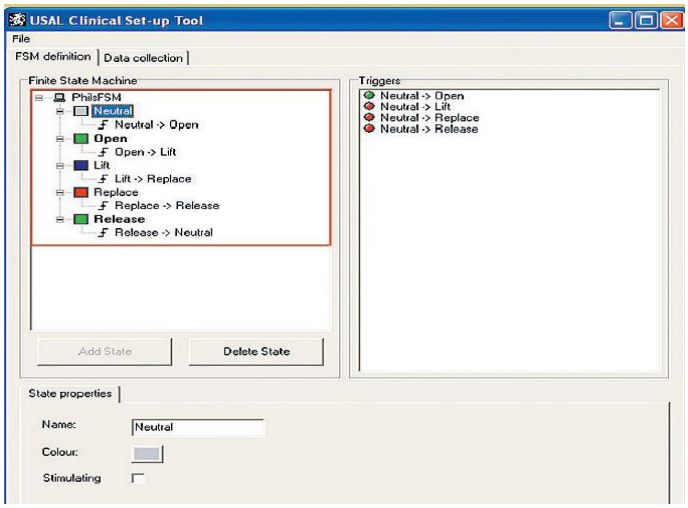


Figure 3.2: **The CST software interface. The upper section of the screen highlighted in red, displays a tree-view structure and finite state machine example for the drinking from a glass task. The labels attached to the arrows (x,y,t -state transitions)) indicate the inputs that were necessary to detect a 'trigger'. X and Y signify angle triggers, T = a timed trigger`. State machines are explained further in chapter 3.**

3.2 The NEAT LO30 Project

The aim of the NEAT LO30 was to build on the research that led to the CST to develop a multichannel and flexible UL FES Rehab Tool to allow therapists to quickly and easily set up task- and patient-FES controllers. In line with current evidence, the device was to be triggered by movement sensors making stimulation voluntary (Mann et al., 2011), rather than static timer based cyclic triggering. There needed to be more flexibility regarding the type of sensor that could be used and where it could be located on the upper limb. In order to align with the current evidence-base and therapy approaches, the device also needed to offer a wide variety of functional tasks in which FES assists with the provision of smooth, coordinated movement patterns (Timmermans, Seelen, Willmann, & Kingma, 2009). Due to the complexity of this FES-assisted movement, each movement patterns would necessitate patient-tailored stimulation parameters. For such an advanced device, a graphical user interface (GUI) was required, in order to guide the user through the setup process. These difficulties provided the rationale for the proposed advanced Upper Limb FES Rehabilitation Tool (UL FES Rehab Tool).

Funding was obtained from the New and Emerging Assistive Technologies body (NEAT) (DoH) in 2009, to form a collaboration between four research centres, namely the University of Salford, the National Clinical FES Centre in Salisbury, the University of Leeds and the Department of Rehabilitation Medicine, NHS Grampian in Aberdeen (Appendix 2) (http://www.seek.salford.ac.uk/data/projects/viewDetails.do?pid=2738&version=1). The thesis author was a co-investigator on the project. Salford's contribution was to design the software for the system and to undertake the user consultation and usability evaluation. Salisbury designed and produced the system hardware. The Leeds team already had a robotic system (iPAM), which had shown significant promise as an upper limb intervention; however it did not address hand function. During the NEAT LO30 project, FES was included to address this deficiency.

The challenge faced by the design team was to develop an interface that allowed therapists to rapidly and easily specify the FES controller structure and parameters. In the following section, the reader is introduced to the concept of finite state machine control, followed by an overview of the system hardware and software environment,

and finally an overview of the concept for the graphical user interface (GUI) structure, the detailed development of which is the focus of chapters 5 and 6.

In order to guide the reader through the background theory that underpins such a device, an explanation of finite state-machine control and the hardware and programing environment used in the study, is provided in sections 3.3.1 and 3.3.2.

3.3 The UL FES Rehab Tool

3.3.1 Finite state-machine control

The UL FES Rehab Tool uses the movement of limb segments, or time, as input signals to a finite state-machine (FSM) controller. A FSM controller comprises a set of states, input signals, output functions, and state transition conditions (Chu, 2006). Each state represents a possible situation (Ferdinand, Ruedi, Wagner, & Wolstenholme, 2006), each of which in this case is associated with stimulation outputs (which may be zero in some states). Movement from one state to another ('a transition'), is governed by the current state and one or more 'conditions' or rules, which take as inputs signals, in this case from body-worn sensors or time. When a given 'condition' is satisfied, movement to the next state will be 'triggered'. An example is provided in of a simple FSM designed to assist a person with weakness of biceps and finger extensors to practice drinking from a glass.

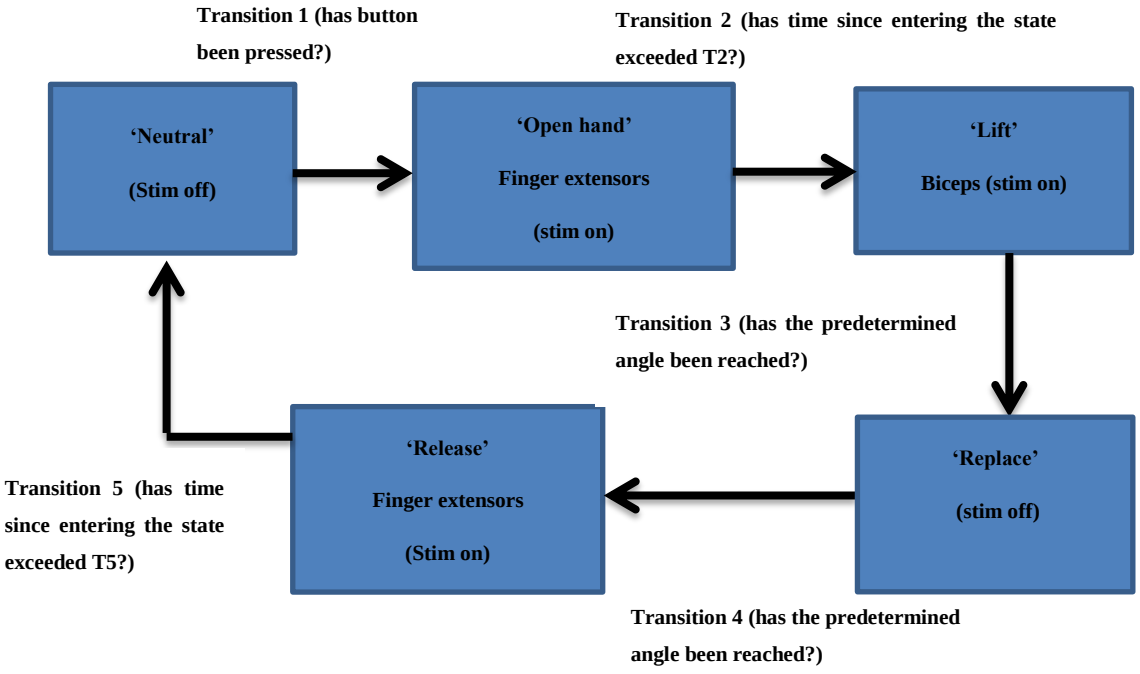


Figure 3.3: Example FSM for drinking from a glass. Boxes represent the states and T1-T5 the transitions between states.

In the example shown in Figure 3.3, the participant starts with their limb in a neutral position ('Neutral'). To initiate leaving 'neutral' and moving to the next state 'open hand' a button press is used as the trigger (Transition1). Stimulation to the finger extensors commences and the hand opens ('Open hand'). Following a pre-specified time, (Transition 2) stimulation to finger extensors is terminated. The participant closes their hand around the glass. Stimulation is initiated to the biceps muscle to assist with lifting the glass to the mouth ('Lift'). One the pre-determined angle has been reached, (Transition 3), stimulation ceases to biceps and the glass is replaced ('Replace'). On replacing the glass, another pre-determined angle is reached (Transition 4), and stimulation to the wrist and finger extensors is triggered to allow release of the glass ('Release'). Once released, following a pre-specified time (Transition 5), the participant returns to the starting position ('Neutral').

As such an approach required robust measurement of limb segment angle from a body worn accelerometer, a new method was developed by a fellow PhD student (Sun, 2014). Sun (2014) also implemented a novel state machine controller which uses limb segment angle as one of the inputs (Sun, 2014).

3.3.2 The hardware and programming environment

The hardware for the UL FES Rehab Tool used throughout this thesis consisted of a four channel programmable CE marked electrical stimulator RehaStim^{TM} (Hasomed GmbH, Germany) and two inertial sensor units (Xsens) (MTx, Xsens technologies B.V., Netherlands), connected to a laptop computer on which the graphical user interface (GUI) was to run. The GUI software and underlying controller were developed in the Matlab Simulink programming environment by (Sun, 2014). The system is represented diagrammatically in Figure 3.4 below.

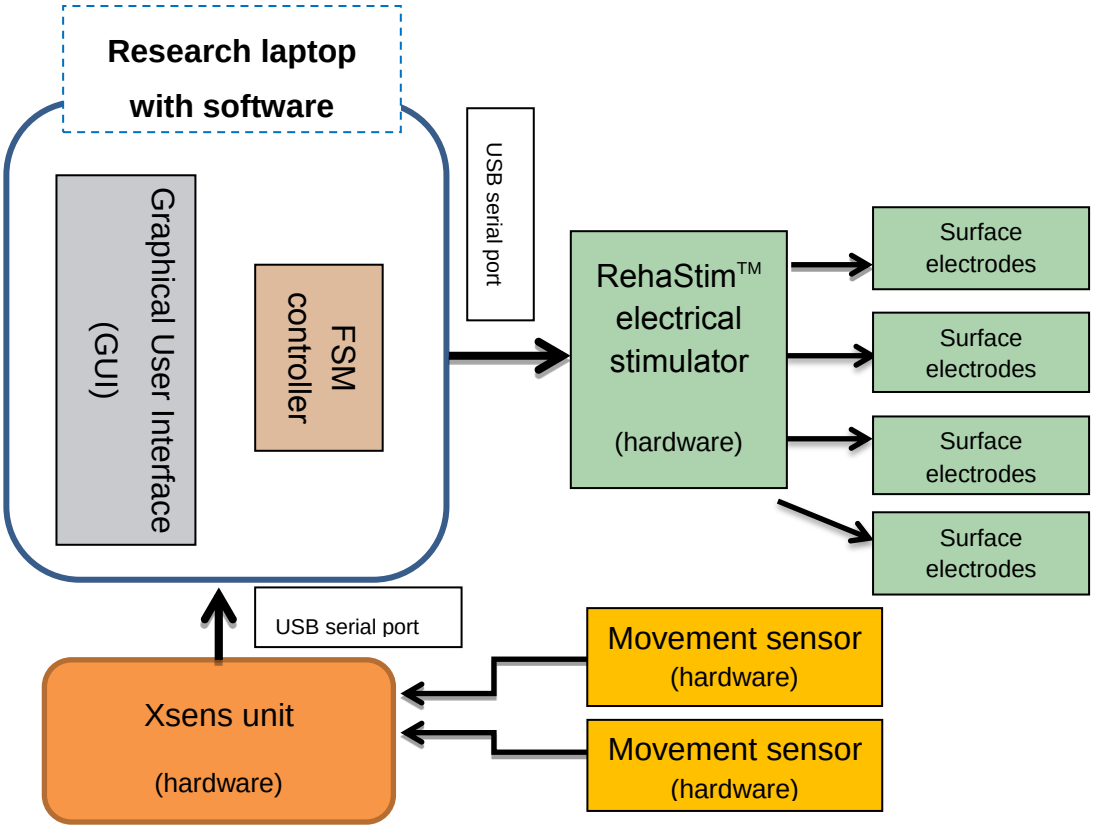


Figure 3.4: **Graphical representation of the laptop with GUI, RehaStim™ (FES unit) and surface electrodes, the inertial sensor system (Xsens) with 2 inertial measurement units (each comprising a 3 axis accelerometer, 3 axis gyroscope and 3 axis magnetometer).**

The FSM-based controller involved a series of states (hereafter referred to as movement phases) and transitions, as well as stimulation outputs for each state, to be specified by the user. Based on an initial proof of concept work by the design team, led by the author, a high level setup framework for the GUI was designed that consisted of 5 stages as follows:

Stage 1: Loading and saving the patient file, defining the FES assisted upper limb task, including movement phases and the muscles (channels) stimulated in each phase.

Before commencing treatment, the therapist selected the functional task to be practised, taking into account the patients' level of impairment and functional ability. Hence it was logical to set this as stage 1 of the setup process. In addition, this stage can be set up independent from the patient, thereby saving face to face therapy time.

Stage 2: Don electrodes and sensors, assign them to devices and channels, and then establish two reference stimulation levels for each channel (movement threshold and maximum).

Donning and assigning electrodes and sensors is necessary prior to stimulation. Stimulation thresholds are set for each individual muscle group before moving to combined stimulation of muscles.

Stage 3: Setup a manual state-machine controller to achieve as seamless a sequence of movement phases as possible, including setting stimulation targets and ramp rates for each channel in each movement phase. Inevitably once movement sequences are combined and incorporated into a functional task, stimulation levels need to be fine-tuned to enable smooth, co-ordinated movement sequences.

Stage 4: Setup automatic transition conditions so that movement from one state to the next does not require manual control. Once the efficient movement sequences have been established, the most appropriate exiting triggers can be stipulated.

Stage 5: Run the FES controller and the practice session.

Although a proof of concept framework had been developed by the design team, there had been no user involvement in this process.

The following chapter details the usability design framework used to develop and evaluate the UL FES Rehab Tool. The system was to be explicitly designed to be used under the supervision of a therapist rather than as an unsupervised home based system. The chapter describes the early phases of the design process, specifically demonstrating how user involvement, (via therapist advisory group meetings) influenced the design.

4 Chapter 4: User involvement in the early stages of the design process: implementation and assessment of its impact on the design of the software and Graphical User Interface (GUI).

4.1 Introduction

Chapter 2 discussed the challenges faced by patients and therapists for rehabilitation of the hemiplegic upper limb. As described, there is growing evidence that FES appears to be beneficial (Lin & Yan, 2011; Hsu et al., 2010; Chan et al., 2009; Popović et al., 2009; Timmermans et al., 2009; Thrasher et al., 2008), and may be more effective when stimulation is initiated by the patient's own effort (e.g. via EMG signals or movement). However, as highlighted in previous studies (Hayward, Barker, & Brauer, 2010), and by the review of commercially available FES devices (chapter 2, section 2.4) current devices are insufficiently flexible to support practice of meaningful functional tasks, necessary for skill acquisition across a broad range of patients and uptake has been limited.

As increases in flexibility of a design may be associated with increases in complexity and hence challenges for the user of the system, the usability of the system was likely to be of central importance to uptake. Although a literature review of medical device technology development (MDTD) by (Shah & Robinson, 2006) found user involvement to have a beneficial impact on improving medical device designs and user interfaces together with an improvement in the functionality, usability and quality of the devices, the vast majority of these studies focused on areas other than ANRT. Further, as discussed below, the details and validity with which the impact of user involvement on the design outcomes are generally less well documented.

User involvement has become an essential ingredient in the design of medical devices, including rehabilitation technologies. Collaborative research between academia and industry, such as those undertaken by the Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH), have provided important insights into the role of user engagement and usability testing (MATCH, 2010). This increased emphasis on user involvement is evident in funding bodies such as the National Institute for Health Research (NIHR). However, users of medical devices are a heterogeneous group often operating in diverse environments, and therefore

accurately capturing users' perspectives can in itself be challenging (Grocott et al., 2007). The practicalities of engaging users in device development has received less attention (Bridgelal & Weir, 2007). The methods used to elicit user requirements need to be tailored not only to the device and its context of use, but also the different stages of the development cycle (Bridgelal, Browne, Grocott, & Weir, 2005). Studies often fall foul of not explicitly stating the impact of user involvement on the final device design.

In the area of ANRT, the evidence to demonstrate the detailed impact of user involvement on the design of ANRT has been very limited. Of the 37 studies reviewed in chapter 2, section 2.7, only 15 of these explicitly stated changes made as a result of this involvement to the final device design. The remaining studies tended to either merely elicit user requirements, or report on usability problems, without stating whether these translated into tangible changes to the device. Clearer methods of translating what can often be large volumes of data, into product development are required (Money et al., 2011).

The aim of this chapter was therefore to demonstrate the impact of therapists in the early design stages of an ANRT. As the UL FES Rehab Tool was designed to be used for patients post stroke whilst under supervision of a therapist, therapists were considered to be the primary users. The chapter begins with an introduction to phases of the usability engineering model used in the thesis. This is followed by a description of the processes and discussion of the findings from therapist advisory group meetings which formed phase one of the design process.

In line with the iterative nature of design work, and the need to match the usability method to the stage of the design process (Grocott et al., 2007), in total, the usability-engineering approach comprised five phases as outlined below. Phase one is outlined in this chapter. Phases two and three are covered in chapter five and the final two phases (four and five) are described in chapters 6 and 7 respectively.

Phase 1 (chapter 4): As discussed in Chapter 3, at this stage in the work, the design was in the very early stages. The research team had built on the ideas and work from the CST and utilised the teams' technical and clinical expertise to devise an outline structure for the GUI. Although the research team had devised an early structure for the GUI which outlined the 5 stages of the setup process, there had been no user

involvement in this process. Hence, the aim of this phase was to elicit design requirements for the UL FES Rehab Tool from therapists by means of focus group meetings. The output of this work informed a first working prototype of the software (v1.).

Phase 2 (chapter 5, sections 5.3 and 5.4): The aim for this part of the work was to determine the effectiveness of the first prototype Graphical User Interface (GUI) in guiding users through the setup process and identify problems to be relayed to the technical design team. Both novice and expert FES users (5 physiotherapists and 1 engineer) were involved in this process. The output of this work was version 2.0 (v2.) of the software.

Phase 3 (chapter 5, section 5.5 onwards): The aim of this phase was to evaluate and identify specific problems with the first prototype of the full system, including hardware and software and identify problems to be relayed to the technical design team. Testing was performed with healthy participants. The output of this work was a new version of both the GUI and FSM controller GUI, version 3.0 (v3.). Once the research team was satisfied with the functionality and safety of the software and hardware combined, phase 4 was commenced.

Phase 4 (chapter 6): Further formative usability testing of the software & hardware was conducted, but in this case patients with stroke were recruited for the work. In addition, an early stage model to predict setup time of the device was devised. The output of this phase was a system that was demonstrably usable and safe for the final in-field clinical evaluation.

Phase 5 (chapter 7): The aim of the final stage of the approach was to evaluate the UL FES Rehab Tool under supervision of therapists in a sub-acute stroke rehabilitation setting.

In order to ensure that the design of the system was compatible with therapy approaches and that its design met the expectation and needs of end users, it was imperative that their views were sought early on in the design process.

4.2 Phase One study

The aim of the study was to gather information from therapists that would inform the design of an UL FES Rehab Tool for treatment of the hemiplegic upper limb post stroke.

4.2.1 Methods

A combination of secondary and primary data collection was used for three of the four therapist advisory group meetings. The secondary data collection utilised the literature review in chapter 2 (the neuroscience literature that underpins motor re-learning following stroke, a review of FES studies, particularly those that use sensors to trigger stimulation, a review of existing FES systems and their efficacy, technology adoption and usability). This was necessary to inform the focus of the therapist advisory groups (deductive approach). The primary data collection was the data generated from within the four advisory groups (inductive approach). The inductive approach (Boyatzis, 1998) was felt to be essential in order to allow ideas and comments to flow freely from the therapists during the meetings. Constraining these discussions too much could have led to a 'loss of richness' of the data. This combination of secondary and primary data was used to inform the overall design requirements of the new system.

All meetings followed a participatory design (PD) philosophy. PD has been defined as "a strong commitment to understanding practice, guided by the recognition that designing the technologies people use in their everyday activities shapes, in crucial ways, how those activities might be done" (Robertson & Simonsen, 2012, pg.5). Every participant is viewed as an expert and as a stakeholder whose voice needs to be heard. This type of approach goes some way to ensuring that the final design of the UL FES Rehab Tool is usable in practice. Fundamental to this project, it enabled technical and non-technical participants to take part on equal terms. It provides a forum that is conducive to understanding professional backgrounds and practice, identifying issues and perhaps most importantly, provides an opportunity to enhance user buy-in.

The first therapist advisory group meeting explored current rehabilitation practice for the hemiplegic upper limb and identified patients who might benefit from an advanced FES Rehab Tool. Specific trigger questions were put to the therapists to facilitate discussion. The second meeting identified relevant FES tasks, FES

parameters and practice schedules for patients who might use the system. At the third meeting the attendees were invited to comment on a mock-up of the first prototype of the software user interface (GUI). The fourth meeting's aim was to identify how bio-feedback was used in current practice and what type of feedback might be useful to guide patient performance during the relearning of functional tasks. In addition to this, therapists were asked to identify which data from the system would be useful when it came to analysing patient's performance during and following treatment sessions. The fifth and final meeting was used to validate the therapists design requirements. They were asked to rank these in order of importance using a 5 point Likert type scale, where 0 = not important, through to 4 = extremely important. It was also used to gain therapists input to the design of the proof of concept clinical trial.

4.2.2 Advisory group participants

In order to gain a range of views from potential users of the software tool, invitations to join the therapist advisory group were sent to a number of clinicians from both community and acute stroke settings across Greater Manchester, using clinical networks from the authors' department. Although convenience sampling is a non-probability sampling technique (Lund Research Ltd, 2012), the sample was felt to be sufficiently representative of the final FES system users to allow generalisability of the findings. Previous researchers have advocated that user involvement in medical assistive technology design be sufficiently representative of the final users of the device, in this case, occupational therapists and physiotherapists (MATCH, 2010). A decision was made in advance to allow a maximum number of 12 participants, as this was felt to be the maximum manageable size for this type of group, and would allow for drop out in the eventuality that participants were unable to attend. Ultimately only 11 senior clinicians, namely, 6 physiotherapists and 5 occupational therapists (2 males & 9 females) expressed an interest in joining the group. A total of 5 advisory groups were planned for the first stage of the design. Each user group was facilitated by an experienced academic physiotherapist. A combination of semi-structured group discussions, patient case studies and mock up design presentations were used to focus the discussions. Each meeting was video recorded and 2 researchers also took field notes during the meetings. Only the data from meetings 1 to 4 will be reported on in

this chapter, as they were most pertinent to the design requirements. Table 4.1 below displays the therapist composition of each meeting and the meeting number attended.

Table 4.1: Table displaying the participant ID, designation, novice (N) or expert FES user (E) and meeting number attended

Participant ID	Designation	Novice (N) or Expert (E) FES user	Meeting number attended
PT1	Band 8, Physiotherapist	E	1,2,3,5
OT1	Band 7, Occupational therapist	N	1,3,5
PT2	Band 7, Physiotherapist	N	1,2,3,4,5
PT3	Band 6, Physiotherapist	N	1,2,3,
OT2	Band 6, Occupational therapist	N	1,2,3,4
PT4	Band 7, Physiotherapist	N	1,2,3
PT5	Band 6, Physiotherapist	N	1,2,3,4,5
OT3	Band 5, Occupational therapist	N	1, 3
PT6	Independent Physiotherapist	E	1,2,3,4,5
OT4	Band 6, Occupational therapist	N	1,2,3,4,5
OT5	Band 7, Occupational therapist	E	3

4.2.3 Data analysis

Thematic analysis was used to analyse the data from the first meeting in order to identify key themes that emerged (Daly, Kellehear, & Gliksman, 1997). The process involved the identification of themes through "careful reading and re-reading of the data" (Rice & Ezzy, 1999, pg. 258). Thematic analysis is a form of pattern recognition where the emerging themes become the categories for the analysis (Fereday & Muir-Cochrane, 2006). The stages of data analysis were as follows:

Table 4.2: **Stages of the data analysis process, adapted from Fereday and Muir-Cochrane (2006).**

Stage	Action	Conducted by
Stage 1	Transcribing the raw data	Author
Stage 2	Summarising and identifying initial themes	Author
Stage 3	Review of initial themes and coding to form 'higher order' themes	Author, co-researchers and the design team collectively
Stage 4	Connecting, ordering & re-coding the themes to establish relationships between themes	Author and design team collectively.
Stage 5	Corroborating and legitimating coded themes	Author with advisory group therapists and by referring back to the literature

4.3 Results

The first meeting generated data that was elicited via specific trigger questions. An example of one of the questions with a summary of the response gathered from the transcribed data is provided below in Table 4.3.

Table 4.3*:* **Results from stage 2 of the analysis - an advisory group trigger question with a summary of the responses.**

Research question 1: What are the biggest challenges for you as therapists in the rehabilitation of the upper limb post-stroke?

Summary of Responses:

- Keeping patients motivated
- Matching treatment to patient's expectations to maintain motivation.
- Equipment to provide feedback for the patient otherwise can lose interest.
- More severe patients tend to lose motivation due to lack of functional options possible for them.
- Patient variation – 'good shoulder no hand, good hand no shoulder.'
- Increasing number of patients with a dystonic hand.
- Maintaining soft tissue extensibility
- Some differences noted in recovery between dominant and non-dominant hand
- Fast turn-over of patients
- Patients with accompanying cognitive and perceptual deficits

A "theme" is a word or phrase used to summarise certain comments. For example, one theme that emerged was "type of patient that would benefit from the system" (PB). Table 4.4 displays all of the initial 'higher order' themes.

Table 4.4: **Stage 3 initial 'higher order' themes with coding**

(AI)	Adoption issues
(PWL)	Practitioners wish list for FES system
(PB)	Type of patient that would benefit from the system
(PP)	Type of patient presentation
(TI)	Treatment interventions
(FUR)	Factors affecting upper limb rehabilitation

The initial 'higher order' themes allowed the data from the advisory groups to be condensed under three broad headings that related directly to the design process. 1) Context for the design requirements i.e. data that provided background information for the design process; 2) Design requirements i.e. actual design features and 3) External factors affecting adoption. This ensured that the data from subsequent meetings was constrained in accordance with this process. The initial 'higher order' themes tended to reappear across a number of the advisory group meetings serving to reinforce the importance of these themes.

Table 4.5: **Stage 4 initial 'higher order' themes mapped on to design process themes, (displayed as the headings in bold), of the UL FES Rehab Tool. The codes from the initial higher order themes are also included.**

1. Context for the design requirements	**Codes for initial higher order themes**
1.1. Patient presentation including those most likely to benefit from FES	PP & PB
1.2. Current treatment approaches & beliefs	TI
1.3. Patient motivational factors	PB
1.4. Organisational influences	FUR
1.5. Adoption issues as design inputs	AI
2. Design requirements	
2.1. Setup and user interface	PWL
2.2. Patient biofeedback	PWL
2.3. Within sessions adjustments	PWL
2.4. Patient adaptation	PWL
2.5. Performance feedback for therapist	PWL
3. External factors affecting adoption	
3.1 Adoption issues independent of design	AI

Key: AI = adoption issues; FUR = factors affecting upper limb rehabilitation; PB = type of patient presentation; PB = type of patient that would benefit from the system; PWL = practitioners wish list for FES systems; TI = treatment interventions.

After each subsequent meeting the data were transcribed, coded and categorised under the existing themes or new themes were developed if there was sufficient data to support a new theme. The process was iterative in nature with the raw data being periodically reviewed against the themes to ensure their validity.

A summary of the results from the third advisory group meeting are displayed in 4.6 below:

Table 4.6: Summary of tasks, FES parameters and practice schedules for each category of patient, taken from the third advisory group meeting.

Type of Patient	Tasks	FES parameters	Practice schedules
Early complex presentation, (in-patient)	Functional tasks e.g. washing, dressing, combing hair, reaching for a glass, cleaning teeth. Tasks that combined reach, grasp, manipulate, as well as weight bearing (possibly triceps or activate shoulder girdle muscles) and protective balance reaction movements for the upper limb.	Adjust to minimise fatigue.	Up to an hour x2 per day depending on levels of fatigue.
Moderately severe patient, early stages residing at home	Functional tasks using objects from around the house incorporating reach and grasp, manipulate and release.	If possible frequencies to match type of muscle stimulated.	30 -45 mins, 2-3 times a day
Mild affected patient (wrist and hand only) residing at home	Functional tasks incorporating reach and grasp, manipulate and open/release of varied objects carried out in various planes/directions. Use of hobbies and employment needs.	If possible frequencies to match type of muscle.	45mins- 1hour, 3-4 times a day but importantly to fit in with patient's lifestyle.

Data from this meeting was also used to validate data from the first meeting e.g. types of patients that would benefit, use of other treatment approaches to compliment the UL FES Rehab Tool.

Results from the third and fourth meetings mapped directly onto the 'higher order' themes and ultimately the design process themes. Data from all meetings was compared with the relevant literature for that area to further validate the findings.

The fifth meeting was used to validate the design requirements. Therapists were asked to rank them in order of importance with 0=not important and 4 = extremely important. Only 6 of the 11 clinicians were able to attend this final meeting. The results are presented below in Table 4.7.

Table 4.7: **UL FES Rehab Tool therapists' design requirements in rank order of importance (when used in a hospital rehabilitation setting).**

DESIGN REQUIREMENTS 0 = not important; 1= mild importance; 2= moderately important; 3= very important; 4= extremely important	Meeting	Number of therapist responses per order of importance					
		0	1	2	3	4	Total No.
Takes less than 30 min to set-up	1, 3					6	24
Allows adjustment of device parameters in accordance with patients progress	1, 2					6	24
Device is comfortable to wear	3					6	24
Electrodes are easy to apply & position	1, 2					6	24
Sensors are easy to apply & position	3					6	24
Triggers stimulation on & off reliably	3					6	24
Stimulation is comfortable for patient	3					6	24
Patients are able to practise on their own where appropriate	1, 2					6	24
Device functions and interface are easy to understand	1, 3					6	24
Easy selection of muscles to be stimulated	1, 2				1	5	23
Device is easy to put on	3				1	5	23
Effective co-ordination of muscle stimulation (where multiple muscles involved)	3				1	5	23
Easy to adjust settings once administering treatment	3				1	5	23
Adjustable stimulation settings (e.g. frequency)	2, 3				2	4	22
Choice of functional upper limb tasks	1, 2				2	4	22
Sensors are easy to select and adjust	3				2	4	22
Stimulation intensity easily adjusted	3				2	4	22
Adjustable ramp settings	3			1	1	4	21
Wires unobtrusive - wireless preferred	3			1	1	4	21
Guides the user during the set-up process & highlights any incorrect parameter settings	1, 2, 3			1	1	4	21
Device is easy to take off	3				3	3	21
Able to be used to treat a variety of patient presentations	1, 2				4	2	20
Aesthetically acceptable to patients	3			1	2	3	20
Intuitive set-up process that follows a natural & logical order with minimum redundancy	1, 3			1	4	1	18
Bio-feedback serves to motivate the patient	1, 3, 4			1	4	1	18
Provides performance data that can inform treatment parameters & outcome measures	1,3			1	4	1	18
Good battery life	3			1	4	1	18
Choice of bio-feedback methods tailored to suit each patient	1, 2,4			3	1	2	17
Choice of sensors e.g. movement sensor, EMG, goniometer	2, 3, 4			1	5		17
Compact & portable	1, 3			1	5		17
Automated processes wherever possible (1 none response)	1, 3			1	2	2	16

4.4 Discussion of findings from the therapist advisory group meetings

The higher order themes have been used to structure the discussion section using direct quotes from the therapists to validate the findings.

4.4.1 Inputs to the design requirements

This first category clustered together the comments from therapists and provided background contextual information without them specifically relating to some of the hard and fast design specification issues. Researchers have stressed the importance of gaining an understanding of the context of use for medical devices (Sharples et al., 2012). Alongside the quotes, the codes PT and OT signify the professional designation of Physiotherapy and Occupational Therapy.

a) Patients most likely to benefit from an UL FES Rehab Tool

Therapists described the patient case load that they dealt with on a day to day basis and proceeded to suggest which patients might benefit from an UL FES Rehab Tool. Unanimously therapists reported that they continued to see a wide range of patient presentations in clinical practice. They concurred that patients who recovered quickly and were left with only a mild to moderate level of functional limitation were discharged to the community at an increasingly rapid pace (sometimes within days of admission). Hence the patients that remained as in-patients were those with severe and complex presentations, including older patients with co-morbidities. With reference to upper limb presentations they felt that patients fell into two broad categories:

"Good hand no shoulder, no hand good shoulder" (PT1, advisory group 1).

Therapists added that the *"Most problematic patients are those with low tone, a non-functional arm, minimal muscle activity as there are few treatment options currently available" (PT2, advisory group 1).* This view is supported in the literature where only a few studies have focused on acute, severe patients with little or no arm activity (Zondervan et al., 2015; Popovic, Thrasher, Zivanovic, Takaki, & Hajek, 2005).

If the UL FES Rehab Tool was able to tackle this problem by offering an alternative treatment modality, it would need to allow severe and complex patients to be treated. However, therapists commented on the need for other forms of therapy to supplement FES, particularly in this category of patients where multiple interventions are necessary.

"As they (patients) start to get more postural control, then you can start to ask for volitional movement, possibly with FES" (PT4, Advisory group 1).

b) Current treatment approaches & beliefs.

Repeatedly the therapists commented on using functional activity during therapy sessions and to some extent advocated following a motor re-learning approach to treatment.

"We'd use functional exercises with or without stimulation" *(group feedback, advisory group meeting 1.)*

In the second advisory group meeting when discussing case studies the therapists were clearly comfortable with the notion that FES could work alongside a traditional hands-on approach and indeed that the two facets of treatment could be used at the same time during patient treatments.

"The therapist would work proximally around the shoulder with FES being used to elicit hand opening." This might reduce the number of therapist required (PT4 & PT1, 2nd advisory group meeting).

This reaffirms the findings of Islam, Harris, and Eccleston (2006) who stress the importance of devices being promoted as an adjunct to therapy rather than substituting it. In conjunction with the need to promote FES as an adjunct to traditional forms of therapy McNair, Islam, Eccleston, Mountain, and Harris (2005) highlight the philosophies that underpin therapy provision, such as a 'hands-on approach' and the need for rehabilitation devices to incorporate these philosophies into their design.

There were a number of beliefs that the therapists held about how patients viewed rehabilitation of the upper limb:

"As therapists we want to treat the upper limb as much as lower limb but we are led by the patient and it is often not their priority."(PT2, advisory group meeting 1).

c) Patient motivational factors

The ability to motivate patients and to keep that motivation at a sustained level was a recurring theme across all of the advisory group meetings. Therapists saw this as a significant challenge for them as patients often need to incorporate movement therapy over a prolonged timescale of many years and arguably for life in some cases. Understandably ways of motivating patients to sustain therapy programmes is high on the agenda of therapists and technologies that can help with this endeavour are highly

valued. Some therapist had recently utilised Wii games consoles to motivate patients and provide a means of therapy being goal directed.

"In the community I use the Wii computer games which helps to motivate patients by providing feedback to the patient and being target driven" (OT2, advisory group meeting 1.)

d) Organisational influences

The organisational influences on rehabilitation, particularly for the upper limb were repeatedly commented on during the meetings. The array of comments highlighted the impact this was having on therapist's approaches to rehabilitation:

"There is mounting pressure to get patients thorough the system and out of hospital beds" (PT2, advisory group meeting 1). Another participant responded:

"Some districts have an 18 day discharge target to meet. The system is driving to get patients up and on their feet to aid discharge" (OT3, advisory group meeting 1)

These comments reaffirm the literature which highlights the need for the new system to be available not only in the acute rehab setting, but also to follow the patient into post-acute care.

4.4.2 Design Requirements

a) Setup and user interface

Five out of the top equal nine highest ranked therapist design requirements related to the setup of the device, or the user interface (Table 4.7). This is in accordance with recent research by Hughes, Burridge, Demain, et al. (2014) and Demain et al. (2013) where therapists also highlighted ease of setup as important. With the pressures of a heavy caseload and the rapid turn-over of patients already commented on by therapists, setup time and ease of set up were high priorities for therapists. Therapists' views on set up time were as follows:

"Depended on whether this was a one off investment that would be more automated on subsequent occasions" (PT6, advisory group meeting 1).

"…….Also, if it meant I could leave patient to practise independently allowing treatment of more patients that would make a difference" (PT4, advisory group meeting 1).

However, in spite of these potential benefits therapists were still keen to stress that *"30 minutes is the absolute maximum set up time and ideally the less the better" (PT 1, advisory group meeting 1)*

One therapist summed up the groups views that there needed to be …….

"A balance of level of complexity versus ease of setup" (PT6, advisory group meeting 1).

The therapists during the initial advisory group meeting were invited to create a wish list for their ideal advanced FES Rehab Tool to which they freely commented. The list of requirements included providing a menu of arm movements and functional tasks, pictures of where to place electrodes, an easily programmable system that was automated wherever possible and used intelligent set up processes, an ability to treat sensory & motor components and the scope for patients to determine some settings for themselves in order to empower patients who were capable of managing their own condition.

Within session adjustments will sometimes need to occur due to the need to refine FES stimulation parameters or as a result of allowing for patient changes as the treatment session progresses e.g. due to fatigue. This was particularly commented on during the mock up demonstration of the GUI.

"Because the patient varies, when you stimulate a patient they may not need that same level of stimulation throughout that task" (PT6, advisory meeting 3).

Therapists wanted to be able to make these adjustments without necessarily having to use the laptop computer interface. This once again demonstrated that ease of use is paramount if adoption is to be embraced.

b) Extrinsic Feedback and Performance Evaluation

Extrinsic feedback provided by the new system fell into two distinct categories: 1) Patient biofeedback and 2) Performance evaluation data needed by the therapist. The therapists advocated the following requirements for patient feedback:

"Needs to provide both visual and auditory feedback for patients to cover the range of patient deficits that might be encountered" (OT4, advisory group meeting 4)

Clearly the method in which feedback is provided is important, be it a *"motivating voice"* or *"a green light"* (PT6, advisory group meeting 4), when it had been used for the correct amount of time."

Although the project did not allow the time to include biofeedback in the design specification, this data was kept on file for inclusion in the next iteration of the UL FES Rehab Tool.

In addition to biofeedback for patients, the other area therapists felt would be useful and potentially would act as a trade off against set up time, is if the system provided performance feedback for them to afford the opportunity to more objectively record patient's progress over time (group feedback, advisory group meetings 1, 3 and 4).

4.4.3 External Factors Affecting Adoption

There were some additional factors that would be likely to affect adoption that were independent of the design process.

"It is important that undergraduate Physiotherapists are trained in these types of systems in order to help adoption" (PT4, advisory group meeting 1).

"Communication between the PCT's and commissioners is very important in order to resolve funding issues" (PT1, advisory group meeting 1).

In spite of this problem with funding therapists felt that in their experience *"patients would seek out technology that worked and pay for it themselves if necessary" (PT6, advisory group meeting 1).*

4.5 Conclusion

Involving users in the design of rehabilitation technologies is a complex but beneficial process. When designing technologies for use in rehabilitation settings it is important to seek the views of primary users, in this case therapists. The five therapist advisory groups elicited information that informed the context of use for the UL FES Rehab Tool and their design requirements, hence fulfilling the main aim of phase one of the thesis i.e. to gather information from therapists that would inform the design of an FES Rehab Tool for treatment of the hemiplegic upper limb post stroke. In accordance with other published work, short setup times and ease of use featured

highly in terms of their importance for therapists, if the device is to be adopted in clinical practice.

The following chapter describes phases two and three of the usability engineering approach.

5 Chapter five: Application of a usability engineering approach to the design of the graphical user interface (GUI): Phases two and three

The GUI supports therapists in the setup of FES controllers. The system was designed to assist patients with particular impairments to practise particular upper limb functional tasks. It was explicitly designed to be set up by therapists and used by patients under supervision of a therapist. This chapter focuses on phases two and three of the usability engineering cycle, specifically the design, development and usability evaluation. The work details the iterative process by which users influenced the design of versions 1.0 to 3.0 of the Upper Limb (UL) FES Rehab Tool.

Phase two was an in-house evaluation of the graphical user interface (GUI) (hardware independent) by novice and expert FES users. Phase three encompassed prototype testing of the UL FES Rehab Tool with healthy participants, in which the software was used in conjunction with the hardware (RehaStim™ and Xsens). In each phase, the findings are discussed and critically analysed in light of their impact on the GUI design.

5.1 Current status of the UL FES Rehab Tool

At this stage of the design process, version 1.0 of the GUI was merely the software interface with no functionality, i.e. it did not link to the FES controller or the hardware components, the stimulator (RehaStim™) and the accelerometer unit (Xsens).

To recap, v1.0 of the GUI contained the following setup stages which had been endorsed by the therapist advisory group during meeting 3:

Stage 1: Loading and saving the patient file, defining the FES assisted upper limb task, including movement phases and the muscles (channels) stimulated in each phase.

Stage 2: Don electrodes and sensors, assigning them to devices and channels, and then establishing two reference stimulation levels for each channel (movement threshold and maximum).

Stage 3: Working through a manual state-machine controller to achieve as seamless a sequence of movement phases as possible, including setting stimulation targets and ramp rates for each channel in each movement phase.

Stage 4: Setup automatic transition conditions so that movement from one state to the next did not require manual control.

Stage 5: Run the FES controller and the practice session.

As there was no functionality attached to the GUI at this point, usability testing focused on stages 1-4.

5.2 Chapter aims

Specifically, the following chapter aims to:

1) Report on the aims and objectives, methods and findings from phase two (GUI independent usability evaluation, with novice and expert FES users) and phase three (software and hardware combined, with healthy participants) of the usability evaluation of the GUI; and

2) Demonstrate the impact of user involvement on the design of the GUI.

5.3 Protocol for the phase two usability evaluation: software design refinement

5.3.1 Protocol aims

The aims for phase two of the design and usability evaluation process were to:

1) Evaluate the usability of v1.0 of the GUI software in guiding expert and novice FES users through the setup process (hardware independent)

2) Identify and prioritise specific problems in the software to be addressed leading to v2.0 of the GUI.

The author led the usability testing throughout all phases. During this phase of usability testing, the author's role was to act as the in-test observer, documenting relevant usability data and ensuring that testing ran according to plan. The author also designed and facilitated the usability testing procedure and acted as the first evaluator in order to formulate the initial list of usability problems.

5.3.2 User selection and justification

The users' role is pivotal during usability testing and can be a significant source of error (Hertzum & Jacobsen, 2003; Vermeeren, Kesteren, & Behkker, 2003). Based on the literature (Lindgaard & Chattratichart, 2007; Turner et al., 2006; Faulkner, 2003) and the practicalities of testing, six professional HCP users (three novice and three expert FES users) were purposively recruited by the author from external and internal networks, into phase two of the usability evaluation. There are only a small number of expert users in the United Kingdom, hence the decision to select 3 expert users was a pragmatic decision. Users were recruited in accordance with the following inclusion criteria:

I. Either experienced (a minimum of monthly FES on a regular basis) or novice FES users (no FES use or minimal use i.e. 1 or 2 isolated exposures).

