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On the effect of Functional Electrical Stimulation upon Spasticity and Gait in the Individual with Incomplete Spinal Cord Injury

Elaine May Scott

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Abstract

Functional electrical stimulation (FES) has been used for many years as a method of improving walking ability in individuals with neurological damage. In spite of this, its use in mainstream physiotherapy practice continues to be limited. One of the possible reasons for this may be the persistent belief that FES somehow increases spasticity in this subject group.

This study had two main aims: to investigate the effects of FES upon spasticity, and upon the walking abilities in the individual with incomplete spinal cord injury (ISCI).

Review of the literature relating to FES, spasticity and gait resulted in the following conclusions. FES has not been shown to increase spasticity; in fact it is far more likely to decrease it via the activation of spinal inhibitory neuronal mechanisms. FES has been found to have an overall beneficial affect on gait parameters. Although it is perceived as a substantially disabling impairment, spasticity is a hugely complex phenomenon that has proven difficult to measure. Conclusions as to the effects of spasticity upon gait need to be made with care. Due to this final point consideration was also given to the theoretical links between spasticity and gait.

As the measurement of spasticity was shown to be substantially problematic, a review of the psychometric properties of the measures chosen to answer the research questions was undertaken.

Given the stated aims of the project, two research questions were asked:

1. What changes in spasticity does an individual who receives FES as a treatment experience?
2. What changes in gait does an individual who receives FES as a treatment experience?

The chosen methodology was that of a single subject experimental design. Ten subjects with incomplete spinal cord injury were recruited to the study; eight completed the programme. FES systems were applied cutaneously to improve the walking abilities of all subjects. The Modified Ashworth Scale (MAS) and isokinetic dynamometric analysis of lower limb resistance to movement were used as measures of spasticity. The Rancho Los Amigos Observational Gait Analysis System (OGA) was chosen to analyse walking ability. TELER Gait Indicators were developed, also to analyse gait, due to the perceived issues with the Rancho Los Amigos system.

The results of this study show that spasticity, when measured by the MAS, did not increase in 7 out of 8 subjects. When considered as a group, the subjects demonstrated substantial improvement in their walking abilities. When considered individually the degree of improvement varied substantially.

The overall conclusion is that FES can be a useful treatment option for the subject with ISCI. However, careful assessment and application is needed to optimise benefit for the individual. This study also adds to the literature regarding FES, spasticity and gait in its use of a methodology that allows the clinician to consider potential benefits to the individual subject.

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CHAPTER 1: INTRODUCTION

1.1 Background to this study

The purpose of this study was to investigate the use of functional electrical stimulation applied to subjects with incomplete spinal cord injury to improve their walking ability. The effects of this treatment upon spasticity and gait were considered.

Spinal cord injury (SCI) is seen as a result of trauma or pathological damage to the spinal cord. There are an approximated 600-900 new injuries in this country every year. The majority of injuries treated in Spinal Injury Units are due to trauma, the age group often young. SCI results in a very substantial degree of disability for the individual, having a devastating impact upon all areas of their lifestyle. Damage to the spinal cord may result in a complete or incomplete injury. Incomplete injuries (ISCI) have some degree of either motor or sensory sparing below the level of damage to the cord.

Functional electrical stimulation (FES) has been used as a treatment modality for subjects with neurological conditions, including spinal cord injury, since Liberson's work in the early 1960's. Kidd (1992) defined FES as:

> *"A form of electrical stimulation that will cause a muscle to generate a force adequate to perform an artificial function expected of it"*

Electrical stimulation can also be used for pain relief, muscle training and diagnostic nerve testing. For the purposes of this study FES was cutaneously applied to the lower limbs to enhance gait in the chosen subject population. Whilst most literature relating to the subject suggests that FES is likely to decrease spasticity, there are some articles that report increases in spasticity.

Spasticity is an impairment that may occur following injury to the central nervous system (CNS). Many people who sustain spinal cord injury go on to develop a significant level of spasticity. Spasticity has been linked to decreased ability to produce normal movement, to the development of joint and soft tissue contractures, to pain and to the development of pressure sores. All of these issues can substantially limit functional abilities and therefore add to the level of disability and handicap experienced by these individuals. Physiotherapists working in the field of neurology spend much

time attempting to decrease and control its effects. Any intervention that may be considered as increasing spasticity is likely to be discarded as a viable treatment option. With spasticity as one variable under consideration, its valid and reliable measurement was seen as the key to the overall validity of the study. Definitions of spasticity and tools for its measurement are varied and disparate. Spasticity is often used not as an exclusive term, but rather as an umbrella term for the features of the upper motor neurone syndrome (a complex collection of pathological sequelae to CNS damage). To avoid confusion and aid clarity in this thesis Lance's (1980) definition of spasticity was used:

> *'Spasticity is a motor disorder characterised by a velocity dependent increase in tonic stretch reflexes ('muscle tone') with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex, as one component of the upper motor neurone syndrome'*

The research study for this thesis ran in conjunction with a three-year European Union funded study titled 'Clinical Rehabilitation using Electrical Stimulation via Telematics' (CREST). This project ran from 1997-2000 and investigated both the use of FES for gait enhancement in spinal cord injury and the exchange of computerised clinical information between treatment centres. The Princess Royal Spinal Injuries Unit at the Northern General Hospital Trust in Sheffield was one of five European Centres, specialising in the treatment of spinal cord injuries, involved in the CREST study. The ten CREST study subjects chosen for Sheffield's part in the project were used for this authors study. The chosen methodology of the CREST study was that of repeated single case studies. A large variety of parameters were measured for the CREST project – for example - muscle strength, spasticity, gait and disability status. The Modified Ashworth Scale and Rancho Los Amigos Observational Gait Analysis System specified in the CREST study were therefore two of the measures used in this authors study. Due to the perceived issues with these tests further measures of spasticity and gait were chosen. Isokinetic dynamometry was used to quantify spasticity during passive movement of the knee joint. TELER® Normal Gait Indicators were developed as an observational gait analysis tool.