II. A minimum of five years' experience of working in neurological rehabilitation

III. A basic level of computer literacy.

5.3.3 User profiles

The pre-test questionnaire aimed to characterize the professional users according to factors that may have influenced their ability to assess the prototype GUI. As can be seen from Table 5.1, Users 1, 2 & 3 were deemed to be expert FES users due their significant experience with FES (daily or monthly use). Users 4, 5and 6 had not used FES prior to the study and were therefore categorized as novice FES users. All users met the inclusion criteria, in that they possessed a basic level of computer literacy, i.e. daily use for work or social purposes and were experienced practitioners with a mean of 18.83 years of treating patients (range 6-25 years).

Table 5.1: Novice and expert FES users' characteristics

Participant ID	Job title	Client group	Years treating ptns.	Use of FES	Types of FES	Frequency	PC use	Type of use
User 1	Biomedical engineer	CVA, MS, SCI, PD, TBI	25	Y	Various	Daily	Daily	WP, S, D
User 2	Consultant physiotherapist	CVA, MS	25	Y	Various	Daily	Daily	BW, WP, S, D
User 3	Independent physiotherapist	CVA, MS, CP	22	Y	Various	Monthly	Daily	WP
User 4	PT Lecturer	CVA, MS, PD	20	N	N/A	N/A	Daily	BW, WP, D
User 5	PT Lecturer	CVA, MS, PD	15	N	N/A	N/A	Daily	BW, WP
User 6	PT Lecturer	CVA, PD, MS, HI	6	N	N/A	N/A	Daily	SD, SI

Key to abbreviations*:*

BW = browsing the web; CVA = cerebrovascular accident; D=searching databases; LL = lower limb; MS = multiple sclerosis; PD = Parkinson's disease; PT = physiotherapy; SCI = spinal cord injury; SI = social interaction; S = working with spreadsheets; TBI = traumatic brain injury; UL = upper limb; WP = word processing.

5.3.4 Methods and procedure for evaluating usability of GUI version 1.0

All professional users recruited into the study were provided with an information sheet (Appendix 3) prior to attending the usability testing session. Informed consent (Appendix 3) was obtained by the author before the usability testing commenced. Once consent was obtained the pre-test questionnaire was administered. Prior to testing each FES user was provided with a manual which outlined the format of the GUI and explained the functionality of each stage of the setup process. Users were given sufficient time to read the information and were permitted to ask questions in order to clarify any material within the manual. Every attempt was made to make the testing conditions as informal as possible within the constraints of standardising the procedure across FES users, in order to make the participants feel at ease.

The same patient scenarios, modified from those used in the therapist advisory group meetings, were used for both novice and expert FES users. Two versions of each task were designed that both sets of users were required to complete using the GUI

(Appendix 4). The tasks were adapted so that novice FES users utilised the basic functions of the GUI, whilst expert FES users worked through a more complex task, requiring use of additional functions.

A video camera, and specialist mouse tracking software, Adobe 'Captivate' version 6, USA were utilized in order to capture users feedback. The author recorded any significant usability events, using a paper based data collection tool (Appendix 5).

Once the FES user was sat comfortably in front of the PC, the assistive usability walk-through of the GUI (version 1.0) commenced. Each user completed two tasks compatible to their level of FES experience, whilst 'thinking-aloud' (Fonteyn, Kuipers, & Grobe, 1993). The in-test observer only intervened if the user asked for assistance or stopped 'thinking-aloud' for more than 30 seconds. Each FES user completed two tasks. Some functions, for example, creating tasks, were conceptually more difficult than merely editing pre-determined tasks.

There was a short break in-between tasks to debrief the FES user and reset the GUI. Post-task debriefs were used to allow the user to clarify any remaining issues. The usability testing session ended with the users completing a post-test questionnaire (Appendix 6). The post-test questionnaire gauged users' overall impression of the GUI. It was divided into questions for each stage of setup process, allowing issues specific to each stage of setup process to be elucidated. The questions related to ease of use of the GUI and used a five point Likert scale. Descriptors were anchored with a positive statement related to usability on the left and a more negative statement on the right. An example is provided below in Figure 5.1.

Question 1: How easy was it to adjustment the following device parameters?

a) <u>Stage 1</u> – Choosing tasks:

1	2	3	4	5
Very Easy	**Easy**	**Neither Easy Nor Difficult**	**Difficult**	**Very Difficult**

Figure 5.1: An example question from the post-test questionnaire.

A lower score thereby represented a more favorable response. Three additional questions namely, amount of support offered by the GUI, setup time and ease of understanding were also included.

5.3.5 Data analysis

Due to the amount and diverse nature of the data, the analysis process was broken down into two stages as depicted in Figure 5.3 and Figure 5.4.

Stage 1 was carried out by the author independently. At this stage the focus was to collate the data from each of the usability methods and ensure that the most significant usability issues had been identified. Stage 2 analysis involved 2 additional raters along with the author and a moderator (n=4), to verify what was classed as a usability problem, categorise the problems according to whether they were general to the GUI or stage specific and finally allocate the problem a priority weighting, in order to arrive at a consensus regarding which problems would be addressed.

a) Stage one data analysis

The data from each usability data collection form which had recorded both usability errors and users feedback via 'think-aloud', which had been supplemented by the post-task user feedback, was checked against the 'Captivate' video recordings to ensure that all relevant data had been captured and to ensure the data was accurate.

An excerpt from the in-test observer notes is provided in Figure 5.2 below.

Creating task	**First attempt at task:** Named new task without any problems. Decided on 2 movement phases. Unsure whether had to save task. Asked question. ... *"Do I need to save the task?"* Unsure how to allocate muscles. Allowed user to add wrist extensors twice in same phase. No error message. Wouldn't allow user to go back and edit task – forgot to add names to phases so needed to go back and add in. Locked user in. System failed here.

Second attempt:

Created task again with no problems. Added name into phase.

Needed a verbal prompt to guide select new task created.

Figure 5.2: **An example of the in-test usability notes taken from the observers' paper based data collection form**

The text from the usability observation forms was used to formulate usability issues. The two examples of text from Figure 5.2 have been used to demonstrate how the usability issues were documented, and are provided below:

[Text from usability observation form]…*"Wouldn't allow user to go back and edit task"* became [Usability issue l, stage 1, Appendix 7], listed as…. *"Couldn't edit task once created."*

[Text from usability observation form] ……*"Locked user in. System failed whilst attempting to edit task*" became [Usability issue p, stage 1, Appendix 7], listed as….. *"System crashed when tried to edit task"*

The usability issues were then transferred into an Excel spread sheet *(1)*. Duplicate data was removed and the remainder were ranked in order of frequency of occurrence *(2)* i.e. the number of users who encountered the issue (Hertzum, 2006). This helped to inform the impact of each usability issue on the user, assuming that the more severe issues would have a higher frequency. The objective usability data, observed through the expert and novice 'assisted walkthrough' of the GUI, and the post-task feedback were valuable. However, the post-test questionnaires *(3)* gathered users' subjective views according to each stage of the setup process and also the level of support provided by the GUI. The author (first evaluator) triangulated data (Garmer, Ylvén, & Karlsson, 2004) from each method, in order to weigh-up the balance of evidence for each usability issue *(4)*. An initial list of usability problems was formulated *(5)* (Appendix 7).

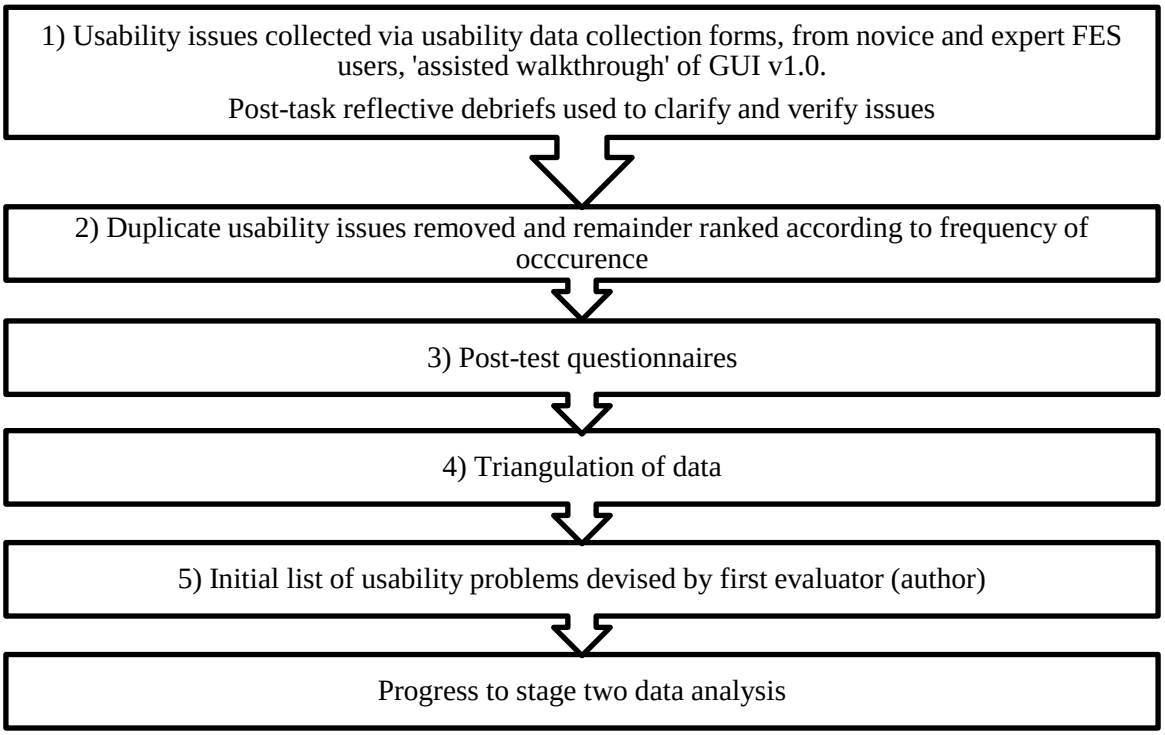


Figure 5.3: **Flow diagram showing the various components of the stage one usability analysis.**

b) Stage two of the data analysis: verification, categorisation and prioritisation using a rating system

A second evaluator, a senior engineer who was part of the design team, carried out the initial part of the second stage of the data analysis *(6).*

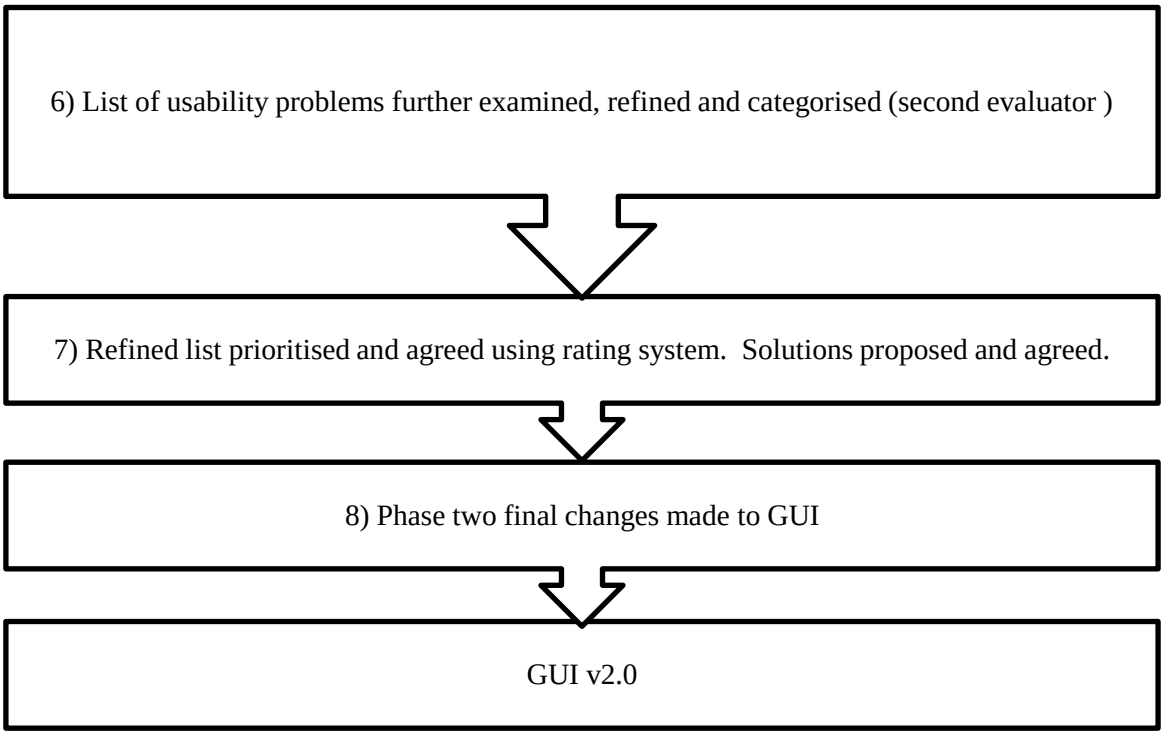


Figure 5.4: **Flow diagram showing the various components of the stage two usability analysis.**

In order to make sense of this initial list and aid decision making, the usability problems were grouped together (categorised) according to two high level categories:

A) Problems that generalized to the whole of the GUI; and B) Stage specific problems. In order to remain within the NEAT LO30 project timelines and resources, these high level categories were further sub-divided into: i) Problems affecting FES & State Machine Functionality and ii) Ergonomics problems which were likely to require significant coding and iii) Ergonomics problems which could be resolved without significant coding.

This process reduced the initial list of usability problems from 92 to 34.

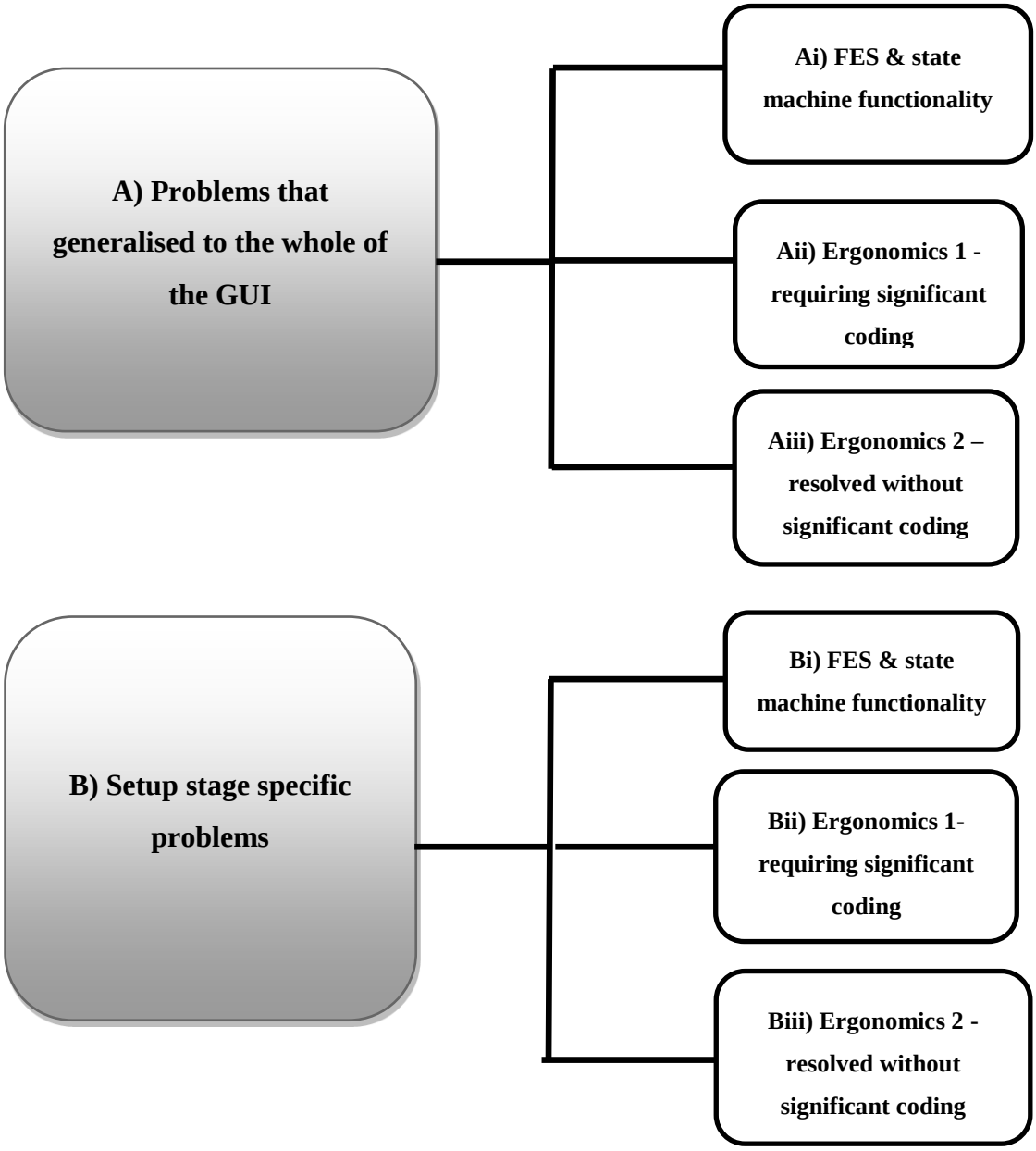


Figure 5.5: **Structure of the usability problem categories.**

In order to identify which of the usability problems to address first, three members of the design team, a software programmer (Rater 2), bioengineer (Rater 3) and the author (Rater 1) a research physiotherapist independently rated the usability problems in accordance with the following categories *(7)*, adapted from Hertzum (2006):

Priority 1 = a minor problem;

Priority 2 = a persistent problem, but not critical to safety;

Priority 3 = a critical problem, i.e. had the potential to impact on patient safety, discomfort or prevent the user from completing the task effectively.

A fourth member of the design team (Rater 4) acted as a moderator where there was a lack of agreement amongst the three raters. This allowed the design team to identify the most problematic areas and prioritise the changes to be made.

A final ranked list of usability problems was agreed and solutions were identified where possible *(8)* (Appendix 8). The changes resulted in version 2.0 of the GUI.

5.4 Results

5.4.1 Results from stage one of the data analysis

Initial analysis identified a total of 191 usability instances from the 6 user walkthroughs. Following removal of repeat instances of the same problem, a total of 92 unique usability problems were identified across the four stages of the setup process.

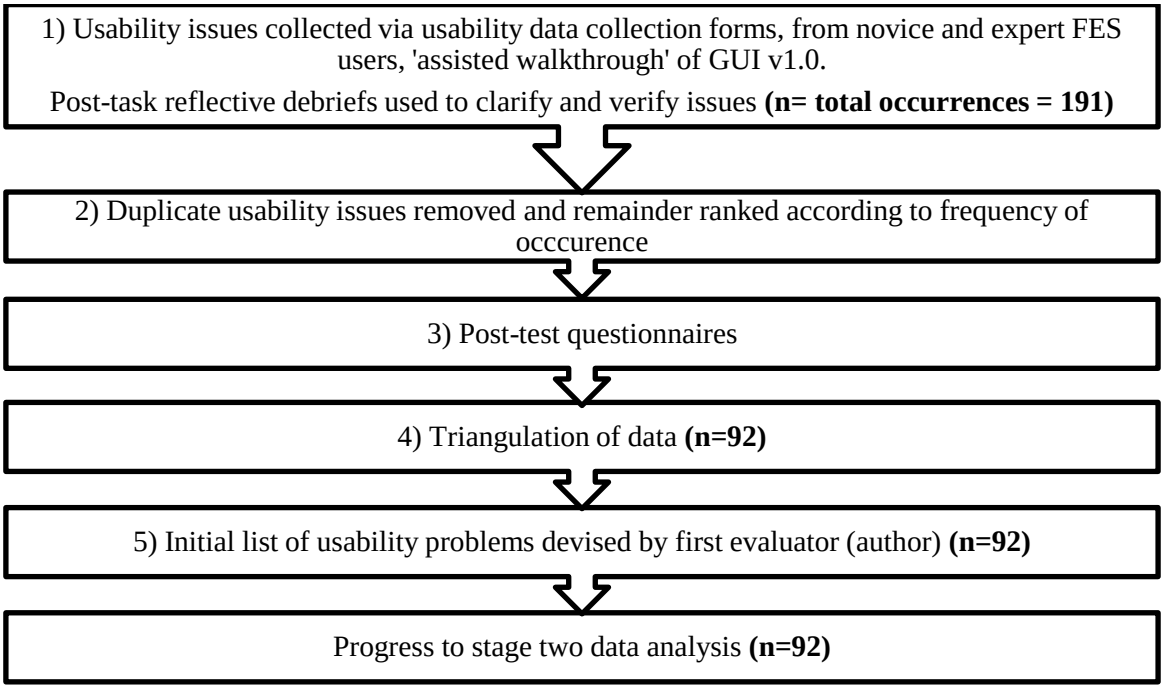


Figure 5.6: **Results from stage 1 of the usability problem analysis**

5.4.2 The type of issue and the frequency

The type of usability problem and the number of users reporting the problem (frequency) was recorded for each stage of the setup. Table 5.2 details the list of identified problems along with frequency of occurrence for stage one of the FES user 'assisted walkthrough'. Data for the remaining stages can be found in Appendix 7.

Table 5.2: **Stage one usability data ranked in order of frequency of occurrence as an example of the data from the FES user 'assisted walkthrough'.**

Usability Problem Stage 1	Number of users reporting the problem
Didn't click save button or unsure re. saving	5
Some muscles not in alphabetical order – deltoids	5
Needed prompting when navigating through set up sequence	4
Unsure where to type name of phase	4
No listing of finger extensors	2
Unsure if needed to click save button to save muscles added	2
Needed prompting to use task once created	2
Couldn't edit task once created	2
Unsure how to add muscles	2
Typed in movement name in movement phase box	1
Couldn't use control button to delete multiple muscles	1
Thumb muscles not listed	1
Text too small to read easily	1
Expected phase 0 to be included in number of phases	1
Requested to use more than 1 group of muscles	1
Allowed user to type same muscle in twice to same phase	1
System crashed when tried to edit task	1
Default setting of biceps in muscle list caused user to choose muscle incorrectly	1
Unsure whether to progress to stage 2 once task created	1

5.4.3 Post-test questionnaires

The post-test questionnaires gathered quantitative and qualitative data, and provided a general overview of the usability of the GUI. The quantitative data comprised of users' responses to eight questions (1a-d, 2a, 2b, 3 & 4), each of which related to a

stage of the setup process, using a Likert scale 1-5. A high score represented a less favourable rating of the GUI.

Table 5.3: **Individual FES user totals and median scores for questions 1 to 4 of the post-test questionnaire. MD = missing data (user did not record their answer).**

User	Question Number							
	1a	**1b**	**1c**	**1d**	**2a**	**2b**	**3**	**4**
User 1	2	3	4	4	3	3	2	2
User 2	1	3	4	3	2	2	2	5
User 3	4	5	5	3	4	2	3	4
User 4	1	MD	2	2	1	3	4	4
User 5	4	3	3	5	3	3	3	3
User 6	1	1	2	4	1	1	1	1
Total	13	15	20	21	14	14	15	19
Median	1.5	3	3.5	3.5	2.5	2.5	2.5	3.5

For each question, the individual and total FES user score and median were recorded as displayed above in Table 5.3.

The full table of quantitative and qualitative comments can be found in Appendix 9.

5.4.4 Triangulation

Triangulation proved quite challenging, as the data from the walkthrough and post-test questionnaire were somewhat inconsistent at first sight. For example, there were a high number of usability issues (n=30) in stage 2a, whereas subjectively, users rated it one of the least problematic stages of setup in the post-test questionnaires. As stage 2a was one of the largest components of the setup process, it perhaps was not surprising that the frequency of usability issues was high. However, users rarely became lost navigating through this stage.

Equally, stage 3 had the second highest number of usability errors (n=18) and yet users rated it the equal second easiest to setup in the post-test questionnaire.

5.4.5 Stage two data analysis results.

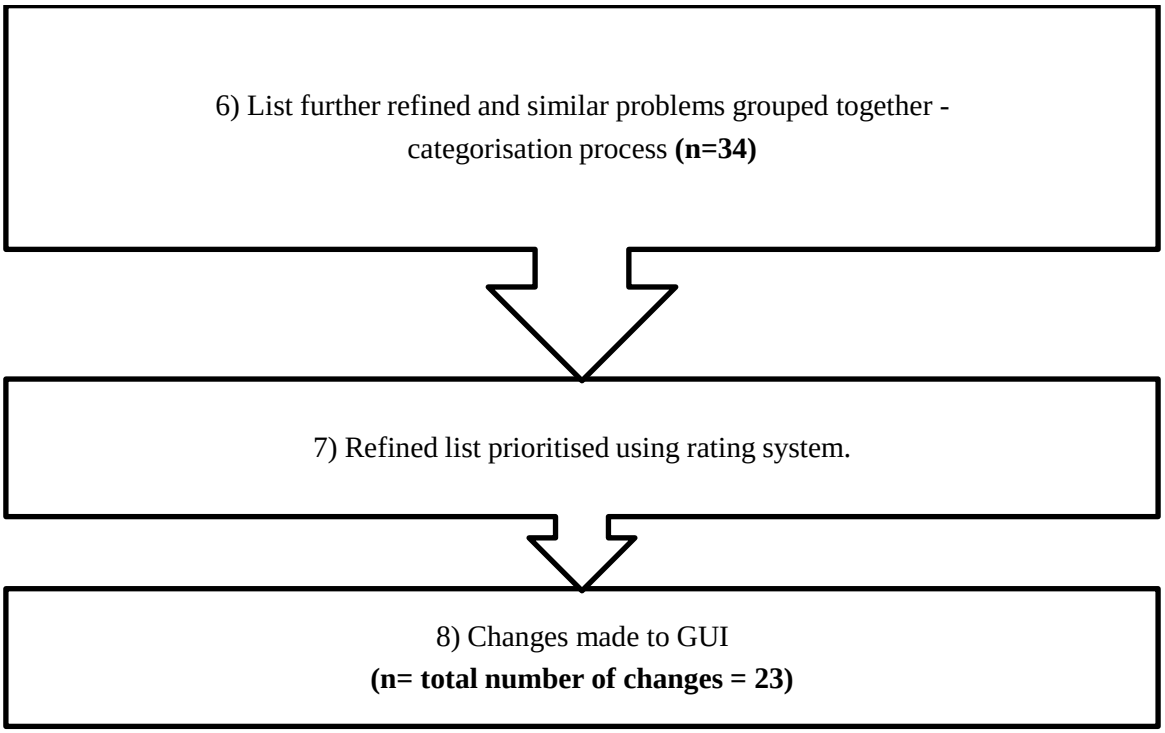


Figure 5.7: Stage 2 data analysis resulting in n= 23 changes made to the GUI.

5.4.6 Refined list prioritised using rating system

An example of the list of Ai) General Usability Problems - FES & State Machine Functionality has been provided below. The full list of design changes and ratings can be found in Appendix 8.

Key to priority ratings: Priority 1 = a minor problem; Priority 2 = a persistent problem, but not critical to safety; Priority 3 = a critical problem, i.e. had the potential to impact on patient safety, discomfort or prevent the user from completing the task effectively.

Key to raters: Rater 1 (R1) – author, PhD student (1st evaluator & rater); Rater 2 (R2) – software programmer; Rater 3 (R3) – bioengineer; Rater 4 (R4) – senior bioengineer (2nd evaluator & moderator).

Table 5.4:**An example of the Ai) General usability problems -FES and state machine functionality.**

A) <u>General usability problems</u>		
i) FES & State Machine Functionality	**Ratings (in bold) and rationale**	**Final moderated priority rating (in bold) (R4), design recommendations and outcome (underlined)**
1) Slider response too slow or inaccurate in stages 2 & 3.	R1: **3** as this was a repeated nuisance and could affect stimulation levels given to patients R2: **1** as not sure what this refers to. The sliders seem to work OK in both sections 2 & 3. There is a default ramp in section 3. R3: **3** Anything that could unintentionally affect stimulation levels has top priority.	**Priority 3** Check carefully that sliders are functioning correctly in all situations. Check with R2 about whether a default ramp is applied when using sliders to avoid rapid changes. In stage 2 this should include an overriding maximum ramp rate to avoid step changes in stimulation level. <u>Changes implemented.</u>
2) When using sliders it would be easier if the arrow keys could be used (avoids mouse and screen). So, if the muscle is selected, the arrow keys control the slider position.	R1: **3** quite critical when trying to handle patients at same time as accessing GUI. R2: **1** as the arrow keys already work for controlling the sliders. R3: **2** It is difficult to imagine that a user could set stimulation without looking at the hand/limb, but it is not a safety critical issue	**Priority 3** <u>Arrow key function added</u>
3) Similarly, in some selected cases, key presses may be easier than GUI button presses (avoids mouse and screen). For example, transition (Enter or spacebar) and stop stimulation (Esc).	R1: **3** for transition button as likely to impact on ability to handle limb as working through phases. Maybe other function buttons not quite so critical. R2: **1** as not sure if this can be implemented in Matlab GUI. R3: **3**. Anything that could directly impact on stimulation duration/intensity needs addressing	**Priority 3** <u>Key presses implemented</u>

5.4.7 Summary of findings for version 1.0 of the GUI and usability problems that were addressed

Version 1.0 of the GUI proved to be a useful starting point for guiding users through the setup process for the UL FES Rehab Tool. However, the findings from phase two of the usability evaluation highlighted a number of areas that warranted design revisions. As a result of the user walk-throughs and feedback, 23 design revisions were made to the GUI. All 10 priority 3 problems, 11 out of 12 priority 2 problems and 2 out of 12 priority 1 problems were addressed. Only a priority 2 problem that related to how to deal with ramp times was omitted, as the design team wanted to determine how this worked in practice once stimulation was applied. The 12 priority 1 problems were deemed to have a low impact on users and did not affect the functionality of the software. Hence, only 2 of these problems were addressed. The most significant revisions have been summarised below (referred to as P# plus number, to correspond with the list in Appendix 8), along with direct quotes from users in order to illustrate the point.

Ai) FES and state machine functionality that generalized across the GUI

One of the main design changes related to the functionality of the GUI was the inclusion of the option to use a keyboard button press to adjust stimulation settings as an alternative to using the mouse (P#2 & 3, Appendix 8). During the usability 'walkthrough' two users [Users 1 & 2] reported that the mouse was difficult to use for setting stimulation levels in stage two, whilst a further user reported that adjusting stimulation levels in stage three was ..."*Definitely not a 1 person job!"* [User 5, post-test questionnaire]. User feedback suggested that that an alternative method would make it easier to interact with the GUI whilst handling a patients' limb *"Adjusting stimulation levels not suitable using mouse - would prefer a dial e.g. hifi volume dial."* [User 5, post-test questionnaire]. Often patients require assistance from the therapist in order to move their hemiplegic arm, particularly when moving against gravity. The option of using the keyboard to adjust stimulation levels meant that the therapist could concentrate on observing and interacting with the patient, rather than needing to accurately position the mouse cursor on the stimulation slider bar. Similarly, keyboard input for moving between transitions and stopping stimulation was implemented.

Four users (‘*walkthrough data’*) felt that the slider that adjusted stimulation responded too slowly in stages two and three (P#1). More importantly, there was no maximum stimulation level imposed on the system for stage two. Due to the lag in stimulation adjustment displayed by the GUI, hypothetically this could have allowed the user to inadvertently adjust the stimulation to an uncomfortable level without realising. As a result, a maximum stimulation level was imposed in stage two. In addition, a safety block was added as a final safety feature. The safety block was the final gateway for stimulation before it passed to the patient. Introducing a safety block at this stage meant that it was not possible for stimulation levels to exceed a critical comfort threshold, whether this was due to a software ‘bug’ or user error (Sun, 2014). Another example of a comfort/safety-related problem with v1.0 that was raised by the users was the absence of a timeout function. During the usability ‘walkthrough’ in both stages two and three, all six users left stimulation on without realising it. In addition [User 5] in the post-test questionnaire commented……*“I did feel I was stimulating the patient (hypothetically) rather a lot and this could be uncomfortable.”* A timeout function could, in the eventuality that stimulation was left on for too long sound a buzzer to alert users that stimulation was still on (P#4 & 5).

Although software ‘bugs’ did not appear to be critical to the safety of the device, they were very irritating to the user and twice during the usability ‘walkthrough’ result in the system ‘crashing’. Four software ‘bugs’ were identified from the user ‘walkthroughs’ and subsequently resolved (P#34). In order to ensure that any remaining software ‘bugs’ could not affect the level of stimulation provided to patients, a safety block was implemented as an additional safety mechanism (Sun, 2014).

Opinion on the length of time it took to setup the device was divided. However, none of the users rated the setup time better than acceptable. One novice user (User 5) rated the setup as excessively long, one expert and one novice user (User 2 & User 4) rated the setup time as quite lengthy, whilst the remainder, two expert and one novice user (Users 1, 3 & 6), rated it as acceptable. [User 6] stated setup time should be *“10 mins max to setup and adjust stimulation. 20 mins for a new patient.”*

Aii) Ergonomics

Changes that fell into category Aii) were predominantly design revision that would make navigation around the GUI more intuitive e.g. renaming of buttons (P#10), inclusion of a save button (P#6), and avoiding errors in navigation (P#8) e.g. error message when users attempt to move to the next stage of the setup process without completing the existing stage. Where changes required little effort to amend the design, even if listed as a low priority, they were implemented. An example of a simple change was listing the muscles in alphabetical order to make finding suitable muscles easier and quicker (P#12).

5.4.8 Stage specific changes to the GUI

Stage two: FES and state machine functionality

Design issues related to administering stimulation were all given high priority. Therefore including a feature where stimulation could be paused (P#15) and if muscles selection was changed stimulation automatically stopped (P#14) were important changes that would facilitate ease of setup for the therapist.

During the usability 'walkthrough' it was apparent that stage two setup, which involved assigning muscles and adjusting stimulation values, was not intuitive to users, as 30 usability issues were identified. One user [User 5] reported… *"For someone who hasn't had any FES in practice rather unclear re. difference between units & channels" [*post-test questionnaire*]*. As a result the design was adjusted (P#23) to incorporate an error message if the user tried to assign too many channels (P#17). Four users were unsure where to navigate to once muscles assigned, therefore other setup options were greyed out to guide the user down the correct setup route (P#18). Maximum stimulation values and minimum stimulation thresholds were displayed in the channel list to act as an aid memoire for users (P#20). One user [User 3] reported…. *"Only wanted one sensor - allowed me to choose one sensor up to the end then had to go back."* [*post-test questionnaire*], therefore the design was changed so that one sensor could be assigned where two sensors were not required (P#25).

Stage four: Ergonomics

The 16 usability issues identified during the usability 'walkthrough', and feedback from the post-test questionnaire, [User 5]……"*rather difficult to relate choices /*

parameters to patients movement", [User 4]…….. *"Words not obvious. Need button to save*", highlighted that stage 4 of the setup process was the least intuitive. Consequently a number of ergonomic changes were made to this stage (P#32, 33, 34). Stage 4 was redesigned to remove the need to click on the windows to highlight the relevant transition, and instead a *"select transition"* button was included (P#7). Some buttons were also removed to reduce redundancy.

5.4.9 Rationale for progressing to next stage of testing

The user 'assisted walkthrough' appeared to be extremely thorough and highlighted the main usability problems. All 10 priority 3 problems and 11 out of 12 priority 2 problems were addressed. Only a priority 2 problem related to how to deal with ramp times was omitted, as the design team wanted to determine how this worked in practice once stimulation was applied. The remaining 10 priority 1 problems were deemed to have a low impact on users and did not affect the functionality of the software.

Following implementation of the revisions to the software and GUI, notably the safety features, the design and research team felt sufficiently reassured to take v2.0 forward to the next phase of the usability evaluation (*phase 3*). In this phase the software was combined with the hardware, initially with healthy users. Only by combining the software with the hardware was it possible to further establish the usability of the system and also test the robustness of state machine functionality, including the algorithm that triggered stimulation developed by Sun (2014). In addition, it was important to meet the deadlines imposed by the funding body.

5.5 Phase 3: Usability engineering during the rapid prototyping phase of the full system, including hardware and development from v2.0 to v3.0 of the software.

5.5.1 Overview of the challenge and solution to state machine functioning

At the start of phase three, the design team had achieved an improved Graphical User Interface (v2.0 GUI), which was envisaged would be sufficiently user-friendly to allow therapists with no software skills to setup and implement electrically stimulated

functional tasks. However, to date the usability evaluation had been hardware independent.

In a previous chapter the concept of a finite state machine (FSM) as an alternative method of controlling FES was introduced, which allowed therapists the flexibility to create functional tasks and adapt them to meet the needs of a diverse range of stroke patients. In order to allow real-time FSM control of the UL FES Rehab Tool, a number of new methods had been developed in parallel with the usability work that required testing to ensure their robustness (Sun, 2014). This included a new angle tracking algorithm and methods to improve the robustness of angle-based triggering between state transitions. Hence our aims for the next phases of testing were to:

a) Continue to evaluate the usability of the GUI following the design revisions

b) Design and evaluate a library of suitable functional tasks that therapists could use during the hospital based, final phase of the usability testing.

c) Evaluate the functionality of the state machine controller, including the robustness of the angle tracking algorithms, initially on healthy participants.

The lab based testing that involved 6 patients in the chronic stage post stroke will be covered in chapter 6.

5.5.2 Methods - Description of staged approach (healthy followed by stroke patients)

Due to the nature of the work, we adopted an incremental approach. The usability testing took place in the lab at the laboratory at the University of Salford, and initially consisted of the author and the PhD student (Mingxu Sun), who was writing the software code and the FSM controller, working together to address any remaining software 'bugs'. Once the majority of software 'bugs' had been addressed, testing was commenced using another member of the research team and a post graduate student, using the whole UL FES Rehab Tool.

In order to progress testing, the author needed to create a library of tasks that would be suitable to meet the rehabilitation requirements for a range of post-stroke upper limb impairments. The tasks were selected on the basis of: i) their close match with everyday functional tasks; ii) tasks that involved the use of both hands i.e. bilateral and bimanual training, as this has been shown to be important to skill reacquisition.

Bilateral training is defined as use of both hands in a synchronous manner e.g. moving a tray. Bimanual training is the use of both hands in an asynchronous manner e.g. opening a jar; iii) utilisation of objects that could easily be found in most homes or therapy departments creating the real-world feel advocated in a task-oriented approach. In total seven functional tasks were devised. An example for 'sweeping coins into contralateral hand' has been provided below in Figure 5.8. Movement phases (n=2, 'reach &'brush'), muscles to be stimulated (in brackets), types of triggers (button press, angle and time) and stimulation states (stim 'on' or 'off') are displayed.

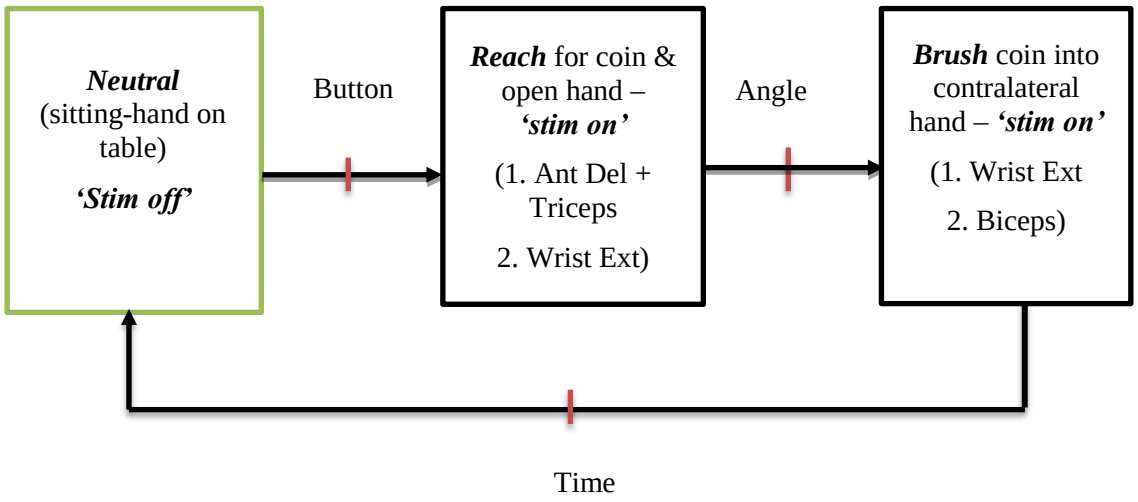


Figure 5.8: **State machine diagram for sweeping coins into contralateral hand.**

The author and another research physiotherapist worked alongside the software developer to ensure consistency of approach throughout this phase of the testing process. Each of the tasks were examined systematically, refining the FSM as the work progressed, and noting usability problems with the system. The process was iterative, as it allowed the software developer to address the problems at each stage of the design cycle. The system was then re-tested and re-evaluated resulting in rapid prototyping of the system at each stage.

5.5.3 Usability problems identified during phase three, rapid prototyping and implemented solutions

The FSM controller and the newly devised angle tracking algorithms proved to be extremely robust throughout the testing. The most significant usability problem encountered during phase three was the length of time it took the user to correctly estimate the values for the exiting triggers within stage four of the setup process. The

user had the option of a button press (manual trigger), angle, time out or a combination of the three conditions, and was required to estimate the values for the angle or time conditions. Time out was not problematic. However, estimation of the angle value in order to successfully achieve a transition to the next movement phase took up to fifteen minutes on some occasions. Often assistance was required from the software engineer in order to ascertain the correct angle values and included referring to the data capture graphs within Matlab.

The solution to this problem was found by using real time data collected during stage three of the setup process to feed into stage four. The real time data collected during stage three (angles and time) were displayed in stage four as a guide to the user. The suggested values could be used or discarded as appropriate. This change in the GUI reduced the setup time for stage four to approximately five minutes, which was a significant reduction in setup time. During stage three (the manual cycle through the movement phases), the user was required to specify when they felt the sequence of movements had been performed as effectively and efficiently as possible. The user then clicked the "Good trial" button, upon which the data was recorded. Users were encouraged to collect a minimum of three good trials before moving on to stage four. Screen shots of the GUI before and after phase three rapid prototyping are presented in figures Figure 5.9 and Figure 5.10.

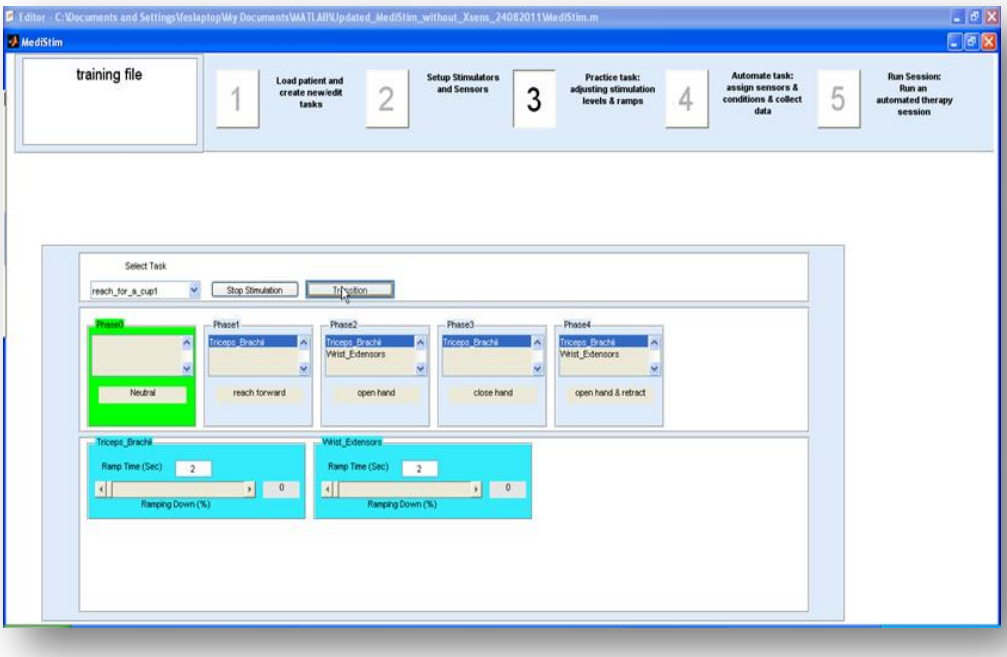


Figure 5.9: Screen shot of stage 3 GUI, v2.0 before changes.

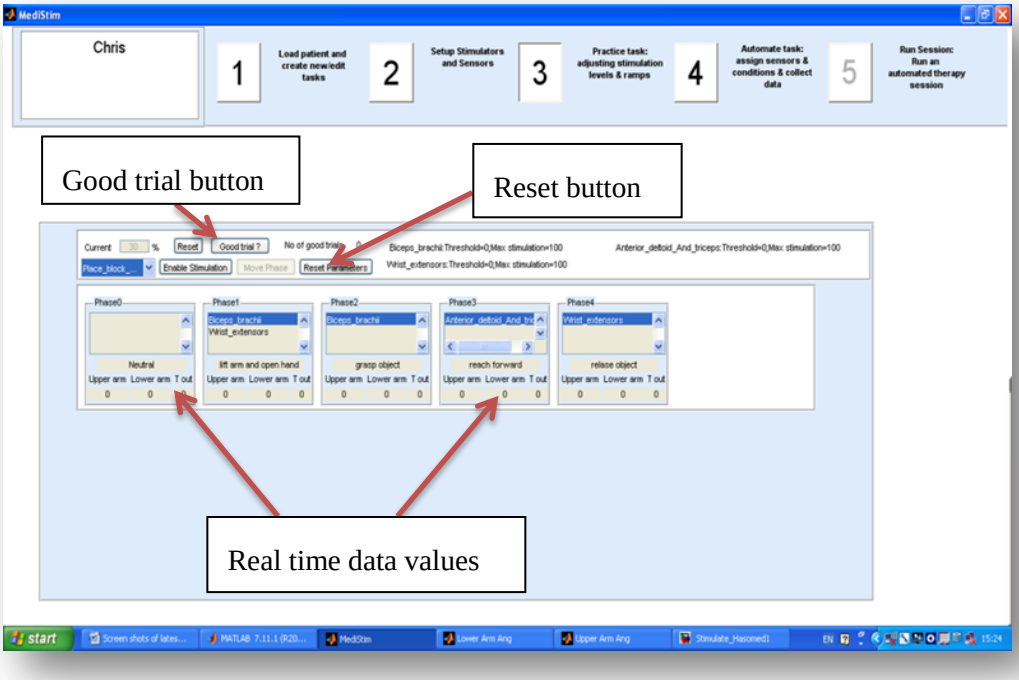


Figure 5.10: **Screen shot of stage 3 GUI , v3.0 following changes. Note addition of good trial, rest buttons and windows showing real time data capture for angles and time elapsed.**

The full list of usability problems identified during phase three testing are tabulated below in Table 5.5.

Table 5.5: Summary of the software usability problems found during phase three usability testing

Phase 3 software usability problems
1. Stage 1: removal of muscle in edit section still left muscle present but greyed out. Solution: Software bug. Coding checked and re-written.
2. Stage 3: 1st time cycled through the phases the settings did not work. Had to repeat process and only on 2nd cycle was it possible to change settings. Solution: Software bug. Coding checked and addressed.
3. Stage 4: Stopped triggering after 3 cycles. Solution: Coding checked and re-coded to address problem.
4. Stage 1: When saved task new task didn't appear in today's task window. Solution: coding checked and fault fixed.
5. Stage 1: Error message appearing inappropriately. Solution: Removal of error message warning box
6. Stage 3: Didn't' hold stimulation values even when full cycle completed. Solution: Software re-coded
7. Stages 2 & 3: Stimulation settings need to start afresh otherwise the system was storing data that was not necessarily relevant for the next patient. Solution: A reset button was included in both stages to address this problem. In addition, a new copy of the library was created as the default template so that no stimulation settings were present.
Functionality problems
8. Stage 3: * Estimating angle values was too difficult for user and took a significant amount of time to establish correct values. Solution: Introduced capturing of real time data during stage 3 to feed forward into stage 4.

* Critical change with high impact on setup time

5.6 Discussion of results, challenges and next steps

5.6.1 A critical review and discussion of the usability testing in relation to the literature

a) Number and type of user

It has long since been recognised the pivotal role that users play with in usability testing. In spite of this, the number of users to recruit in order to ensure that the majority of usability problems have been identified has still to reach consensus. The number of users can vary depending on the aim of the test and the complexity and quality of the system under investigation (Turner, Lewis, & Nielsen, 2006). Usability testing is resource intensive; hence the economic, scientific and commercial imperatives need to be carefully considered when it comes to deciding on the optimum number of users. In addition, different user groups tend to identify different types of usability problems (Caulton, 2001; Nielsen, 1994). Turner et al. (2006) advocate including a minimum of three to four users where there are two sub-groups of users and three users for more than two sub-groups. In the authors' phase two usability testing, the sub-groups of expert and novice FES users were felt to be representative of therapy practice for the UL FES Rehab Tool. Hence three expert and three novice FES users were recruited. Expert FES users are still fairly rare in the UK, as such three expert users was a suitable and realistic number. The addition of three novice users gave a total of six users. Although a low number of users risks not identifying usability problems when they exist, in this case the number of users appeared to be effective in identifying the majority of usability problems for the software only phase. The remaining problems that became apparent during phases three and four of testing were generally related to the hardware and finite state machine controller, rather than the GUI per se (see Table 5.5, phase 3 usability problems). In addition, as explained in chapter 6, only minor usability problems were found in the final phase of the usability testing.

b) Usability methods, tools and measures

The International Standards Organisation, standard 9241-11 (ISO, 1998) encourages measurement of outcomes that pertain to effectiveness (i.e., how well the system's performances meet the tasks for which it was designed), efficiency (amount of

resource required to use the device e.g. time) and satisfaction. In this phase of the testing, the focus was on effectiveness and satisfaction, to identify the set of problems with v1.0 of the GUI and inform design of v2.0. The resources needed to use the device (e.g. setup time) were not directly relevant at this stage, as a measure based on software elements only would not be accurate. The issue of setup time is discussed in the following chapter.

Effectiveness and efficiency of a device are only two pieces of the usability evaluation jigsaw. A device may be effective and efficient to use, however users may dislike it for a number of reasons. It is important to understand how users feel about using the device and specifically in this case, the GUI. The questionnaire aimed to gather users' attitudes towards working with the GUI and ultimately their level of satisfaction. As the design team wished to specifically identify users' satisfaction with each stage of the GUI setup process to inform on prioritisation of changes to be made, the author designed their own post-test questionnaire rather than use an existing validated measure. Although useful for gaining stage specific feedback on the GUI, the disadvantage of this approach is the lack of reliability and validity of the questionnaire. However, the quantitative data augmented by the qualitative responses did shed light on users' satisfaction with the system and which areas of the GUI they found particularly challenging.

c) Usability analysis

One of the issues to plague usability analysis is the lack of agreement between evaluators, commonly known in the usability field as the 'Evaluator Effect' (Hertzum & Jacobsen, 2003). Hertzum and Jacobsen (2003) reviewed eleven studies that had used the usability evaluation methods of 'cognitive walkthrough', heuristic evaluation and 'think aloud' and found that the average agreement between two evaluators using the same method ranged between 5% to 65%. Poorly defined goals, loosely structured usability procedures and a lack of definition for what constituted a usability problem were the main reasons. In the authors' usability study, 6 FES users were recruited in order to detect usability issues within the GUI. These issues were examined by the first evaluator (Rater 1) to determine the impact they had on users and therefore whether they were sufficiently troublesome to classify as a usability problem. In order to offset any potential 'evaluator effect', an additional evaluator

(Rater 4 – a senior bioengineer) also examined the problems. A consensus about the usability problems was reached following discussions.

Problem detection is a useful first step in usability testing, however it does not enable prioritisation of problems to be 'fixed'. As with most projects, resources and timescales are limited, hence there is a need to utilise methods that will rate the severity of problems, and thereby guide the designers as to the benefits of fixing the problem. Rating has been used in other studies (Hertzum, 2006). The rating system used in this study was adapted from those found in Hertzum (2006) and Travis (2009).

5.6.2 Next steps following phase 3, the iterative design process

The iterative design process was protracted, spanning many months, due to the technical nature of the work. It was important that the development process allowed sufficient time and space for the interactive nature of design activities. It was helpful for this phase of the development not to be hindered by an overly formalised process (Göransson, Gulliksen, & Boivie, 2003). Close working of the multidisciplinary team, finally resulted in:

- A library of seven functional tasks that had been refined through testing
- A prototype UL FES Rehab Tool that safely delivered stimulation in a consistent manner,
- A robust method of tracking acceleration and angle data, via the movement Xsens sensors, allowing effective identification of angle thresholds.
- Further modification to the GUI, including a new version of the GUI that captured real-time data (angle and time) that informed the user when selecting exiting trigger values (stage 4 of the setup process).

At this point the research team were satisfied that the system was sufficiently safe and robust to implement with stroke participants. A number of design features had been introduced to ensure that the device was safe to use, most notably the introduction of a 'safety block' (Sun, 2014). Although, the system was working effectively with healthy participants we still needed to establish if the system would be as effective when faced with a different population. Stroke participant's move with greater trial to

trial variability and reduced smoothness, making angle-based triggering more challenging. Hand opening and coupling of shoulder flexion with elbow extension is typically problematic. Hence, we needed to determine how effective the system, particularly the stimulation parameters and angle tracking algorithms would prove to be when used on participants with a range of impairments. In addition, it was necessary to examine the suitability of the library of tasks and the practicalities of setting up the system simultaneous to dealing with a participant with limited movement of their hemiplegic upper limb.

5.7 Chapter summary

The phase two 'walkthrough' of the Graphical User Interface (GUI), (hardware and control independent) resulted in version 2.0 of the software for the UL FES Rehab Tool. As a result of the user feedback, 23 design revisions were made to the GUI and demonstrated the impact of user involvement and usability testing on the design process. Testing the software and hardware in combination during phase three on healthy participants allowed further refinement of the software and GUI. In addition, a library of suitable functional tasks that therapists could use during the hospital based, final phase of the usability testing was designed and evaluated. Finally, and importantly the functionality of the state machine controller, including the robustness of the angle tracking algorithms, was evaluated on healthy participants. This allowed the design team to iteratively adjust the functionality and GUI at each stage the development process. This is the first study in the UK that provides a detailed report of the impact of therapist involvement on the design of an ANR. A usability engineering approach was successfully utilised in order to identify and address the most significant usability problems with the GUI.

The next chapter, chapter six, covers phase four, the lab based usability evaluation with stroke patients. Due to the importance of setup time on the adoption of medical devices, this phase includes further detail of an early method to predict setup time.

6 Chapter 6: Development of a tool to predict setup time

6.1 Introduction

Chapter five outlined the methods and findings from phases two and three of the usability evaluation process (software design refinement and full system rapid prototyping, with healthy participants). Phase three, the rapid prototyping of version 2.0 of the software with healthy participants resulted in a demonstrably robust and usable platform, version 3.0. The next stage in the design process was to test the UL FES Rehab Tool with stroke patients.

Upper limb impairments exhibited post stroke are frequently associated with reduced movement speed, smoothness of movement, precision, as well as an increase in variability of movement and poor coordination (van Vliet et al., 2013; Zackowski et al., 2004). These impairments mean that system evaluation with healthy participants does not provide a sufficient demonstration of efficacy or usability of the system. Specific challenges include: achieving FES-assisted, voluntary-initiated hand opening in the presence of spasticity or contractures (Makowski, Knutson, Chae, & Crago, 2014), achieving robust triggering in the presence of variable movement, together with the potential limits on the extent of stimulation-assisted movement. Additional challenges were delivering an optimum amount of stimulation, to coincide with the particpants' voluntary effort, so as to produce efficient and smooth movement sequences (Makowski, Knutson, Chae, & Crago, 2013), at the same time as avoiding a hypersensitive response to stimulation. These additional challenges when attempting to use the system with stroke patients are likely to increase the difficulty and hence time taken to setup up the system.

As discussed in chapter two, and highlighted in the literature (Demain et al., 2013; Hochstenbach-Waelen & Seelen, 2012), rapid setup times are crucial to the adoption of rehabilitation technologies. A factor highlighted both throughout the literature (McHugh, Swain, & Jenkinson, 2013), and in the early study advisory group meetings, is the short amount of time available for upper limb therapy. Unsurprisingly, a short setup time was ranked equal first as the most desirable system requirement to emerge from the therapist advisory group meetings. In spite of the importance of short setup times, the literature review in chapter four highlighted the scarcity of studies that have examined setup time for rehabilitation devices (Pedrocchi et al., 2013; Fitzgerald,

Kelly, et al., 2008; Dijkers et al., 1991). Even those that did measure setup time tended to rely on self-reports and did not clearly state what they defined as setup time (e.g. when timing commenced and finished) (Prenton et al., 2014; Heller et al., 2013; van Swigchem, Vloothuis, den Boer, Weerdesteyn, & Geurts, 2010; Burridge et al., 2008). A better understanding of these factors has the potential to inform the design and use of future rehabilitation devices.

Although it is clear that setup time should be as short as possible, one issue that has not been addressed in the literature is the need for setup time to be predictable. As has been highlighted previously, therapy time per patient is typically constrained due to limited resources, and as such commencing an ANRT-assisted session, only to run out of time, could dissuade therapists from using the system. Some aspects of setup time for ANRT are inherent in the design of the device, e.g. donning of electrodes and sensors, and adjustment of stimulation levels. Whereas other aspects, such as the choice of functional task and the alignment of this to the patients level of impairment and functional goals are modifiable. Some researchers have already recognised the need to utilise patients' clinical presentation to inform setup parameters for ANRT (Cozens et al., 2013), in this case robotic therapy. The author was part of a clinical team of experts that developed an informatics framework, SILCK (Synthesising and Interpreting Language for Clinical Kinematics), that has been embedded within software to allow automated control of a rehabilitation robotic device, iPAM. This concept has the potential to be utilised and developed for other ANRT, ultimately reducing the overhead of setup time and improving device usability. Therefore, the aim of the work is to develop a tool for the prediction of setup time for the UL FES Rehab Tool.

6.2 Model development

6.2.1 Justification of the factors likely to influence setup time

In version 3.0 of the software, factors that require input from the therapist are: S*tage 1*) choice of the most suitable functional task from the library of tasks or creating a new task, should a suitable task not exist. *Stage 2)* based on the assessment of the patient's impairment, the therapist assigns channels to muscles and sets distinct threshold and maximum stimulation targets for each muscle. The sensors, in this case accelerometers, are also assigned to limb segments, signals from which are to be

available for setting up transitions. *Stage 3)* the therapist manually cycles through the functional task refining stimulation targets and ramps for each movement phase. *Stage 4)* allows the most suitable exiting triggers for each phase of the movement to be stipulated, (in this case, angle, time out or button). Once all parameters are working effectively, the patient can then enter *stage 5* where they can repeatedly practise the functional task. Setup time can therefore be defined as the time taken to progress from the start of stage 1 to the end of stage 4 of the software using the Graphical User Interface (GUI).

Within the proposed model (Figure 6.2, page 121) it was hypothesized that setup time was likely to be influenced in the first instance by two FES independent (internal) factors. The two FES-independent factors were: a) the patients' level of upper limb impairment and b) the complexity of the task. It was therefore postulated that if it was possible to quantify a) and b), this would allow prediction of c) setup time. By using the lab based testing to examine potential relationships between a) and b) it was anticipated to be possible to derive an equation that could predict setup time c).

6.2.2 Upper limb impairment

For individuals with no impairment and hence requiring no FES support, the setup time should be zero. Conversely, an individual with a high level of impairment, attempting the same task, would require a high degree of assistance from the system. It is reasonable therefore to propose that for a given task, the number of channels of stimulation and hence associated time needed to place electrodes and find stimulation targets, will be positively related to the patients' level of impairment.

There are a number of validated clinical measures that aim to quantity the level of upper limb impairment post stroke, such as the 'Motricity Index' (Collin & Wade, 1990) and the Modified Ashworth Scale (Gregson et al., 2000). Due to the Fugl-Meyer Upper Extremity's robust psychometric properties (Gladstone, Danells, & Black, 2002), and its widespread use in previous studies (Hemmen & Seelen, 2007; de Kroon, IJzerman, Lankhorst, & Zilvold, 2004; Cauraugh, Light, Kim, Thigpen, & Behrman, 2000), it was favoured over other upper limb measures of impairment.

6.2.3 Task complexity

In contrast to the impairment aspect of the model discussed above, task complexity was a more difficult factor to model. It was reasonable to assume that a simple task, involving a small number of movement phases should take less time to setup than a complex task involving more movement phases, as setting up of each transition between movement phases has an associated time cost, largely arising from stage 4 of the setup process. In order to examine task complexity, a literature review was initially conducted to establish if a suitable model was available.

A suitable model of task complexity should fulfill the following characteristics:

- Be independent of impairment level, as this is represented in the other part of the model;
- Characterise functional movement for the upper limb, either using measures of joint or muscle activity, based on the assumption that the more changes of muscle or joint activity there are within a given task, the more complex the task;
- Be applicable to 'real world' functional tasks.

As the measure of task complexity of interest in this study is impairment independent, attempting to adapt one of the clinical scales of upper limb function was rejected and a literature search carried out.

A search was carried out in the databases of Medline, AMED & Psychinfo using the keywords task performance and analysis, task difficulty, psychomotor performance. This found 620 papers of potential relevance. However, when combined with 'Activities of Daily Living (expanded to include MESH terms)' this was reduced to 14. However, all of these were either related to the effect of clinical interventions on 'reach to grasp' and 'function' or on kinematics of the upper limb, rather than quantification of task complexity.

As no suitable model was identified in the literature, a basic model was developed, based on descriptions of joint movements that could be both directly observed and easily interpreted.

6.2.4 Components of the model that needed to be developed

6.2.4.1 Task complexity

The task complexity method developed for this study focused on the movements of the major joints in the upper limb, shoulder, elbow, radio-ulnar joint and wrist, all of which could be controlled using FES. The model considered a task to consist of a number of phases. Within each phase, each of the four joints was considered to be in one of three states:

1) At rest, in the starting position

2) Moving in a single direction e.g. flexion, extension, pronation, supination *or*

3) Held in a static position, actively working against gravity.

In order to illustrate how the task complexity calculation was arrived at, an example of 'sweeping coins' into the contralateral hand is provided below in Figure 6.1:

The participant was positioned in a seated position with their arms resting on the table in the '*starting position'* (state 1). They were asked to '*reach'* for coins placed on the table directly in front (state 2). Figure 6.1 illustrates the participants' shoulder moving forward into '*flexion,*' simultaneous to both the elbow and wrist moving from the starting position into '*extension*'. All three components of movement are necessary in order to position the hand adjacent to the coins.

Once the participant had gathered the coins, they were '*swept'* into their contralateral hand. In so doing, the participants' shoulder joint moved from a position of *'flexion'* towards '*extension*'(state 2), simultaneous to the elbow joint moving from *'extension'* into a position of *'flexion* whilst the wrist was actively maintained in '*extension*'.

For a given task, the number of times a change in status occurred at each joint during each phase was recorded and the sum calculated. This number was then multiplied by the number of joints involved in the whole functional task, as a weighting factor. This takes into account that tasks that involved co-ordinated movement at multiple joints are intuitively likely to be more complex than the sum of the complexity of individual joint movements (i.e. a movement involving coordination of two joints is likely more than twice as complex as a movement involving a single joint). This figure (i.e. sum of changes in joint status, multiplied by number of joints involved in the task) provided the task complexity score for a specific task.

Sweeping coins

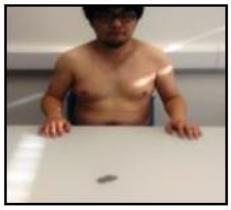
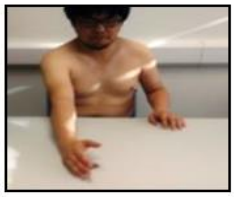
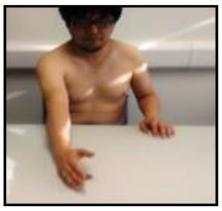
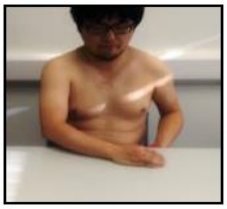
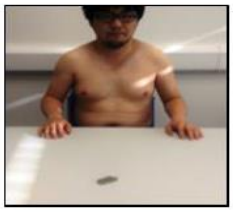
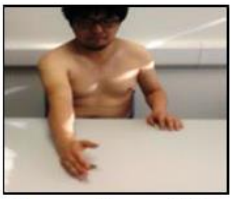
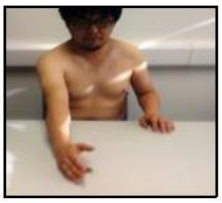
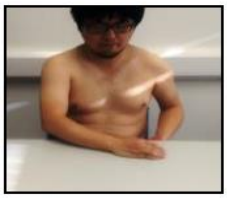
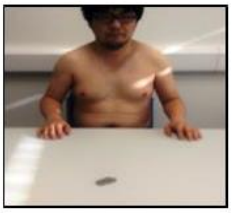
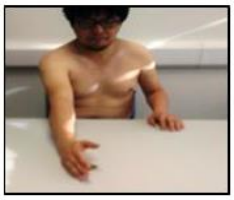
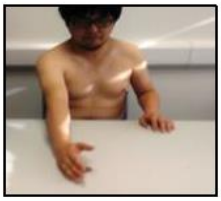
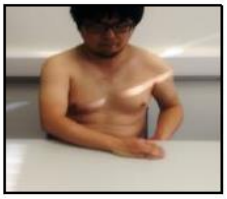
	Reach	Sweep	No. of changes in joint status
Shoulder Joint	  Starting position →Flexion	  Flexion→Extension	2
Elbow Joint	  Starting position →Extension	  Extension →Flexion	2
Wrist	  Starting position →Extension	  Extension → Extension	2
		SUB TOTAL	**6**
		TOTAL	**6 x 3 =18**

Figure 6.1: **An example of the task, sweeping coins into contralateral hand**.

It is worthy of note that our method of calculating task complexity is impairment independent.

6.2.4.2 Library of tasks

To allow development of the tool to predict setup time a suitable set of tasks needed to be identified that would be representative of those that might be used in a therapy session. In chapter two the importance of specificity of training was highlighted, as transfer of skills has been found to be small unless the skills of the training closely matched those to be learned (Schmidt & Young, 2005). This is due to the highly specialised manner in which motor skills are represented within memory (Keetch, Schmidt, Lee, & Young, 2005) and hence the tasks used in a therapy session should be real-world relevant. In addition, bilateral training has been shown to be important to skill reacquisition, due to the many tasks in everyday life that involve bilateral activity (Barreca et al., 2004); indeed the Accelerated Skill Acquisition Program (ASAP) advocated by (Stein, Harvey, Macko, Winstein, & Zorowitz, 2009) recommends that at least 1 task incorporated into training schedules should be bimanual. We also considered the real-world relevance of objects in the tasks and chose real objects which could be found in therapy departments. Finally, we used results from a previous study to provide examples of functional tasks that are important to stroke survivors and that they find difficulty in achieving (Barker & Brauer, 2005). The set of tasks chosen is illustrated below in Table 6.1.

Table 6.1: **FES library of tasks with rationale for choice and source of supporting evidence for inclusion (where available).**

Functional task	Key characteristic	Source of supporting evidence where applicable
Sweeping coins into contralateral hand	Unilateral, uniplanar reaching activity. Can be performed with gravity counterbalanced, thereby providing a task that was easy to achieve for the more impaired participants and easy to setup for therapists.	
Pushing up from a chair	Bilateral, synchronous, weight bearing task	(Stein et al., 2009); (Barreca et al., 2004)
Picking up tray	Bilateral synchronous task	Stein et al, (2009); Barreca et al, (2004)
Placing block on shelf	Unilateral reach & grasp activity performed against gravity up to 90°	
Answering phone	Unilateral activity. Contains all 4 aspects of reach to grasp i.e. reach, grasp, manipulate and return	Barker and Brauer, (2005)
Pouring from bottle to glass	With the participant holding the glass steady this is a bimanual, asynchronous activity. Contains all 4 components with added pronation & supination of forearm.	Barker and Brauer, (2005)
Opening door	Standing activity	Barker and Brauer, (2005)

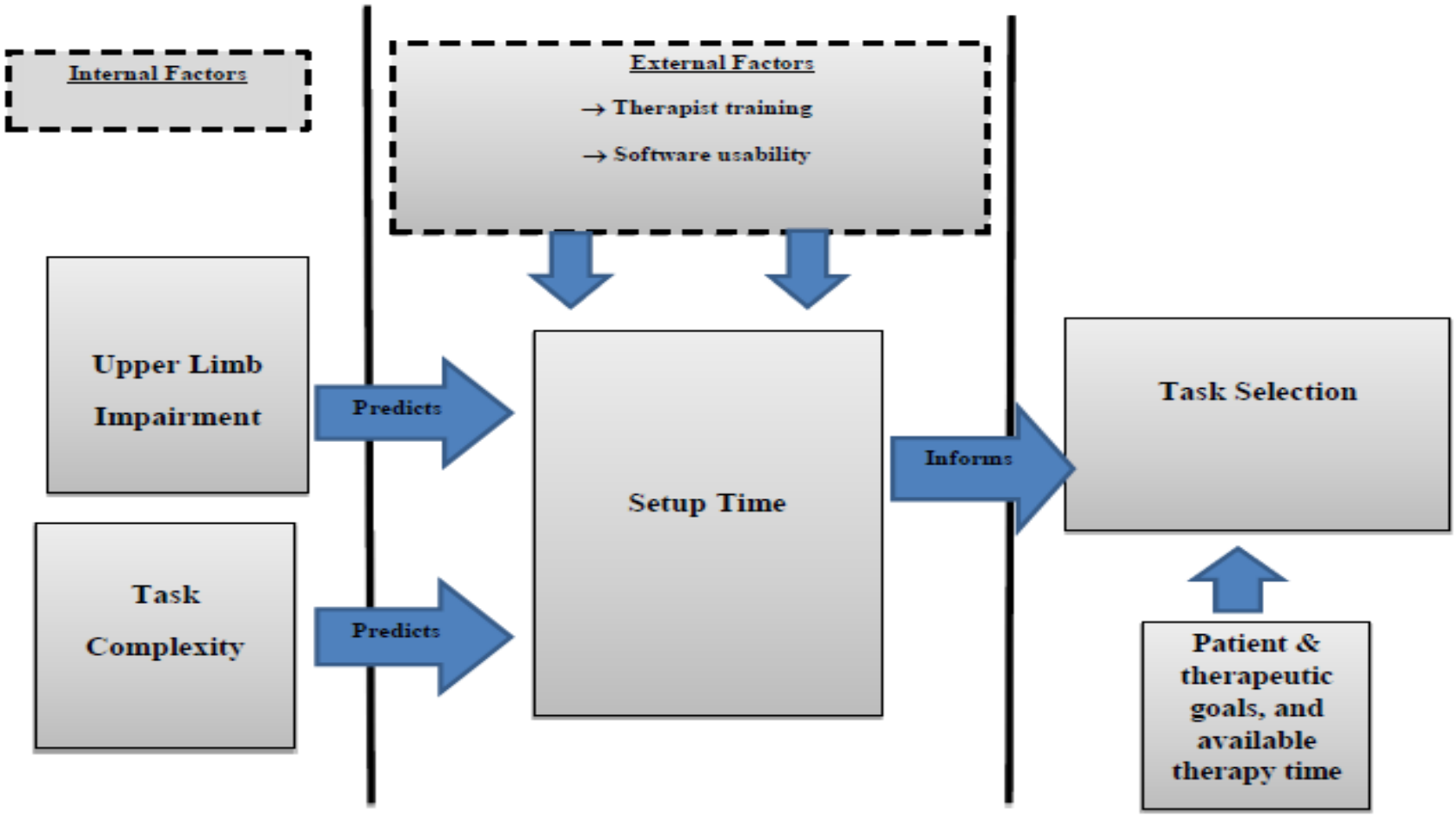


Figure 6.2: The inter-relationship between upper limb impairment, task complexity and additional factors when predicting setup time and task selection.

6.3 Model implementation

The impairment measure selected, Fugl Meyer UE, had already been extensively validated and shown to have high inter-rater reliability (overall intraclass correlation coefficient of 0.96) (Sanford, Moreland, Swanson, Stratford, & Gowland, 1993) (Sanford et al., 1993), good content validity (Fugl-Meyer, Jaasko, Leyman, Olsson, & Steglind, 1975), and good construct validity (Wood-Dauphinee, Williams, & Shapiro, 1990). However, the method of calculating task complexity had been devised by the author for this study (Research Physiotherapist 1 –RP1), and it was important to ensure there was some merit in this approach. It was deemed too early in the development of this method to conduct more formal inter-rater reliability testing, however we needed to examine and refine our approach where possible. A second senior research physiotherapist (Research Physiotherapist 2 – RP2), was provided with the definition for calculating task complexity and asked to independently calculate the task complexity scores for the library of tasks. Based on each therapist's individual scores, the set of tasks were ranked, placing the least complex task first and the most complex task last. Results were compared by plotting the results of RP1 against RP2 (Figure 6.3), including a line of best fit. Full details of the outcomes for each of the research physiotherapists can be found in Appendix 10.

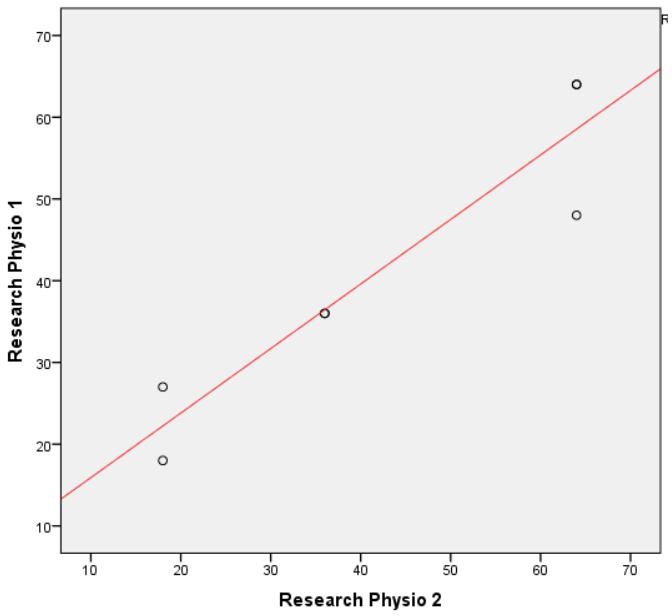


Figure 6.3: **Scatterplot of task complexity scores for Research Physiotherapist 1 (author) & Research Physiotherapist 2. Line of best fit shown in red.**

There was a high level of agreement across the research physiotherapists. The task complexity totals were the same for 5 out of the 7 tasks and the ranking of task complexity was the same for all tasks.

The score for 'pushing up from a chair' differed across the 2 raters (n=18 for RP2 versus RP1 n=27) due to research physiotherapist 2 omitting the grasp phase (Tables 9 & 10). Both the 'opening a door' task complexity score and complexity category differed across raters, as an additional movement phase had been included by researcher physiotherapist 2 (RP1 n=48 versus RP2 n=64). Following discussions, it was agreed to include the additional movement phase (Table 6.2).

Table 6.2: **Revised agreed scores and rankings**.

Revised agreed scores and ranking	
Task	**Total score**
Sweeping coins	18
Pushing up from chair	27
Place block on shelf	36
Picking up tray	36
Answering phone	64
Pouring from bottle	64
Opening door	64

6.3.1 Participant selection

Ethical approval was gained from the NHS Ethics Committee (LREC, 10/H1005/26: UoS, REP10/146, (Appendix 11). Six chronic stroke participants already known to the research team, and spanning a range of impairments were invited to take part in the study in accordance with the inclusion and exclusion criteria (Table 6.3). Unfortunately due to the challenges of recruitment, four of the participants' ARAT scores fell below the minimum specified in the inclusion criteria. An information sheet was provided outlining the details of the study. Informed consent was gained

on the first visit to the lab. Each participant was asked to visit the laboratory on up to six occasions.

Table 6.3: **Lab based testing stroke participant inclusion and exclusion criteria.**

Inclusion criteria
• A single stroke
• At least 6 months post stroke
• Medically stable
• Sufficient cognitive ability to understand the experimental protocols
• Over 18 years of age
• Adequate motor response to surface stimulation and able to tolerate sensation
• Reduced arm function as represented by an Action Research Arm Test between 15 and 40
Exclusion criteria
• Premorbid orthopaedic, neurologic or other medical condition including poorly controlled epilepsy, which would affect the response to electrical stimulation
• Cardiac demand pacemaker or other active medical implant/device that may be affected by FES
• Fixed contractures of elbow, wrist or fingers
• Pain due to shoulder subluxation

6.3.2 Method

During the first visit, once informed consent had been provided, clinical data was gathered to characterise the participant. Their level of impairment, Fugl-Meyer Upper Extremity (UE) Assessment, (FMA-UE) (Fugl-Meyer et al., 1975), functional ability, Action Research Arm Test, (ARAT) (Lyle, 1981) and Mini-Mental State, (MMSE) (Folstein, Folstein, & McHugh, 1975) were measured. To remove one (external) source of variability in setup time, throughout testing the same physiotherapist, who specialised in stroke, carried out all the clinical measures, and acted as the operator when setting up the FES device. As well as characterising the participants' abilities, the measures were intended to feed into the development of the model to predict setup time. Participants who demonstrated tightness in the hemiplegic finger flexor muscles, sufficient that it prevented them from attaining hand opening, were prescribed a period of exercise stimulation prior to commencing use of the FES system.

At subsequent visits the same physiotherapist used the GUI to setup the FES device for each of the tasks in the library, taking into account the participants' level of

capability. Where a task was either too easy (able to be completed without the use of FES) or too difficult (unable to be complete even with the assistance of FES) they were omitted. Where this situation arose this information was recorded. Where possible, participants progressed through the tasks from simplest to most complex, in accordance with the task complexity ranking. This allowed participants to build confidence by successfully achieving some of the simpler tasks before being asked to attempt more complex tasks.

The author used the usability data collection form (Appendix 5) to record time taken to setup each stage of the FES device and to record relevant usability observations of the setup process, for use in subsequent final refinement of the GUI. The setup process only began once all of the hardware was laid out and both the physiotherapist and the participant were ready to commence. Setting up the Hasomed FES Rehastim, the Xsens and loading the GUI, (at this stage in the development, the software was loaded through Matlab commands), was carried out by an independent researcher who had written the code. This ensured that the FES system was setup consistently across all of the lab-based testing. In addition, this researcher was on hand when there were technical difficulties with either the software or the hardware.

Times were captured using a stopwatch and were recorded from when the operator commenced stage 1 of the setup process. The end point for setup was deemed to be on completion of stage 4. In the event that an interruption occurred to the setting up of the device, for example a family member asking questions about the device, every attempt was made to exclude this period of time from the overall setup time calculations. In addition, during the early part of the lab testing the software still required some minor modifications and occasionally malfunctioned. When this occurred, timing was stopped and only restarted once the operator reached the same point in the setup process as prior to the software malfunction.

In order to test the lab based protocol, and the reliability of the software on stroke participants, the first participant (participant 0) was used as a pilot. The data from this participant was therefore not included in the results. The tasks used in the testing are listed above in Table 6.2.

6.4 Results

6.4.1 Participant characteristics

Six participants were recruited into the study (Table 6.4). The mean age of the participants was 60 years and the mean time since stroke was 9.8 years. All participants were therefore classified as in the chronic stage post stroke. All participants were right hand dominant with an even split of right and left sided hemiplegia. Participants were graded using the Fugl-Meyer UE Scale as mild (50-65), moderate (30-49) or severe (below 30) according to the criteria used by (Michelson, Selles, Stam, Ribbers, & Bussmann, 2012). Four participants were therefore categorised as severely impaired whilst 2 were moderate. The mean ARAT score was 10.4 (on a scale in which a score of 66 corresponds to maximum upper limb function). Participants therefore generally had a low level of functional ability. One participant had expressive language difficulties as a result of the stroke. All other participants had no communication or language deficits. All participants scored highly on the mini mental scale with a mean score of 26.1 (on a scale on which a score of 30 corresponds to unimpaired cognitive function).

Table 6.4: **Participant characteristics: impairment, function and Mini Mental scores for the lab based testing.**

Participant No.	Time since CVA (yrs)	Age (yrs)	Affected Side	Hand dom	Gender	FM UE/66	ARAT / 57	Mini Mental /30
1	28	59	R	R	M	18	4	24
2	3	80	L	R	M	29	10	26
3	5	41	R	R	M	29	8	23
4	3	79	L	R	M	28	6	25
5	13	42	R	R	F	37	NK	30
6	7	59	L	R	M	38	24	29
Mean (SD)	**9.8 (9.6)**	**60 (17)**				**31.1 (6)**	**10.4 (7.9)**	**26.1 (2.7)**

Key to abbreviations: NK = not known; yrs = years; FM UE = Fugl Meyer Upper Extremity Scale; ARAT = Action Research Arm Test.

6.4.2 Setup times

Setup times were recorded for each stage of the setup process together with the overall setup time (stages 1-4) for each of the 7 functional tasks. Table 6.5 below displays the overall initial setup times (mins) for each participant, per completed task. A key for the functional task code is also provided.

Table 6.5: **Impairment level and setup times per participant and functional task. Task complexity scores shown in brackets.**

Participant Number	Age (years)	FM-UE	Task SC (18)	Task PC (27)	Task BS (36)	Task PT (36)	Task OD (64)	Task PB (64)	Task AP (64)
1	59	18	28.51	38.93					50.71
2	80	29	29.33		37.51	39.36	23.88	49.85	41.73
3	41	29	20.98		49.80	33.96			
4	79	28	23.31	23.90		27.30			37.56
5	42	37	14.50			16.08		17.15	22.38
6	59	38	19.71			16.32		18.11	24.15
Mean (SD)	**60 (17)**	**29.8 (7.2)**	**22.7 (5.6)**	**31.4 (10.6)**	**43.6 (8.6)**	**26.6 (10.4)**	**N/A**	**28.3 (18.6)**	**35.3 (11.9)**

Key to functional task codes:

Task code	Functional Task	Task code	Functional Task
AP	Answering phone	PC	Pushing up from chair
BS	Place block on shelf	PT	Picking up tray
OD	Opening door	SC	Sweeping coins
PB	Pouring from bottle		

The table shows a general trend for setup time to increase with task complexity, with ‘sweeping coins’ being the quickest to setup, and on average, ‘answering a phone’ taking the longest. It also shows a general trend for the set up time to be longer with patients with greater levels of impairment.

6.4.3 Relationship between task complexity and setup times

A Pearson correlation was run to assess the relationship between task complexity and setup time. Preliminary analysis showed the relationship to be linear as assessed by visual inspection of a scatterplot (

Figure **6.4**).

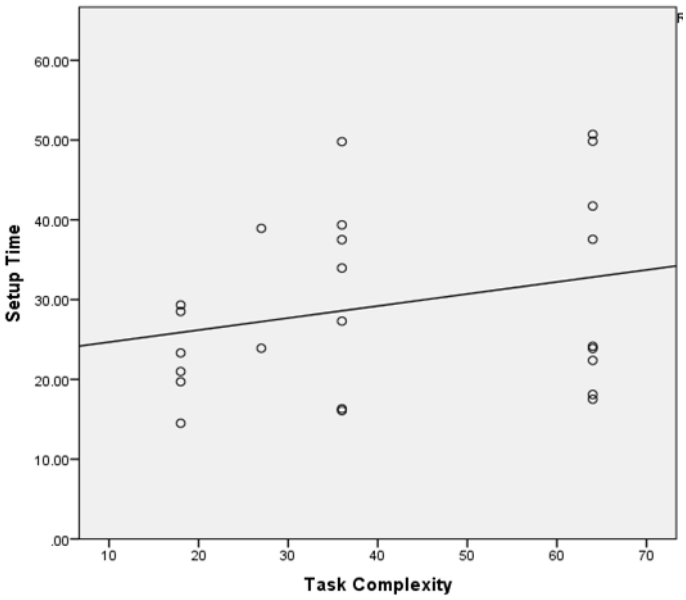


Figure 6.4: **Scatterplot of task complexity against setup times**

On running the analysis through SPSS (version 20.0) (Appendix 19), there was a weak positive correlation (0.225) between task complexity and setup time for the UL FES Rehab Tool, r (22) = 0.255; however it was not statistically significant (p < 0.229).

The other variable in the model to predict setup times was the participants' level of upper limb impairment. Hence, further analysis that examined the relationship between upper limb impairment scores (as measured by Fugl-Meyer UE scale) and setup times was required.

6.4.4 Relationship between the level of participants' upper limb impairment and setup times.

A scatterplot was conducted to visually establish the nature of any relationship between participants' upper limb impairment scores and setup times for the FES Rehab Tool (Figure 6.5). There appeared to be a negative linear relationship between impairment levels and setup times.

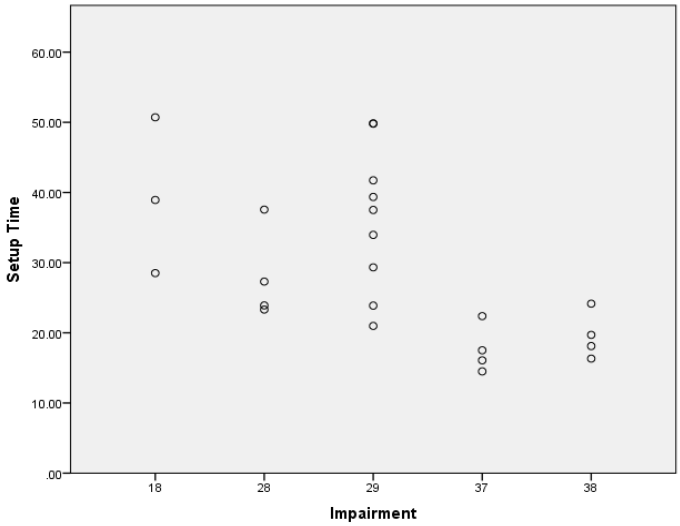


Figure 6.5: A scatterplot of participants' upper limb impairment scores plotted against setup times.