In undertaking a Master of Philosophy degree, the issue of evidence-based practice comes into focus in three key areas: the findings of the already existing evidence-base in

the literature, the potential place for the findings of this study within that evidence-base and the implications for clinical practice. In 1993 the Department of Health's Research and Development Strategy for the National Health Service stated that its main aim was 'to see that research became an integral part of healthcare'. This was so that practitioners, managers and other staff found it natural to rely on the results of research in their day-to-day decision-making and long term strategic planning. It went on to comment that there remained an issue where 'belief-based views' rather than relevant knowledge from reliable sources still had a major effect upon the provision of healthcare. The clearly stated intent in this document was that research-based evidence should become an integral part of healthcare provision. There have been many debates in the literature since the publication of this research report regarding the benefits or otherwise of evidence-based practice. Detractors fear that it will negatively affect clinical autonomy, that treatment would become an oversimplified set of guidelines and that clinicians would be reduced to mere technicians. Other authors see this as the chance to bring research-based practice more formally into the working lives of therapists and to enhance patient care.

In her article from 1997, Newham took the view that research is of vital importance to direct treatment. However, little attention appears to be given to the experience of the clinician in the process of treatment. Other authors, whilst promoting the need for evidence-based practice (EBP), emphasise the role of the clinician. Sackett *et al* (1996) defined evidence-based medicine as '*the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients*'. The authors went on to discuss the importance of the expert clinician in the interpretation of research data and the appropriate application or rejection of it dependent upon the individual patient's situation.

The research strategy of the Chartered Society of Physiotherapy (Chartered Society of Physiotherapy, 1995) stated that research is an integral and essential aspect of physiotherapy. Many authors concur with this statement (Moore, 1997, Bury & Mead, 1998, Barnard & Wiles, 2001). There is a perceived need to increase the profile of research within the profession at a clinical level – an acknowledged need to break down some of the barriers to research findings being implemented in clinical practice and to increase collaboration between clinicians and academics (Moore *op. cit.*). Within this recognised need for improvements in research dissemination and integration into day-

to-day clinical practice, Sumsion (1997) echoes Sackett *et als'* (1996) emphasis on the importance of the patient in this process. Due to increased levels of awareness, patients are less and less the passive recipients of clinicians perceived 'best practice'. Any intervention must be appropriate to their needs.

Evidence-based practice should ensure the use of research to optimise patient care appropriate to the individual. For research to be directed towards improving care, clinicians and academics must collaborate to benefit from each other's specialist knowledge and to ensure dissemination of research findings. However, Bannigan & Bryar's (2002) recent review of research utilization, the final stage of the evidence-based practice process, discovered that allied health professionals in clinical practice seldom use research findings. A number of possible reasons were given for this, conflicting reports and lack of clarity of implications for practice in the literature being two stated possibilities. There remains a gap between research and clinical practice. The pinnacle of research is often seen as the randomised controlled trial. The results from such research may be of limited use to the therapist working in a clinical setting and dealing on a daily basis with a host of enmeshed, possibly confounding issues. By its very nature the randomised controlled trial gives information on the 'average' in a very sanitised setting. Within a clinical neurorehabilitative setting treatment is not 'by rote' or 'applied', but rather an active process of informed negotiation that directs treatment towards the individual's needs and particular problems.

1.2 Aims and Objectives

The above key themes (incomplete spinal cord injury, FES, spasticity and the need for clinically applicable findings in research), and the links with the CREST Project, directed the course of this study. The initial purpose of this study was to investigate the effects of functional electrical stimulation (FES) applied to the lower limb upon spasticity in the individual with incomplete spinal cord injury. In clinical practice spasticity is considered to have a negative effect upon walking ability. Whilst FES, applied as a dynamic orthosis, has been shown to improve gait, spasticity may be an undesirable side-effect of such treatment. The initial aims of this study were therefore to investigate the effects of FES upon spasticity in subjects with spinal cord injury, and in particular the effects of any such changes upon gait. However, review of the literature relating to spasticity, and in particular to the valid measurement of spasticity,

necessitated a change in direction as a natural development of the study. The reviewed objectives were therefore to:

1. Investigate the effects of FES upon spasticity in the individual with incomplete spinal cord injury
2. Investigate the effects of FES upon the walking abilities of the individual with incomplete spinal cord injury

Consideration was also given to the theoretical links between spasticity and walking ability.

As the purpose of this project was to evaluate the effects of FES in the individual, the chosen methodology was that of a single subject experimental design (SSED). Measurements were taken at initial and final baselines (AB design). Ten subjects were initially recruited, giving a multiple baseline design across subjects (Ottenbacher, 1986). Whilst the chosen methodology may not meet the upper echelons of the hierarchy of research evidence as recognised by the Chartered Society of Physiotherapy (table 1.1), it is hoped that the strength of the SSED in answering clinical questions for the individual will be demonstrated.

Table 1.1: Hierarchy of strength of evidence (Ref. Moore, 1995)

I	Strong evidence from at least one systematic review of multiple well-designed randomised control trials
II	Strong evidence from at least one properly designed randomised control trial of appropriate size
III	Evidence from well-designed trials without randomisation, single group pre-post, cohort, time series or matched case-controlled studies
IV	Evidence from well-designed non-experimental studies from more than one centre or research group
V	Opinions of respected authorities, based on clinical evidence, descriptive studies or reports of expert committees

1.3 Summary

This thesis will present a review of the effects of FES upon spasticity and upon gait for ten individuals with incomplete spinal cord injury. The following chapters will define spasticity and its effects upon spinal cord injury, review the literature relating to FES, spasticity and gait, describe the methodology and measurement tools used, present results and draw conclusions for these subjects. Where possible, implications for clinical practice from these findings will be discussed.