A Pearson Correlation analysis was conducted in SPSS (version 20.0) in order to establish the strength of the relationship (Appendix 19). The analysis showed a large negative relationship between the participants' level of impairment and setup time, with a Pearson Correlation Coefficient of -0.643, which was statistically significant at a 0.01 level (2-tailed).

6.4.5 A linear regression analysis for upper limb impairment and setup times.

Initial analysis showed the assumptions of linearity, independence of errors, homoscedasticity, unusual points and normality of residuals were met.

A linear regression analysis, (Appendix 19) showed that upper limb impairment scores were statistically significant when predicting setup time, F(1,22) = 15.48, p<0.001 adj. R^2 = 0.386, with a p value of, $p < .05$. Upper limb impairment accounted for 38.6% of the variability in setup times.

From the analysis so far, it appears that within the model of factors likely to predict setup times for the FES Rehab Tool, the participants' level of upper limb impairment is the strongest predictor. In order to establish whether task complexity would improve the level of prediction, a multiple regression analysis was performed.

6.4.6 Multiple regression analysis to predict setup time

In the proposed model the dependent variable is setup time whilst the independent variables are upper limb impairment and task complexity scores. Multiple regression analysis was used to determine the overall fit of the proposed model to predict setup time, based on knowledge of the participants' level of upper limb impairment and the complexity of the task undertaken. It also allowed the relative contribution of each of the independent variables to be calculated.

The assumptions of linearity, independence of errors, homoscedasticity, unusual points and normality of residuals were met.

6.4.6.1 How well did the proposed model fit? Model summaries for prediction of setup time from upper limb impairment and task complexity.

The first option within the model (Model 1) was to use upper limb impairment or task complexity individually in order to predict setup time. From the analysis so far, for model 1, only upper limb impairment had any value when attempting to predict setup time. The second option (Model 2) was to perform a regression analysis using upper limb impairment combined with task complexity to ascertain if this offered more promise. The outputs for this regression analysis can be found in Appendix 19.

The R value of 0.741 indicated a good level of 'fit'. When corrected for any positive bias (*adj.* R^2) a value of 0.506 (50.6%) is arrived at (Appendix 19). This is indicative of a medium to large effect size, (Cohen,1992) of the independent variables on setup time.

The upper limb impairment and task complexity scores statistically significantly predicted setup time, F(2,21) = 12.782, p<0.000234, adj.R^2 = 0.506 with a p value of $p < .05$ (Appendix 19).

6.4.6.2 Impact of impairment and task complexity on the model and equation to predict setup time.

When comparing the goodness of fit of the two models ($R^{2)}$ i.e. Model 1 using the variable of impairment and setup time, versus Model 2 using the two variables of impairment and task complexity and setup time, Model 2 that incorporated both variables explained more of the variation in the outcome (51% as compared with 39%).

Each additional increase (improvement) in upper limb impairment score reduces setup time by an average of 1.28 minutes, after taking into account the effect of task complexity. Similarly each increase in task complexity score increases setup time by an average of 0.221 min after taking into account the effect of impairment score. Therefore, in the current scenario when setting up upper limb functional tasks, the setup time difference between the easiest task (sweeping coins, 18), and one of the more complex tasks (answering the phone, 64), would on average take just over 10 minutes longer to setup. Likewise, when setting up the upper limb functional tasks, the setup time for the least impaired participant (Participant 6, FM-UE 38) and the most impaired participant (Participant 1, FM-UE 18), would take on average and extra 25.6 minutes.

As derived from the regression analysis (Appendix 19), the equation to predict setup time is:

Predicted setup time = 59.042 – (1.28 x impairment) + (0.221 x task complexity).

A scatterplot of predicted setup times against measured setup times is displayed below in Figure 6.6.

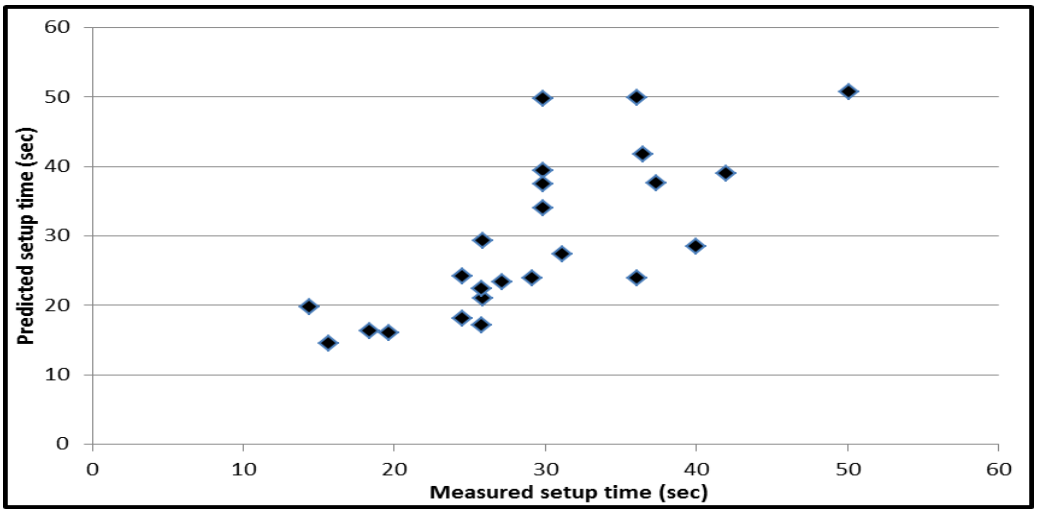


Figure 6.6: **Predicted setup times plotted against measured setup times**

6.5 Discussion

The literature has highlighted that adoption of health technologies has been notoriously slow, particularly in the NHS (Liddell, Adshead, & Burgess, 2008). If this situation is not to be further compounded, it is important for new rehabilitation devices to be quick to setup (Hochstenbach-Waelen, 2012). The challenges faced by therapists in the present health care climate in the United Kingdom are unprecedented (RCP, 2012; Ham, Imison, Goodwin, Dixon, & South, 2011), making the need to consider setup time for devices even more important.

As highlighted in the literature review in chapter two on usability methods (section 2.7.2), there are only a small number of studies that have examined the influence of setup time (Dijkers et al., 1991) in particular FES (Pedrocchi et al., 2013; Burridge et al., 2008). This study explicitly addressed for the first time the factors which might influence and subsequently help to predict setup time.

6.5.1 Participants' level of upper limb impairment

From the regression analysis, the participants' level of upper limb impairment, as measured by Fugl-Meyer UE, appears to have the greatest influence within the proposed model on the prediction of setup time for the UL FES Rehab Tool. Generally speaking the more impaired the participant, the greater the overhead in

terms of setup. Within the range of tasks selected, task complexity appeared to have less influence on set up time. This finding is consistent with the author's observations.

6.5.2 The model

6.5.2.1 Internal factors affecting setup time

a) Upper limb impairment

Although the proposed model and findings from the lab-based testing appear promising, it is important to recognise that the model only predicts 50.6% of the variance in setup time and hence needs refining. Other characteristics such as presence of spasticity, cognitive involvement or communication deficits can potentially impact on setup times. Although one of participants recruited for the lab testing had expressive language difficulties, this participant was well known to the testing team, resulting in minimal increase in setup time. Introducing other variables into the model at this stage of the development process was not possible as this would have required additional testing to gather more data. In addition, although the Fugl-Meyer UL scale was felt to be a reliable and valid measure of impairment, other measures of impairment may offer a more sensitive measure of impairment level. The model only applies to people with some form of neurological impairment. Clearly the model is invalid for people with no impairment.

b) Task complexity

Although task complexity also significantly contributed to the prediction of setup time, it contributed less than participants' impairment scores. The method of calculating task complexity provided a useful starting point that allowed exploration of the relationship between task complexity and upper limb impairment and subsequently the effect of these variables on setup. In the current study a pragmatic approach was adopted, that merely aimed to refine the scoring of the set of tasks, using two raters. However, as the method appears to have some merits, more formal reliability testing would be warranted. It is worthy of note that the proposed method is only applicable for the range of tasks included in the lab based testing. It remains to be seen how well the method generalises to other functional tasks.

6.5.2.2 External factors affecting setup time

There are other factors that potentially influence setup time for FES devices outside of the lab (Figure 6.2). Firstly the effectiveness of training that therapists receive is critical to effective use and indeed adoption of rehabilitation devices. Hochstenbach-Waelen, (2012) highlighted the need for therapists to become familiar with technology by spending time at workshops and learn from peers whilst using the device.

One way of mitigating against the impact of time away from patients in the clinical setting would be for rehabilitation technology to feature more prominently in therapists' pre-registration education. Presently there is only a small amount of time dedicated to rehabilitation technologies in the majority of pre and post qualification curricula.

Secondly, the usability of the software and indeed its level of robustness have the potential to influence setup times. In the current study usability factors such as the amount of support the GUI provided to the therapist was unchanged throughout testing. Although the software occasionally malfunctioned during the pilot testing, throughout the remainder of the testing the software was generally robust. Pilot data was discarded from the final analysis.

Finally, the model has only been developed for a single system (the UL FES Rehab tool). Further work would be needed to explore to what extent the two factors (impairment and task complexity) might influence setup time of other upper limb rehabilitation devices.

6.6 Limitations & conclusions

6.6.1 Limitations

In spite of the promising findings only a small number of participants were recruited for the lab based testing (n=6). The impairment profile of these participants was also quite narrow with all participants categorized as either moderate or severely affected. This meant that it was not possible to ascertain if the model would have generalised to participants with only mild levels of impairment. In addition, these participants were all in the chronic stage of stroke and therefore at this point it was not possible to

determine if the proposed model of calculating setup time would generalise to participants in the acute or sub-acute phases post stroke. Testing in the lab, in only a partially controlled environment, at times proved to be challenging when attempting to standardise the method for timing the setup process. However every attempt was made to ensure any disruption to the timing of setup was excluded from the setup time calculations.

6.6.2 Conclusions

This is the first model that has attempted to predict setup time for a rehabilitation technology, namely FES. The model, based on participants' level of upper limb impairment combined with a task complexity score, predicted initial setup time for participants in the chronic stage post stroke. However, further testing needs to be carried out on participants in the acute and sub-acute stages post stroke, and on those with only a mild level of impairment. In addition, it remains to be seen if the model will apply when the UL FES Rehab Tool is used in a real world clinical environment. Chapter seven, which describes the results of initial testing of the full system in a clinical environment, will also report on setup times and influencing factors in such an environment.

7 Chapter 7: Usability and feasibility testing of the final prototype upper limb FES Rehab Tool, in two sub-acute stroke rehabilitation centres.

7.1 Introduction

The upper limb (UL) FES Rehab Tool had been developed to its current status using an adapted usability engineering process, which encompassed four iterative development cycles (chapter 8, Figure 8.1): Chapter four, sections 4.2 to 4.5 described phase one of the process (Figure 8.1), in which four therapist advisory groups gathered therapists' views of their requirements for an UL FES Rehab Tool. Sections 4.6 to 4.9 described two phases of the design process. Firstly the software refinement, in particular the GUI, using both expert and novice FES users (phase two, Figure 8.1) and secondly the rapid prototyping of the full system, software and hardware with healthy participants (phase three, Figure 8.1). Chapter five outlined the continued rapid prototyping of the full system with six chronic stroke patients and the development of an early stage model to predict setup time of the device.

Although the early part of phase four testing highlighted a few additional software issues that warranted further refinement, the latter part of the testing had demonstrated that the software and hardware combined was stable. Any software crashes were very infrequent and when they did occur, it was usually due to a minor hardware malfunction. The GUI had consistently and effectively allowed the same research physiotherapist to setup the system with six moderate to severely impaired, chronic stroke patients. The final prototype system was deemed to be ready for the next stage of user evaluation. Figure 7.1 below displays the software and hardware components of the final prototype UL FES Rehab Tool.

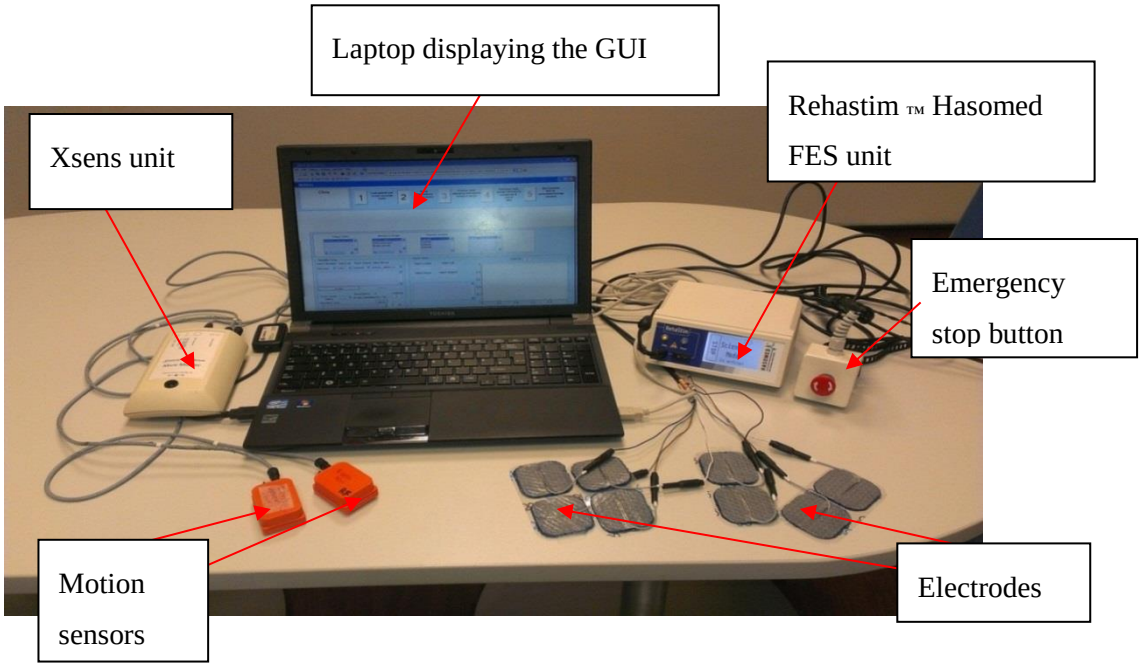


Figure 7.1: The final prototype UL FES Rehab Tool – software and hardware components

The International Standards Organisation (ISO) 9241-11 (ISO, 1997), part 11, includes context of use in its definition of usability…"Usability is the extent to which a product can be used with efficiency and satisfaction by specific users to achieve specific goals *in specific environments*." 'Context of use' is also encompassed within the ISO 13407 standard on user-centred design (ISO, 1999), and indeed is highlighted as one of the main stages of the user-centred design process. 'Context of use' includes analysis of users and other stakeholder groups, their characteristics, the tasks to be undertaken and the environment. Numerous authors have stressed the importance of testing health technologies (including medical devices) in real world settings (Sharples et al., 2012; Croll, 2009; Maguire, 2001).

The following section revisits the literature reviewed in chapter 2, section 2.8 which examined studies that had included usability evaluation of Advanced Neurological Rehabilitation Technologies (ANRT). The focus in section 2.8 was on the usability methods and tools employed. For this subsequent review, the usability test environment is examined in order to identify ANRT that were summatively tested in an acute or sub-acute clinical environment, report on their findings and identify any gaps. The final section of the review will highlight reasons for the novel approach adopted for the final study (phase five) of the usability engineering process.

7.2 Summative usability evaluation of Advanced Neurological Rehabilitation Technologies in a sub-acute clinical setting

In chapter 2 (section 2.8) 37 studies that included usability evaluation of ANRT were reviewed. Out of these, only 15 studies conducted summative usability testing in an acute or sub-acute clinical environment, where the device was ultimately to be used. The remaining studies were concerned with formative usability evaluation in laboratory environments, such as those found in a university research department. Of the 15 studies conducted in a sub-acute clinical setting, 10 of these included healthy participants and or patients, whilst only 5 incorporated therapists as part of the usability testing process.

7.2.1 Studies of usability from the patients' viewpoint only

Of the studies that focused primarily on patients' views of usability, 2 studies (Lloréns, Colomer-Font, Alcañiz, & Noé-Sebastián, 2013; Meldrum, Glennon, Herdman, Murray, & McConn-Walsh, 2012) examined the use of Virtual Reality (VR) and gaming systems on the re-education of balance. Testing for both studies was carried out in a rehabilitation gym of a local hospital. Lloréns et al. (2013), examined the usability of Biotrack, a VR balance system with 10 stroke patients using an ad hoc questionnaire. Meldrum et al. (2012), used the System Usability Scale (SUS) and a self-devised eight-item post-test questionnaire to survey 26 patients who had either sustained a stroke or suffered from vestibular problems. Patients were asked about their experience and opinions of the Nintendo Wii Fit (NWFP®) in comparison to more traditional methods of balance rehabilitation.

Crosbie et al. (2009) summarised the groups' extensive work over a period of 6 years, in developing virtual reality rehabilitation technology (including gaming) to promote both unilateral and bilateral exercises for the upper limb. This work included several patient case studies and a pilot randomised control trial (RCT). However, although there was involvement of therapists in the development of the system, the final summative testing did not specifically examine therapist feedback on implementation of the technology, nor report on setup time. Indeed, Crosbie et al (2009) stipulated that it would be useful to extend their work into this area.

Two studies (Cameirao, Badia, Oller, & Verschure, 2010; Kizony et al., 2006), conducted usability evaluations within a therapy department, on the use of gaming technology for rehabilitation of the upper limb. Cameirao et al. (2010) utilised a four item patient focused self-report questionnaire on 10 healthy control participants and 12 stroke patients, whilst Kizony et al. (2006), used the Short Feedback Questionnaire (SFQ) and the System Usability Scale (SUS) on 12 healthy elderly control participants and 4 stroke patients. Two further studies examined the use of robotic devices in rehabilitation departments, (Laffont et al., 2009; Colombo et al., 2007), and as with the previous studies, primarily focused on the patient experience and effectiveness of the device, rather than therapists' feedback on the device's usability and utility. One of the few studies that explored the use of Functional Electrical Stimulation (FES) in a rehabilitation situation, (Bijaka et al., 2005), using an eight channel lower limb device for people with paraplegia. Once again only patient feedback was sought from the 7 patients regarding the effectiveness of the device. This was despite the fact that the system was complex (involving up to eight channels of stimulation) and involved the use of a GUI for setup.

Due to the increasing pressure on national health resources, including therapists' time, there has been growing interest in the remote monitoring of patient rehabilitation programmes. Weiss et al. (2012) developed an upper extremity tele-motion system (the Gartner tele-motion rehabilitation system). As in previous studies, neither focused on the operator of the technology i.e. the therapists, in spite of therapists being central to the setting up of the devices.

A very promising rehabilitation technology developed by Timmermans et al. (2010) T-TOAT, based on the Phillips Research Stroke Rehabilitation Exerciser, incorporated inertial measurement units containing accelerometers, magnetometers and gyroscopes, worn in garments on the thorax, upper and lower arm, as well as real world interactive objects. The system provided instructions to the patient and gave real time and post task feedback. Testing was conducted in an out-patient rehabilitation centre on 9 stroke patients. However, the study predominantly examined the efficacy of the system and patients motivation to use the system. Although feasibility and usability was examined, again this was solely from the patients' perspective.

7.2.2 Studies of usability from both patients' and therapists viewpoint

As can be seen, none of the studies described above focused in detail on the impact of ANRT on therapists as operators of the devices. Only 5 out of the 15 studies reviewed considered usability from the therapists' viewpoint to any extent. The first two studies by Gil-Gomez, Llorens, Alcaniz, and Colomer (2011), and Kyoungwon, Kim, Lee, Jang, and Ryu (2011) had only minimal involvement of therapists. Gil-Gomez et al, (2011) issued a feedback questionnaire (SFQ) to 17 stroke patients in order to obtain subjective information about their Wii balance board technology to promote balance re-education. Although therapists were involved in evaluation of the efficacy of the system, they were only informally asked about its usability. Kyoungwon et al, (2011) included a novel approach to usability testing by devising core usability factors based on feedback from focus groups. However, the summative usability evaluation only asked three broad usability questions and no direct observation of therapists using the system.

The next 3 studies involved more extensive use of therapists as operators of the device. Whitworth et al. (2003) developed the Rutgers ankle rehabilitation system (RARS) which is a robotic device which includes a remote monitoring (telerehabilitation) subsystem. The system was developed collaboratively by engineers and a clinical scientist and was designed to be used by patients who had lower limb dysfunction, for example following a fracture or post-stroke. This was one of the few studies to include a therapist assistant as an operator of the device. Multiple users, operating multiple interfaces, were involved simultaneously in the usability evaluation. The local session had two users: an expert therapist-user and a patient-user. The remote monitoring involved three users. The same expert therapist-user, a therapy assistant and a patient-user. An instrument-specific usability questionnaire was administered as well as actual observations of use. Video of patients using the system and therapist-users using 'think-aloud,' allowed closer monitoring of users' thoughts and actions. Two novel usability methods were utilised, true-false questionnaires administered to therapist post-testing to ascertain their understanding of the system, and explanation of how to operate the system to the patient and a therapy assistant by the therapist-user. Although this study had many

novel usability features, it was based on single use, a limited number of therapist-users and did not examine setup time of the system.

Pedrocchi et al. (2013) developed MUNDUS, an upper limb exoskeleton, including a sensorised glove, with an 8 channel close-looped controlled Neuromuscular Stimulation unit (RehaStim™, Hasomed GmbH) and interactive objects. The system was aimed at individuals with high level spinal cord injury and neurodegenerative and genetic neuromuscular diseases, such as Friedreichs ataxia and multiple sclerosis. A choice of sensors was offered depending on the patients' level of ability. Surface EMG and/or a contra laterally patient controlled USB button, an eye tracking system or a Brain Computer Interface (BCI) could be selected. The overall system was governed by a state machine controller (MUNDUS CC) that utilised a GUI framework to guide the operator through the setup process. Therapists were involved in the performance evaluation of the device on the five patients (3 with a spinal cord injury and 2 with multiple sclerosis) in a hospital rehabilitation centre. They were asked to grade the amount of support offered by the technology from 0 = unsuccessful; 1 = acceptable and 2 = completely functional. The study did not look in-depth at operator usability. However, it did report on setup time as being between 6 and 15 minutes for the simplest configuration. More complex configurations took between 35-45 minutes to setup. The BCI took 20 minutes merely to calibrate the device. This study highlighted the importance of considering duration of setup time when developing ANRT. As reported in Chapter four, the therapist advisory group advised that setup times above 30 minutes are likely to be deemed excessive, and could impact on device utilisation. This study stopped short of examining in more depth the usability of the technology from a therapists' perspective. There was no direct observation of therapists setting up the device, nor feedback on setting up and using the device in a rehabilitation environment.

An extensive study, from a therapist usability perspective, of a rehabilitation device was carried out by Dijkers et al, in 1991. They reported on a field trial of a robotic system for rehabilitation of the upper limb, co-designed by Occupational Therapists and engineers. The study focused on safety of the device, its acceptance to patients and therapists and its utility to therapists. Eleven Occupational Therapists used the system with 22 patients (8 out-patients and 14 in-patients) over a period of 5 months.

Patient pathologies included recent stroke, Guillain-Barre´ Syndrome, traumatic brain injury, multiple sclerosis and amputation with a co-morbidity of chronic stroke. An average of 2.2 sessions per patient was administered. Therapists recorded their comments, system suggestions and system problems by means of a log situated next to the computer and this information was complemented by patient feedback forms and a therapist questionnaire, which asked therapists to estimate setup time and whether in their opinion this was satisfactory or not. Patient performance information was collected from the robotic systems database Although the system was judged not to be difficult to operate by therapists, they did report that it was time consuming, with 5 out of the 11 therapists estimating setup time to be 10 minutes or above and stipulating that setup cut into therapy time. However, the therapists were not directly observed using the robotic system as part of the evaluation process and setup time was only estimated. Although more subjective usability evaluation methods are useful to identify reasons for any usability issues, there can sometimes be a mismatch between users' subjective feedback and direct observation of practice.

In spite of the promise of this device, the Occupational Therapists maintained a critical stance to the technology due to problems with robustness of the system, and its inability to deliver sufficiently flexible therapeutic programmes that could be adapted for a broad range of patient abilities. One of the challenges faced by robotic devices has been their inability to deliver upper limb interventions that relate sufficiently closely to activities of daily living (ADL), particularly that include the hand as part of the system. As Occupational Therapists focus on restoring function in relation to ADL, promotion of functional activities by the device would be a highly desirable requirement. A previous study by Holt et al. (2007) found significant differences in the priority of design requirements for Occupational Therapists when compared with Physiotherapists and reinforced the need to conduct usability testing specifically with the ultimate end users of the device. More recently, Hochstenbach-Waelen (2012) discussed the practical and theoretical considerations for successful upper limb rehabilitation technologies, and reaffirmed the need for devices to be flexible, facilitate the successful achievement of functional tasks, be easy to setup and to function stably.

7.2.3 Conclusion

In summary, the studies reviewed predominantly examined usability from a patient's perspective and tended to focus on efficacy of the device. Only a small number (n=5) included therapists in summative usability testing, and none of these attempted to characterise the therapist in relation to their previous experience of using technology. Where training was provided for therapists prior to commencement of the study, most studies failed to describe the training in any detail or indeed evaluate its impact. Users' previous experience of technology has been shown to have an influence on its adoption and use (Venkatesh & Davis, 2000, 1996). In addition, although one study, Dijkers et al, (1991), did consider setup time as one aspect of usability, this was not directly observed or recorded. Consequently setup time has only received very limited attention throughout the literature on ANRT.

In the following sections, a novel in-depth usability evaluation is presented. In contrast to most of the previous studies, this study attempts to characterise therapists and therapy assistants' previous experience of using technology and directly observes them using the final prototype FES Rehab Tool, with patients in the sub-acute environment where their rehabilitation was taking place. Direct observation of end users working with prototype technology presents many challenges. However, as highlighted by Sharples et al. (2012), the importance of 'context of use' and usability testing in 'real world' settings should not be underestimated. In addition, it examines the functionality (effectiveness) and usability (ease of use) of the system, as both are equally important. The study includes objective and subjective measures of usability, including the time taken to setup the system. It also examines how effective the system is at enabling patients to practice functional tasks that they would not have been able to perform without the assistance of FES. This chapter presents the aims, methods and findings from the usability and feasibility testing of the FES Rehab Tool in two sub-acute clinical settings.

7.3 Study protocol

7.3.1 Aims

1. To determine the extent to which the UL FES Rehab Tool enables stroke patients with a range of impairments to perform functional tasks over and above those they can perform without FES;

2. To evaluate the usability of the UL FES Rehab Tool in two sub-acute, in-patient stroke centres and, hence the usability of the proposed GUI setup procedure;

3. To determine the cost in terms of time involved in setting up the test system and the training required, in order to effectively administer upper limb FES in the clinical settings.**Ethical approval**As the study involved both therapists and patients at local NHS trust sites, ethical approval was sought via the Integrated Research Ethics Application System (IRAS) to the National Research Ethics Service (NRES) Committee North West, Greater Manchester North (12/NW/0315) and Salford Royal Foundation Trust (SRFT) Research & Development Committee (2012/133neuro – 95988) (Appendix 12). The study was adopted onto the National Institute for Health Research (NIHR) Clinical Research Network Portfolio. Ethical permission was also gained from the University of Salford Governance and Ethics Committee (HSCR12/43) (Appendix 12).

7.3.3 Identification and description of clinical sites

The study was initially discussed in principle with clinicians at two local stroke centres (Centre A and Centre B). A pragmatic approach to the selection of clinical sites was adopted, as both centres had relatively easy access to sub-acute stroke patients with upper limb dysfunction and therapists assigned to their rehabilitation. Both sites were local to the University of Salford thereby reducing travel time to and from the centres.

Both stroke centres were research led and were felt to be proactive when it came to conducting clinical research of this nature. Each of the stroke centres were slightly different in their organisational structure, as Centre B's stroke unit incorporated an acute stroke unit alongside their sub-acute rehabilitation unit, whereas Centre A's acute stroke unit was entirely separate to the sub-acute stroke rehabilitation unit. The therapists at Centre B covered both acute and sub-acute units whereas at Centre A, the

therapists were predominantly based on the sub-acute unit. Both centres comprised a multi-disciplinary team which included a Stroke Physician, Nurses, senior and junior Physiotherapists and Occupational Therapists and a generic Rehabilitation (Therapy) Assistant (RA).

7.3.4 Therapist and Rehabilitation Assistant recruitment

All therapists who were responsible for the treatment of the stroke patients were given the opportunity to take part in the study. However, the Occupational Therapists at each site felt that the Physiotherapists were more conversant with FES and so deferred participation to the Physiotherapists and RA.

At each site, two physiotherapists and one RA (n=3) expressed an interest in participating. All therapists were provided with a Therapist Information Sheet explaining the purpose and content of the study prior to seeking consent. Therapists were given up to 48 hours to consider their involvement and all six therapists were subsequently recruited.

7.3.5 Training for Therapists and Rehabilitation Assistants

As the UL FES Rehab Tool and GUI were new to the therapists and rehabilitation assistants, a period of training was required in order to familiarise them with the equipment and the setup process. Before commencing the study, therapists were provided with a total of 1.5 day's training, spread over 3 sessions at the University of Salford. All training was delivered by research staff based at the University, including the thesis author. The training comprised the following elements:

a) Background information on FES for the upper limb;

b) Training on the use of the UL FES Rehab Tool, and the setup procedure;

c) Demonstration of the system on a stroke patient and training on the trial procedures, including screening and recruitment.

A post-training evaluation was conducted to identify the effectiveness of the training package and to ensure that therapists were sufficiently confident to proceed with using the UL FES Rehab Tool in their own practice area (Appendix 17).

7.3.6 Characterisation of Therapists and Rehabilitation Assistants

As highlighted in the literature review in section 7.2, very few studies have attempted to characterise therapists as operators of the rehabilitation technology and in particular, their disposition to using technology. In order to address this issue, first a purpose designed therapist / RA profile questionnaire was administered to record the therapist / RA characteristics. Once the final training session had been completed, a widely validated measure, the Technology Acceptance Model questionnaire, training version (TAM), (Davis, 1989), (Appendix 13), was distributed in order to ascertain therapists' predisposition to using the technology, prior to commencing the study. TAM encompasses two categories: 1) perceived usefulness (PU) - the extent to which a user believes that using the system will enhance their job performance and 2) perceived ease of use (PEU) – the extent to which using the system is free of effort. TAM has been used as a predictive measure of technology usage and behaviours for over a decade, establishing it as a robust and reliable tool. The TAM was re-issued to therapists once the study was completed in order to establish if there had been any shift in their perception of the technology.

7.3.7 Patient recruitment

The therapists from each stroke centre recruited into the study along with a member of staff from the Greater Manchester Stroke Research Network, who predominantly consented patients into the study and undertook the clinical measures. The inclusion and exclusion criteria were drawn up following consultation with medical staff and therapists at both centres. Patients were screened for their eligibility to enter the study according to the following inclusion, exclusion, and areas to be discussed with study co-ordinator criteria.

Inclusion criteria:

- Stroke
- Medically stable
- Sufficient cognitive ability to understand the experimental protocols
- Over 18 years of age

- Lower than 7 on the Chedoke McMaster Stroke Impairment Scale (Gowland et al., 1993)
- Able to tolerate a minimum of 20 minutes of therapy (to allow for setup time)
- Adequate motor response to surface stimulation and able to tolerate sensation.

Exclusion criteria:

- Premorbid orthopaedic, neurologic or other medical condition including poorly controlled epilepsy, which would affect the response to electrical stimulation
- Cardiac demand pacemaker or other active medical implant/device that may be affected by FES
- Fixed contractures of elbow, wrist or fingers
- Cancerous tumour on affected upper limb (s)
- Pregnancy
- Broken skin on affected upper limb (s).
- Easily fatigued
- Become medically unstable during the study
- Wish to withdraw from study.

Criteria to be discussed with study coordinator:

- Diabetic neuropathy affecting upper limb sensation
- Painful shoulder
- Current treatment with botulinum neurotoxin

All patients who were potentially eligible to take part were provided with an information sheet explaining the study prior to seeking consent. The information sheet was compiled following consultation with the patient and carer advisory group.

Patients were given sufficient time to consider the study before consent was sought (up to 48 hours). They were reassured that they could leave the study at any time without it affecting their standard rehabilitation programme. For patients who were not eligible, the reasons for non-recruitment were also documented.

7.3.8 Characterisation of patients

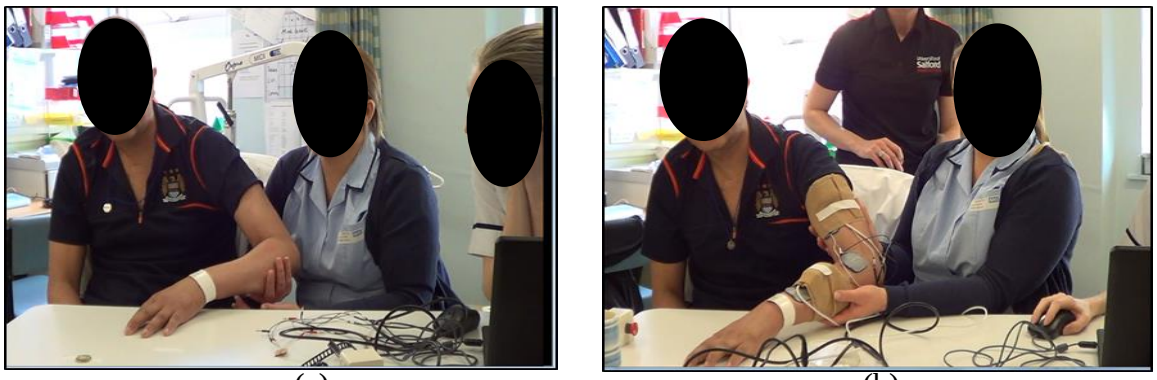
Prior to the first treatment session therapists recorded the patients' level of impairment in the affected upper limb using a well-established and reliable measure (Fugl-Meyer UE Scale) (Fugl-Meyer et al., 1975).

Patients who met the inclusion criteria across both centres, and who had given informed consent were recruited into the study. Patients remained in the study for up to two weeks. Patients were reviewed in accordance with their medical stability throughout the study.

7.3.9 Data capture

Data was captured by three research physiotherapists from the University of Salford, trained in the use of the UL FES Rehab Tool. This included the author of the thesis who recorded the majority of the data. A team of researchers was required to ensure that data capture could occur whenever a patient was available at either of the centres. In addition, a PhD student who was responsible for writing the FES controller software was on-hand in case software or hardware difficulties occurred. Due to the prototype nature of the system, and the relatively short training period, it was felt to be advantageous to have a research therapist and technical support on site. However, this was only accessed in the eventuality that the therapists required support (any support provided was documented). Under normal circumstances, the therapists and RA used the FES system independently.

In order to capture therapist behaviours during the setup process, and to record their views on the setup procedure, a video camera was utilised. Patients were requested to attempt the functional task with and without FES. Both movement sequences were recorded (Figure 7.2).



(a) (b)

Figure 7.2: Patient attempting the 'reach for coins' task (a) with and (b) without the UL FES Rehab Tool.

7.3.10 Procedure used during setup and practice

Due to the prototype nature of the system, the hardware (laptop, Rehastim Hasomed and Xsens), was connected and started up for the therapist by the research team. Once the patient was positioned comfortably and ready to start the session, the therapist who was designated to use the FES system began to set up the system using the GUI. It was important to observe and record two principal outcomes for the UL FES Rehab Tool during both setup (stages 1-4) and practice (stage 5). The first was to determine the extent to which the UL FES Rehab Tool enabled stroke patients with a range of impairments to perform functional tasks over and above those they can perform without FES, and secondly to evaluate the usability of the UL FES Rehab Tool and, hence the usability of the proposed GUI setup procedure. In order to aid clarity, for the remainder of the chapter these two outcomes have been referred to as i) the functionality (effectiveness or robustness) and ii) the usability (ease of use) of the system.

a) Setup functionality

At the start of each session an agreed functional task (or component of a task), was selected by the treating therapist. The therapist used the GUI to commence setting up the task for the practice session. Data recorded were the task, number of movement phases; number of channels with corresponding muscles, number, type and location of sensors, and for each phase, the number of distinct stimulation targets and type of transition e.g. angle, button or time out.

The task performance was documented by the therapist using an FES Task Attainment form (Appendix 14). The attainment form described the task and allowed the therapist to score the performance of the task with FES relative to the patient's performance without FES assistance.

b) Setup usability

An assistive evaluation approach was employed, whereby therapists were only prompted by the researcher if they encountered difficulties during the setup procedure. This approach served to capture the usability information and also ensured that therapists were supported whilst using the device, where it was required. The extent of support required by the researchers was recorded using a usability data collection proforma similar to that used in phase two. Quantitative data such as number of times that assistance was required, time taken to complete each stage of the setup procedure and number and type of therapist errors were recorded. Therapists were encouraged to offer feedback on their reasoning, intuition and feelings whilst using the FES system ('think-aloud').

c) Practice functionality

Task completion of the UL FES rehab Tool during therapeutic sessions was deemed to be critical to its' success. As such, how often tasks were aborted and how often the setup parameters required readjustment were recorded. Reasons for any readjustment were also recorded. Task completion was quantified by calculating the number of successfully achieved FES-assisted repetitions divided by the total number of repetitions attempted. Reasons for partial or non-completion were documented.

$$\text{Task Completion Score (\%)} = \frac{\text{Number of successfully achieved FES assisted repetitions} \times 100}{\text{Total number of assisted FES repetitions attempted}}$$

d) Practice usability

Usability of the FES system during the practice session was measured by recording the extent to which the researcher needed to intervene to maintain the functionality achieved at the end of the setup procedures. Therapists provided verbal feedback on

the usability of the system which was recorded via a video recorder. The number and type of therapists (therapist or assistant) actively involved in supporting the use of the system was recorded on the usability data collection proforma, in order to determine resources required to deliver FES practice schedules.

7.3.11 Post-session feedback

A post-session semi-structured interview method was used to capture and verify data, and to act as a debrief and support mechanism for the therapist (Appendix 15). After the final practice session had been completed (maximum of two weeks), therapists were asked to complete the TAM post-intervention questionnaire to identify any changes in acceptance or ease of use of the FES system *(*Appendix 13*).* During the final week of the study (6 months) a validated usability tool, the Software Usability Measurement Inventory (SUMI) (Kirakowski & Corbett, 1993) was administered to each therapist / rehabilitation assistant in order to measure more global perceptions and opinions of the UL FES Rehab Tool (Appendix 16). SUMI consists of a 50 item questionnaire, devised in accordance with psychometric practice. The research from this tool has been developed into a standardised database containing over 200 profiles of different applications. The strength of this tool is that it allows comparison across various products and for different versions of the same product. The scoring of SUMI is done using a programme called SUMISCO. In the development of SUMI the main subcomponents of user satisfaction were identified as follows:

1. *Efficiency* - does the user feel the software is aiding them to perform the task quickly and efficiently?
2. *Affect* - does the user have a 'pleasant' experience with the software?
3. *Helpfulness* - does the software communicate in a helpful way particularly with respect to operational issues?
4. *Control* - does the user feel the software reacts in a consistent way?
5. *Learnability* - does the user feel the software is easy to learn or become familiar with?

7.4 Results

7.4.1 Participant characteristics

7.4.1.1 Therapist and Rehabilitation Assistant characteristics

Table 7.1 below details the characteristics of the therapists and RA recruited to the study. Four physiotherapists (PT) (two grade 7 and two grade 6), plus two RA were recruited to the study (NHS Careers), five out of six who worked predominantly with stroke.

The overall mean level of clinical experience treating stroke patients was 7.75 years (SD = 5.4). Only 2 of the therapists (both in centre B) had any previous experience of using FES and in both cases this was the Odstock Microstim. Only 1 therapist (PT3B) had used this for the upper limb and her use was described as "occasional". All therapists, and the RA who used the FES Rehab Tool, used a computer on a daily basis, for work and social reasons. [2]

[2] Although RA2 was recruited into the study and took part in the training, they did not use the FES Rehab Tool when back in their own practice area. As the questionnaire that collected the therapist & RA's characteristics was issued on their first use of the system, this resulted in some missing data for the RA2 at centre B.

Table 7.1: **Therapist & RA grade, level of experience in clinical practice, pre-study experience with FES and amount & type of computer use. A or B in the therapist ID depicts the centre. Key shown below.**

Therapist ID	Role & grade	Clinical experience		Previous FES experience				Computer use	
		Patients treated	Length (years)	Use of FES	Type of FES	UL/LL	Frequency	Frequency	Type
PT1A	PT, 7	Stroke	8	No	N/A	N/A	N/A	D	BW, SI, PR, S
PT2A	PT, 6	Stroke	6	No	N/A	N/A	N/A	D	BW, WP, SI, PR
RA1 A	RA	Stroke	2	No	N/A	N/A	N/A	D	BW, WP, SI, PR
PT3B	PT, 7	Stroke	15	Yes	Micro-stim	UL & LL	OC	D	BW, WP, S, PG, SI
PT4B	PT 6,	Stroke	10	Yes	Odstock Micro-stim	LL	O	D	BW, WP, SI
RA2 B	RA 4	MD	14	MD	MD	MD	MD	MD	MD
Mean (SD)			**9.1 (4.9)**						

Key to abbreviations: BW = browsing web; D = daily; F = fortnightly; M = monthly; MD = missing data; N/A = not applicable; O = once only; OC = occasionally; PG = playing games; PR = patient records; PT = Physiotherapist; RA = Rehabilitation Assistant; S = spread sheets; SI = social interaction; SD = searching databases; W = weekly; WP = word processing.

7.4.1.2 Patient characteristics

Patients were recruited into the study at both centres (centres A and B), according to the recruitment criteria, by the centre therapists and an independent physiotherapist employed by the Greater Manchester Stroke Association Network. Table 7.2 shows the breakdown for number of patients screened and subsequently recruited. A large number of patients were screened at each centre. Centre B had a greater throughput of patients and consequently screened over twice as many patients as Centre A. Only a very small number of patients were recruited in total across both centres (n=6).

Table 7.2: Number and gender of patient's screened and recruited at both centres. M= male; F = female.

Centre Code	Number of patients screened	Number of patients recruited
A	73 (30 M, 43 F)	4 (1 M, 3 F)
B	171 (95 M, 76 F)	2 (2 M)
Total	**244** **(125 M, 119 F)**	**6** **(3M, 3F)**

Table 7.3 below displays the reasons for exclusion from the study and the numbers excluded at each centre.