CHAPTER 2: LITERATURE REVIEW

The intent of this study was to investigate the effects of functional electrical stimulation (FES) upon spasticity. In this instance FES was applied to improve the gait of individuals with incomplete spinal cord injury, so the effect of spasticity change upon gait was also to be considered. This chapter presents a review of the literature relating to spinal cord injury (SCI), FES, spasticity and gait, pulling together links between all four topics.

The aetiology and incidence of spinal cord injury are introduced, along with the resultant effects of the pathology upon the individual. The increasing population sustaining, and living with, incomplete spinal cord injury is also presented, as this was the subject group under study.

The clinical uses and physiological effects of FES as a treatment for neurological conditions are explored. The final sections of this chapter consider the literature relating FES to spasticity and to gait, and to the links between spasticity and gait.

The section relating to spasticity is substantial. Initial reading on the subject of spasticity showed that the subject is hugely complex and poorly understood. Given that this was one of the phenomena to be measured the author considered that a comprehensive understanding of the neuropathology of spasticity was necessary both to be able to chose appropriate outcome measures and to be able to consider the possible effect of FES upon this impairment.

2.1 Spinal Cord Injury

2.1.a An Overview:

Spinal cord injury (SCI) occurs due to traumatic or pathological damage to the spinal cord or *cauda equina*. It may result in a loss of motor, sensory or autonomic function, or any combination of these, below the level of the injury. Normal bladder, bowel and sexual function may also be lost.

In the UK, patients with SCI are managed in one of the ten Spinal Injury Units scattered across the country. Sir Ludwig Guttman, a neurologist, set up the first Spinal Injuries Unit at Stoke Mandeville Hospital in Aylesbury in 1944 for the treatment of ex-servicemen. He prescribed systems for the management and prevention of the major complications of SCI and emphasised the importance of specialist nursing and therapy management of such injuries. He strongly advocated that these patients should be managed within specialist units. Other units in the UK, the United States and Australia soon opened. This approach to the management of SCI brought about huge positive change in the life and health expectancy of those sustaining spinal cord damage (Bedbrook, 1985).

2.1.b Aetiology and Incidence:

The incidence of SCI in this country is 10-15 cases per million of the population (Grundy *et al*, 1986). This means that there are approximately 600-900 new injuries per annum: 80% of these injuries are due to trauma; 20% to pathology. The main cause of traumatic injury is road traffic accidents (up to 50%). Industrial accidents, falls at home, sport, assaults and self-harm are some of the other main causes. There are two peak age ranges: 16-30 year olds and the 60-plus age group. The male to female ratio is 4:1.

Cervical spine injuries result in tetra/quadriplegia - a paralysis that involves all four limbs. Neck injuries account for up to 50% of all Spinal Injury Unit admissions. Injuries to the thoracic, lumbar or sacral spine result in paraplegia – a paralysis that affects lower limbs and trunk to a greater or lesser degree. Level of injury is described in terms of the last intact neurological segment, for example, C5 complete (an injury complete below the 5^{th} cervical level) and T9 incomplete (an injury with some degree of sparing below the 9^{th} thoracic level).

Zejdlik (1992) reports spinal cord injury statistics for the USA similar to those in the UK. The main difference seen in the States is the percentage of injuries due to gunshot wounds and assault in some sectors of the population.

Admission statistics for a five-year period from 1995-2000 (Ash, unpublished) are shown in figures 2.1 to 2.4, inclusive, for the Princess Royal Spinal Injuries Unit

Princess Royal Spinal Injuries Unit
Admission Statistics 1995-2000

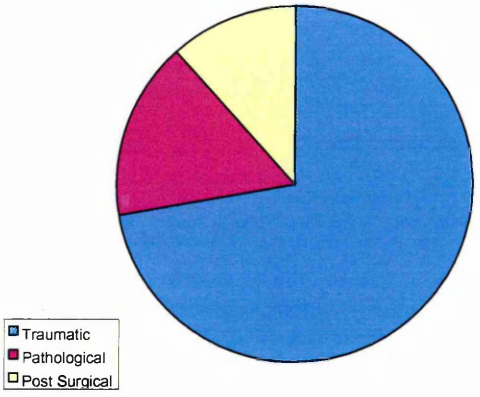


Figure 2.1: Causative Factors

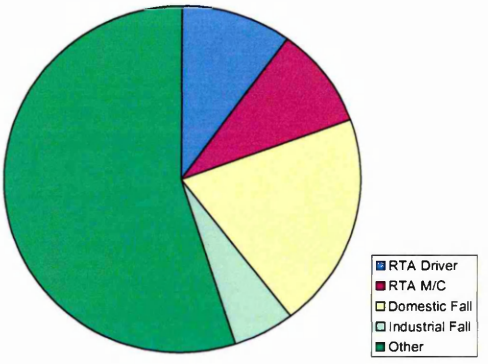


Figure 2.2: Mechanism of Injury

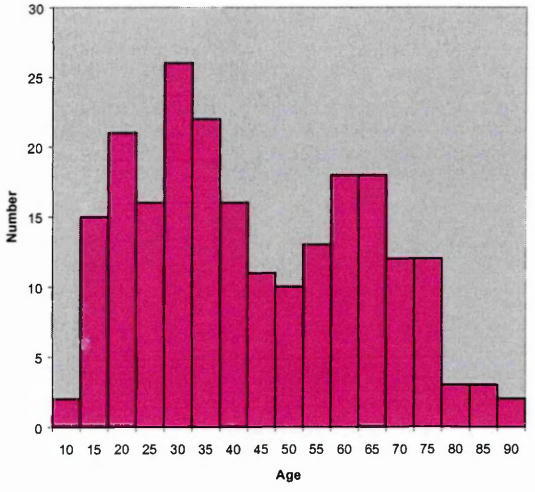


Figure 2.3: Age at Injury

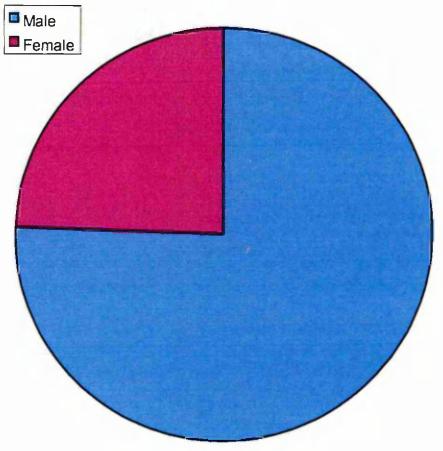


Figure 2.4: Gender

(PRSIU), where this project was conducted. The statistics are similar to those for the UK (Grundy *et al,* 1986).

2.1.c Incomplete Injuries:

An incomplete injury is one in which any combination of motor, sensory or autonomic function remains intact below the level of the lesion. There are a number of ways of defining incomplete injuries – either by describing the pattern of paralysis following injury (Figure 2.5) or by categorising the neurology remaining to the patient such as the American Spinal Injuries Association Impairment Scale (Maynard *et al,* 1997).

Table 2.1: ASIA Impairment Scale (Maynard *et al* 1997)

Classification	Neurological sparing
A – complete	No motor or sensory function is preserved below the level of the lesion
B – incomplete	Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-5
C – incomplete	Motor function is preserved below the neurological level, more than half of key muscles below this have a muscle grade less than 3
D – incomplete	Motor function is preserved below the neurological level, at least half of key muscles below the level have a muscle grade of 3 or more
E - normal	Motor and sensory function is normal

For the purposes of this study the American Spinal Injuries Association (ASIA) impairment scale definitions (Table 2.1) were used to give a broad definition of the level of neurology remaining to the subject. This is a widely recognised scale, which is in frequent use in clinical practice. This scale was used in the CREST project.

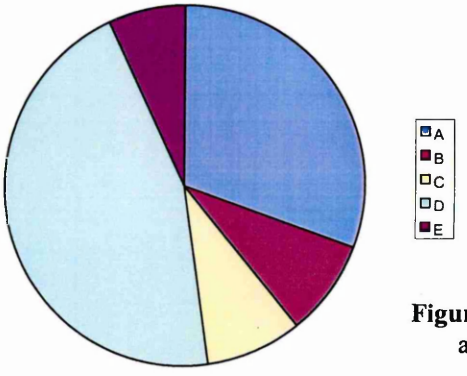
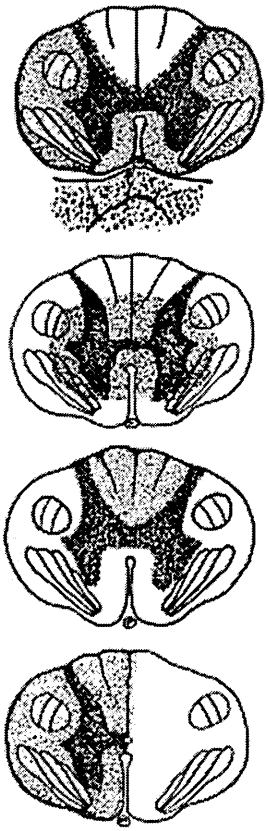


Figure 2.6: ASIA Grades on admission to PRSIU



Anterior Cord Syndrome – the anterior part of the cord is damaged due to a flexion injury, producing an anterior dislocation or a compression wedge fracture. Corticospinal and spinothalamic tracts are damaged due to direct trauma and spinal artery compression leads to ischaemia. Clinical picture is of loss of power and reduced pain and temperature sensation below the level of the lesion.

Central Cord Syndrome – typically seen in older patients with cervical spondylosis. Mechanism is a hyperextension injury that compresses the cord between osteophytic vertebral body and intervertebral disc and the ligamentum flavum. Grey matter at the level of the lesion and centrally situated cervical tracts are most damaged. Classic picture is of flaccid weakness of arms with relatively strong but spastic trunk and legs.

Posterior Cord Syndrome – most common in hyperextension injuries where the spinal arch has been damaged. This results in loss of proprioception due to posterior column damage. Patients may have good power and pain and temperature but profound ataxia.

Brown-Sequard Syndrome – classically due to stab injuries but also occurs where the lateral mass fractures of the vertebrae have occurred. Signs are those of a hemisection of the cord. Reduced or absent power and proprioception but good pain and temperature on the side of the injury as the spinothalamic tract decussates in the cord. The uninjured side has good power and proprioception but reduced or absent pain and temperature.

Figure 2.5: Incomplete Syndromes (Ref. Grundy *et al*, 1986)

Edwards (1991) stated that a considerable percentage of patients with spinal cord injury had incomplete injuries– on average 50% of patients on a SIU at any one time may have some degree of sparing. Unpublished work from the Princess Royal Spinal Injuries Unit (Ash, unpublished) showed that approximately 70% of the admissions to the Unit during the period 1995-2000 were incomplete injuries (Figure 2.6). This work mirrors the findings of the author in a small study over an 18-month period in the early 1990's where it was again found that over 70% of admissions to the Unit were incomplete.

Incomplete spinal cord injuries can also be divided into upper or lower motor neurone lesions. Upper motor neurone lesions occur where the spinal cord is damaged at or above the level of the first lumbar vertebrae. The spinal cord terminates at this level in the *conus medullaris,* then *cauda equina*, which compromises the nerve roots of the lumbar, sacral and coccygeal segments. Damage below T12 therefore results in a lower motor neurone lesion whose clinical presentation is effectively that of a peripheral injury – with a complete loss of spinal reflexes and often profound muscle wasting.

Subjects for this project were all classified as either ASIA C or D lesions. All had injuries above the level of T12.

2.1.d Health and Life Expectancy;

An Egyptian physician noted the first recorded case of spinal cord injury in 2500BC when he described the signs and symptoms of a young man with tetraplegia. His final words were *'...an ailment not to be treated'*. This very much remained the popular perception, as the prognosis following injury was so poor. Statistics from World War I showed that 90% of patients suffering a spinal cord injury died within one year. Approximately 1% were still alive 20 years post-injury. The main causes of death were either early complications such as respiratory distress, paralytic ileus or deep venous thrombosis, or 'any time' complications such as decubitus ulcers leading to septicaemia or poorly managed bladder and bowel leading to renal failure or bowel complications.