Table 7.3: **Reasons for exclusion and number of patients excluded at each centre**

Reason for Exclusion	Centre A	Centre B	Total no. of exclusions
No weakness	3	51	54
Medically unstable	18	31	49
Cognitive impairment	13	34	47
Discharge already arranged	9	8	17
Repatriated	0	17	17
Weakness resolved	0	10	10
Lower limb weakness only	8	1	9
Unable to tolerate stimulation	1	6	7
In-patient with other condition (not stroke)	5	1	6
Pre-morbid condition	5	0	5
No input required	0	4	4
Minimal upper limb weakness	0	3	3
Unable to tolerate 20 mins therapy	2	0	2
Tumour	2	0	2
Staffing issues	2	0	2
Painful upper limb	0	1	1
Pacemaker	0	1	1
Complex social issues	0	1	1
Skin integrity	1	0	1
Total	**69**	**169**	**238**

When examining the total numbers of patients excluded across both centres, no arm weakness (n=54) was the main reason for exclusion. The next most frequent reason was due to medical instability (n=49), followed by cognitive impairment (n=47). One of the main differences between the two centres was that Centre A did not have any

patients whose upper limb weakness resolved during their hospital stay, whereas centre B had 10. Centre B is a hyper-acute stroke service with a large and rapid turnover of patients, as opposed to Centre A which is predominantly rehabilitation focused, and has a smaller patient throughput.

Of the 6 patients recruited into the study (Table 7.4), the mean age was 74.5 years with a range of 46-88 years (standard deviation 15.1 years). The mean time since stroke was 6.8 weeks (standard deviation 6.6 weeks). There was an even split of male to female patients, with all patients exhibiting a right sided hand preference. Four patients presented with left sided hemiplegia and 2 with right sided hemiplegia. The mean Fugl-Meyer UE score was 43.2, range 8-65 with a standard deviation of 19.2. According to Michaelsen, Dannenbaum, and Levin (2006), mild impairment is deemed to be from 50 to 66 on the Fugl-Meyer UE scale; 20 to 49 is moderate impairment and below 20 severely impaired. Using this classification, 2 patients were mildly impaired (P2A & P3A), 3 patients were moderately impaired (P4A, P5B & P6B) and one patient had a severe level of impairment (P1A).

Table 7.4: Time since stroke, age (years), side affected by stroke, hand dominance, gender and Fugl-Meyer UE score per patient.

Patient ID.	Age (years)	Gender	Hand dominance	Time since CVA (weeks)	Affected Side	FM UL/66
P1A	46	M	R	20	L	8
P2A	88	F	R	4	R	65
P3A	81	F	R	1	R	54
P4A	80	F	R	5	L	47
P5B	70	M	R	5	L	45
P6B	82	M	R	6	L	40
Mean (SD)	74.5 (15.1)			6.8 (6.6)		43.2 (19.2)

7.4.2 Extent to which the FES Rehab Tool was used by therapists and possible explanatory factors

7.4.2.1 Usage

Each therapist and RA recruited to the study was invited to setup and use the UL FES Rehab Tool with patients recruited into the study at their centre. Therapists were encouraged to use the system as much as possible with as diverse a range of patients available. Table 7.5 below shows the amount of usage for each therapist / RA and each of the six patients. The RA at centre B (RA2B) did not use the UL FES Rehab Tool beyond the training period. PT1A used the system most frequently and RA2B the least frequently. Centre A, which recruited 4 patients used the system most frequently (10 sessions), an average of 2.5 sessions/patient. Centre B recruited 2 patients and used the system 3 times (average of 1.5 sessions/patient). Four of the therapists used the UL FES Rehab Tool for repeat sessions. A session was classified as a repeat session when the same task was performed by the same patient on more than 1 occasion.

Table 7.5: Frequency of use of the UL FES Rehab Tool for patients and therapists / RA

Patient ID	Therapist / RA ID						Total no. of sessions per patient
	PT1A	PT2A	RA1A	PT3B	PT4B	RA2B	
P1A	SC SC-R Mob P						3
P2A	PC-R PB	SC PC					4
P3A		SC					1
P4A			SC SC-R				2
P5B				PC PC-R			2
P6B					SC		1
Total no. of sessions / therapist	**5**	**3**	**2**	**2**	**1**	**0**	**13**
Total no. of sessions / centre	**10**			**3**			

Key to abbreviations: Mob P – picking up mobile phone; N indicates a newly created task not taken from the existing FES library; PB – pouring from bottle; PC – pushing up from chair; PC-R – pushing up from chair repeat session; R indicates a repeat session for the same task and patient; SC – sweeping coins; SC-R – sweeping coins repeat session.

From the library of 6 tasks created for the study, 3 were utilised. Of these, 'sweeping coins into the contralateral hand' was the therapists' most frequently chosen task (n=7), followed by 'pushing up from chair' (n=4) and 'pouring from a bottle into a glass' (n=1). On the third use of the system, one of the therapists from centre A (PT1A) elected to create a new task, 'Mob P', picking up mobile phone, in order to tailor the practice session to the patient's everyday function.

7.4.2.2 Post-training confidence questionnaire

Following completion of training, a questionnaire (Appendix 17) assessing the confidence of each participant to use the system, was administered. It consisted of 8 closed questions and 3 open-ended questions. Each of the closed questions asked therapists to rate their confidence (using a 5 point Likert scale) with respect to a single aspect of the setup (e.g. logging into the system, completing a stage of the setup process etc). A grade of 5 represented that they were confident in that aspect of the setup process and 1 represented that they were not confident. Consequently, the total maximum confidence score possible for each individual therapist was 8 x 5 = 40 (number of questions x maximum score per question). At this stage, each of the two centres had 2 therapists and 1 RA (total n=3 at each centre) participating in the study.

All individuals informally reported that they were satisfied with the training. Figure 7.3 below illustrates that the individual therapist confidence scores were comparable. However, overall both RAs scored themselves lower with the RA in centre B (RA2B) reporting the lowest level of confidence. The results of the open questions indicated that the practical component of the training was perceived to be the most useful.

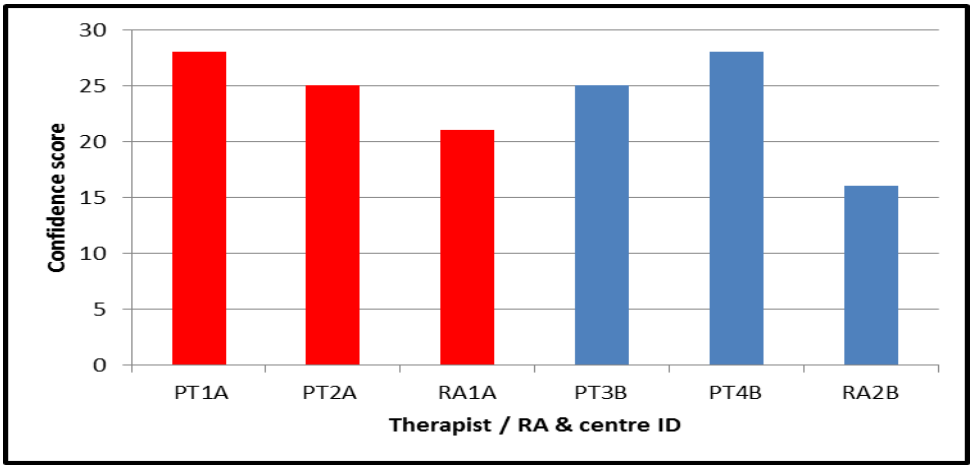


Figure 7.3: **Total post training confidence scores, per therapist & RA**

Key:

Centre A = Centre B =

7.4.2.3 Post-training Technology Acceptance Model (TAM) Questionnaire

The TAM questionnaire was distributed to therapists and RA immediately after the final UL FES Rehab Tool training session. It was used at this point in the study to provide an indication of the therapists and RA predisposition to using the proposed technology. The questionnaire was divided into two categories, 'usefulness' (U) and 'ease of use' (EoU), as explained in section 5.3.5. Each category had 6 statements, 12 in total. The scoring system used a five point Likert scale, anchored by a score of 1 'not all' which indicated a negative response, through to 5 'definitely', signifying a positive response. The maximum possible individual score was 60 with 12 being the minimum possible score.

Table 7.6 below displays the individual therapists and RA's total TAM scores in rank order (high to low).

Table 7.6: **Individual therapists' usefulness (U) and ease of use (EoU) TAM scores, in rank order of highest to lowest scores**.

Therapist ID	'U'	'EoU'	Total TAM score
PT2A	26	21	47
RA1A	23	23	46
PT1A	21	20	41
PT3B	17	18	35
PT4B	15	17	32
RA2B	8	9	17
Mean (SD)	**18.3 (6.4)**	**18.0 (4.8)**	**36.3 (11.1)**

An additional question (also scored on the same 5 point Likert scale) was asked at the end of the TAM questionnaire, to assess to what extent they felt ready to start using the FES system in the study. All participants responded to this question with a "3" (neither confident nor unconfident), except RA2B who gave a "1" (not at all confident).

7.4.2.4 Relationships between clinical experience, post training confidence and TAM scores and FES Rehab Tool usage

The relationships between the number of times the UL FES Rehab Tool was used by each therapist and RA, (normalised by the number of patients recruited, to account for the difference between the two centres) and their clinical experience with stroke patients, post training confidence scores, and TAM scores ('Usefulness' and 'Ease of use'), respectively are illustrated below in Figures 7.4, 7.5, 7.6 and 7.7.

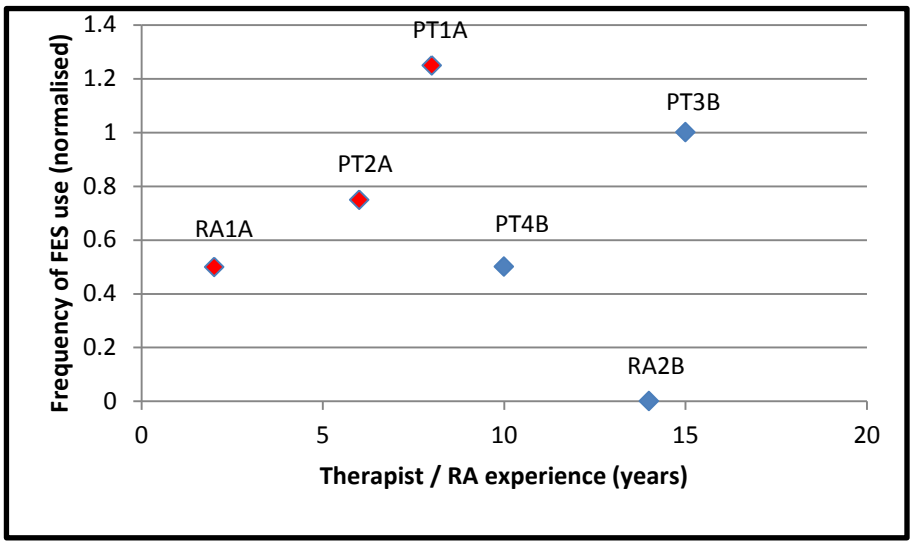


Figure 7.4: A scatter plot of frequency of use of the UL FES Rehab Tool (normalised for no. of patients recruited at each centre) plotted against therapist & RA experience.

There was no relationship between frequency of use and number of years of experience treating stroke patients (Figure 7.4). This was confirmed by a Spearman's rank-order correlation analysis r_s (4) = 0.000, which was not significant p<1.0.

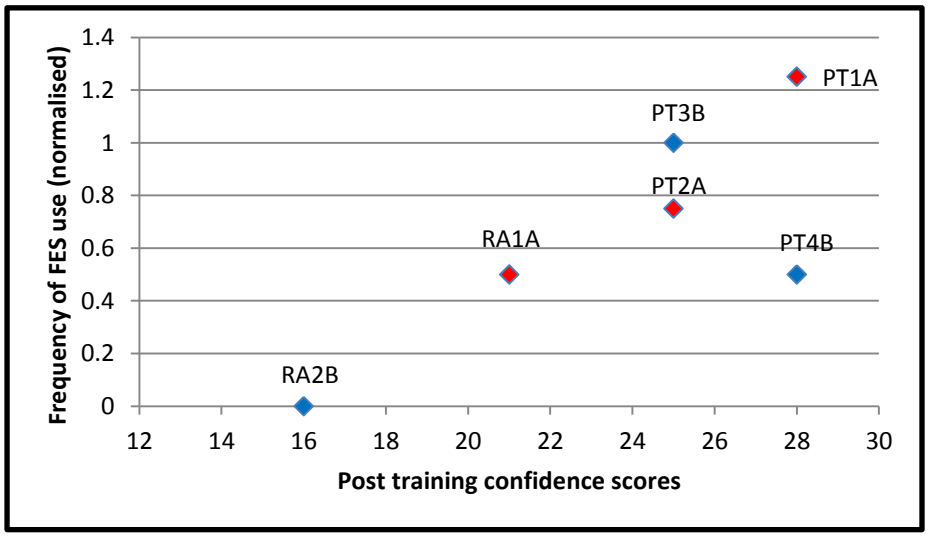


Figure 7.5: A scatter plot of frequency of use of the UL FES Rehab Tool plotted against the post training confidence scores (normalised for no. of patients recruited at each centre).

There was a moderately strong positive linear relationship between frequency of FES usage and post training confidence scores, r_s (4) = 0.642, p<0.169 (Figure 7.5).

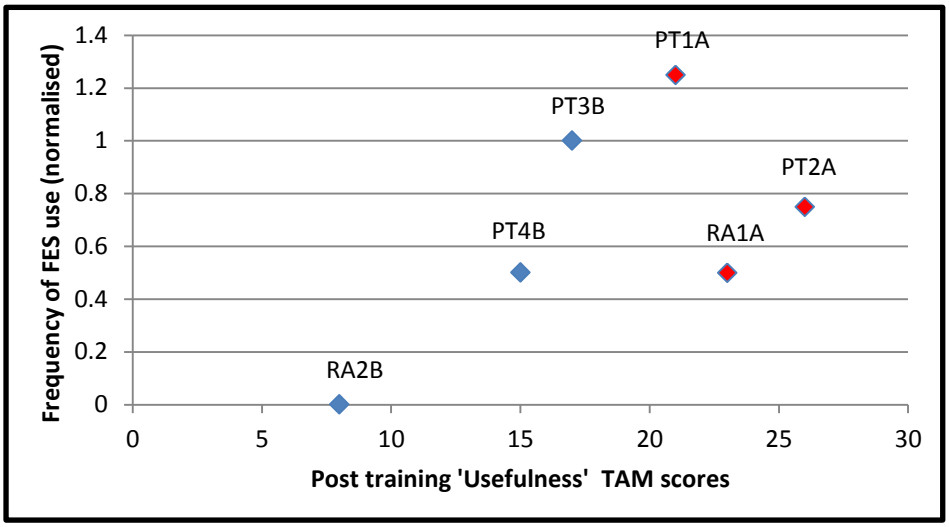


Figure 7.6: **A scatter plot of frequency of use of the UL FES Rehab Tool (normalised for no. of patients recruited at each centre) plotted against post training 'Usefulness' (U) TAM scores.**

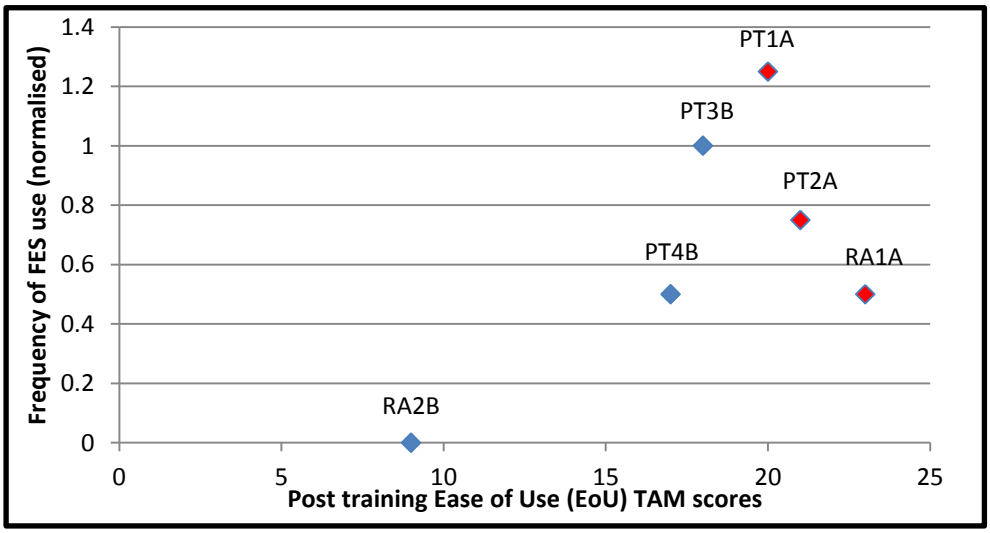


Figure 7.7: A scatter plot of frequency of use of the UL FES Rehab Tool (normalised for no. of patients recruited at each centre) plotted against post training 'Ease of Use' (EoU) TAM scores.

The final two figures (Figure 7.6 and Figure 7.7) display the post training TAM scores for 'Usefulness' (U) and 'Ease of Use' (EoU). Spearman rank-order analysis for frequency of FES use and TAM 'Usefulness' was r_s (4) = 0.464, p<0.354 and frequency of FES use and TAM 'Ease of Use' r_s (4) = 0.377, p<0.461. Both sets of data showed a negligible positive correlation (Mukaka, 2012).

7.4.3 Functionality

Functionality in this study was defined as the system's ability to deliver appropriately sequenced and pre-specified electrical stimulation to the patients' hemiplegic upper limb during functional tasks. Functional tasks were graded according to their complexity as described in chapter six, section 6.2.4.1. The higher the task complexity score, the more complex the task in relation to number of movement sequences. Task complexity scores for the tasks contained in the FES library ranged from 18 to 64 with a mean task complexity score of 44. The mean task complexity score for the 4 tasks used by the therapists and RA was 26.6 (SD 14), showing that the therapists tended to choose tasks with lower than average complexity scores.

As described in Sun (2014), we defined completion rate as:

"Number of successful repetitions of the task / total number of attempts at the tasks"

A total of 109 FES-assisted upper limb repetitions were successfully completed across all 13 FES sessions, (mean successful attempts = 8.3; SD 5.0), with 43 unsuccessful attempts (mean unsuccessful attempts = 3.3; SD 3.2). The mean % completion rate was 76.6% (SD 18.1), (min 42%, max 100%.). The 3 sessions with 100% completion rates were characterised by a relatively small number of repetitions (3, 1 & 4 respectively) and 2 out of 3 of these sessions used repeat tasks where the parameters from the initial setup had already been stored in the laptop. Table 7.7 below displays the type of tasks chosen by the therapists, the patients' level of upper limb impairment as measured by the Fugl-Meyer UE score, the task complexity score, number of successful FES assisted repetitions and unsuccessful attempts and the percentage FES task completion rate.

Table 7.7: Type of tasks, patients' Fugl Meyer UE scores, number of successful and unsuccessful UL FES assisted repetitions and task completion scores.

Therapist / RA ID	Patient ID & (FM-UE score)	Session No.	Task	Task complexity score	No. of successful reps	No. of unsuccessful attempts	Task completion rate (%)
PT1	P1A (8)	1	SC	18	17	7	71
		2	SC - R		9	7	56
		3	Mob P (N)	48	5	2	71
PT2	P2A (65)	1	SC	18	12	3	80
		2	PC	27	4	2	60
PT1	P2A (65)	3	PC-R		3	0	100
		4	PB	64	9	3	75
PT2	P3A (54)	1	SC	18	8	11	42
RA1	P4A(47)	1	SC	18	8	4	66
		2	SC-R		16	2	89
PT3	P5B (45)	1	PC	27	1	0	100
		2	PC-R		4	0	100
PT4	P6B (40)	1	SC	18	13	2	86
Total (T), Mean (M) & (SD)	**M=43.2 (19.2)**	**Total no. of sessions = 13**		**M = 26.6 (14)**	**T = 109; M = 8.3; (5.0)**	**T = 43; M = 3.3; (3.2)**	**M = 76.6% (18.1)**

Key to abbreviations: Mob P – picking up mobile phone; N - indicates a newly created task not taken from the existing FES library; PB – pouring from bottle; PC – pushing up from chair; PC-R – pushing up from chair repeat session; R indicates a repeat session for the same task and patient; SC – sweeping coins; SC-R – sweeping coins repeat session

Table 7.8 below displays the main reasons for non-completion of FES assisted tasks. Where attempts were unsuccessful, the main reasons were due to difficulties with triggering the transitions between movement phases. As discussed in Sun (2014), difficulties with attaining the pre-specified angle transition target, was the main reason for non-completion (n=31).

Table 7.8: Reasons for non-completion of upper limb reaching repetitions

Reason for non-completion	No. of non-completions
Angle not reached	31
Time out too long or too short	3
Patient error e.g. missed the object, hand stuck on plinth, lost balance	3
Patient not in sync with FES.	3
Hardware failure e.g. Xsens switched off	2
Therapist error e.g. failed to press start button	1
TOTAL number of uncompleted repetitions	**43**

In order to explore the relationship between patients' level of upper limb impairment and the number of successful FES repetitions, the impairment scores were plotted against the % task completion rates for each session. Figure 7.8 displays a scatter plot of % task completion rates against patients' upper limb impairment levels.

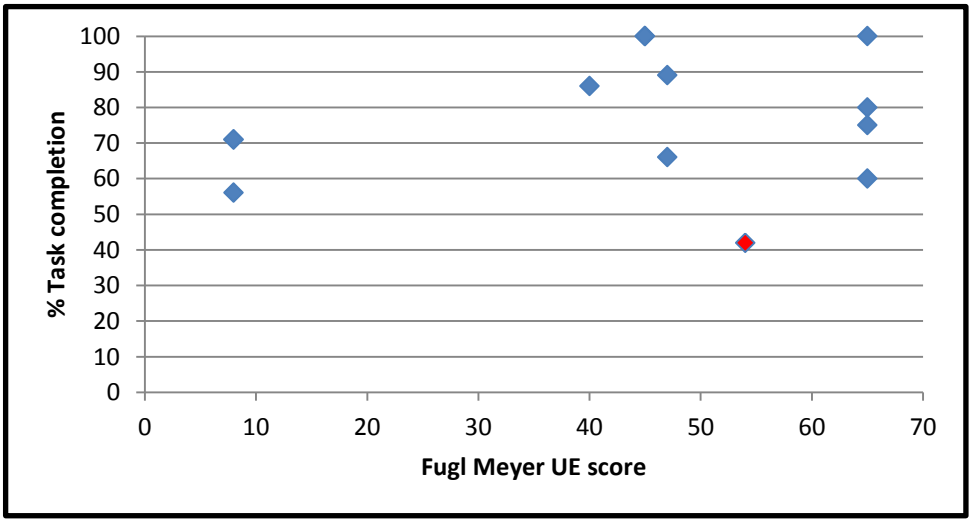


Figure 7.8: Scatter plot of Fugl-Meyer UE scores against % task completion rates. Outlier data point highlighted in red. [3]

[3] This data point was an outlier due to a hardware malfunction

There was a negligible positive relationship for task completion rates to increase for those patients' with a higher Fugl-Meyer UE score i.e. for those patients who were less impaired. A Spearman's rank-order correlation analysis indicated r_s (11) = 0.091, p<0.769. When the outlier data point for P3A was removed (highlighted in red in the scatterplot), r_2 (11) increased to 0.21, p< 0.511 which indicated a negligible correlation. Neither analysis achieved statistical significance.

When this analysis was repeated for task complexity and % FES task completion rates, r_2 (11) = 0.297, p<0.325. Again, a negligible relationship was exhibited which did not achieve statistical significance.

As only one therapist (RA1A) used the FES Rehab Tool more than three times, there was insufficient data to explore whether % FES task completion rates tended to improve with repeated use of the system.

7.4.3.1 Task attainment

After each FES practice session had been completed, the therapist scored the task according to how effectively it had been achieved, using a study specific scale where: -2 = task aborted, unable to achieve goal; -1 = task partly achieved but not sufficiently beneficial to warrant use of FES; 0 = patients current level of ability without FES; 1 = task partly achieved, FES beneficial although task had to be adapted or movement facilitated by therapist; 2 = task fully and independently achieved.

Table 7.9: displays the FES Task Attainment Scale scores for each session. The score illustrates how effectively the patient achieved the functional task with assistance of FES as opposed to without. Mob P-N = picking up mobile phone; N = newly created task; .PB = pouring bottle; PC = pushing up from chair; R = repeat of same task; SC = sweeping coins.

Task code	Patient ID	FES task attainment score	Amount of therapy support required
SC	P1A	1	Needed significant facilitation of 1 therapist for shoulder & elbow.
SC-R	P1A	1	Needed significant facilitation of 1 therapist for shoulder & elbow.
Mob P-N	P1A	1	Patient required normalisation of tone in between repetitions and facilitation from 1 therapist.
SC	P2A	2	None
PC	P2A	1	Minimal facilitation by 1 therapist
PC-R	P2A	1	Minimal facilitation by 1 therapist
PB	P2A	2	High level patient who did not require facilitation
SC	P3A	2	None
SC	P4A	2	None
SC-R	P4A	2	None
PC	P5B	1	Required facilitation of upper limb by 2 therapists
PC-R	P5B	1	Required facilitation of upper limb by 2 therapists
SC	P6B	1	Needed some facilitation to ensure upper limb cleared table from 1 therapist. Verbal cues provided to ensure adequate elbow extension.

All scores were either 1 or 2 (Table 7.9), illustrating that all 13 uses of the UL FES Rehab Tool had enabled patients to achieve the FES assisted functional task, either with facilitation from a therapist (n=8), or independently (n=5). All patients achieved the functional task more effectively with FES than without FES for each therapist and RA.

7.4.4 Usability

7.4.4.1 Assistance needed by therapists to use the FES Rehab Tool

The following section presents the observational quantitative and qualitative usability (ease of use) data for the UL FES Rehab Tool collected during the setup process, (stages 1 to 4 of the GUI). Table 7.10 displays the number of times assistance was

required by therapists and the RA each time they setup the device. Whenever the therapist or RA had difficulty at any stage during the GUI setup process, a researcher was on hand from the University of Salford to provide assistance. The data has been grouped for each therapist and RA to allow closer examination of the number of times assistance was required across FES sessions.

Table 7.10: **Number of times assistance required during the setup process for each therapist and RA across FES sessions. Mob P-N = picking up mobile phone; N = newly created task; PB = pouring bottle; PC = pushing up from chair; R = repeat of same task; SC = sweeping coins.**

Session number	Therapist & RA ID				
	PT1A	PT2A	RA1A	PT3B	PT4B
	No. of times assistance required & task ID				
1	8 (SC)	5 (SC)	6 (SC)	7 (PC)	8 (SC)
2	1 (SC-R)	5 (PC)	1 (SC-R)	7 ((PC-R)	
3	4 (Mob P- N)	3 (SC)			
4	0 (PC-R)				
5	4 (PB)				
Median	**4**	**5**	**3.5**	**7**	**N/A**

The median value for number of times assistance was required was generally less for the therapists at centre A, when compared with centre B. There was insufficient data to demonstrate a trend in amount of assistance required by the therapists over time i.e. if there had been a learning effect.

Certain functions within the GUI, e.g. reset parameters in stages 2 (assigning FES channels and setting stimulation thresholds and maximum comfortable stimulation levels) and 3 (manually cycling through the FES assisted task) and the time out function, proved to be an on-going, albeit it low impact usability problem.

7.4.4.2 Setup time

Setup times were recorded for each stage of the setup process together with the overall setup time (stages 1-4), for each of the functional tasks. Table 7.11 below displays the overall setup times (min) for each therapist and patient per completed task, together with the mean setup times and their corresponding standard deviations. All setup times have been displayed, however the initial setup times have been marked with an asterix (*) as tasks that were repeated with the same patient are not applicable to the predictive setup time model.

On average, setup time in the clinical setting was much longer than in the lab (10 minutes), where the setup was done by the same physiotherapist with 6 months experience of using the UL FES Rehab Tool. The longer clinical setup times were in spite of the therapists choosing less complex tasks and having less impaired patients. The mean task complexity and impairment scores for the lab based testing were 41.25 and 29.8 respectively. In comparison, the mean task complexity and impairment scores for the clinically based testing were 23.61 and 42.2. The two therapists who repeated the initial setup more than once both showed improved setup times on subsequent occasions, even though the tasks were more complex, and in one case (PT1A task PB), the patient was also more impaired. This seems to indicate that it would be a good idea to allow therapists time to practice before embarking on any future clinical study, although our numbers are small and this needs further testing to establish how much practice might be reasonable to allow. Setup times for repeat sessions, were lower, (by up to a third) than initial setup times.

Table 7.11 Total setup times (min) for the FES Rehab Tool, The task complexity score shown in brackets alongside the task code. Initial setup times are marked with an asterix (*). FM-UE = Fugl-Meyer Upper Extremity Scale; Mob P= picking up mobile phone; PB = pouring bottle; PC = pushing up from chair; SC = sweeping coins.

Therapist ID	Patient ID (FM-UE)	Task and setup time (mins). Task complexity score in brackets			
		Task SC (18)	Task PC (27)	Task Mob P (48)	Task PB (64)
PT1A	P1A (8)	*47.48		*39.35	
		12.51			
	P2A (65)		15.29		*32.05
PT2	P2A (65)	*30.05	*26.21		
	P3A (54)	29.23			
RA1	P4A (47)	*31.0			
		10.44			
PT3	P5B (45)		* 56.56		
			20.18		
PT4	P6B (40)	*28.39			
Overall mean setup times (SD)		**27.0 (12.4)**	**29.56 (18.5)**		
*** Initial clinical mean setup times (SD)**		**34.23 (8.8)**	**41.3 (21.4)**		
Mean lab setup times (SD)		**22.7 (5.6)**	**31.4 (10.6)**	**No equivalent task**	**28.3 (18.6)**

7.4.4.3 Effects of task complexity and impairment on setup times

A scatterplot was conducted to visually examine the nature of any relationship between task complexity and setup times for the UL FES Rehab Tool, as recorded during the clinical testing (Figure 7.9).

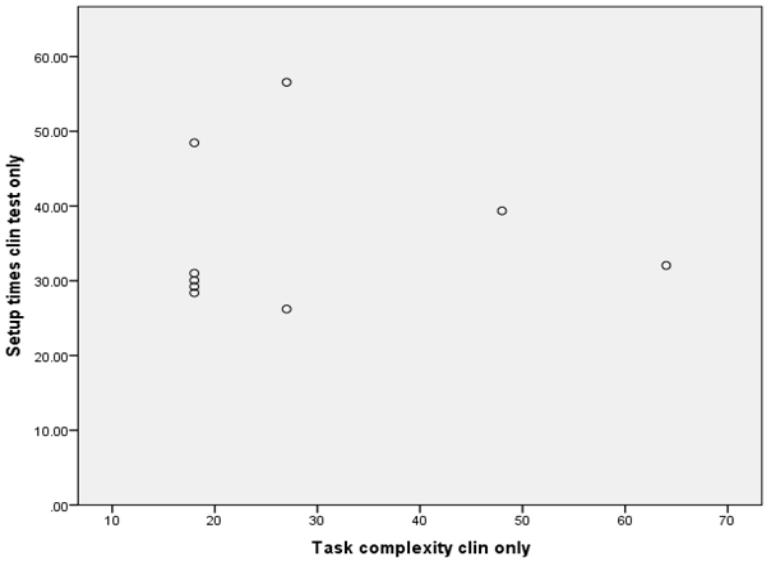


Figure 7.9: **Scatterplot of task complexity against setup times**

From the scatterplot there did not appear to by a relationship between these two variables. Therefore no further statistical testing was conducted.

A further scatterplot was carried out to examine any relationship between setup times and level of upper limb impairment. As can be seen from Figure 7.10 below, there appeared to be a weak negative correlation between these two variables.

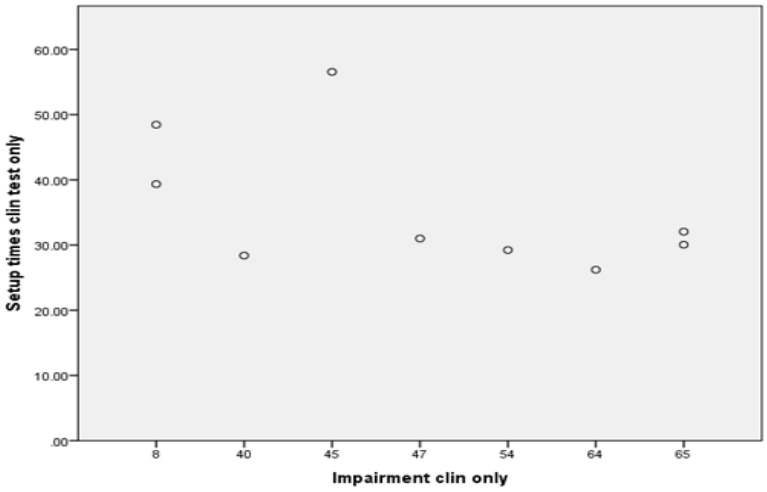


Figure 7.10: **Scatterplot of upper limb impairment against setup times**.

A Pearsons correlation analysis (Appendix 19) was carried out to examine the strength of the relationship. The Pearson correlation analysis did not confirm a statistically significant negative linear relationship between impairment and setup times, (-0.540). Low numbers plus the inclusion of therapists' first attempt, whilst still getting to know the system, is likely to have had an impact on attainment of statistical significance.

A linear regression analysis was not performed due to the absence of a clear relationship between task complexity and setup time, or upper limb impairment with setup time. In addition, there was insufficient setup time data from the clinical based testing to allow further meaningful statistical analysis. Only 2 of the therapists went on to setup more than 1 patient, making it difficult to establish any relationship between impairment and task complexity on setup time, and their relative contributions to the predictive model.

7.4.5 Post study data

7.4.5.1 Post-study TAM

Table 7.12 below displays the individual therapist and RA pre and post study TAM scores in rank order of highest (most accepting of technology) to lowest (least accepting of technology). The pre study scores are those taken following the training session. PT2A, PT1A and RA1A had the most favourable total TAM scores with a clear delineation to the next three scores for PT3B, PT4B and RA2B. As RA2B did

not use the UL FES Rehab Tool at their own clinical centre it was not possible to collect their post study TAM scores.

Table 7.12: Individual therapists and RA's pre and post usefulness (U) and ease of use 'EoU' scores, difference in pre and post 'U' and 'EoU' and total pre and post-study TAM scores, in rank order of highest to lowest scores.

Therapist ID	Pre U	Post U	Difference in pre & post U	Pre EoU	Post EoU	Difference in pre & post EoU	Total pre study score	Total post study score	Total TAM score
PT2A	26	20	-6	21	23	2	47	43	90
PT1A	21	20	-1	20	24	4	41	44	85
RA1A	23	17	-6	23	20	-3	46	37	83
PT3B	17	6	-11	18	18	0	35	24	59
PT4B	15	6	-9	17	14	-3	32	20	52
RA2B	8	MD	N/A	9	MD	N/A	17	MD	17
Mean (SD)	**18.3 (6.4)**	**13.8 (7.2)**	**-6.6 (3.7)**	**18.0 (4.8)**	**19.8 (4)**	**0.0 (3)**	**36.3 (11.1)**	**33.6 (11)**	**64.3 (27.7)**

The post- study 'usefulness' dropped across both centres. However this was most marked at centre B. The post study 'ease of use' remained similar across both centres.

7.4.5.2 Therapist post-session debrief questionnaires

On completion of each session, a post session therapist debrief questionnaire was completed. The questionnaire asked therapists to state their treatment goals, whether they had been achieved or not, describe what worked well in the session and where there were any difficulties. They were also asked to score the 'ease of setup' on a 5 part Likert scale, with a score of 1 indicating that it was very difficult and a score of 5 indicating very easy. Table 7.13 below displays the data. The full table of data can be found in Appendix 18.

Table 7.13: Total and median ease of setup scores taken from the post-session therapist debrief questionnaire.

	Therapist & RA ID				
	PT1A	**PT2A**	**RA1A**	**PT3A**	**PT4A**
Ease of setup score	3	3	3	2	2
	3	4	4	2	
	4	4			
	4				
Total setup score	**14**	**11**	**7**	**4**	**2**
Median	**3.5**	**4**	**3.5**	**2**	**N/A**

Therapists PT1A, PT2A and RA1A (at centre A) rated the FES Rehab Tool at 3 and above, showing that it was neither easy nor difficult (n=3) or easy (n=4) to setup. Therapists PT3B and PT4B at centre B consistently rated it as 2, indicating that they found it difficult to setup.

Out of 13 FES treatment sessions, on 12 occasions therapist reported that the treatment goals had been fully met. For the remaining session, treatment goals were partially met, as the therapist had to mobilise the patients upper limb in order to 'normalise' a potential increase in muscle tonus of the elbow flexors.

Difficulties encountered were, a) repeated need to adjust the angle trigger thresholds, b) difficulty co-coordinating the software whilst facilitating the patients' upper limb movement, c) timing out of the system during setup and occasional software / hardware malfunctions.

Qualitative feedback regarding what went well in the sessions included two patients' (P1A and P2A) responses, indicating their enjoyment with using the FES Rehab Tool and their increased level of engagement in therapy. Patient P2A also reported…… "*felt FES helped to lift my arm more effectively."*

7.4.5.3 Software Usability Measurement Inventory (SUMI)

The SUMI data was analysed using a programme called SUMISCO. The raw question data were coded, combined, and transformed into a Global subscale and five additional subscales, namely ***Efficiency*** (does the user feel the software is aiding them perform the task quickly and efficiently); ***Affect*** (does the user have a 'pleasant' experience with the software); ***Helpfulness*** (does the software communicate in a helpful way particularly with respect to operational issues); ***Controllability*** (does the user feel the software reacts in a consistent way), and ***Learnability*** (does the user feel the software is easy to learn or become familiar with). The scores are not percentages, but are graded against the database of previous SUMI evaluations. A z-score transformation was used to make the scales have an expected (population) mean of 50, and a standard deviation of 10. This allowed for usability comparisons across separate software applications.

Table 7.14 below displays the global SUMI score for each therapist and the rehabilitation assistant together with the individual scores across the five domains.

Table 7.14: **Therapists and Rehabilitation Assistant SUMI global, efficiency, affect, helpfulness, control and learnability.**

Participant	Global	Efficiency	Affect	Helpfulness	Control	Learnability
PT1A	59	50	60	67	51	48
PT2A	58	57	72	54	43	60
RA1	57	58	47	58	50	42
PT3B	50	48	57	46	46	51
PT4B	42	29	43	58	38	37

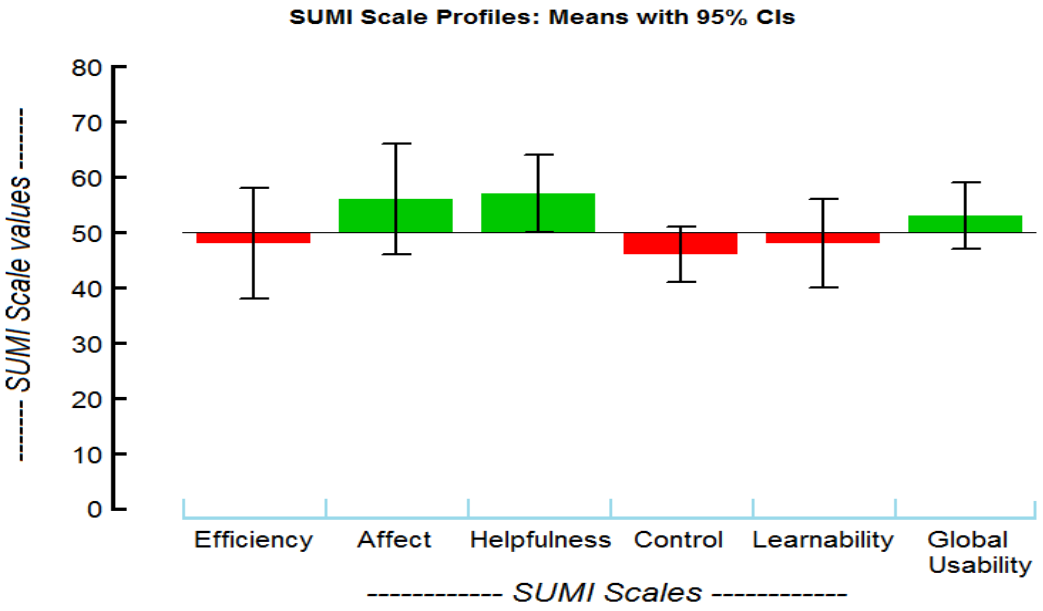


Figure 7.11: **SUMI Scale profiles**

From Figure 7.11 above it can be seen that three of the SUMI scale value scores, global usability, affect and helpfulness scored above the required usability threshold (mean of 50). However, controllability, learnability and efficiency fell below the threshold.

Therapists were asked to comment on what they liked best about the software (Table 7.15) and what needed most improvement (Table 7.16).

<u>Question</u>: What do you think is the best aspect of this software, and why?

Table 7.15: **Therapists and RA qualitative data regarding best aspects of the software**

Therapist ID	Comment
PT1A	Easy to follow prompts
PT2A	Display format
RA1A	Functional movement patterns, patient centred goals
PT3B	The storage of information to ensure most efficient use after initial setup
PT4B	Choice of tasks

Question: What do you think needs most improvement, and why?

Table 7.16: **Areas for improvement for the FES Rehab Tool**

Therapist ID	Comment
PT1A	Can't comment
PT2A	Making transitions between each stage of the programme
RA1A	Needs to be wireless
PT3B	Less wires
PT4B	Usability without technical support and reduce repeated steps

7.5 Discussion

7.5.1 Recruitment

Patient recruitment into the study was low despite the large throughput of patients, with upper limb weakness, particularly at centre B, the hyper-acute stroke centre.

However the screening figures need to be interpreted carefully, as screening was carried out differently across the two sites. All patients were screened at centre B, whereas only the patients that were deemed fit to progress on to rehabilitation were screened at centre A. For future studies a standardised screening tool will be developed to overcome this discrepancy. Although the same independent physiotherapist recruited patients into the study across both centres, often the initial screening was carried out by the study physiotherapist at each centre, which would have left recruitment open to the judgement of the study therapists. Although this study was not a randomised controlled trial (RCT), it mirrors some of the challenges reported in the literature for RCT's, where patient recruitment has been slower than expected. In a review of clinical trials funded by the UK Medical Research Council (MRC) and the Health Technology Assessment (HTA) Programme, only one third of trials recruited to their original recruitment target (McDonald et al., 2006).

7.5.2 Functionality

The first aim of the study was achieved, namely to determine the extent to which the FES Rehab Tool enabled stroke patients with a range of impairments to perform functional tasks over and above those they could perform without FES. The system was effectively used on patients with a broad range of impairments, from mild to severe (as measured by the Fugl-Meyer UE scale). In all cases the system allowed patients to achieve functional tasks more effectively than would have been achievable without FES. In one case (P2A) the system was used to prompt the sequencing of moving from sitting to standing, rather than a traditional upper limb functional task. Therapists tended to select functional task from the FES library that were less complex than average and thereby easier to setup, although one of the therapists (PT1A) was sufficiently confident in their ability to use the system by the third session to create their own task, bespoke to the patients' needs. This demonstrates how important it is for rehabilitation technologies to be sufficiently flexible to allow therapists and patients to choose tasks that relate closely to every day function (Hochstenbach-Waelen, 2012; Hayward et al., 2010).

The UL FES Rehab Tool achieved a mean completion rate of 76.6% for tasks once in the practice stage of the GUI (stage 5), demonstrating that on average on 3 out of 4 attempts, it successfully delivered appropriately sequenced and pre-specified electrical stimulation to the patients' hemiplegic upper limb during functional tasks. The main reason for non-completion was a failure to attain the pre-specified target angle necessary to trigger a transition to the next movement phase or 'state'. As explained previously, a new angle triggering method developed by a fellow PhD student, Mingxu Sun (2014) was incorporated into the FES Rehab Tool. This was because previous angle triggering methods had proven to be unreliable. Chapters 4 and 6 in Sun (2014), explains that this method is different in a number of ways. Firstly, it uses the change in angle on entering a 'state', rather than an absolute angle. Secondly it ignores readings where the magnitude of the acceleration vector is significantly different to the magnitude of the gravity vector i.e. 9.8 m/s^2. And finally, it requires 6 consecutive or non-consecutive valid readings before a transition is triggered. Although this new method is significantly more robust than previous methods, it is clear from the results in Table 7.8, and the SUMI feedback from PT2A

that further development is required to establish the optimum combination, particularly with respect to the second and third points. Due to insufficient uses of the UL FES Rehab Tool by all therapists, it was not possible to compare therapists' task completion rates over time. This would have allowed us to establish whether increased frequency of use, thereby assuming greater accuracy of setup, would have resulted in an improvement in task completion rates.

7.5.3 Usability

The second aim of this final phase of testing was to evaluate the usability of the UL FES Rehab Tool in a sub-acute stroke setting and, hence the usability of the proposed setup procedure. As highlighted in section 7.2, previous studies have relied on users to rate their satisfaction with rehabilitation devices (Meldrum et al, 2012; Cameirão et al, 2010; Weiss et al, 2012; Burdea et al, 2010; Llorénsa et al, 2013), rather than observing how they interacted with the system in a clinical setting. This study is the first in the UK to use direct usability observations of therapists in a sub-acute stroke rehabilitation setting to assess the usability of a complex rehabilitation system. Whilst challenging to implement in a busy clinical environment, often in small multipurpose rehabilitation departments, this method established that the GUI effectively allowed therapists with no software programming skills to setup a small range of FES assisted functional tasks. The SUMI data indicated that although the therapists were generally satisfied with the software, there were further improvements to be made in terms of its efficiency, controllability and learnability. The data mirrored the other data sets, in that there were some differences in how the two centres rated the system. Therapists liked the choice of tasks and the systems' ability to retain some of the setup parameters which made the system quicker to setup for subsequent practice sessions. Generally they found the setup easy to follow. Their preference for a future system was for it to be wireless where possible. This final phase of clinically-based usability testing demonstrated that the design and lab based prototyping work had been effective in producing an upper limb FES system that could be used effectively in real life clinical settings with stroke patients.

Even where therapists have been involved in usability evaluation studies (Mawson et al 2014; Pedrocchi et al 2013, Anacleto et al, 2013), their characteristics as users are

rarely examined. This is in spite of many authors highlighting the importance of understanding the pre-determinants of technology acceptance and usage (Liu et al., 2014; Chen & Bode, 2011). The Technology Acceptance Measure (TAM) was originally designed for use within information technology (Davis 1989). It is based on the theory of reasoned action (Ajzen & Fishbein, 1980; Fishbein & Azjens, 1975) and since its inception, has proven to be a robust tool to predict the acceptance and use of a broad range of technologies. Perceived ease of use (usability) and perceived usefulness are the principles that underpin the TAM. Research has shown that perceived ease of use is a determinant of a person's intention to use technology and has also been found to be a determinant of perceived usefulness (Venkatesh & Davis, 1996). This study is the first study to gather detailed information on therapists' characteristics, including their general computer literacy, and the TAM, in order to explore the potential relationship between frequency of use of an ANRT, the FES Rehab Tool, and these characteristics. Due to the nature of their roles, the therapists and rehabilitation assistant had a similar level of computer efficacy, as they were required to use computer systems within their workplace. It was not possible to collect computer experience data for the rehabilitation assistant at centre B (RA2B), as following the training they elected not to use the system in their own workplace. These findings were in agreement of those of (Liu et al., 2014), in that amount of experience treating patients and previous experience of using technologies, in this case FES, did not relate to frequency of usage. In this study a conservative approach was taken to analysing the frequency of use data due to the difference in number of patients recruited between the two centres. It was sensible to assume that where fewer patients were recruited, the less opportunity there would be to use the UL FES Rehab Tool, and hence the analysis normalised all usage data at each centre by the number of patients recruited.

It was interesting to note that therapists' low TAM and confidence scores were consistent with their subsequent non-use of the system. The results of the author's study have some similarity to the study by Liu et al, (2014) which used the Unified Theory of Acceptance and Use of Technology scale (UTAUT) to survey 91 Occupational Therapists (OT) and Physiotherapists (PT) at a large rehabilitation hospital in Canada. The UTAUT scale was developed by (Venkatesh, Morris, Davis,

& Davis, 2003), who developed the TAM. The aim of Liu et al's study was to examine the factors that influenced therapists' acceptance behaviour and usage of new technologies. Their findings confirmed those of previous studies (Heselmans, Aertgeerts, & Donceel, 2012; BenMessaoud, Kharrazi, & MacDorman, 2011), in that the most important factor for therapists when using technology is how it can help them in their work (performance expectancy). The amount of effort required to learn or use the technology (effort expectancy) was deemed to be less important. Previous studies have highlighted that effort-oriented constructs are more likely to be important in the early stage when using new technologies (Thompson, Higgins, & Howell, 1991; Davis, 1989).

There are some important differences between Liu et al's (2014) study and the authors'. The Liu et al. study centre had a large number of therapists (138) who regularly used rehabilitation technologies and had done so for more than 3 years. This situation is less common place in the United Kingdom. In direct contrast to the author's study, the main users of the technologies, particularly for upper limb therapy, were OT's as opposed to PT's. One finding that concurred across both studies was that the main barrier to using rehabilitation technologies was time constraints, sometimes as a result of limited staffing. In Liu et al's study (2014) 51.7% of therapists reported this to be the case. In the author's study, informal feedback regarding staff shortages at centre B appeared to have a direct impact on technology usage. In such cases, the length of time to setup the device becomes particularly important. In agreement with previous rehabilitation technology studies (Pedrocchi et al, 2013; Hughes et al, 2010), informal qualitative feedback from the patients who used the technology was very positive. Patients' acceptance and motivation to use rehabilitation technologies is an important consideration for therapists in their decision to adopt technology (Chen & Bode, 2011). Further studies, with more patients, are required to fully explore the potential relationship between frequency of use of this type of technology and factors that influence acceptance and usage. Other researchers, such as the Southampton FES group are recognising the importance of this relationship (Hughes et al, 2014).

7.5.4 Setup time

The final aim of the study was to determine the cost, in terms of time involved in setting up the FES Rehab Tool, and the training required, in order to effectively administer upper limb FES in a clinical setting. The literature review in section 2.8 of the thesis identified 3 studies that examined setup as part of the process (Pedrocchi et al, 2013; Fitzgerald et al, 2008; Dijkers et al, 1991), and only two of these (Pedrocchi et al, 2013; Dijkers et al, 1991) actually reported setup time, although in Dijkers et al, (1991), this was only estimated setup time. In the current study only the 'sweeping coins' and 'pushing up from a chair' tasks had sufficient initial setup time data to be compared with the lab based setup times. The average setup time for the clinical based testing 'sweeping coins' task was 34.28 mins (range 28.39-47.48) as opposed to 22.7 mins (range 14.50-29.33) for the lab based testing. Similarly for the 'pushing up from chair' task the mean setup time for the clinic based testing was 41.53 mins (range 26.21-56.56) as opposed to 31.4 mins (range 23.90-38.93). For both tasks setup time in the clinical setting took significantly longer than for the lab- based testing. This demonstrates the influence of training, regular use and familiarity with the technology on setup times. The therapists' advisory group reported that setup time should not take more than 30 minutes. By contract, Pedrocchi et al, (2013) reported setup times of between 6-65 minutes depending on the complexity of the configuration. Considering the prototype nature of the UL FES Rehab Tool, with its' multitude of wires and sensors, setup times for the system compare favourably when compared with technology of a similar level of complexity. Given the pressure on therapists' time to deliver rehabilitation, and therefore the importance of setup time for new technologies, a method of allowing therapists to predict setup time in advance of commencing FES assisted treatment could be extremely helpful.

Chapter six of the thesis proposed a model that allowed prediction of setup times based on the patients' level of impairment and the complexity of the task. The intention was to pool the setup time data collected from the clinical setting with that lab based data in order to strengthen the predictive model. However, when comparing setup times from the lab-based setting with the clinical testing, it was clear from Table 7.11 that factors other than impairment and task complexity were having a significant effect on setup time in the clinical setting. This difference in setup times

between the two studies was not surprising given that all therapists were inexperienced in using the system in comparison to the therapist that setup the system for the lab- based testing, who had the opportunity to use the system with 6 patients over a period of the approximately 6 months. A factor highlighted both in the literature (McHugh et al., 2013), and in the early study advisory group meetings, is the small amount of time available for rehabilitation of the upper limb. Continuing to build on this early work of a model to predict setup time would allow therapist to make informed choices regarding which task to select for the time available, thereby avoiding the situation where the therapist runs out of time to effectively complete an FES assisted treatment session.

Due to delays with patient recruitment, especially at centre B, training had occurred approximately 6 months prior to the start of the study. The importance of training and therapist confidence in using technology for therapists cannot be over stated. One way of addressing this current gap would be to introduce training on relevant rehabilitation technologies in the undergraduate curriculum for both physiotherapists and occupational therapists. It was notable in this study, that in spite of an invitation to be involved in the clinical study, the OT's at both sites declined the invitation. In some universities in the UK, the undergraduate curriculum for OT's is less likely to include rehabilitation technologies and there is less time dedicated to Anatomy in comparison to Physiotherapy. Both of these factors could be barriers to rehabilitation technology acceptance and use.

To date, rehabilitation technologies have not been found to be more effective at promoting upper limb recovery than intensive conventional therapies (Farmer et al., 2014; Burridge & Hughes, 2010). However, they might provide an opportunity for delivery of intensive training of the kind needed to promote upper limb recovery (MacLellan, 2011; Kwakkel, 2006; Boyd & Winstein, 2006) and free up valuable therapist time, allowing more patients to be treated. In 12 out of 13 sessions, two therapists were still required in order to effectively administer an FES-assisted practice session (one to setup the system and one to assist the patient) (Table 7.9). This was primarily due to patients requiring additional support in order to overcome the weight of the arm against gravity during a reaching movement. In these cases, FES alone could not generate sufficient proximal muscle recruitment i.e. around the

shoulder, requiring additional support from a therapist or rehabilitation assistant. In such cases, a de-weighting system such as the SaeboMAS might prove to be advantageous, thereby removing the need for the support from a second person. However, in the future this technology has the potential to offer other advantages over traditional therapies such as biofeedback, use of instrumented objects to aid incorporation of real life objects, and the ability to provide metrics to measure patient outcomes. The follow-on project from the NEAT LO30 project intends to incorporate these technological advances.

7.6 Limitations and future work

The main limitation of the clinical based study was the low number of patients recruited into the study (n=6), and subsequently the relatively low number of system uses (n=13). This made it difficult to draw robust conclusions about the influence of therapists' predisposition to using technology and their actual use of the system. TAM was chosen for this study due to its longstanding evidence base and ease of administration. However, a number of other measures have built on TAM's success e.g. USUAT, TAM2, and may be more inclusive of the social influences on technology acceptance (Holden & Karsh, 2010). The follow-on study to develop the next iteration of the UL FES Rehab Tool, will build on the authors' findings to further explore the relationship between therapists behavioural intentions and system usage. The importance of including rehabilitation technologies in therapists' undergraduate and post graduate education continues to be highlighted if rehabilitation technology is to become part of main stream clinical practice. Future studies could explore the amount and nature of rehabilitation technology that is included in therapist educational programmes in order to address this gap.

The low number of patients exposed to the system also restricted the ability to include the clinical setup time data into the data collected during the lab based testing. Future studies would allow sufficient time for therapists to use the system over a longer period of time, and will include collection of setup time data. Longitudinal studies that capture the realities of using rehabilitation technologies in clinical environments are urgently needed (Hughes et al, 2014). Observing technology usage in early supported discharge environments should also maximise patient recruitment

rates and avoid the situation whereby rapid discharge of patients from sub-acute settings makes access to patients problematic.

The clinical study did not utilise a standardised screening tool across both centres which made it difficult to compare patient recruitment rates, and the factors that influenced recruitment patterns. In the future a standardised screening tool will be adopted, to include recording not only patient characteristics, but also their duration of time receiving rehabilitation.

Although the therapists at centre A were very positive about the system, the prototype nature of the UL FES Rehab Tool with its numerous wires and sensors could have influenced therapists' perception of the technology, particularly at centre B. Therapist have requested that future system be wireless wherever possible. Although the angle triggering system used in this study was an improvement on those used in a previous study (REAcH), further minor modifications could potentially improve the systems functional robustness. The future FES system plans to include biofeedback and patient outcome data to further enhance the benefits available to therapists and patients.

Finally, in cases where patients' level of upper limb impairment was severe, the muscle activity generated by the FES Rehab Tool was insufficient to overcome the weight of the arm. This impacted on the systems' ability to reduce the number of therapist required to effectively deliver FES assisted therapy. The next study will explore the use of a de-weighting system in order to maximise the potential of upper limb FES assisted therapy.

7.7 Conclusions

In spite of the prototype nature the UL FES Rehab Tool, it was able to effectively deliver FES assisted upper limb task oriented therapy to a range of stroke patients. The inclusion of biofeedback and clinical outcome data in the next generation of the UL FES Rehab Tool will further enhance its rehabilitation potential.

Although it was challenging to conduct usability evaluations in busy sub-acute clinical environments, where patient turn-over was rapid, the usability methods adopted proved to be invaluable in capturing objective and subjective feedback from therapists, and to some extent patients. This study was the first in the UK to use

usability observations to directly observe therapists actually using a complex rehabilitation technology in a sub-acute rehabilitation environment, and to attempt to examine the factors influencing system usage. It adds to the growing body of evidence that highlights the importance of capturing therapist characteristics and in particular their predisposition to using technology (Hughes et al, 2014; Liu et al 2014; Chen & Bode, 2011). These methods can be generalised to other studies seeking to explore the usability of new forms of rehabilitation technologies. Further examination of the best tools and methods to study the factors influencing usage are required.

The model to predict setup time for the UL FES Rehab Tool is the first of its kind. Considering the scarcity of resources and the pressure on therapists to deliver rehabilitation programmes, continued development of this model would be advantageous and should help to inform rehabilitation technology usage.

8 Chapter 8.0: Summary of the thesis and future work

8.1 Discussion

8.1.1 Introduction

Chronic physical impairment of the hemiplegic upper limb occurs in an estimated 50-70% of stroke patients (Gebruers et al., 2010). Patients place a high priority on regaining upper limb function (Barker & Brauer, 2005), however current therapy is insufficiently intensive (The Intercollegiate Stroke Working Party, 2014), often not task-oriented and hence poorly aligned with the evidence base. Functional electrical stimulation (FES) has the potential to not only increase the intensity of task-focused therapy (Hughes et al., 2010), but also provide certain unique features, notably direct excitation of lower motor neurons (Rushton, 2003). However, current FES systems are limited in their functionality and/or difficult to use. Systems are also poorly aligned to therapists' ways of working and as a consequence uptake remains limited.

The author's PhD work ran in parallel with that of a fellow PhD student (Sun, 2014), both of which were aligned with a New and Emerging Assistive Technology (NEAT LO30) grant. Sun's role was to write the software and develop engineering techniques for robust triggering of the FES system. The author's role was the usability engineering work that informed the design of the GUI, and the laboratory and hospital based usability evaluation of the UL FES Rehab Tool.

This chapter will summarise the key points covered within the thesis, namely a review of the usability methods employed across all phases and how this compares with the current literature; a summary of the impact that the usability engineering approach had on the final FES system design, and how this has informed the subsequent NIHR i4i funded project; the importance of short setup time for devices and the advantages and challenges of implementing a model to predict setup time in a clinical setting; and finally the importance of education / training in rehabilitation technologies within undergraduate and post graduate curricula as a means of encouraging uptake of rehabilitation technology within main stream, clinical practice.

8.2 Review of the thesis

8.2.1 Usability methods: what worked and what didn't

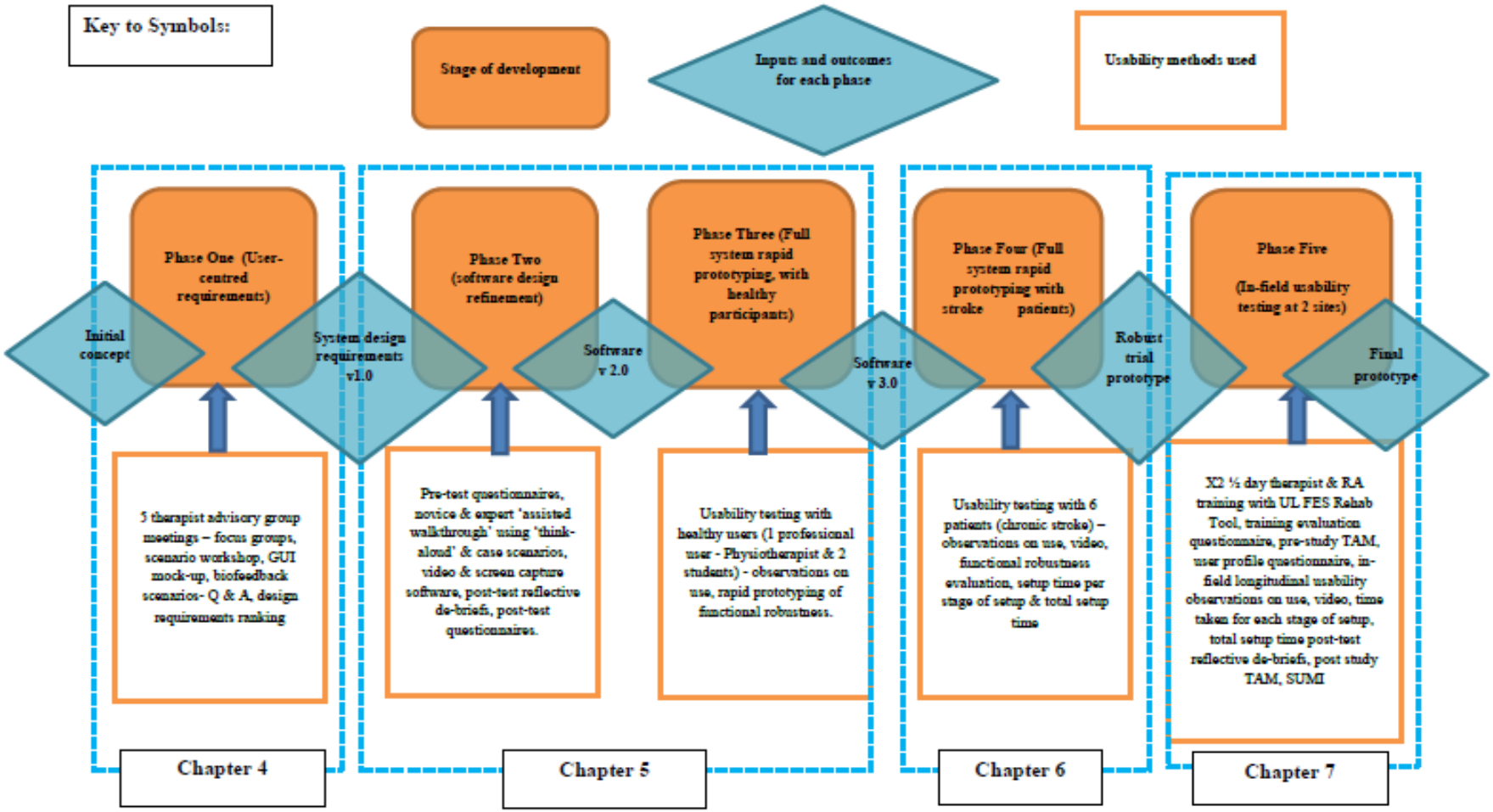


Figure 8.1: UL FES Rehab Tool development lifecycle, inputs and outputs and the associated usability evaluation methods for phases 1-5, based on Money et al, (2011).

Figure 8.1 displays all five phases of the iterative usability development cycle and the corresponding usability methods. The design inputs and outputs are clearly highlighted from initial concept through to the final working prototype that was used by therapists and rehabilitation assistants in two sub-acute, stroke settings. The five therapist advisory group meetings used a combination of methods, namely focus group discussions, patient scenarios and mock-ups of the GUI as advocated by previous authors (Mawson et al., 2013; MATCH, 2010). The level of user involvement has been described as a continuum, ranging from informative, through to consultative and finally participative (Damodaran, 1996). Managing multi-disciplinary groups and their respective expectations of the benefits of user involvement in the design process has been shown to vary (Williamson et al., 2015) Acting as 'the bridge' between the therapists and the design team required some compromises in order to ensure that a functional prototype system was developed in time for the proof of concept clinical trial. The therapists 'wish list' for their ideal FES system had to be balanced against the logistics of project deliverables. For example it was not possible to include biofeedback and patient performance data in the current version of the UL FES Rehab Tool. However, it will be incorporated into the subsequent version of the device. In addition, the data generated in the advisory group meetings covered a wide spectrum of topics, making analysis time consuming. However, this was made easier by imposing a design-focused high level structure on the data.

The novice and expert assisted walk-throughs of the GUI (hardware independent) using 'think-aloud' successfully identified a significant number of usability issues. The relevance of these scenarios was helped by the use of patient-scenarios, adapted from those used in the second advisory group meeting helped to add a more realistic feel to the usability testing. This stage of testing generated a large amount of data that was challenging to analyse and the lack of agreement within the literature about how to analyse such data compounded this difficulty. For example the ranking of usability problems is still in its infancy with no 'gold standard' method to adopt. Further, the comprehensive range of usability methods was, as previously reported, time consuming to administer (Travis, 2009; Hornbæk, 2006), and hence a smaller subset of measures would be used in a future study.

However, the ranking of usability issues proved to be effective when it came to prioritising which usability issues to address. Observational data combined with qualitative data from the post-test questionnaires provided a more rounded view of the key usability issues. This is agreement with approaches advocated within the literature (Horsky et al., 2010).

The testing on healthy participants was useful to identify and rectify software 'bugs', but more importantly to identify important functionality issues. Pre-prototype testing has been advocated as essential to avoid costly system failures (Davis & Venkatesh, 2004). The lab-based usability testing involving patients with stroke, allowed further direct observation of users' behaviour with the complete FES system. This was successful at uncovering a number of practical difficulties. Extending the testing to more severe patients may have helped to uncover more issues, but the logistics were too challenging for this study. However, the process reassured the team that the prototype UL FES Rehab Tool was safe and ready to use in a clinical environment, where it was hoped that the system would be used with a more diverse range of patients with stroke. And finally, the testing with stroke patients allowed the author to develop an early model to predict setup time for the UL FES Rehab Tool. Although it requires further refinement and testing with both the UL FES Rehab Tool and other rehabilitation technologies, it is the first development of such a model.

Direct observation of therapists and rehabilitation assistants setting up and using the UL FES Rehab Tool in two sub-acute environments provided a real-world view of the usability and functionality of the system. The direct observations combined with post-test subjective feedback and quantitative data on effectiveness of the device provided important data that has informed the subsequent i4i funded project (currently underway). Although a formal 'think-aloud method was not used due to avoiding over-loading therapists whilst dealing with patients, therapists naturally voiced their views when setting up and using the system. The small number of patients and overall uses of the system made it difficult to formulate definitive conclusions about the differences between the two centres. However, both TAM and post-training confidence scores did appear to show promise when it came to predicting usage of the system. Technology acceptance measures have developed in recent years culminating in the Unified Theory of Acceptance and Use of Technology scale (UTAUT)

(Venkatesh, Morris, Davis, & Davis, 2003). The theory underpinning UTAUT has four constructs: 1) performance expectancy, 2) effort expectancy, 3) social influences, and 4) facilitating conditions. The first three constructs are deemed to be direct determinants of usage intention and behaviour, whilst the fourth is a direct determinant of use behaviour. These all-encompassing constructs make the UTAUT a more comprehensive measurement tool. However, this advantage needs to be balanced carefully against its longer administration times. Some of the scales used within the final study, for instance the FES Task Attainment Scale, were devised by the author, due to the lack of independent validated evaluation tools for ANRT's and in order to meet the requirements of the study. This difficulty has been noted in other studies who also advocate further development of tools designed in collaboration with therapists, engineers and people with stroke (Hughes et al., 2011). Inclusion of the SUMI in the authors' study was an attempt to offset the difficulty of a lack of validated measures. However, although SUMI is a robust measure, it is primarily designed to evaluate the usability of software, (partly applicable in this case), rather than technologies that combine software and hardware.

8.2.2 The impact of the usability engineering approach on the final system design

The five therapist advisory group meetings elicited therapists key design requirements. Although the design team had a high level design concept for the GUI, the advisory meeting data served to validate these ideas and highlighted therapists' most important design features. Importantly the meetings were effective at gaining contextual information about the clinical environment and the challenges therapists faced when rehabilitating the upper limb post stroke, both of which have been highlighted as important considerations in the design cycle (Martin, Norris, Murphy, & Crowe, 2008). In agreement with other studies, (Demain et al., 2013; Hochstenbach-Waelen, 2012; Hughes et al., 2010) the findings reaffirmed that the UL FES Rehab Tool needed to be adaptable to individual patients' needs, quick to setup and easy to use. Chapter five highlighted the relatively small number of studies of rehabilitation technology that explicitly report on the impact of user involvement in the design process.

The six novice and expert assisted walk-throughs of the GUI (hardware independent) using think-aloud successfully identified 191 usability occurrences, which were later distilled and prioritised to leave 34 usability issues. In total 23 design revisions were made to the system as a result of the usability testing process.

Testing on healthy participants was useful to 'iron out' software bugs, but more importantly, to identify functionality issues such as the difficulty estimating angle trigger parameters, which if left unchanged, would have proven to be extremely time consuming when setting up the device. The lab-based testing with stroke patients highlighted difficulties such as short duration of software time outs, the challenge of handling the hemiplegic limb simultaneous to working through the setup process, and difficulty generating sufficient forces in some patients' proximal musculature via stimulation in order to overcome gravity during functional reaching tasks. The latter problem invariably required assistance from an additional therapist for successful completion of the task. This has prompted the team to explore the inclusion of a de-weighting system for subsequent projects.

The final proof of concept clinical trial confirmed that a device such as the UL FES Rehab Tool Clinical, albeit still in a prototype stage, could feasibly be used in a busy sub-acute clinical environment, to allow practice of functional tasks not possible without FES. These promising results were instrumental in securing funding for an NIHR i4i funded project, in which the thesis author is a co-applicant (reference number: II-LB-0313-20002), to develop "A practical yet flexible upper limb FES system for upper limb functional rehabilitation".

8.2.3 Setup time

As highlighted in chapter two, section 2.8.4, in spite of the importance of setup time for ANRT (Demain et al., 2013; Hochstenbach-Waelen & Seelen, 2012), only three studies in the literature review examined setup as part of the process (Pedrocchi et al., 2013; Fitzgerald, Kelly, et al., 2008; Dijkers et al., 1991). Studies that accurately record setup time for ANRT are limited and tend to focus on patient setup times rather than clinician setup times of the device. From the lab-based testing, the author proposed an early stage model, based on patients' level of impairment and task complexity, which was able to predict 50.6% of the variance in setup time for the UL

FES Rehab Tool. However, when applied in the clinical settings due to the early stage of using the system, the model was much less effective at predicting setup times. Nevertheless, there is merit in further exploration and development of this model.

The factors that influence therapists decision making about when, and how they use rehabilitation technologies, is worthy of further study. As part of the NEAT LO30 project, the Aberdeen partner, along with a group of therapists acting as collaborators, which included the thesis author, developed an informatics framework termed 'Synthesising and Interpreting Language for Clinical Kinematics (SILCK)' (Cozens et al., 2013). This framework fed into the development of software which can control the setup of automated rehabilitation devices, such as iPAM, an UL robotic device. Further development of this type of framework that incorporates knowledge of therapists' decision making processes could aid adoption of ANRT, by bridging the gap between clinical practice and internal device operation.

8.2.4 Education and training to facilitate uptake of rehabilitation technologies

Numerous barriers have been cited impacting on clinical uptake of rehabilitation technologies (Demain et al., 2013). One suggestion for familiarising therapists with technologies has been to include them in the core curriculum of therapy education and training programmes (Hughes, Burridge, Holtum Demain, et al., 2014). Increasing therapists' knowledge of rehabilitation technologies in addition to allowing them graded exposure in both the undergraduate (UG) and post graduate (PG) curricula is highly likely to influence adoption. Encouraging inclusion can be challenging due to competing demands on curricula that are already perceived to be content heavy. In addition, the shift towards content that is evidence-based makes it difficult for technologies such as FES, where its use for rehabilitation of the upper limb remains equivocal. However, in the author's own institution this has occurred in UG and PG programmes for physiotherapists, although not for other allied health programmes e.g. Occupational therapy.

8.3 Limitations

This thesis has utilised a usability engineering approach, and usability methods taken and adapted from the area of human-computer science. However, many of these methods still require further evidence to support their use in the growing field of rehabilitation technology. The lack of robust and validated tools with which to evaluate new technologies remains a problem. The author's approach was based on the best available evidence, and the need to adapt the approaches in order to meet the NEAT LO30 project requirements. Overall, the methods employed were successful at identifying usability issues and provided a useful insight into the usability of the UL FES Rehab Tool in two sub-acute stroke environments.

During the NEAT LO30 project there were four changes in staffing related to the development of the software. At times this necessitated a pragmatic approach to ensure the safety and functional robustness of the software, which had a small impact on usability of the system and the timescales of the larger project.

The small number of patients recruited into the final proof of concept clinical trial made it difficult to draw definitive conclusions about the usability of the UL FES Rehab Tool and evaluation of therapists' predisposition to using the system using the TAM. However, sufficient evidence was gathered to inform he subsequent NIHR funded project. Inclusion of the TAM or a similar tool appears to offer promise.

The use of FES alone to generate sufficient forces in proximal musculature, in order to overcome the weight of the hemiplegic arm, in moderate or severe patients can be difficult. This sometimes resulted in two therapists being required in order to administer effective therapy. If FES is to allow more patients to be treated by a single therapist it will need to explore additional options to supplement the benefits of FES.

Due to the time delay in recruiting patients into the proof of concept clinical trial, a significant amount of time elapsed between the therapist training and therapist use of the system (5 months, centre 1 and 7 months, centre 2). This had a significant impact on the length of time therapists took to become familiar with the system, and impacted on the early use setup times for the device.

8.4 Conclusions

The first aim of the study was to design a Graphical user Interface (GUI) that would enable therapists with no software skills, to quickly and easily set up an individually tailored library of FES tasks for each patient, together with the corresponding bespoke FES controllers.

The study resulted in a GUI that was adaptable to individual patients' needs, quick to setup and easy to use. Therapists and a therapy assistant were able to use the UL FES Rehab Tool in two busy, sub-acute clinical environments to support stroke patients to practice individually tailored tasks. The findings have been used to secure funding to continue to develop the system into a commercially available device. This work commenced in January 2015 and the author is responsible for the usability evaluation of the new system.

The second aim was to develop appropriate methods and carry out a usability and functionality evaluation of the UL FES Rehab Tool (software and hardware) in both laboratory (lab) and clinical settings.

The usability engineering methods, which were adapted from those used within human factors science, were successfully utilised in both lab and clinical environments. These methods were used to identify a significant number of both usability and functionality issues, which were subsequently ranked, and the most important ones addressed. The demonstrable usability of the system in busy clinical environments supported the utility of the methods adopted.

8.4.1 Novelty contributions

- The first study to show the detailed impact of user involvement by utilising usability engineering methods, on the design of an ANRT, from early concept through to first clinical deployment
- The first study to report on directly observed setup times of an ANRT in both lab and sub-acute clinical situations
- The first model for predicting setup time of an ANRT

9 Appendices

Appendix 1: All Usability Studies (n=37)

Author(s)	Year	Objective(s)	Device	Usability Method(s)	Number & type of user	Impact on design	Comments	Context of use
Hughes A.M, Burridge J, Freeman C.T, Donovan-Hall M, Chappell P.H, Lewin P.L, Rogers E, Dibb B.	2009	To understand stroke patients experiences of using the ICL system and to gain insights into how systems might be improved in the future.	Robot + electrical stimulation (ICL system)	Interview using structured and semi-structured questions designed for the study based on the literature and a previous ES study. Designed with therapists and a psychologist. Topics covered effectiveness of the system, usability, ideas on how system could be improved and general questions.	5 Stroke patients who had taken part in the ILC study	Authors highlighted changes to be made to the system as a result of user feedback.	Multi-professional research team, however no mention of their involvement in the design or development of the device.	Lab based setting
Lam P, Herbert D, Boger J et al	2008	To develop and evaluate an easy-to-use, intuitive haptic robotic device that could deliver upper-limb reaching therapy to moderate-level stroke patients	Portable 2D haptic robotic system for UL therapy	Pilot testing using semi-structured interviews using 4 point Likert scale and open ended questions	8 experienced PT & OT's from local hospitals. Inclusion criteria 1 yr experience, practicing clinician, not involved with development of device.	Both positive aspects and areas for further development were identified. Design changes highlighted. Therapists were most interested in the software interface	Useful study that involved therapists in all aspects of the design process. Other aspects of the design process were not covered in detail.	Lab based setting
Lu E.C, Wang R.H, Herbert D, Boger J, Galea M.P, Mihailidis A.	2011	1) To survey therapists to gain an understanding of current stroke rehabilitation methods and aims, 2) To understand what features would be desirable in an upper limb rehabilitation robot.	Portable 2D haptic robotic system for UL therapy	Questionnaire based on previous survey in 1994 by Carr et al. Distributed to PT's & OT's in USA, Canada, UK, Australia. 95% conf level = 233 completed Q's.	233 PT's & OT's with min of 1 year experience in neuro rehab	Design requirements clearly reported. Requirements ranked in order of importance. Able to perform a range of movements, provision of feedback for patients, clinic and home use, virtual ADL activities, adjustment of amount of assistance and resistance required.	Thorough survey that reported on current treatment approaches as well as design requirements.	Survey only. No testing

Huq R, Lu E, Wang R, Mihailidis A.	2012	1) To develop a portable robotic system with a hapticinterface that facilitates the concept of rehabilitation ata remote location, e.g., at a home.2) To develop a graphical user interface (GUI) that integratesdifferent control techniques and VR games inthe same screen, and allows therapists to easily interactwith the system.3) To evaluate the current system with therapists in afocus group study.	Portable 2D haptic robotic system for UL therapy	Early discussion with an expert neurorehab therapist. Focus group with 7 therapists 43 OT & 4 PT for 80 mins. Design changes clearly demonstrated. Further work on-going with patients and clinical trial.	3 OT & 4 PT	Clear design changes highlighted for hardware and GUI	Follow on to 2008 study. Clearly making headway with user involvement. No more formal usability methods yet seen	Lab based setting
Jackson A.E, Holt R.J, Culmer P.R, Makower S.G, Levesley M.C, Richardson R.C, Cozens J.A, Mon Williams M.	2007	1) To present the design process of a dual robot system for use in the rehabilitation of people with stroke. 2) To present the methods used to engage patients and health professionals in its development	iPAM robot for UL rehabilitation	Focus groups, mock ups, accompanied therapist with patients to understand use, questionnaires, rapid prototyping.	4 therapists, 6 stroke patients, doctors, engineers, research physiotherapist	Changes to the design were clearly presented.	Multi-professional research team. Extensive user engagement from requirement specification.	Lab based setting
Holt R, Makower S, Jackson A, Culmer P, Levesley M, Richardson R,Cozens A,Mon Williams M, Bhakta B.	2007	The aim of user involvement in this project is to influence the design process and to test out the usability of the system	iPAM - Rehabilitation robotic device for upper limb therapy	Quarterly meetings - identification of user requirements, mock ups of device, testing with stroke patients and healthy participants to identify any problems with the chosen design, Use of closed, standardised questionnaires	Stroke patients, PT's & OT's	Clear design implications. Feedback on hardware and software design. Interesting difference in responses between PT & OT's. OT's more worried about lack of functional movements e.g. hand to mouth.	Limited detail on usability testing in prototype design stage. Further testing to be conducted in future studies.	Lab based setting

Fitzgerald D, Trakarnratanakul N, Dunne L, Smyth B, Caulfield B.	2008	To evaluate the usability of the prototype virtual rehabilitation system for wobble board balance training	Prototype virtual rehabilitation system for wobble board balance training	Informal observations during setup and use. Post test VRUSE questionnaire	12 healthy participants	Users identified 5 specific problems. Impact on design stated. Follow up no mention of further usability testing.	Classed as development due to prototype evaluation. Included set-up as part of the testing protocol	Lab based setting
Fitzgerald D, Kelly D, Ward T, Markham C, Caulfield B.	2008a	To evaluate the usability of the system andsubsequently implement modifications aimed at improvingfidelity and ease of use.	E-motion: A virtual rehabilitation system that demonstrates, instructs and monitors a therapeutic exercise programme.	An expert walkthrough to identifyinitial usability problems using think-aloud ®system refinements. Followed by a user evaluation study using post test VRUSE. All participantquestions and comments were noted during evaluation,and appropriate answers provided. Immediately followingexercise, the abridged VRUSE questionnaire wascompleted.	six 'experts' -An ergonomist, a psychologist, an exercise scientist, a physiotherapist, a computer scientist, a yoga teacher. Twelve healthy participants took part in the userevaluation study.	List of usability problem from expert walk-through and user testing provided. Future work to carry out an evaluation from a therapist's perspective,integration of a suite of additional therapeutic exerciseprogrammes and testing with a patient population.		Lab based setting
Crosbie J.H, McDonough S.M, Lennon S, Pokluda L, McNeill M.D.J.	2004	1) To ascertain the views of potential users of a virtual reality rehabilitation (VRR) system with respect to the type of task to be practised 2) To establish the specification of these tasks to encourage arm and hand movement in people following stroke 3) To assess the interaction of the user, in both the healthy and stroke populations, in terms of their experience of presence in the VE and their perceived exertion 4) To investigate the rate of self- reported side effects from use of the VRR system in both healthy & stroke users.	VR rehab system	Focus groups, ITQ, TSFQ & Borg.	Healthy & stroke participants	No changes to the design of the system reported		Not specifically reported but appears to be lab based testing

Crosbie J.H, McNeill M.D.J, Burk J and McDonough S	2009	To present a summary of work to date and discuss lessons learned throughout the development, testing and implementation of this type of intervention.	Unilateral & bilateral VR system for upper limb stroke rehabilitation and games for rehabilitation	Immersive tendencies questionnaire (ITQ), Task specific feedback questionnaire (TSFQ), Borg CR10 scale of perceived exertion, post participation verbal feedback from users,	Healthy & stroke participants	Changes to VR systems made	Follow on to Crosbie et al 2004 study	A pilot RCT. Context not mentioned. Presumed to be a rehab setting.
Lewis G.N, Woods C, Rosie J.A, McPherson K.M	2011	1) To design a VR-basedintervention to improve the upper limb movement inpeople with stroke. 2) To determine the effectsof the developed intervention on arm function. 3) To determine the users' perspectives ofthe intervention.	Virtual reality games	A post-intervention questionnaire and a semi-structured interview. The post-intervention questionnairewas adapted from used in a previous study. Although thereliability and validity of the post-intervention questionnairehad not been established, the questionswere selected and modified from a validated andreliable questionnaire used by industry usabilitylaboratories to evaluate user interfaces. Users scores during testing were also used.	6 stroke patients	Suggestions for improvement were recorded. No mention of changes implemented as a result of feedback or of future work.		Lab based setting
Gil-Gómez J, Lloréns R, Alcañiz M and Colomer C.	2011	To evaluate the efficacy of the eBaViR system as a rehabilitation tool for balance recovery.	eBaViR (easy Balance Virtual Rehabilitation), a system based on the Nintendo® Wii Balance Board® (WBB),	A feedback questionnaire (SFQ) was handed out to patients in order to obtain subjective information about the treatment. Therapists were also informally asked about the system.	17 stroke ptns - 9 ptns intervention, 8 control. Informal therapist feedback	No explicit reporting of how patient / therapist feedback impacted on the systems design.		A specialised neuro-rehabilitation service of a large metropolitan hospital.

Whitworth E, Lewis J.A, Boian R, tremaine M, Burdea G, Deutch J.E.	2003	To describe how usability testing and software design iteration were performed collaboratively by a group of engineers and clinician scientists.	The Rutgers Ankle Rehabilitation System (RARS) and its telerehabilitation sub-system	Usability questionnaire, instrument specific questionnaire, testing observations, video data, think-aloud, true-false questionnaires administered to therapist post testing to ascertain understanding of the system, cognitive comprehension questionnaires, therapist-user explanation of system to the patient and therapy assistant.	System developed collaboratively between engineers & a clinical scientist. Stroke ptn, therapist using system locally, remote - therapist, ptn and therapy assistant	Key problems identified. Changes were made to the user interfaces and screen to reduce the difficulty the user had in finding information, the command structure was altered to better reflect the clinical decision making process. The toggle switch which started the machine in a state that the user did not specify and then required a toggle switch to alternate between states was also modified . The most substantial changes were made to the therapist-training manual to reduce the cognitive load experienced by the reader. Knowledge retention of the system was 87%	First study to use a therapy assistant as part of the usability testing . Formal usability testing used . New addition of true false questionnaires	Not stated. Local and remote use. ? Lab & hospital base.
Meldrum D, Glennon A, Herdman S, Murray D, McConn-Walsh R	2012	1) To investigate the usability ofthe Nintendo Wii Fit Plus® (NWFP) in the treatment of balanceimpairment in vestibular and other neurological disease 2) To qualitatively investigate participants experience when using NWFP as a treatment for balance impairment	Nintendo Wii Fit Plus® (NWFP)	Post use: the System Usability Scale (SUS) and a self-devised eight-item questionnaire to survey participants on their experience andopinions of the NWFP® in relation to usual rehabilitation of their balance.	26 participants with quantified balance impairments - stroke and vestibular impairments	No mention of any likely changes to the device as a result of the evaluation.	Pure evaluation study	Physiotherapy department of a neurosurgical hospital.