However, since Ludwig Guttman's pioneering work following the Second World War, with the setting up of specialist units, life and health expectancy has gradually increased. Improved management at the scene of the accident, in Accident and Emergency Units, the early transfer of patients to SIU's and other developments in

medical science have undoubtedly also added to life expectancy for this patient population.

Bedbrook (1985) emphasised the need for total care in specialist units. It is not just the acute management that is of importance but the provision of a comprehensive rehabilitation package and follow-up, which ensures early identification, and treatment of possible complications. The Princess Royal Spinal Injuries Unit, like many others, provides a 'cradle to grave' service. Following discharge from hospital, patients return for annual review. They can also self refer for assessment. Where complications develop – such as pressure sores, urological problems, fractures or long term respiratory problems – patients are managed on the Spinal Unit.

Where septicaemia following pressure sores and urological complications leading to renal failure were once the main causes of mortality, vascular disease and cancers are an increasing cause of death in individuals with spinal cord injury. Life expectancy is now within a few years of the expected average for the rest of the population.

2.1.e Spasticity in the Spinal Cord Injured Subject

Spasticity in spinal cord injury is a topic to which much time and space in literature is devoted. Studies show that approximately 78% of people with spinal cord injury develop some level of spasticity by discharge from hospital. 40% of these subjects report it as 'problematic'- that is affecting activities of daily living, linked to pain, and not well controlled by medication. Reports of problematic spasticity correlate with level of injury (cervical and upper thoracic injuries) and degree of incompleteness (ASIA C and D categories). All the subjects for this study are categorised as ASIA C or D injuries. There is therefore a substantial possibility of these candidates already having a 'problematic' level of spasticity. This is of importance as it is these categories of subjects, who have some ability or potential to walk, who are subjects for this study.

A small number of studies have been published which consider the epidemology of spasticity. Maynard *et al* (1990) published the results of two studies they had undertaken. Spasticity was considered to be present if deep tendon reflexes were increased, if muscle tone was increased during passive movement, and if involuntary muscle spasms were present. The assessments were undertaken on discharge and at the

subjects' first annual follow-up. The scale used was an ordinal one, where no spasticity was graded as 0 and 'problematic' spasticity (that which had been treated with unsatisfactory results) was graded as 3. The assessing physician graded spasticity. The second study followed the same basis as above. 466 patients with traumatic spinal cord injury were assessed. Both sets of results were collated by level of injury and by Frankel grading for classification of degree of incompleteness. Study 1 found that 67% of subjects developed spasticity by discharge from hospital with 37% needing medication by that time. By follow up 78% presented with spasticity with 49% medicated. Study 2 found that 26% of subjects were medicated by discharge and 46% by follow up. The most frequently medicated subjects fell into Frankel categories C and D with 50% and 52% respectively being treated. The ASIA classification system is based upon that developed by Frankel, C and D grades from each system are very similar.

Skold (1999) gained similar results. This author studied 354 SCI subjects and found that 65% of subjects reported developing spasticity, 43% of who said their spasticity was problematic. Skold's operational definition of spasticity was as above but included pathological radiation of reflexes. There were significant links between reports of problematic spasticity and incomplete injuries. As well as subjects' self reports on spasticity levels, assessment was undertaken using the Modified Ashworth Scale (MAS) (Bohannon & Smith, 1987). Only 60% of the subjects reporting it were found to have elicitable spasticity on assessment.

Johnson *et al* (1998) again corroborated the above findings. They undertook initial assessments then telephone questionnaire follow-ups over a five-year period and found that approximately 30% of subjects reported spasticity as problematic.

Maynard *et al* (1990) identified some of the main issues with their studies: the subjectivity of the measurement scale, the discrepancy between the two sets of subjects being medicated by discharge (37% and 26%). They believed that this could have been due to different criteria used for indications for treating spasticity. Skold (1999) suggested that the reason for the discrepancy between self-reported and clinician elicited spasticity could be that the MAS may only measure one aspect of spasticity.

All three papers use different clinical scales or other investigative methods. The scales may raise questions as to their validity as true measures of spasticity. Different

understandings – operationalisation - of what spasticity is between groups of clinicians and subjects may also be expected to cause differences in results. However, in spite of these issues these three independent studies have produced remarkable similar findings as to the epidemiology of 'spasticity' within the spinal cord injured population. The accurate definition of spasticity and its valid measurement are key issues to this thesis.

2.1.f Section Summary

SCI affects a very small but significant percentage of the population each year. Life expectancy is now almost normal, and there is a growing population of people living with SCI. The relative percentage of incomplete injuries - who may have the potential to walk - is increasing. Spasticity is significantly problematic following injury, in particular amongst those with incomplete injuries, adding to disability levels. The main group affected by SCI is the young. The percentage returning to work is low. As Trieschmann (1986) states SCI is a 'low-incidence but high-cost disability that makes tremendous changes in a person's lifestyle'. Treatments, such as FES, which may have a beneficial impact upon levels of handicap and disability need to be fully explored and, if appropriate, considered as possible treatment options.

2.2 Functional Electrical Stimulation

Early experiments by Swammerdam and Galvani in the 17^{th} and 18^{th} centuries respectively demonstrated that the electrical excitation of nerve caused muscle to contract. The knowledge needed to evolve neural prostheses of a size small enough to be practical in a clinical setting became available with the development of the transistor in the 1950s. Since that time there has been a substantial development in the technology needed to produce function via electrical stimulation. FES has found its way into everyday clinical practice in the form of pacemakers, bladder stimulators and phrenic nerve stimulators. Other applications have included its use in the facilitation of standing and gait.