Lange B, Flynn S, Rizzo A	2009	To identify and define the characteristics of off-the-shelf video game systems (Sony PlayStation 2 EyeToy, Nintendo Wii) that were most enjoyable, user friendly, and motivating for individuals with SCI and CVA.	Off the shelf Nintendo Wii consoles & games	Combination of formative and summative evaluation. Focus group research was undertaken with a sample of people with SCI and CVA to gain feedback on existing games. Participants trialled the games whilst being observed and then asked to complete a series of questionnaires (Likeability Questionnaire, Usability Questionnaire) regarding their perception of each system's usability, appeal and enjoyment. Finally, participants took part in 2 hours of group discussion with the investigators regarding the devices, including a brainstorming session exploring potential changes to improve games for rehabilitation. New games devised and then summatively tested plus final focus group meeting.	7 participants with SCI and CVA. Bimanual training and game evaluation - A sample of 6 participants for final testing.	Problems were identified by users. Observations gathered provided useful feedback on use. therapy. Method used during observation not reported. Impact of user feedback on changes made to the design of the system and the games was evident.	Study where users were fully engaged.	Lab based and therapy department, although therapy department not specifically stated.
Cameirão M.S, Bermúdezi Badia S, Duarte Oller E, Verschure P.	2010	1) To investigate the psychometrics of the RGS in stroke patients and healthy controls. 2) To investigate the transfer between physical and virtual environments. 3) To assessed the usability and acceptance of the RGS as a rehabilitation tool.	Rehabilitation Gaming System (RGS), a VR based neurorehabilitation paradigm for the treatment of motor deficits	A 4-item self-report questionnaire, using a 5-point Likert scale where patients reported their agreement/disagreement with respect to a number of statements. Enjoyment of the task understanding and ease of the task, and subjective performance. Questionnaire was not validated	10 healthy control participants and 12 hemiplegic patients participated in the trials. For the assessment of the PTM and the study of transfer between physical and virtual tasks two new groups of controls and patients were enrolled. 10 control participants and 9 patients	Only usability results reported. No mention of any changes to the device.		Occupational therapy department in hospital

Feng X, Winters J.M	2007	To present the implementation of a consumer centered alternative therapeutic strategy for neurorehabilitative therapy	UniTherapy - a framework to support assessment and therapy in the home environment	In addition to performancedata collected by the framework, video data were collectedusing the Mobile Usability Lab (MU-Lab) for usabilityanalysis purposes. Post use usability surveys were conducted to determine the prospective use of the system in the participants home and their impression of the UniTherapy software and joysticks.	8 stroke patients and 8 healthy participants as controls, 1 of these was a paediatric OT.	Some suggestions for improvement but not explicit. Although claim that the interface is user centred, there was no mention of users as part of the design or development cycle.	Interesting example of a interface framework with different levels of access dependent on the type of user.	Lab based
Mawson S, Nasr N, Parker J, Zheng H, Davies R, Mountain G.	2013	1) To translate current models of stroke rehabilitation into an ICT-based rehabilitation system. 2) To explore how the system could be designed as a self-managed system with motivational feedback of personalized rehabilitation outcomes. 3) To design a system that integrated 'life' goals that reflected the needs of the individual stroke survivor. 4) To establish whether a technology solution that records physical activity could be integrated into a personalized rehabilitation system to provide motivational feedback on the attainment of key motor behaviours.	The Personalised self-managed Rehabilitation System (PSMrS)	Phase one utilised a holistic mixed methods user-centred design approach - a series of home visits, focus groups, in-depth interviews, cultural probes and technology biographies. The prototype was initially evaluated with four research colleagues using a cognitive walkthrough where they provided feedback on the screens. The prototype was evaluated further with nine people with stroke and their carers at home using a cooperative evaluation, and think aloud non-participant observation. Individual or dyad technology biography interviews were conducted.	First focus group - 7 professionals. Second focus group - 7 stroke ptns & their family. Home visit 1 - 8 patients	Changes to the system were evident throughout.	Innovative use of user-centred and health & social care methodologies.	Lab based followed by home based

Johnson L.M, Winters J.M	2004	1) To compare the horizontal and vertical uses of TheraJoy by persons with stroke-induced impairment. 2) To better understand functional usability of the technologies and the need for resisted versus active assisted modes	TheraJoy system - joystick,	Initial usability testing with healthy participants. The second phase of testing includes at least ten stroke participants 30 mins testing a range of commercial of games. Second session is data collection - through the use of EMG electrodes (Motion Lab Systems, Inc.), the Mobile Usability Lab (MU-Lab) and Flock of Birds motion analysis system (Ascension Technology Corp). An optional ninety-minute focus group for stroke patients to discuss ease of use and effectiveness of each of the technologies including any ideas for design alternatives. An additional discussion will focus on the viability of tele-supported home-based neurorehabilitation.	Healthy then up to 10 stroke ptns	No results provided.	No data analysis or findings presented. Although mention of PT's & OT's in development no detail provided.	Not stated but appears to be lab based.
Johnson M.J, Feng X, Johnson L.M, Winters J.M	2007	To evaluate the usability of the conventional joysticks and the TheraJoy system with Uni-Therapy	TheraJoy system - joystick,	Video data was collected using the Mobile Usability Lab (MU-Lab). Post session usability surveys to determinethe prospective use of the system in the participants home and their impression of the software and hardware. Questions focused on participants enjoyment of the device, ease of use and understanding and completion of tasks.	16 stroke patients, 20 healthy participants	Impact on design not stated	Follow up to the 2004 study	Lab & home
Standen P.J, Threapleton K, Connell L, Richardson A, Brown d.J, Battersby S, Platts F.	2012	Virtual glove - Home based VR system for hand rehabilitation	Home based system that employs infrared captures to translate the position of the hand, fingers & thumb into game play via a virtual glove. Games developed with feedback from stroke research group, pilot group and steering group.	Observations from researchers visiting the patients at home, interviews with participants.	15 stroke patients	Some barriers to use identified.	Interesting approach with therapists visiting patients as part of the evaluation research design	Patients home.

Weiss PL, Kizony R, Elion O, Harel S, Baum-Cohen I, Krasovsky T, Feldman Y, Shani M	2012	To present the development , validation and usability/feasibility testing of a low-cost, markerless full body tracking virtual reality system designed to provide remote rehabilitation of the UE in patients post stroke.	Gertner tele-motion rehab system	Five point short feedback questionnaire (SFQ), usability questionnaire re. enjoyment of using the system & Borg scale for perceived effort.	8 stroke patients	Changes not explicitly mentioned		Lab based & hospital based mock-up tele setting.
Bijaka M, Rakosb M, Hoferc C, Mayra W, Strohhoferc M, Raschkac D, Kernc H.	2005	8 channel FES for people with paraplegia. Gui included for set-up.	FES	No formalised feedback methods were mentioned	Seven individuals with paraplegia (T6–T9), all experienced FES users.	No details of actual change to the system were reported, although authors state feedback will result in changes	One of the few studies testing an FES device that includes a GUI. Although therapists set up the device an engineer was on hand to troubleshoot.	Rehabilitation centre.
Merians A.S, Jack D, Boian R, Tremaine M, Burdea G.C, Adamovich S.V, Recce M, Poizner H.	2002	To describe computerized training in a virtual reality (VR) environment as an enhancement to existing methods of retraining the hand in patients in the later phase of recovery after a stroke (case report)	An existing VR system two hand input devices were used, a CyberGlove§ and the Rutgers Master II-ND(RMII) force feedback glove prototype	2 short questionnaires. First to assess the patients' perceptions of their current motor and their motivation to participate in the intervention. This questionnaire was administered at the beginning of the study. The second questionnaire had 3 goals - ptns self - assessment of motor function in their hand; valuation of the exercises; questions mechanisms for introducing the therapy in the home. third set of questions was designed to assess the potential for the continued use and perceived value of this type of exercise. The reliability and validity for the questions were not established;however, the questions were selected and modified from a published, validated and reliable (Cronbach alpha .94) questionnaire commonly used for user interface evaluation by usability laboratories in industry. Some observation of ptns using the system from which changes were made to the glove. A follow up usability interview with 2 ptns.	3 stroke patients	Although patients gave feedback on the exercises, this was very subjective therefore no definitive conclusion drawn re. changes made	Pure evaluation study	University setting.

Weiss P.L, Kizony R, Elion O, Hare S, Baum-Cohen I, Krasovsky T, Feldman Y, Shani M.	2012	The development, validation and usability testing of a low-cost, markerless full body tracking virtual reality system designed to provide remote rehabilitation of the upper extremity in patients post stroke.	3 D video capture camera, software that provides assessment, tele-motion rehab games (self developed) and evaluation functions	A hospital-based mock-up "tele" setting. 5-point Short Feedback Questionnaire (SFQ), a usability questionnaire documenting their enjoyment, and perception of success and control while using the system, Borg scale. In addition to the subjective ratings, game performance scores were tabulated.	Stroke patients	Several modifications to the software were made as a result of both the development and usability evaluation stages.	Group report plan to undertake an RCT	Hospital.
Timmermans A.A.A, Seelen H.A.M, Geers R.P.J, Saini P.K, Winter S, te Vrugt J, Kingma H.	2010	To evaluate patient motivation for and the feasibility and effects of a new technology-supported task-oriented arm training regime (T-TOAT).	A sensor based technology supported task-oriented arm training system with real-world object manipulation. Uses the Philips Research Stroke Rehab Exerciser.	Quantitative data collected for the usability. Visual Analogue Scale (VAS), Usefulness Satisfaction and Ease of Use Questionnaire (USE), Computer system usability questionnaire (CSUQ) . Two questions rated on a VAS: 1) How well did you manage to use the system? and 2) How challenging did you find the exercises offered? The USE focused on the experience (ease of use and learning) of usage and the CSUQ on the understanding (information and interface quality) of the system, but an overlap exists on two scales: usefulness and satisfaction.	9 stroke patients	Only reported on usability scores. No mention of impact on changes to the system.		Out patient at rehabilitation centre.

Burdea G.C, Cioi D, Martin J, Fensterheim D, Holenski M.	2010	1) To examine potential changes in impairment and hand function following training on the Rutgers Arm II and the retention of these gains, and 2) To examine acceptance of this technology by adults in the chronic phase post-stroke and determine any necessary changes to the system.	Rutgers Arm II (RA II) UL trainer . Low friction tilting table, sensorised forearm support, shoulder assembly, including software, to prevent unwanted compensatory trunk movements, active vision tracker, 3 VR games	A self-report system evaluation completed by the participants online at the end of every rehabilitation week. This form was not standardized and consisted of nine questions rated on a five-point scale, with 1 corresponding to the least desirable outcome and 5 to the most desirable one. A post intervention interview was taped with one of the participants	3 stroke patients	Pure evaluation study. No problems identified nor proposed changes		Lab based
Kizony R, Weiss P.L, Shahar M, Rand D.	2006	1. To present the system and a number of the current applications. 2. To present initial pilot usage results of an on-going study, with elderly people as well as people with neurological disabilities.	VR system - TheraGame which operates on a standard PC with a simple webcam.	healthy measures & process - Post use SFQ, SUS and Borg scale. 3 stroke patients used the system once. The 4th patient , a system with four games was installed at his home. Following the installation, an occupational therapist trained the participant and his wife how to operate the system. They were asked to record in a journal when, for how long and what games he played with the system. After a period of two and a half weeks the therapist returned to the participant's home and carried out a structured interview with the couple. Ptns. wife also completed the SUS.	12 healthy elderly participants followed by four stroke participants.	Impact - an increase the size of the screen and a display of the scores for all the games. Difficulty touching the correct arrow. The participant who used the system for the extended period of time used it for 10 sessions over 16 days for a total of 213 minutes. Their responses to the structured interview were reported as variable but no further detail was provided.	Interesting study that allowed longer term use for 1 of the stroke participants.	Therapy department & patients home.
Llorénsa R, Colomer-Fontb C, Alca˜niza M,Noé-Sebastiánc E	2013	To study effectiveness and satisfaction with a virtual reality-based balance rehabilitation system (BioTrak) for patients with acquired brain injury (ABI).	BioTrak - VR based balance rehab system	The usability study was conducted using an ad hoc questionnaire.	10 stroke patients	No changes to design noted.		Rehab gym in a hospital setting.

Anacleto J, Silvestre R, Filho C.S, Santana B.	2012	To provide healthcare professionals with ICT tools that help them in their daily activities within the hospital.	Natural User Interface (NUI) technology	Participatory design, questionnaire to gather user IT characteristics, mock up, case scenarios, in situ observations ® workflow activities ® redesigned by research team and validated by focus group.	5 health professionals - 1 PT, 2 nurses, 1 OT, 1 social worker	Only design ideas. No actual technology composition.	Useful mix of design methods that actively involved therapists	Hospital.
Sugar T.G, He J, Koeneman E.J, Koeneman J.B, Herman R, Huang H, Schultz R.S, Herring D.E, Wanberg J , Balasubramanian S, Swenson P, Ward J.A	2007	To report on the design and Control of RUPERT: A Device for Robotic Upper Extremity Repetitive Therapy	Upper limb Exoskeleton	Although user and therapist feedback was stated there were no formalised feedback methods reported. Healthy & stroke participants tried the device during the development stage	8 healthy participants plus 5 stroke patients	Some user involvement but not captured in anyway. Report that design modifications were made but not explicitly specified	Interesting inclusion of the scapula.	Lab based.
Laffont I, Biard N, Chalubert G, Delahoche L, Marhic B, Boyer F.C, Leroux C.	2009	The goal of this study was to validate among users a recently developed HMI to control a robotic arm for persons with mild to severe disabilities.	Upper limb robotic device	Previous studies had tested the prototype with SCI patients. Failure to achieve the task was quantified. Device failure was separated from user related failure. Number of times the panoramic camera was used by patients. Number of clicks to achieve the task. User satisfaction 3 questions on a 4 point Likert scale . Users design suggestions noted.	Healthy participants and 20 chronic patients with arm deficits	Changes to the design explicitly stated for all phases of the studies		Rehabilitation departments

Choi Y, Gordon J, Park H, Schweighofer N.	2011	The primary aim of this feasibility study was to establish the feasibility of ADAPT for a single training session of participants with chronic stroke. Specifically, we evaluated ADAPT's safety, ADAPT's overall functionality, possible improvement of performance between pre and post-test, and participants' subjective experience.	A novel robotic task-practice system, ADAPT	Safety - the number of adverse event occurring in the operation of the ADAPT and qualitatively via a participant questionnaire. Functionality - a) whether ADAPT could successfully present the different tasks to the participants without human intervention. b) evaluated the fidelity of the dynamics of the simulated tasks by comparing it to actual task dynamics and via questionnaire. c) evaluated whether the adaptive algorithm could successfully modulate task difficulty based on performance during training. Participants' subjective experience was assessed via the Intrinsic Motivation Inventory (IMI) questionnaire.	5 mild to moderate chronic stroke patients. Inclusion criteria stated.	Study mainly focused on the adaptive algorithm, with less focus on usability. This had been covered in a previous study.	Novel method of including functional tasks designed by the research team to allow specific measurements to be taken.	Lab based.
Colombo R, Pisano F, Mazzone A, Delconte C, Micera S, Carrozza M.C, Dario P, Minuco G.	2007	to present two rehabilitation robots and the design strategies we implemented in order to boost patient motivation and improve adherence. In addition, we outline a new evaluation metric for quantifying the patient's rate of improvement and allowing a regular review of the performance.	2 robots with VR interface & PC to set up	Active movement index (AMI), movement accuracy and normalised path length. Latter was deemed to be a measure of efficiency. Intrinsic Motivation Inventory questionnaire (IMI) - Interest/Enjoyment, Perceived Competence, Effort/Importance, Value/Usefulness, Pressure/Tension, Pain	Mild to moderate stroke patients. 8 + 12= 20	No explicit mention therapist involvement although OT's did set up the device for patients during the study.	Interesting measures of active movement and task performance that appeared to effectively inform the adaptive task difficulty algorithm.	Out patient at rehabilitation centre.

Pedrocchi A, Ferrante S, Ambrosini E, Gandolla M, et al.	2013	To provide a global overview of the MUNDUS (robotic & NMES) platform and of its first validation on end-users.	MUNDUS modularly combines an antigravity lightweight and non-cumbersome exoskeleton, closed-loop controlled Neuromuscular Electrical Stimulation for arm and hand motion, and potentially a motorized hand orthosis, for grasping interactive objects.	User-centred approach. The definition of the requirements and of the interaction tasks were designed by a focus group with experts and a questionnaire with 36 potential end-users. Five end-users tested the prototype system Three experts evaluated over a 3-level score (from 0, unsuccessful, to 2, completely functional) the execution of each assisted sub-action.	FG - 7 doctors, 1 psychologist, 1 physiotherapist, 1 engineer, 1 patient affected by Amyotrophic Lateral Sclerosis. 36 potential users - interviewed 1 caregiver, and 2 social enterprise representatives employing disabled people. 5 patients -3 SCI and 2 MS, all chronic presentation.	Main requirements from focus group - modularity, reproduction of movements as close as possible to "natural", low encumbering device, multitask device, reasonable costs and ease of use. They would like to have a device useable mostly at home during the activities of daily living. The device should be easy to use, light, and wearable, even if all the selected users depended on a wheelchair.	This system can be used as a rehab or an assistive device. Testing included both sets of users. One of the few studies to examine set up time	Hospital based rehabilitation centre.
Dijkers M.P, deBear P.C, Erlandson R.F, Kristy K, Geer D.M, Nichols A.	1991	1) To determine safety of the system for the patients; 2) assess acceptance of the system by the patients and the therapists: and. 3) explore utility of the robotic system as perceived by the therapists.	UL robotic device	1) a log located next to the computer in which therapists recorded comments, suggestions, and system problems: 2) the system database; 3) patient feedback forms, completed with help from the therapist (aphasic patients answered with nods 4) a comprehensive therapist questionnaire, completed at the end of the pilot study. Patient acceptance, system utility, estimated setup time.	Designed by research team - OT's & engineers. 11 therapists & 22 patients (stroke, GBS, MS, TBI) used the system.	Some impact on design stated. Also suggestions re. development of the development. Therapist acceptance very mixed.	Set up time and ease of use highlighted as draw backs. Setup time only estimated by the therapists. Estimated between 2-15 mins	OT clinic at a rehab institute.
Kyoungwon S, Kim J, Lee J, Jang S, Ryu H.	2011	To report on the design of a natural interaction based rehabilitation program 'RehabMaster' addressing the different requirements of clinical staff	Gaming intervention - high fidelity prototype RehabMaster	Focus groups and individual interviews with clinical staff to understand the requirements. A set of core usability factors identified for each user group. Prototype testing with patients. Evaluation study in hospital with users - usability evaluation used 3 very broad questions generated from research team.	16 stroke patients, 7 physiotherapists, 3 OT's	3 different user interfaces were developed based on the design requirements.	Novel approach where usability factors were identified by each of the user groups. .	Lab & hospital

Appendix 2: NEAT LO30 funding documentation

NEAT L030:

An advanced FES rehabilitation tool for upper limb therapy after stroke

Project Dates and Additional Details

Start	**Date:**	01/01/2009
End	**Date:**	30/06/2011

Project Duration (months): 30.0

Full Economic Cost: £518,208.00

Award	**Date:**	17/02/2009

Award Amount: £470,753.00

University Grant Code: SGRB20

1. Layman's summary

After stroke, many people cannot use their affected hand and arm, and this has considerable impact on their quality of life. This is exacerbated by the limited availability of physiotherapists, with less than 1 hour of therapy per day being typical. Possibly as a result, recovery over the rehabilitation period is often poor and approximately 50% of patients are left with long term arm problems. So there is an important need to increase arm and hand therapy without increasing the burden on therapists.

Electrical muscle stimulation (FES) is a low cost solution which could enable stroke physiotherapists to look after several patients simultaneously. Indeed, some patients may be able to use FES at home without supervision, greatly increasing therapy time. Furthermore, because it leads to natural muscle driven movement, and the associated sensations, it can be very effective in promoting recovery. In small trials, robot systems have successfully delivered controlled arm exercise for those with arm weakness. But most robot systems do not facilitate hand opening when paresis of the finger muscles is present. A hybrid system combining electrical stimulation for hand

opening and robot assisted shoulder and elbow exercise would be particularly effective in this situation.

The proposed research is a collaboration between the Universities of Salford and Leeds, the National Clinical FES Centre (Salisbury District Hospital) and NHS Grampian Department of Rehabilitation Medicine (Aberdeen); the objective being to create a muscle stimulation system (the FES Rehab Tool) for hand and arm therapy after stroke. A number of problems will need to be solved including volitional control by the patient and easy to use methods for adapting to the individual needs of each patient. We also plan to demonstrate a hybrid system based on the new FES Rehab Tool and an existing rehabilitation robot (iPAM).

Aims and objectives

To realise the full potential of FES as an upper limb rehabilitation tool is a significant challenge requiring the development of an advanced FES Rehabilitation Tool (represented schematically in Figure 1), which should combine the following functions:

- Enables therapists with no software skills to quickly and easily set up an individually tailored library of FES tasks for each patient, together with the corresponding bespoke FES controllers.
- Allows the patient to voluntarily initiate movement via signals generated by residual arm movement or residual EMG or both.
- Allows the patient to independently practice functional tasks, randomly selected from the library (allowing one therapist to look after several patients simultaneously).
- Monitors the patient's performance, providing essential bio-feedback for the patient and information to inform clinical decisions on changes to the training regime.
- Potential for integration with an upper limb robot exercise system (iPAM).

Appendix 3: Phase two usability testing information sheet and consent form

Usability Evaluation, July 2011

A Pilot Usability Evaluation of the FES Rehab Tool's Graphical User Interface.

Participant Information Sheet (phase 1).

Project title

A Pilot Usability Evaluation of the FES Rehab Tool's Graphical User Interface.

Background information

To increase practice without increasing the burden on therapists, researchers have investigated the use of Functional Electrical Stimulation (FES) and rehabilitation robots. FES directly activates paralysed muscles through electrical stimulation via skin surface electrodes, it has significant potential as a stroke rehabilitation tool and can even help patients with severe hand arm paralysis (Chedoke McMaster Severity Measurement Rating scores of 1 and 2). FES provides a means of directly tapping into the nervous system, actively producing movement and exciting the associated proprioceptive pathways. If this is synchronised with the patient's efforts to carry out meaningful tasks, it provides afferent inputs associated with the intention to create functional movement. This provides the most appropriate set of neural inputs to promote learning and recent studies have reported significant success.

However in order for FES to realise its potential for upper limb rehabilitation, a number of problems need to be resolved, including volitional control by the patient and an easy to use methods for adapting to the individual needs of each patient. In order to address this problem a new type of device, a FES Rehab Tool is being developed to address the current limitations. One of the main aims of the project is to enable therapists with no software skills to quickly and easily set-up an individually tailored library of upper limb FES-supported tasks for each patient, together with the corresponding bespoke FES controllers. This will be achieved by using a laptop computer that communicates wirelessly with the stimulator and the movement sensors.

The aim of this phase of the usability evaluation is to gather formative qualitative and quantitative usability data from users on the graphical user interface (GUI) for the FES Rehab Tool so that it can inform the iterative design process.

Who will be involved?

Six practitioners (Physiotherapists & Rehabilitation Engineers) who are experienced in neurological rehabilitation will be recruited into the study from within the University of Salfords academic team. A combination of experienced and more novice FES practitioners will be recruited in order to evaluate the GUI from a range of perspectives.

What does the study entail?

You will be asked to attend one two hour session at the University of Salford in order to carry out the usability evaluation. The evaluation procedure will be explained at the start of the session and an overview of how the GUI operates, including the concepts that underpin it will be explained in order to allow familiarization with the software set-up process. Once you are comfortable with how the GUI functions, you will be asked to complete two pre-determined set-up tasks for a given clinical scenario. During the evaluation process you will be asked to use a method called 'think-aloud' where you verbalise your thoughts, reasoning, intuition and feelings whilst using the GUI. This approach aims to capture thought processes that might otherwise not be visible. You will be asked to practice this method in advance of attending the evaluation in order to minimise potential cognitive overload. You will be observed by one of the research team who will document any relevant observations and comments during this process. In addition a video camera and a software package called 'Captivate' will be used to assist with data collection. In order to ensure we have gathered all your feedback, a brief post task interview and a post test questionnaire will also be administered.

Will my views be confidential?

Yes, the results of the study will be entirely confidential. All data collected from the usability evaluations will remain anonymous and will be stored according to research ethics guidelines in a secure storage space.

If you have any questions or want further information, please contact Christine Smith on - ***Tel: 0161 295 2411*** or email: c.smith1@salford.ac.uk

University of Salford
A Greater Manchester University

Researcher's copy

CONSENT FORM

Title of Project: A Pilot Usability Evaluation of the FES Rehab Tool's Graphical User Interface.

Please initial box

1. *I confirm that I have read and understand the information sheet dated July 2011 for the above study and have had the opportunity to ask questions.* ☐
2. *I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.* ☐
3. *I understand that at the end of the study data collected from me will be stored at the University of Salford in line with the institutional guidelines for good clinical practice in research and in line with the policies for postgraduate research.* ☐
4. *I agree to be video recorded for the purpose of collecting usability data* ☐
5. *I agree that the video can be used for teaching and scientific conferences.* ☐
6. *I agree to take part in the above study.* ☐

_____	_____	_____
Name of Participant	**Date**	**Signature**
_____	_____	_____
Researcher	**Date**	**Signature**

Appendix 4: Phase two usability testing task sheets

Patient Scenario's for the UL FES Rehab Tool.

Scenario 1b

Tony is 42 years old and sustained a stroke 9 months ago. He is employed as a mechanic and enjoys playing computer games with his friends especially motorbike racing. He is keen to get back to his job or at least some type of similar employment.
He is able to walk independently for relatively long distances in any environment and is independent in all ADL's, although he presently has to compensate to some extent for the deficit in function of his right arm. He has no cognitive or perceptual deficits.
He is very keen to regain further functional use in his right hand but when he tries to use it he becomes frustrated at his poor functional ability. He currently has ¾ active range of movement at his shoulder (flexion and abduction with all other movements full range), with 50% active range flexion & extension at his elbow. He has 50% active range of supination, full active ROM pronation, 10 degrees of wrist extension, full active range of wrist flexion. He has flickers of active movement at all fingers on his right hand but is not able to use this functionally. Grip strength is 3/5.

Task 1

1. Load the file named 'standard library' form the laptop and save the profile as file name Tony2.
2. Choose to use the existing functional task 'pick up a phone'
3. Set up the stimulators and sensors
4. Choose the Hasomed stimulator, unit 1. Assign the channels to each of the pre-determined muscle groups.
5. Set stimulation thresholds and maximum stimulation levels for each muscle group as follows:

Muscle group	*Threshold*	*Max stimulation*
Anterior deltoid	8	50
Triceps	7	40
Wrist extensors	4	30

6. Choose to use the Xsens system and unit 1.
7. Choose to use a movement sensor on the lower arm.
8. Practice the 'pick up a phone' task adjusting stimulation levels and ramps in accordance with the settings in the table below.

Phase	*Muscle*	*Stimulation level*
Phase 1	Biceps	38
Phase 2	Anterior deltoid	40
Phase 2	Triceps	30
Phase 3	Anterior deltoid	40
Phase 3	Triceps	30
Phase 3	Wrist extensors	22

9. Change the ramp settings for phase 2 to a setting of 4.
10. Run through automating the task assigning sensors and conditions. Opt to stay with the 'pick up a phone' task.
11. Change the 'exiting phase 2' from an angle of 70 degrees to 60 degrees.
12. Run the session

Task 2

1. Load the file named 'standard library' form the laptop and save the profile as file name Tony2.
2. Create a new task called 'move plate with both hands'.
3. Decide on the number of movement phases and muscles groups. Give each phase a relevant name.
4. Save the task
5. Choose to use the task you have created and then begin to set-up stimulators and sensors by assigning each muscles group to a channel.
6. Change the pulse width to 40%
7. Adjust stimulation thresholds and maximum stimulation settings as listed in the table below:

Muscle group	*Threshold*	*Max stimulation*
Anterior deltoid	9	55
Lateral deltoid	7	53
Triceps	4	35
Wrist extensors	3	28

8. Choose to use the Xsens system and unit 1
9. Appropriately locate a movement sensor.
10. Practice the 'move plate with both hands' task adjusting stimulation levels and ramps in accordance with the settings in the table below.

Phase	*Muscle*	*Stimulation level*	*Ramp up or down*
Phase 1	Anterior deltoid	44	1
Phase 1	Triceps	30	1
Phase 1	Wrist extensors	25	3
Phase 2	Anterior deltoid	44	0
Phase 2	Triceps	30	0
Phase 2	Wrist extensors	N/A	3
Phase 3	Lateral deltoid	48	2
Phase 3	Triceps	30	0
Phase 3	Wrist extensors	25	2
Phase 3	Anterior deltoid	N/A	1
Phase 0	Lat deltoid, triceps & wrist extensors	N/A	3

11. Run through automating the task assigning sensors and conditions. Opt to stay with the same task.
12. Select suitable exiting triggers for each phase.
13. Run the session.

Appendix 5: Phase 2, usability testing observation tool

Usability Testing Data Collection Form

WP 2 Usability Test for FES Rehab Tool				
Participant:	N= menu error	S = satisfaction observed	SU = successful completion	TF = system failed
Date: Scenario:	R = repeated error	F = frustration observed	IW = Selecting inactive window/icon	TA = task abandoned
Recorder:	A = assistance needed	C = confusion observed	TP = task prolonged	CE = corrected error

User ID & Task:	Time	Notes
Stage 1: *Loading & choosing task*		
Editing		
Creating task		
Stage 2a: *Assigning channels to muscles*		
Setting minimum threshold		
Setting maximum stimulation level		
Stage 2b: *Assigning sensors*		
Stage 3: *Practicing task - adjusting stimulation levels and ramps.*		
Stage 4: *Selecting exiting triggers*		

Appendix 6: Phase two usability testing post-test questionnaire

Participant ID: _____ **Date:** _____

This questionnaire is designed to tell us how you feel about the software you used today. Please circle the number that most clearly expresses how you feel about a particular statement. Write any comments you have below each question.

1. How easy was it to adjustment the following device parameters:-

a) **Stage 1**

Choosing tasks:

1	2	3	4	5
Very Easy	Easy	Neither Easy Nor Difficult	Difficult	Very Difficult

b) **Editing tasks:**

1	2	3	4	5	N/A
Very Easy	Easy	Neither Easy Nor Difficult	Difficult	Very Difficult	

Comment:

_____

_____

c) **Creating tasks: Navigation perspective**

1	2	3	4	5	N/A
Very Easy	Easy	Neither Easy Nor Difficult	Difficult	Very Difficult	

Comment:

_____

_____

d) **Creating tasks: Conceptual perspective**

1	2	3	4	5	N/A
Very Easy	Easy	Neither Easy Nor Difficult	Difficult	Very Difficult	

Comment:

_____

_____

2a) **<u>Stage 2</u>**

Assigning channels to muscles:

1	2	3	4	5
Very Easy	Easy	Neither Easy Nor Difficult	Difficult	Very Difficult

Comment:

_____

_____

b) **Assigning sensors:**

1	2	3	4	5
Very Easy	Easy	Neither Easy Nor Difficult	Difficult	Very Difficult

Comment:

_____

_____

3. **<u>Stage 3</u> – Practicing the task, adjusting stimulation levels and ramps:**

1	2	3	4	5
Very Easy	Easy	Neither Easy Nor Difficult	Difficult	Very Difficult

Comment:

_____

_____

4. **<u>Stage 4</u> – selecting exiting triggers:**

1	2	3	4	5
Very Easy	Easy	Neither Easy Nor Difficult	Difficult	Very Difficult

Comment:

_____

_____

5. Did the interface effectively prevent you from selecting incorrect setup options and inform you of any errors?

Yes No Sometimes

Comment:

_____

_____

6. The time taken to setup the stimulator was:

1	2	3	4	5
Very quick	Quite quick	Acceptable	Quite lengthy	Excessively long

Comment:

_____

_____

7. Are the device functions and interface easy to understand?

Yes No

Comment:

_____

_____

8. List any other comments you have about the software:

Comment:

_____

_____

_____

Thank you for taking the time to answer this questionnaire.

Appendix 7: Initial list of usability problems from phase two of the usability testing

Usability Data	GM	PT	CM	KW	DD	AW	Frequency of problem	Ranked frequency	Problems in rank order of frequency of problem
Stage 1: 19									Stage 1
a) Needed prompting when navigating through set up sequence	1	1			1	1	4	5	Didn't click save button or unsure re. saving
b) Didn't click save button or unsure re. saving	1	1	1	1	1		5	5	Some muscles not in alphabetical order - deltoids
c) Typed in movement name in movement phase box	1						1	4	Needed prompting when navigating through set up sequence
d) Couldn't use control button to delete multiple muscles	1						1	4	Unsure where to type name of phase
e) No listing of finger extensors	1	1					2	2	No listing of finger extensors
f) Unsure if needed to click save button to save muscles added	1	1					2	2	Unsure if needed to click save button to save muscles added
g) Thumb muscles not listed	1						1	2	Needed prompting to use task once created
h) Unsure where to type name of phase	1			1	1	1	4	2	Couldn't edit task once created
i) Needed prompting to use task once created	1		1				2	2	Unsure how to add muscles
j) Text too small to read easily		1					1	1	Typed in movement name in movement phase box
k) Expected phase 0 to be included in number of phases		1					1	1	Couldn't use control button to delete multiple muscles
l) Couldn't edit task once created		1	1				2	1	Thumb muscles not listed
m) Requested to use more than 1 group of muscles			1				1	1	Text too small to read easily
n) Unsure how to add muscles			1	1			2	1	Expected phase 0 to be included in number of phases
o) Allowed user to type same muscle in twice to same phase			1				1	1	Requested to use more than 1 group of muscles
p) System crashed when tried to edit task			1				1	1	Allowed user to type same muscle in twice to same phase
q) Default setting of biceps in muscle list caused user to choose muscle incorrectly					1		1	1	System crashed when tried to edit task
r) Some muscles not in alphabetical order - deltoids	1	1	1		1	1	5	1	Default setting of biceps in muscle list caused user to choose muscle incorrectly
s) Unsure whether to progress to stage 2 once task created					1		1	1	Unsure whether to progress to stage 2 once task created
SUB-TOTAL	10	8	8	3	6	3	38	38	
Usability Data	**GM**	**PT**	**CM**	**KW**	**DD**	**AW**	**Frequency of problem**	**Ranked frequency**	**Problems in rank order of frequency of problem**
Stage 2a: 30									Stage 2a
a) Trying to assign muscles to channels already assigned	1						1	6	All buttons in lower window greyed out until click off current channel
b) All buttons in lower window greyed out until click off current channel	2	1	2	1	2	2	6	6	Failed to stop stimulation before moving to next muscle
c) Unsure of navigation through next stage once muscles assigned	1	1	1	1		1	5	5	Unsure of navigation through next stage once muscles assigned
d) Failed to stop stimulation before moving to next muscle	1	1	1	1	2	2	6	5	Unsure if values had been stored
e) No warning that stimulation on for long period of time	2		1		1		3	4	Failed to click on stimulate button to start stimulation
f) Unsure how to correct incorrect enteries	1						1	4	Slider not accurate / calibrated
g) Failed to click on stimulate button to start stimulation	1		1		2	1	4	3	No warning that stimulation on for long period of time
h) Slider not accurate / calibrated	1	2		1	2		4	3	Unable to see settings for other muscles
i) Move on to setting up sensors without finishing setting stimulation values	1						1	3	Unsure how to assign channels to muscles, drop down menus not obvious & windows confusing
j) Unsure why setting minimum thresholds	1						1	3	Stimulation settings raced up & down without user initiating
j) Mouse difficult to use when setting up patients	1	1					2	2	Mouse difficult to use when setting up patients
k) Forgot to assign muscles		2	1				2	2	Forgot to assign muscles
l) Unsure of units for stimulation		1					1	1	Trying to assign muscles to channels already assigned
m) Unsure if values had been stored	1	1	1	2	1		5	1	Unsure how to correct incorrect enteries
n) Threshold and max stimulation buttons not intuitive - wrong way round		1					1	1	Move on to setting up sensors without finishing setting stimulation values
o) Unable to see settings for other muscles		1	1		1		3	1	Unsure why setting minimum thresholds
p) Ran out of channels as system let user create too many muscles		1					1	1	Unsure of units for stimulation
q) System crashed when pulse width changed as no stimulation values had been set		1					1	1	Threshold and max stimulation buttons not intuitive - wrong way round
r) Pulse width changes for all muscles which might cause stimulation to be too high		1					1	1	Ran out of channels as system let user create too many muscles
s) Unsure how to assign channels to muscles, drop down menus not obvious & windows confusing			1	1	1		3	1	System crashed when pulse width changed as no stimulation values had been set
t) Didn't click on maximum stimulation			1				1	1	Pulse width changes for all muscles which might cause stimulation to be too high
u) No help to prompt user how to rectify problem			1				1	1	Didn't click on maximum stimulation
v) Overlooked stage 2b			1				1	1	No help to prompt user how to rectify problem
w) Couldn't allocate 2 muscles to 1 channel			1				1	1	Overlooked stage 2b
x) Stimulation settings raced up & down without user initiating			1	1		1	3	1	Couldn't allocate 2 muscles to 1 channel
y) Assigned muscle but didn't show in window				1			1	1	Assigned muscle but didn't show in window
z) Software slow to highlight boxes even when stimulate						1	1	1	Software slow to highlight boxes even when

clicked									stimulate clicked
a2) Unsure how to adjust stimulation levels with slider - not obvious						1	1	1	Unsure how to adjust stimulation levels with slider - not obvious
b2) Unable to type in stimulation settings to box						1	1	1	Unable to type in stimulation settings to box
c2) Found slider values misleading - not % of maximum value						1	1	1	Found slider values misleading - not % of maximum value
SUB-TOTAL	12	13	14	8	8	9	64		
Usability Data	GM	PT	CM	KW	DD	AW	Frequency of problem	Ranked frequency	Problems in rank order of frequency of problem
Stage 2b: 9									Stage 2b
a) Failed to assign sensor(s)	1			1			2	5	Start button not sufficiently obvious
b) Window for sensors disappeared when user didn't assign sensors	1						1	3	Stop button not sufficiently obvious
c) Sensor titles confusing	1	1					2	3	Moved to stage 3 without setting up sensors
d) Start button not sufficiently obvious	1	1	1	1	2		5	2	Failed to assign sensor(s)
e) Moved to stage 3 without setting up sensors	1	1	1				3	2	Sensor titles confusing
f) Stop button not sufficiently obvious		1	1		1		3	2	Currently need to assign both sensors even if not needed
g) Currently need to assign both sensors even if not needed		1	1				2	1	Window for sensors disappeared when user didn't assign sensors
h) Confusion between units in stage 2a & units in stage 2b			1				1	1	Confusion between units in stage 2a & units in stage 2b
i) No error message appeared when stop button not clicked			1				1	1	No error message appeared when stop button not clicked
SUB-TOTAL	5	5	6	2	2	0	20		
Usability Data	GM	PT	CM	KW	DD	AW	Frequency of problem	Ranked frequency	Data in rank order of frequency of occurrence
Stage 3: 18									Stage 3
a) User unsure how to move between movement phases	3	3	2	1	1	1	6	6	User unsure how to move between movement phases
b) Slider didn't increase incrementally	1			2	1		3	6	User forgot to stop stimulation - stimulation on for too long
c) User uncertain as to whether settings had saved automatically	1	1	1	3	1		5	5	User uncertain as to whether settings had saved automatically
d) User forgot to stop stimulation - stimulation on for too long	1	3	2	1	2	1	6	3	Slider didn't increase incrementally
e) Unsure what to set ramp value at when wanting muscle to stay on	1						1	3	Didn't like use of mouse to move between phases or adjust stimulation
f) Shouldn't have to stimulate when changing ramps	1						1	2	No indication that stimulation was on

g) Didn't like use of mouse to move between phases or adjust stimulation		1	1		2		3	2	Clicked on muscles to choose muscles, windows confusing as only 1 muscle highlighted
h) Allowed user to not define a stimulation level and still proceed		1					1	1	Unsure what to set ramp value at when wanting muscle to stay on
i) Unsure how to start process by clicking stimulation button			1				1	1	Shouldn't have to stimulate when changing ramps
j) No indication that stimulation was on			1		1		2	1	Allowed user to not define a stimulation level and still proceed
k) Unsure how to adjust stimulation			1				1	1	Unsure how to start process by clicking stimulation button
l) Clicked on muscles to choose muscles, windows confusing as only 1 muscle highlighted			2		1		2	1	Unsure how to adjust stimulation
m) Didn't allow user to adust stimulation setting once set			1				1	1	Didn't allow user to adust stimulation setting once set
n) Text not fully visible					1		1	1	Text not fully visible
o) Couldn't just select one phase					1		1	1	Couldn't just select one phase
p) Ramp settings don't have a default setting					1		1	1	Ramp settings don't have a default setting
q) User wanted to see a phase zero window at end of phases					1		1	1	User wanted to see a phase zero window at end of phases
r) Unable to type in stimulation value to box						1	1	1	Unable to type in stimulation value to box
SUB-TOTAL	6	5	9	4	11	3	38		
Usability Data	GM	PT	CM	KW	DD	AW	Frequency of problem	Ranked frequency	Data in rank order of frequency of occurrence
Stage 4: 16									Stage 4
a) Unclear how to make windows active	1		2	1	1	1	5	5	Unclear how to make windows active
b) Not obvious which window is active	1		1	1	2		4	4	Not obvious which window is active
c) User didn't like not being able to see what trigger conditions were set at	1				1		2	3	Typed in command for patient without window being active therefore didn't save
d) Typed in command for patient without window being active therefore didn't save	1	1	1				3	3	Unsure if settings had saved
e) Conceptually difficult to work out exiting triggers	1						1	2	User didn't like not being able to see what trigger conditions were set at
f) Difficult to work out multiple time outs values for groups of muscles stimulated in series	1						1	1	Conceptually difficult to work out exiting triggers
g) Unsure whether real angle or pragmatic angle		1					1	1	Difficult to work out multiple time outs values for groups of muscles stimulated in series
h) Unsure where angle was measured from		1					1	1	Unsure whether real angle or pragmatic angle
i) User couldn't remember where sensor units had been assigned		1					1	1	Unsure where angle was measured from
j) Unclear where to type command or even that a command can be typed in		1					1	1	User couldn't remember where sensor units had been assigned

k) Confusion between phases and transitions		1					1	1	Unclear where to type command or even that a command can be typed in
l) Possible to set a time out that is less than the ramp		1					1	1	Confusion between phases and transitions
n) Unsure where to type patient commands			1				1	1	Possible to set a time out that is less than the ramp
o) Option to combine exiting trigger conditions not obvious			1				1	1	Unsure where to type patient commands
p) Unsure if settings had saved			2	2	2	1	3	1	Option to combine exiting trigger conditions not obvious
q) Text extends beyond window					1		1	1	Text extends beyond window
SUB-TOTAL	6	7	6	3	5	2	28		
General									
SUB-TOTAL	1		1		1		3		
OVERALL TOTAL							151		

Appendix 8: Final list of usability problems with priority ratings and outcomes.