FES has been used in the treatment of many neurological conditions. Burridge *et al* (1997a) reported on their work with stroke patients. Bajd *et al* (1999) and Granat *et al* (1993) are amongst many who have used FES extensively with spinal cord injured patients. There are also references to be found in the use of FES with cerebral palsy,

head injury and multiple sclerosis (e.g. Dimitrijevic & Dimitrijevic, 1992). Any pathology that results in motor loss due to damage to the upper motor neurone is potentially responsive to FES.

Electrical stimulation has been used for many years in the treatment of SCI. The literature records a wide variety of possible uses in both upper and lower limb rehabilitation. In the 1980's a group of bio-engineers based in Ljubljana, Slovenia, produced a large body of work relating to the use of electrical stimulation, particularly for SCI. The therapeutic effects of electrical stimulation and its use in the management of spasticity have also been investigated by authors such as Vodovnik (1981).

FES is now used in both research centres and specialist clinical centres. Its more general use in the clinical field however is still limited. The potential demand for FES as a treatment option and possible reasons for its limited use in clinical practice shall be considered in the following section.

2.2.a Demand for Functional Electrical Stimulation in Spinal Cord Injury

Patient demand for FES systems has been assessed in two studies. Jaeger *et al* (1990) undertook a retrospective study of medical records for 192 patients with spinal cord injury. They estimated a minimum of 10.4% and a maximum of 25% (dependent upon relaxation of some inclusion criteria) of their subjects as possible FES users. However, they were considering FES for complete injuries from T4-T12 spinal levels. These authors also estimated their subject group to make up 45% of the SCI population. The above study was therefore of limited use to this thesis where the aim was to enhance gait in incomplete subjects who already had some walking ability. The percentage of incomplete spinal cord injury (approximately 70%) apparent in recent studies may also make the above study less relevant in the present day. As part of the CREST project, Maxwell *et al* (1999) published the results of a questionnaire survey looking at the potential demand for FES devices. Whilst 19% of respondents stated that they had used functional electrical stimulation, only 2% had done so for walking. 16% of respondents stated that they could walk independently but less than half of these could do so for more than 50 metres. 13% had used some form of orthosis. Whilst this article was slightly confusing in its data presentation and should have included a section on level of lesion (FES not being applicable for injuries to the *cauda equina*), it would appear to be

reasonable to conclude that only a tiny percentage of potential users were using FES systems for gait enhancement. The sample group were self selected members of the Spinal Injuries Association.

In spite of the apparent potential population who could benefit from FES and the increasing sophistication of commercially available systems this is not a treatment option that is often chosen in clinical practice. In this author's opinion the following reasons may add to the general reluctance of physiotherapists to use such systems:

- Lack of underpinning knowledge in and the potential uses of FES
- Few reliable, flexible systems available for purchase
- A generally held belief that FES increases spasticity – 'in clinical practice there even exists a widespread attitude that one should not stimulate an already 'overstimulated' spastic muscle' (Stefanovska *et al,* 1989)

Whatever the actual underlying issues, FES is infrequently used in the clinical workplace. Given the emphasis put upon controlling and decreasing spasticity in the clinical management of neurologically damaged subjects, the final point may well be enough to prevent physiotherapists exploring this as an option for treatment.

2.2.b Physiological effects of FES:

The FES systems used for this project make muscle contract via stimulation of nervous tissue. Whilst it is possible to stimulate denervated muscle, this is not practical in the clinical setting at present because the amplitude of current or stimulus pulse width needs to be far greater than that which will stimulate muscle with an intact nerve supply. Electrical stimulation can be applied via surface or implanted electrodes. There are benefits and potential risks with both options. This study used surface applied electrodes. This is a non-invasive technique that is relatively simple to apply.

Electrodes can be placed either directly over the muscle to be stimulated to effect a contraction, or over an afferent nerve to produce a reflex movement. Excitation of the nerve axon (depolarisation) occurs principally at the cathode (negative electrode). Hyperpolarisation occurs at the anode (positive electrode). The placement and size of electrodes and the electrode to skin impedance all need careful consideration to ensure a given stimulus causes an action potential. Electrodes should be placed in close proximity to the nerve. When a stimulus of sufficient intensity and frequency is applied

to the nerve temporal and/or spatial summation of action potentials occur and the muscle is caused to contract. Stimulation will travel both proximally and distally from the point of stimulation. Muscle contraction can therefore be directly affected by the motor efferent or indirectly by a reflex response to the stimulation.

Electrical stimulation initially recruits large diameter axons as they offer lower impedance to current (Baker, 1993). Smaller diameter axons are likely to be the last recruited into activity. This is the opposite pattern of recruitment to that seen in normal physiological muscle contraction. Electrical stimulation is not specific when applied to peripheral, mixed nerve. All types of nerve fibres will potentially be excited. As well as alpha motor neurones, group Ia and II afferents from intrafusal muscle fibres, Ib afferents from golgi tendon organs, sensory, cutaneous and sympathetic nerve fibres are all likely to be stimulated. The effect of electrical stimulation is therefore complex.

Figure 2.7 summarises the potential effects of electrical stimulation (Vodovnik & Stefanovska, 1992). The fourth effect of electrical stimulation 'change in cell membrane transport' relates to trophic systems within nerve and muscle and is not addressed by this thesis. Restorative functional stimulation is also known as therapeutic stimulation.

The potential effects of FES can be considered in two timescales. In the short-term, FES will produce a contraction of muscle and potentially functional movement. This is often described as orthotic stimulation. With continued use over time, many other therapeutic physiological effects have been reported

FES can address the loss or negative aspects of upper motor neurone damage seen in SCI - that is fatigue, weakness and atrophy (Dimitrijevic & Dimitrijevic, 1992). SCI subjects demonstrate a decreased ability to produce smooth, efficient contraction of muscle and they fatigue quickly. Relatively smaller percentages of fatigue-resistant motor units are present in the muscles of SCI subjects than in the 'normal' population. Disturbances in motor unit recruitment and modulation of anterior horn cell firing rates have also been shown (Heckman, 1994). Reported benefits with the use of FES have included changes in muscle phenotype from fast-fatiguable to fatigue-resistant fibres (e.g. Pette & Vrbová, 1999,Gordon & Mao, 1994), increases in muscle bulk (e.g. Mohr *et al*, 1997), improved muscle strength (e.g. Ferguson & Granat, 1992) improved blood flow (e.g. Daly *et al*, 1996) and improved sensation.