KEY: Priority 1 = minor problem; Priority 2 = persistent problem, not critical to safety; priority 3 = critical problem, potential impact on patient safety or discomfort, prevents user from completing task effectively.

A) General usability problems		
i) FES & State Machine Functionality	**Researcher ratings**	**Final rating and design outcome**
1) Slider response too slow or inaccurate in Stages 2 & 3.	Rater 1: 3 as this was a repeated nuisance and could affect stimulation levels given to patients Rater 2: 1 as not sure what this infers to. The sliders seem to work OK in both sections 2 & 3. There is a default ramp in section Rater 3 : 3. Anything that could unintentionally affect stimulation levels has top priority.	**Priority 3** Check carefully that sliders are functioning correctly in all situations. Check with Rater 1 about whether a default ramp is applied when using sliders to avoid rapid changes. In stage 2 this should include an overriding maximum ramp rate to avoid step changes in stimulation level. Implemented.
2) When using sliders it would be easier if the arrow keys could be used (avoids mouse and screen). So, if the muscle is selected, the arrow keys control the slider position.	Rater 1: 3 quite critical when trying to handle patients at same time as accessing GUI. Rater 2: 1 as the arrow keys already work for controlling the sliders. Rater 3: 2 . It is difficult to imagine that a user could set stimulation without looking at the hand/limb, but it is not a safety critical issue	**Priority 3** Arrow key function added
3) Similarly, in some selected cases, key presses may be easier than GUI button presses (avoids mouse and screen). For example, transition (Enter or spacebar) and stop stimulation (Esc).	Rater 1: 3 for transition button as likely to impact on ability to handle limb as working through phases. Maybe other function buttons not quite so critical. Rater 2: 1 as not sure if this can be implemented in Matlab GUI. Rater 3: 3. Anything that could directly impact on stimulation duration/intensity needs addressing	**Priority 3** Key presses implemented
4) Overriding timeout needed so patient isn't left with stimulator on for too long.	Rater 1: 3 again critical impact on patient here and a potential safety issue.	**Priority 3** Default timeouts implemented when stimulation

	Rater 2: 2 Default time out already implemented in Section 3 and working on Section 2 & 5. Rater 3: 3	applied. In stage 2, this was from when stimulation was last changed. In stages 3 & 5, it was time since the last transition.
5) Audio indication of stimulation.	Rrater 1: 3 would allow user to see when stimulation is on without having to watch GUI. Useful when transitioning through set up with triggering in situ. Rater 2:1 as not sure if this can be implemented in Matlab Rater 3: 3. A safety-related issue, as reduces the chance of users not realising when stimulation is on.	**Priority 3** Audio facility added. Allowed user to see when stimulation was on without having to watch GUI. Useful when transitioning through set-up with triggering in situ.
ii) Ergonomics 1 – May involve significant coding	**Researcher ratings**	**Final rating and design outcome**
6) Uncertainty about when to save & suggestion to have prompts to save. ***In general, they prefer to actively press a dedicated button to know something has been done.***	Rater 1: 2 as this cropped up quite frequently Rater 2: 1 as user training would take care of this Rater 3: 2 as this should also be fairly simple to change and have a significant effect on reducing irritation.	**Priority 2** Save buttons included
7) Select buttons are better than clicking on panes. ***In general, they prefer to actively press a dedicated button to know something has been done.***	Rater 1: 2 This was quite irritating especially in stage 4 Rater 2:2 Rater 3 : not sure what this was about???	**Priority 2** Stage 4 redesigned to include select buttons
8) Where users try to move on without first stopping something, use pop up error message.	Rater 1: 2 annoying and time wasting to have to go back when set up is incorrect Rater 2: 1 as user training would take care of this and plenty of error messages already implemented. Rater 3: 2 too many muscles for channels?	**Priority 2** Error message introduced. When blocked from moving on, also used a message to say why.

iii) Ergonomics 2 – Simple design changes that should implement regardless of priority	Researcher ratings	Final rating and design outcome
9) Small text.	Rater 1: I'd grade this at a 1 for clinicians but would be a 3 for patient use Rater 2: 1 Rater 3: I would say 2 for all users. It is trivial to change	**Priority 1** Not implemented in this version of the GUI as mainly for use with clinicians. However, will be considered in next development of GUI
10) Need to improve wording (e.g. use verbs where appropriate).	Rater 1: 2 repeated problem that slowed users down due to confusion re. meaning Rater 2: 2 Rater 3: 2 trivial to change, but will help with usability. Same priority as (a) and (b)	**Priority 2** Wording improved where applicable and possible.
11) % of what when values are shown.	Rater 1: 1 not sure many users would query this. As long as it was consistent and accurate not a real problem Rater 2: 1 Rater 3: 1. However, training needs to clearly explain what is meant by intensity of stimulation (maybe using units – we shouldn't get too hung up on avoiding basic concepts).	**Priority 1** Checked for units throughout
12) Some muscles not in alphabetical order	Rater 1: 2 easy to fix and will improve usability Rater 2: 2 Rater 3: trivial 1	**Priority 2** Muscles listed checked and amended where necessary
13) More training/documentation is needed to explain principles rather than GUI navigation. What are we trying to achieve, particularly in Stages 3 and 4?	Rater 1: 1 Agree training needs to be in place but doesn't in my view excuse navigation that is not to some degree self- explanatory. Therapists might not be using FES every day so needs to be fairly easy to navigate as unlikely to refer to manual each time! Rater 2: 1 Rater 3: 1 not sure this is an issue that should be addressed here	**Priority 1** Was not relevant to this stage of the process but left in as reminder. Design team agreed that training needed to be in place but this shouldn't excuse poor signposting to user.

B) <u>Stage specific usability problems</u>		
<u>Stage Two</u>		
i) FES & State Machine Functionality	**Designer ratings**	**Final rating and design outcome**
14) Changing muscle selection should also stop stimulation (as well as pressing STOP).	Rater 1: 2 persistent problem Rater 2: 1 as user training could take care of this Rater 3: 3. Could directly affect stimulation	**Priority 3** Changed so that changing muscle section stopped stimulation
15) Need a pause stimulation button. When resumed, the stimulation would ramp back to where it was.	Rater 1: 3. Could be critical when on patients. Would be a shame to have to restart from beginning. Rater 2: 1 as there is not much difference from the present scenario. If the user drags the slider to the position before stop, the stimulation would ramp from up to the value. Rater 3: I would have to think about this?	**Priority 3** Pause stimulation button included
ii) **Ergonomics 1 – May involve significant coding**	**Designer ratings**	**Final rating and design outcome**
16) Kept forgetting to click assign (for channels & sensors).	Rater 1: 1 training and familiarity issue although would save time and number of clicks if on second click it automatically paired up the channel and muscle Rater 2: 3 could automatically assign channels to muscles and get rid of the assignment process altogether. Rater 3: 1	**Priority 1** Not implemented due to significant redesign and coding. For next iteration of GUI
17) Ran out of channels – should there be an error message in Stage 1?	Rater 1: 3 a/a Rater 2: 1 as already implemented. Rater 3: 2	**Priority 3** Error message included in stage 1.
18) Navigation unclear but easier in task 2. Need to be led through assignment and then	Rater 1: 2 persistent problem Rater 2: 1 as user training could take care of this	**Priority 2** Other option greyed out so user guided

thresholds and maximums.	Rater 3: 2	through task sequence.
19) Stimulation channels not automatically ordered	Rater 1: 1. Not a big problem and unsure how much value it adds. Rater 2: 1 but could automatically assign channels to muscles and get rid of the assignment process altogether. Rater 3: 1	**Priority 1**. Unchanged as design team preferred to keep flexibility to avoid having to remove and re-apply electrodes.
20) Display thresholds & maximums in channel listing.	Rater 1: 2 persistent problem Rater 2: 1 Rater 3: 2	**Priority 2** GUI changed so that user can see values.
21) Having only *channel* and *muscle* when assigning stimulation channels	Rater 1: 1 although it created some confusion it isn't a major problem. Rater 2: 1 Rater 3: 2. I think it is worth effort to eliminate redundancy in the version of the GUI we test. So, as we only have Hasomed and Xsens available, limit the options to these. No point in demonstrating flexibility in the GUI at this stage, as any practical system would probably be redesigned anyhow	**Priority 1** Unchanged
22) Having only *signal type*, *unit* and *segment* when assigning sensors;	CS: 1. Minor problem. AD: 1 as user training could take care of this LK: 2 see above. Let's keep the GUI we test for usability simple, without redundancy that could confuse	**Priority 1** Unchanged
23) Revisit design of Stage 2 for quick fixes to make navigation easier (better text on GUI) pop up instructions for example).	Rater 1: Yes 2 – a/a for specifics Rater 2: 1 as user training could take care of this Rater 3: 2	**Priority 2** Stage 2 some aspects redesigned to make navigation easier
l. 24) Do we need *start* and *stop* when displaying sensors.	Rater 1: Not sure? It does mean another few clicks so if not necessary better to leave out. Also everyone overlooked it so guess it's a 2 Rater 2: How do we display the sensors if we do not	**Priority 1** Unchanged although this solution was offered. How about the selected signal is displayed on entering Stage 2 and then leaving Stage 2 stops

	'start' them like the stimulator? 1 Rater 3: 1. I would leave this until we start testing in phase 2, with sensors. If it is a problem we could address it then.	it. On entering Stage 2 the selection could be "None".
25) Should not be forced to assign both sensors.	Rater 1: 3. Need to have the option to use only 1 if necessary as will save on time which is critical to the design. Rater 2: 3 Rater 3: 2. Again, an irritation, not a safety critical issue	**Priority 3** Changed to allow option of using 1 or 2 sensors.
Stage 3		
ii) Ergonomics 1 – May involve significant coding	**Designer ratings**	**Final rating and design outcome**
26) No initial ramp times included.	Rater 1: 1 Rater 2: 1 leave as it is Rater 3: At this point it is not obvious that it would help 1	**Priority 1**
27) No need to stimulate to change ramps. We could cycle round the phases without stimulation being on. **In fact, stimulation wouldn't be allowed until all ramps had non-zero values.**	Rater 1: 2. We need zero ramps for some set up's e.g where muscles need to be left on (during isometric contractions). Would be useful to cycle round without stimulation on if need be. Rater 2: 2 Rater 3: not sure???	**Priority 2** Although this was seen as a priority the design team were undecided how best to approach this problem and wanted to see how the system worked with the current design. Hence no change. Next iteration of design will change. .4th rater concluded as follows: N.B. Zero ramp times are NOT a good idea. When two consecutive targets are equal, ramp rate (not time) should be inherited. So how should we handle this? I originally suggested that the ramp box should be greyed out. Perhaps we should allow it to avoid explaining to users. So logic

		should be: IF (targets equal) OR (ramp time=0) THEN Inherit ramp rate
28) Error message if a stimulation target is not set and user tries to move to next phase?	Rater 1: 3 would affect set up so needs to flag up if it occurs. Rater 2: 1 not sure about this one as target can be '0' for a muscle when the user is advanced and no longer needs a stimulation for a certain muscle. Rater 3: 3	**Priority 1 (4th rater over ruled other raters (see comment below)** 4th raters comments – I think it will be obvious that the target is wrong in the same way that it would be for any other target… the movement is not achieved. This would then allow for rater 2's point.
29) Make *transition* and *stop* buttons more prominent.	Rater 1: 2. Repeated nuisance to users during testing. Suggest *'move to next phase'* Rater 2: 2 LK: 2. This needs to be clear, as it may affect stimulation intensity or duration. May be easy to sort out	**Priority 2** Transition button renamed 'to move phase' to avoid confusion. Stop button left unchanged.
iii) Ergonomics 2 – Simple text changes	**Designer ratings**	**Final rating and design outcome**
30) Reword to include verb "enter ramp time".	Rater 1: 1 would make it clearer and easy to change I suspect. Rater 2: Not sure in what form this is wanted, a text/error message? Rater 3: 1	**Priority 1** Unchanged
Stage 4		
i) FES & State Machine Functionality	**Designer ratings**	**Final rating and design outcome**
31) Warning needed if a timeout is shorter than any ramp in that phase (incl. ramp offs).	Rater 1: 3. could affect patient and slow set up down Rater 2: 3 Rater 3: not sure this is a problem 1	**Priority 1** Unchanged as 4th rater (moderator) felt this was unnecessary
ii) **Ergonomics 1 – May involve significant coding**	**Designer ratings**	**Final rating and design outcome**

32) Better layout and text would help including look of transition boxes	Rater 1: I thought this section of the GUI was very confusing and not at all intuitive. Hence would give it a 3 as it needs a rework. Rater 2: 1 as user training would take care of this. Rater 3: Not sure	**Priority 3** This stage of the GUI was redesigned to make it less confusing and reduce redundancy.
33) User unsure where to click to commence set up of this section.	Rater 1: 2 repeatedly confused users Rater 2: 1 Rater 3: 2	**Priority 2** This section redesigned to include select button on panes
34) Unsaved typing problem.	Rater 1: 3 very annoying and time consuming Rater 2: 1 Rater 3: 2	**Priority 2** Bug fixed

Appendix 9: Phase 2, post-test usability questionnaire data

Participant ID	Response value by question number																			Section 8 comments
	1a	1b	1c	1d	1T	2a	2b	2T	3	4	Total	Norm % total	5 Y	5 N	5 S	6	7 Y	7 N	Total	
User 1	2	3	4	4	13	3	3	6	2	2	23	17.55			x	3	x		26	Creating tasks conceptually quite difficult. Assigning channels to muscles not intuitive. Time to set up stimulator acceptable considering first use. Room for improvement and potential to be relatively quick. Device functions and interface easy to understand some of the time.
User 2	1	3	4	3	11	2	2	4	2	5	22	16.79			x	4		x	26	1d) Graphical representation of arm movements with time scales - animation of tasks 2b) Once understood what I was doing. Start wasn't obvious 4) Difficulty with the concept of what happens at end of task as task is an end in itself. Hence is no further movement required. 5) It could have been more helpful 6) Could take at least 30 mines with a patient. Library of default setting would be good to free time. 7) Not initially. Visually okay but needs more prompts / signposting & feedback. 8) Good start but needs refining to make easier to follow with better feedback. Think about the lowest ability.
User 3	4	5	5	3	17	4	2	6	3	4	30	22.9			x	3		x	33	1b) Didn't allow to go back one stage and name the section of tasks. 1c) Not help in resolving error. 2a) Clicking in wrong place. 2b) Only wanted one sensor - allowed me to choose one sensor up to the end then had to go back. 3) Tricky to remember transition button. 4) Did not know it could have to trigger. 5) Allowed me to go too far in wrong direction. 6) Needs practice 7) Some language not easily understood 8) Use of different language. When error occurs - how to correct it. Could do with default.
User 4	1	N/A	2	2	5	1	3	4	4	4	17	12.97			x	4	x		21	2a) Initial confusion with terminology of stimulation and thresholds. Also confusion with stimulate and stop button. 2b) location of start button confusing 3) Due to lack of clarity with transition and stop stimulation button. Could say move to next phase 4) Highlighting issue of each phase. i.e. to double click on time out. Words not obvious. Need button to save. 6) However new to software. 7) Some inconsistency with methods of stop / save. Some ambiguity with wording of buttons. 8) Overall less daunting than expected as a novice user.
User 5	4	3	3	5	15	3	3	6	3	3	27	20.61			x	5		x	32	1) a), b) & c) Needed to be more intuitive and or signposts. Clearer embolding of choices / options / stages. 1d) Would have appreciated some form of avator to remind me of actions chosen. Appeared rather technical - rather long-winded especially as the patient would be stimulated for quite lengthy periods during set-up. 2a) For someone who hasn't had any FES in practice rather unclear re. difference between units & channels. 3) Not very intuitive - needed greater signposting and even information re. what you are doing. 4) Again rather difficult to relate choices / parameters to patients movement. 5) Not very helpful when it happened. 6) Some of this time could be reduced by interface becoming more intuitive - signposting. However I did feel I was stimulating the patient (hypothetically) rather a lot and this could be uncomfortable. Definitely not a 1 person job! 7) Some terminology could be more informative. Same terms on screen and text didn't appear to tally - can't remember an example though. 8) Really rather technical. Patient stimulated for quite long periods. Adjusting stimulation levels not suitable using mouse - would prefer a dial e.g. hifi volume dial. Ideally the software should sense a movement - facilitated by the therapist. It could then complete (roughly) the muscles required and their action so that the therapist can adjust intensity / speed levels as necessary to enhance / progress rehab. More signposting - intuitive programing.
User 6	1	1	2	4	8	1	1	2	1	1	12	9.16		x		4	x		16	1d) In order to divide the phases would require some pre-planning movement analysis activity. 5) If unable to highlight the necessary button some 'help' would be useful e.g. need to STOP and START or STIMULATE / STOP STIMULATION. 6) 10 mins max to set up and adjust stimulation. 20 mins for a new patient. 7) Sort of - once you have used it - it becomes more intuitive. 8) Sliders should also have a type in function for the stimulation threshold setting. A 'help' button related to the function you are adjusting.
Median																				
Total	13	15	20	21	69	14	14	28	15	19	131	99.98	0	1	5	23	3	3	154	
Median																				
Mean	2.1	2.3	3.3	3.5	11.5	2.3	2.3	4.6	2.5	3.1	21.83	16.66	0Y	1N	5S	3.8	3Y	3N	25.7	

Appendix 10: Task complexity calculations for research therapist 1 and 2

Sweeping coins - researcher 2

	Reach	Sweep	No. of changes
shoulder	Neut-flex	flex-Neut	2
elbow	Flex-ext	Ext-flex	2
wrist	Neut-ext	Ext/Ext	2
		Subtotal	6
		Total	6x3(jts)=18

Sweeping coins - researcher 1

	Reach	Sweep	No. of changes
Shoulder	Neutral-Flex	Flex-Ext	2
Elbow	Flex-Ext	Ext-Flex	2
Wrist	Neutral- Ext	Ext-Ext	2
		SUB TOTAL	6
		TOTAL	6 x 3 =18

Pushing up from chair -

	I		No.
s	N	E	_
el			
		syn ext	

Pushing up from chair -

				No.
S	Neut	Ex	Ext-	
Elbow	Fle	Fl	Fle	
	Neut		E	
			SU	
			T	

Placing a tray on shelf - researcher 2

	Reach	Grasp	Lift and place	Release	No. of changes
shoulder	Neut-flex	Flex/flex	Flex-flex	Flex/flex	4
elbow	Flex-ext	Ext/ext	Ext -ext	Ext/ext	4
wrist	Neut-ext	Syn ext	Syn ext	Ext- ext	4
				Sub total	12
				Total	12x3=36

Placing a tray on shelf - researcher 1

	Reach	Grasp	Lift	Place	No. of changes
Shoulder	Neutral-Flex	Flex-Flex	Flex-Flex	Flex-Flex	4
Elbow	Flex-Ext	Ext-Ext	Ext-Ext	Ext-Ext	4
Wrist	Neutral-Ext	Ext-Ext	Ext-Ext	Ext-Ext	4
				SUB TOTAL	12
				TOTAL	36

Answering phone - researcher 2

	reach	grasp and lift	replace	release	No of changes
shoulder	Neut-flex	Flex- flex	Flex-neut	Flex/flex	4
elbow	Flex-ext	Ext-flex	Flex-ext	Ext/ext	4
forearm	Pron/pron	Pron-sup	Sup>pron	Pron/pron	4
wrist	Neut>-ext	Syn ext	Syn ext	Ext-ext	4
				Sub total	12
				Total	16x4=64

Answering Phone - researcher 1

	Reach	Grasp	Lift	Place	No. of changes
Shoulder	Neutral-Flex	Flex-Flex	Flex-Flex	Flex-Flex	4
Elbow	Flex-Ext	Ext-Ext	Ext-Flex	Flex-Ext	4
RU joint	Pro-pro	Pro-Pro	Pro-Sup	Sup-Pro	4
Wrist	Neutral-Ext	Ext-Ext	Ext-Ext	Ext-Ext	4
				SUB TOTAL	16
				TOTAL	64

Pouring from a bottle - researcher 2

	reach	grasp and pour	replace	release	No of changes
shoulder	Neut-flex	Flex/flex	Flex/flex	Flex/flex	4
elbow	Flex-ext	Ext/ext	Ext/ext	Ext/ext	4
forearm	Pr-mid pr	Mid pr-pr	Pr-mid pr	Mid pr/m	4
wrist	Neut-ext	Syn ext	Syn ext	Ext-ext	4
				Subtotal	16
				Total	16x4=**64**

Pouring from bottle - researcher 1

	Reach	Grasp	Pour	Place & release	No. of changes
Shoulder	Neutral-Flex	Flex-Flex	Flex-Flex	Flex-Flex	4
	Same				
Elbow	Flex-Ext	Ext-Ext	Ext-Ext	Ext-Ext	4
	Same				
R/U joints	Pronation-Neutral	Neut-Neut	Neut-Pro	Pro-Neut	4
	Similar				
Wrist	Neutral-Ext	Ext-Ext	Ext-Ext	Ext-Ext	4
				SUB TOTAL	16
				TOTAL	64

Opening a door

	reach	grasp & turn	pull	release	No of changes
shoulder	Neut-flex	Flex/flex	Flex-ext	Ext/ext	4
elbow	Ext-flex	Flex-flex	Flex-flex	Flex/flex	4
forearm	Mid pr-pr	Pron-sup	Sup/sup	Sup/sup	4
wrist	Neut-ext	Syn ext	Syn ext	Ext-ext	4
				Sutotal	16
				Total	16x4=64

Opening door

	Reach	Grasp	Open	No. of changes
Shoulder	Neutral-Flexion	Flex-Flex	Flex-Ext	3
	Same configuration as KW			
Elbow	Neutral-Ext	Ext-Ext	Ext-Flex	3
	slightly different			
R/U joints	Neutral-Pronation	Pro-Pro	Pro-Sup	3
	direction of pro-sup depends on which hand is used!			
Wrist	Neutral-Extension	Ext-Ext	Ext-Ext	3
	Same			
			SUB TOTAL	12
			TOTAL	48

Placing block on shelf

	reach	grasp	place	release	No of changes
shoulder	Neut-flex	Flex/flex	Flex-flex	Flex/flex	4
elbow	Flex-ext	Ext/ext	Ext> ext	Ext/ext	4
wrist	Neut-ext	Syn ext	Syn ext	Ext-ext	4
				Subtotal	12
				Total	12x3=36

	Reach	Grasp	Lift	Place	No. of changes
Shoulder	Neutral-Flex	Flex-Flex	Flex-Flex	Flex-Flex	4
Elbow	Flex-Flex	Flex-Flex	Flex-Flex	Flex-Ext	4
Wrist	Neutral-Ext	Ext-Ext	Ext-Ext	Ext-Ext	4
				SUB TOTAL	12
				TOTAL	36

Appendix 11: Phase four LREC and University of Salford ethical approval letters

NHS
Health Research Authority
National Research Ethics Service

NRES Committee North West - Liverpool Central
HRA NRES Centre - Manchester
3rd Floor
Barlow House
4 Minshull Street
Manchester
M1 3DZ

Tel: 0161 625 7818
Fax: 0161 625 7299

31 July 2013

Prof David Howard
Professor of Biomedical Engineering
University of Salford
School of Computing, Science & Eng
Newton building
University of Salford
M5 4WT

Dear Prof Howard

Study title:	**Signal processing methods for FES control of the upper limb and feedback**
REC reference:	**10/H1005/26**
IRAS project ID;	**52144**

This study was given a favourable ethical opinion by the Committee on 16 July 2010.

Research Ethics Committees are required to keep a favourable opinion under review in the light of progress reports and any developments in the study. You should submit a progress report for the study 12 months after the date on which the favourable opinion was given, and then annually thereafter. Our records indicate that a progress report is overdue. It would be appreciated if you could complete and submit the report by no later than one month from the date of this letter.

Guidance on progress reports and a copy of the standard NRES progress report form is available from the National Research Ethics Service website.

The NRES website also provides guidance on declaring the end of the study.

If you fail to submit regular progress reports – which is a condition of the favourable ethical opinion – the REC may wish to consider suspending or terminating its opinion.

10/H1005/26:	**Please quote this number on all correspondence**

Yours sincerely

Mrs Carol Ebenezer
Committee Co-ordinator

E-mail: nrescommittee.northwest-liverpoolcentral@nhs.net

Copy to: *Mr Tim Clements*

Appendix 12: Phase five, proof of concept clinical trial NHS NRES, SRFT R & D and University of Salford approval letters

R&D Approval of 2012/133neuro (95988)

Reply Reply All Forward

R&D Approval of 2012/133neuro (95988)

Maureen Daniels [Maureen.Daniels@manchester.ac.uk]

To: Smith Christine

Cc: jane.wainwright@srft.nhs.uk

Attachments: SRFT Approval.pdf (92 KB) [Open as Web Page]

06 August 2012 11:33

- This message was sent with High importance.
- You replied on 06/08/2012 12:34.

Dear Christine

Study: Evaluation of an upper limb FES setup procedure in a clinical setting

Please find attached the R&D approval letter for the above study. We no longer send out hard copies of approval letters and you should keep the attached copy for your site file.

Good luck in the research.

PS – The completed Research Passports and letters of access will follow shortly in a separate email.

Best wishes
Maureen

Maureen Daniels
Research Governance Officer (Approvals)
Salford Royal NHS Foundation Trust
Level 3, Mayo Building
Stott Lane, Salford M6 8HD

Tel: 0161 206 7051
Email: Maureen.daniels@manchester.ac.uk

From:	Carter Cynthia (NHSNW)
To:	Smith Christine
Cc:	Kenney Laurence; Braid Susan; Sue.Gowland@manchester.ac.uk
Subject:	RE: 12/NW/0315 Smith - Fav+Conds ack letter
Date:	Thursday, May 17, 2012 6:51:36 PM
Attachments:	12 0315 Smith - PIS Patient v2.0.pdf 12 0315 Smith - PIS Therapist+RA v2.0.pdf 12 0315 Smith - Consent form Patient v2.0.pdf 12 0315 Smith - Consent form Therapist+RA v2.0.pdf 12 0315 Smith - Fav+Conds ack.pdf

Christine

Further to our phone conversation this evening, everything has been addressed except additional condition 2 in our letter dated 03 May 2012. I have deleted the word 'appendix' and number from the PISs and Consent forms to comply with the additional condition. I have not changed anything else and attach copies to ensure that these are the versions used in recruitment, etc.

Please find attached the acknowledgement letter for the revised PISs, Consent forms and the device Product leaflet.

Regards

Cynthia

Ms Cynthia Carter | REC Co-ordinator
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26 July 2012

Dear Chris,

RE: ETHICS APPLICATION HSCR12/43 – Setting up functional electrical stimulation systems in a rehabilitation setting, for treatment of the upper limb post stroke - an exploratory study

Following your responses to the Panel's queries, based on the information you provided, I am pleased to inform you that application HSCR12/43 has now been approved.

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 13: Technology Acceptance Measure (TAM) questionnaire

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Technology Acceptance Model Questionnaire

(Training stage)

Centre Name: **Date:**

Therapist / RA ID:

***Instructions*:** This questionnaire looks at users experience with the FES test system after the training period. There are two parts to the evaluation. The first part is a scale which requires you to circle the number which best describes your experience with the test system with 5 being positive and 1 being negative. The second part requires a written answer to the question. Thank you for your participation in the research.

1. Using the FES test system would improve my job performance.

Definitely **5 4 3 2 1** ***Not at all***

2. Using the FES test system would make it easier to do my job

Definitely **5 4 3 2 1** ***Not at all***

3. Using the FES test system would enhance my effectiveness on the job

Definitely **5 4 3 2 1** ***Not at all***

4. Using the FES test system would increase my productivity

Definitely **5 4 3 2 1** ***Not at all***

5. Using the FES test system would enable me to accomplish tasks more quickly

Definitely **5 4 3 2 1** ***Not at all***

6. I would find the FES test system useful in my job

Definitely **5 4 3 2 1** ***Not at all***

7. Learning to operate the FES test system was easy for me

Definitely **5 4 3 2 1** ***Not at all***

8. My interaction with the FES test system was clear and understandable

Definitely **5 4 3 2 1** ***Not at all***

9. It would be easy for me to become skilful at using the FES test system

Definitely **5 4 3 2 1** ***Not at all***

10. I found it easy to get the FES test system to do what I want

Definitely **5 4 3 2 1** ***Not at all***

11. I found the FES test system flexible to interact with

Definitely **5 4 3 2 1** ***Not at all***

12. I found the FES test system easy to use

Definitely **5 4 3 2 1** ***Not at all***

13. I am ready to start using the FES test system in the study

Definitely **5 4 3 2 1** ***Not at all***

<u>Open ended questions:</u>

What was your overall impression of the FES test system?

What, if any, were the best features of the FES test system?

What, if any, were the worst features of the FES test system?

How could it be made better and why?

Thank you for completing the questionnaire

University of Salford MANCHESTER

Centre Name: **Date:**

Therapist / Rehab Assistant ID:

Technology Acceptance Model Questionnaire

End of study stage

Instructions: This evaluation looks at users experience with the FES test system once the study has finished. There are two parts to the evaluation. The first part is a scale which requires you to circle the number which best describes your experience with the FES test system with 5 being positive and 1 being negative. The second part requires a written answer to the question. Thank you for your participation in the research.

1. Using the FES test system has improved my job performance.

Definitely 5 4 3 2 1 *Not at all*

2. Using the FES test system has made it easier to do my job

Definitely 5 4 3 2 1 *Not at all*

3. Using the FES test system has enhanced my effectiveness on the job

Definitely 5 4 3 2 1 *Not at all*

4. Using the FES test system has increased my productivity

Definitely 5 4 3 2 1 *Not at all*

5. Using the FES test system has enabled me to accomplish tasks more quickly

Definitely 5 4 3 2 1 *Not at all*

6. I have found the FES test system useful in my job

Definitely 5 4 3 2 1 *Not at all*

7. Learning to operate the FES test system was easy for me

Definitely 5 4 3 2 1 *Not at all*

8. My interaction with the FES test system was clear and understandable

Definitely 5 4 3 2 1 *Not at all*

9. I have become skilful at using the FES test system

Definitely 5 4 3 2 1 *Not at all*

10. I have found it easy to get the FES test system to do what I want

Definitely 5 4 3 2 1 *Not at all*

11. I have found the FES test system flexible to interact with

Definitely 5 4 3 2 1 *Not at all*

12. I have found the FES test system easy to use

Definitely 5 4 3 2 1 *Not at all*

Therapist Open ended questions:

What was your overall impression of the FES test system?

What, if any, were the best features?

What, if any, were the worst features?

How could it be made better and why?

Appendix 14: FES task attainment scale

University of Salford MANCHESTER

FES Task Attainment Scale

Centre Name: **Date:**

Therapist / RA ID: **Patient ID:**

Description of functional task	

Indicator

-2	Task aborted, unable to achieve goal
-1	Task partly achieved but not sufficiently beneficial to warrant use of FES
0	Patients current level of ability without FES
1	Task partly achieved, FES beneficial although task had to be adapted
2	Task is achieved is fully and effectively achieved

Comments e.g. if the task needed to be adapted provide description of new task and reasons for adaptation.

Appendix 15: Phase five usability testing, post-test debrief form

University of Salford MANCHESTER

Centre Name: **Date:**

Therapist / Rehab Assistant ID: **Session No:**

Post Session Therapist Debrief

What were your treatment goals when you started the session?

Were these achieved? ***(please circle)*** **YES NO**

If NO, please explain why not:

What worked well within the session?

Were any difficulties encountered?

How would you rate the ease of set up?

Very Easy	Easy	Neither easy nor difficult	Difficult	V difficult
5	4	3	2	1

Comments:

_____
_____
_____
_____
_____

Appendix 16: Software Usability Measurement Inventory (SUMI)

Software Usability Measurement Inventory

SUMI

NB The information you provide is kept completely confidential, and no information is stored on computer media that could identify you as a person.

This questionnaire has 50 statements. Please answer them all. After each statement there are three boxes.

- Check the first box if you generally AGREE with the statement.
- Check the middle box if you are UNDECIDED, or if the statement has no relevance to your software or to your situation.
- Check the right box if you generally DISAGREE with the statement.

In checking the left or right box you are not necessarily indicating strong agreement or disagreement but just your general feeling most of the time.

There are also five general questions at the end.

Statements 1 to 10 of 50	***Agree***	***Undecided***	***Disagree***
This software responds too slowly to inputs			
I would recommend this software to my colleagues			
The instructions and prompts are helpful			
This software has at some time stopped unexpectedly.			
Learning to operate this software initially is full of problems.			
I sometimes don't know what to do next with this software			
I enjoy the time I spend using this software.			
I find that the help information given by this software is not very useful			
If this software stops it is not easy to restart it.			
It takes too long to learn the software functions.			

Statements 11 - 20 of 50	***Agree***	***Undecided***	***Disagree***
I sometimes wonder if I am using the right function.			
Working with this software is satisfying			
The way that system information is presented is clear and understandable			
I feel safer if I use only a few familiar functions.			
The software is very informative			
This software seems to disrupt the way I normally like to arrange my work			
Working with this software is mentally stimulating			
There is never enough information on the screen when it's needed			
I feel in command of this software when I am using it			
I prefer to stick to the functions that I know best			

Statements 21 - 30 of 50.	*Agree*	*Undecided*	*Disagree*
I think this software is inconsistent.			
I would not like to use this software every day.			
I can understand and act on the information provided by this software.			
This software is awkward when I want to do something which is not standard.			
There is too much to read before you can use the software.			
Tasks can be performed in a straight forward manner using this software.			
Using this software is frustrating.			
The software has helped me overcome any problems I have had in using it.			
The speed of this software is fast enough.			
I keep having to go back to look at the guides.			

Statements 31 to 40 of 50.			*Disagree*
It is obvious that user needs have been fully taken into consideration.			

There have been times in using this software when I have felt quite tense.

The organisation of the menus seems quite logical.

The software allows the user to be economic of keystrokes.

Learning how to use new functions is difficult.

There are too many steps required to get something to work.

I think this software has sometimes given me a headache.

Error messages are not adequate.

It is easy to make the software do exactly what you want.

I will never learn to use all that is offered in this software.

There have been times in using this software when I have felt quite tense.

The organisation of the menus seems quite logical.

The software allows the user to be economic of keystrokes.

Learning how to use new functions is difficult.

There are too many steps required to get something to work.

I think this software has sometimes given me a headache.

Error messages are not adequate.

It is easy to make the software do exactly what you want.

I will never learn to use all that is offered in this software.

Statements 41 - 50 of 50. **Agree Undecided Disagree**

The software hasn't always done what I was expecting.

The software presents itself in a very attractive way.

Either the amount or quality of the help information varies across the system.

It is relatively easy to move from one part of a task to another.

It is easy to forget how to do things with this software.

This software occasionally behaves in a way which can't be understood.

This software is really very awkward.

It is easy to see at a glance what the options are at each stage.

Getting data files in and out of the system is not easy.

I have to look for assistance most times when I use this software.

What, in general, do you use this software for?

How important for you is the kind of software you have just been rating?

Extremely important
Important
Not very important
Not important at all

How would you rate your software skills and knowledge?

Very experienced and technical
I'm good but not very technical
I can cope with most software
I find most software difficult to use

What do you think is the best aspect of this software, and why?

What do you think needs most improvement, and why?

Appendix 17: Phase five, post-training confidence questionnaire

University of Salford MANCHESTER

Centre Name: **Date:**

Therapist / RA ID:

FES Test System Training Questionnaire

Please rate your own ability to complete stages 1 to 4 of the Graphical User Interface (GUI) following the training sessions. Thank you for taking part in the research.

1. Log on to the FES test system:

Confident Not confident

Comment:

_____
_____
_____

2. Log out of the FES test system

Confident Not confident

Comment:

_____
_____
_____

3. Completing stage 1 of the set up process

Confident Not confident

Comment:

_____
_____
_____

4. Completing stage 2 of the set up process

Confident Not confident

Comment:

_____
_____

5. Donning electrodes

Confident Not confident

Comment:

_____
_____
_____

6. Donning sensors

Confident Not confident

Comment:

_____
_____
_____

7. Completing stage 3 of the set up process

Confident Not confident

Comment:

_____
_____
_____

8. Completing stage 4 of the set up process

Confident Not confident

Comment:

_____
_____
_____

9. Please indicate the most useful aspects of the training sessions

10. Please indicate the least useful aspects of the training

11. Please suggest how the training could be improved

Appendix 18: Phase five usability testing, post-session debrief data

Therapist / RA ID	Session no.	Task	T/t goals achieved? (Y/P/N)	What worked well	Difficulties	Ease of setup score	Comments
PT1A	1	SC	Y	System reliable. Ptn. liked treatment	Co-ordinating software with facilitation. Software timing out	3	None
PT1A	2	SC-R	Y	Setting up equipment more confidence. Ptn enjoyed session	Reaching angle trigger in stage 4. Sensor stopped working.	3	None
PT1A	3	PM-N	P	Recruitment of wrist extension initially, ptn engagement, tolerance of task	Required normalisation of tone in biceps in between repetitions to avoid clonus	MD	Creating new task not as difficult as had anticipated.
PT2A	1	SC	Y	Positive response for ptn. Goals achieved	None	3	Need to set a more challenging task next session.
PT2A	2	PC	Y	Repetition of task, sequence of task with instruction	Fatigue limited repetition	4	Therapist reported feeling more confident today.
PT1A	3	PC-R	Y	Repetition & carry-over of task. Use of same setup parameters	None	4	Quicker setup with repeated task.
PT1A	4	PB	Y	Completed task successfully. Good feedback from ptn. – felt FES helped to lift arm more effectively.	Timing out during stage 2	4	Feels that reset parameters needs a reminder pop up box, stage 4 becoming easier, time out issues need addressing
PT2A	1	SC	Y	Ptn. Able to	Difficulties reaching	4	None

				identify when to initiate movement phase as they could feel the stimulation	required angle. However, therapist gained confidence regarding what to do when this occurred.		
RA1A	1	SC	Y	Worked well with the ptn.	Some assistance required initially to familiarise but then managed fine.	3	None
RA1A	2	SC-R	Y	Quicker setup time due to parameters already saved from last session.	None	4	None
PT3B	1	PB	Y	Sit to stand easier as session progressed	Ptn. very tired	2	None
PT3B	2	PB-R	Y	Improvement in speed of movement during session	Time pressure, computer issues that required expert intervention.	2	With facilitation by x2 therapists
PT4B	1	SC	Y	Patient engaged well with task and was able to tolerate the setup time	None	2	Felt needed prompting due to length of time since last used. Placement of electrodes was easy enough but setting computer settings felt more difficult. This might feel better if I had more practice.

Appendix 19: SPSS tables from Chapters 6 and 7.

A 2-tailed Pearson Correlation analysis for task complexity and setup time

Correlations		Task Complexity	Setup Time
Task Complexity	Pearson Correlation	1	.255
	Sig. (2-tailed)		.229
	N	24	24
Setup Time	Pearson Correlation	.255	1
	Sig. (2-tailed)	.229	
	N	24	24

A two-tailed Pearson Correlation analysis for upper limb impairment and setup times.

Correlations		Setup Time	Impairment
Setup Time	Pearson Correlation	1	-.643**
	Sig. (2-tailed)		.001
	N	24	24
Impairment	Pearson Correlation	-.643**	1
	Sig. (2-tailed)	.001	
	N	24	24

**. Correlation is significant at the 0.01 level (2-tailed).

Model summary for upper limb impairment on setup time

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Durbin-Watson
1	**.643[a]**	**.413**	**.386**	**8.89770**	**1.307**

a. Predictors: (Constant), Impairment; b. Dependent Variable: Setup Time

Analysis of Variance (ANOVA) for upper limb impairment and setup time

Model 1		Sum of Squares	Df	Mean Square	F	Sig.
1	Regression	1225.964	1	1225.964	15.485	.001[b]
	Residual	1741.721	22	79.169		
	Total	2967.685	23			

a. Dependent Variable: Setup Time b. Predictors: (Constant), Impairment

Model summaries for prediction of setup time from upper limb impairment and task complexity, Section 6.4.6.1

Model 2: Summary for the dependent variable setup time using upper limb impairment and task complexity.

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Durbin-Watson
2	.741[a]	.549	.506	7.99503	1.994

Analysis of Variance (ANOVA) for impairment and task complexity and setup time.

Model 2	Sum of Squares	df	Mean Square	F	Sig.
Regression	**1634.034**	**2**	**817.017**	**12.782**	**.000234***
Residual	**1342.329**	**21**	**63.920**		
Total	**2976.364**	**23**			

Impact of impairment and task complexity on the model and equation to predict setup time, Section 6.4.6.2

Table displaying unstandardized and standardised coefficients, standard error, t values and level of significance, for upper limb impairment and task complexity.

Coefficients [a]					
	Unstandardized Coefficients (unit dependent)		**Standardized Coefficients (unit independent)**	**T**	**Sig.**
	B	Std. Error	Beta		
(Constant)	59.042	8.507		6.940	.000001
Impairment	-1.280	.269	-.707	-4.752	.000108*
Task Complexity	.221	.088	.373	2.509	.020 *

Chapter 7.

Pearson correlation analysis for upper limb impairment and setup times

Correlations		**Setup times (clinical testing)**	**Impairment (clinical testing)**
Setup times (clinical test)	Pearson Correlation	1	-.540
	Sig. (2-tailed)		.133
	N	9	9
Impairment (clinical testing)	Pearson Correlation	-.540	1
	Sig. (2-tailed)	.133	
	N	9	9

Appendix 20: Publications from the thesis

Conference presentations

Smith, C., Kenney, L., Howard, D., Waring, K., Williamson, T., Taylor, P., Batty, R. (2011). Eliciting therapists requirements to inform the design of an advanced FES rehabilitation Tool. *The First European Conference Design4Health, Sheffield, UK*. ISBN: 978-1-84387-352-5

Smith, C & Williamson, T. (2010). Gathering users views for the design of rehabilitation technology devices. *AAATE, Sheffield, UK.*

Poster presentations

Smith, C., Kenney, L., Howard, D., Hardiker, N., Waring, K., Sun, M., Luckie, H. (2015). A method to predict setup time for an FES Rehabilitation Tool for upper limb therapy after stroke. *UKIFESS, Sheffield, UK.*

Smith, C, Kenney, L., Howard, D., Waring, K., Sun, M., Hardiker, N. (2013). The relationship between impairment, functional ability, hand-arm task complexity and set-up difficulty for an Advanced FES Rehab Tool. *UKIFESS, Southampton, UK.*

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