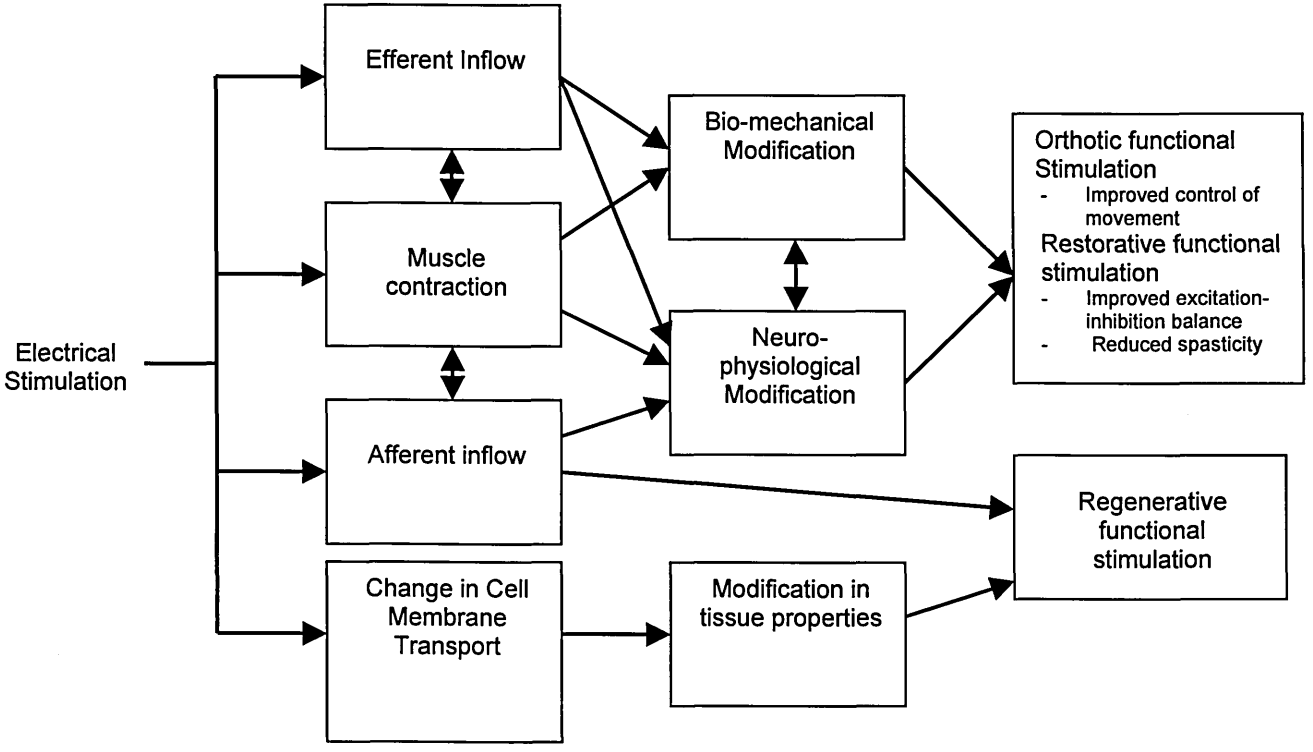


Figure 2.7: The Effects of Electrical Stimulation (Vodovnik & Stefanovska, 1992)

As well as the negative features that are related to a loss of motor activity, FES has been reported as having an effect on the 'motor overactivities' (see table 2.2) that follow central nervous system damage. Evidence of both increases (e.g. Robinson *et al,* 1988) and decreases (e.g. Burridge *et al* 1997b, Stefanovska *et al,* 1989) in spasticity have been reported. Daly *et al* (1996) described the use of electrical stimulation as a tool for neuroplastic change and motor 'learning' at cord level.

2.2.c Section Summary

FES has been used as a therapeutic tool for many years in the treatment of a variety of neurological conditions. It has not, however, come into widespread use in clinical practice. This may be for a variety of reasons, one of which may be a lack of understanding of its complex neurophysiological effects. The above review would suggest that FES is capable of improving gait by both its immediate orthotic effect of producing movement by making muscle contract and in applying a 'training effect' – improving muscle bulk, phenotype and blood supply. It may also be that FES can address the effects of spasticity at a synaptic level. To understand the possible effects of FES upon spasticity an understanding of its underlying neurophysiology – what spasticity is, how it develops and how the central nervous system attempts to compensate for it – is necessary.

2.3 Spasticity

2.3.a Definition:

Spasticity is a much discussed phenomenon in the field of neuroscience and rehabilitation literature. It occurs following damage to the upper motor neurone within the brain or spinal cord. Sheean (1998) described spasticity as hypertonia that shows as an increased resistance to movement. In spite of its being a common sequela to neurological disease, and its being recognised by many practitioners in the field as a substantially disabling one, it is poorly defined in the literature. According to Young (1994) this is *'presumably because the neurobiology of the motor system remains largely a mystery'.*

The term spasticity is frequently used as a generic one to describe an increase in muscle tone or other tonal abnormalities in individuals with central nervous system (CNS) damage. This confusion does not assist in the definition of the impairment. Clarity of definition is of vital importance in the recognition and measurement of spasticity so that clinicians can direct treatment appropriately (Sheean, 1998). From a research viewpoint definition is important so that the validity of measurement tools can be ensured. If validity is considered in its broadest sense as 'the extent to which an item actually measures what the researcher purports it to measure' (Krebs, 1987) then the importance of definition becomes apparent. Accurate measurement depends, in part, upon a clear definition of the dimension in question. If this is clearly defined appropriate measurement tools can be chosen. Much of the literature relating to spasticity is unclear in its definition and therefore hazy in its use of measurement tools and outcomes.

To clarify this issue and for the purposes of this project Lance's (1980) definition of spasticity will be used:

> *'Spasticity is a motor disorder characterised by a velocity dependent increase in tonic stretch reflexes ('muscle tone') with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex, as one component of the upper motor neurone syndrome'*

This definition, although under some debate, is still the most commonly referred to in the literature relating to spasticity.

The stretch reflex has both phasic and tonic components. The phasic stretch reflex is a (mainly) monosynaptic response to quick muscle stretch such as the tendon tap. The tonic stretch reflex implicated in spasticity is an oligo- or polysynaptic reflex compromising a complex variety of possible pathways. Young (1994) stated that the stretch reflex arc includes Ia afferent interneurones, Renshaw recurrent inhibition, disynaptic inhibition, nonreciprocal autogenic Ib inhibition, presynaptic inhibition onto primary afferents, remote inhibition and excitation onto motorneurones and a variety of other poorly understood circuitry. He described these interneuronal systems as acting like pre-motor neuronal integrating centres.

Given the extremely complex nature of spasticity, the often apparently confused use of the term in both clinical practice and research literature, and its importance to this study as the impairment being investigated, a deeper knowledge and understanding of this impairment was necessary to ensure valid measurement and therefore study validity.

2.3.b Spasticity as part of the Upper Motor Neurone Syndrome:

The upper motor neurone syndrome (UMNS) is a useful but non-specific concept which describes a number of phenomena seen when the upper motor neurone is damaged. Upper motor neurones (UMN) are motor neurones in any long, descending tract that control or influence movement and muscle tone. They have a variably direct influence upon the excitability of the lower motor neurone (LMN) or anterior horn cell. The LMN has an enormous dendritic tree with a large surface area covered with thousands of synaptic boutons. The main role of these neurones is to 'translate the huge variety of input from afferent and descending fibres and from interneurones into an output that will precisely control the contraction of muscle fibres in the development of force or patterns of movement' (Burke 1990). The influence of UMN's is effected by either direct synapse onto the LMN or, more commonly, via a network of interneurones. They modulate important segmental motor reflex activity in the spinal cord. The majority of the positive phenomena (Table 2.2) of the UMNS are due to interruption of supraspinal control of these reflexes (Sheean, 1998).

From the breakdown shown in Table 2.2, it can be seen that spasticity is a positive feature of the UMNS. The other positive features, which result in motor overactivities, are frequently mislabelled 'spasticity'. Whilst they tend to occur together, there are clear differences in the pathophysiology of many of these phenomena. It is beyond the scope of this project to describe these differences. Sheean, in 'Spasticity Rehabilitation' (1998), gives a good overview. The use of the terms 'positive' and 'negative' is unfortunately misleading. Both terms relate to abnormal pathological changes, positive to excessive activity, negative to a resultant lack of activity. A positive change in this context is not beneficial.

The positive and negative features are interdependent. Many of the negative features may result from the effects of the positive. The loss of the central nervous system's ability to produce a cohesive input to the LMN may prevent normal efferent activity and

therefore appropriate, efficient functional movement. Effectively a 'disuse' atrophy of musculature is seen with attendant soft tissue change.

Table 2.2: Features of the upper motor neurone syndrome (Sheean 1998)

NEGATIVE
Acute Hypotonia (Shock)
Weakness due to inadequate muscle activation
Loss of dexterity
Loss of cutaneous reflexes
Fatiguability

POSITIVE
At rest in response to peripheral stimulation

Proprioceptive	***Nociceptive***
Increased tendon reflexes with radiation	Positive Babinsky
Clonus	Extensor spasms
Spasticity	Flexor spasms
	Mass reflex

During movement (spastic dystonias)
Dyssynergic patterns of co-contraction
Associated reactions
Flexor withdrawal reflexes
Positive support reaction
Extensor thrust
'Pushing' reactions

The next section shall consider the pathophysiological changes that are believed to lead to spasticity.

2.3.c Pathophysiology of spasticity

Motor systems have three levels of control: the spinal cord, the brainstem and the brain. The spinal cord is considered as the lowest in the hierarchy. These systems are organised serially and in parallel. Spinal segmental mechanisms have an important role to play in the production and control of movement. They are modulated by both proprioceptive and higher centre input through a complex system of interneurones. (Kandel, Schwartz & Jessell, 2000). In the case of CNS damage the normal balance of these mechanisms is lost, spasticity being one of the possible results from this damage.

There are many descending tracts within the brainstem and spinal cord. Those believed to be particularly involved with the development of spasticity and other features of the UMNS are the dorsal reticulospinal tract (inhibitory to spinal stretch reflexes) and the ventral reticulospinal and vestibulospinal tracts (mainly excitatory). These tracts have an effect on the lower motor neurone (LMN) or anterior horn cell via a complex system

of interneurones. It is the balance between these descending tracts which controls the spinal stretch reflexes and flexor and extensor reflexes. Loss or partial loss results in an imbalance of this normal control mechanism.

Sheean (1998) states that spasticity is believed to result from an enhanced tonic stretch reflex (TSR). The TSR is a polysynaptic reflex which occurs in response to a stretch of a relatively long duration (when compared to the phasic or 'tendon jerk' reflex). In the normal neurological system, the excitability of this reflex is dependent upon the balance of higher centre input as described above. It is believed that should a movement need to be adjusted the stretch reflex can be enhanced or diminished, as the situation requires to fine-tune activity (Davidoff, 1992). In spasticity, the individual may be unable to control the reflex which then responds to stretch whether it is relevant or not (Carr & Shepherd, 1998). The tonic stretch reflex can therefore be considered as having an important role to play in functional activity.

There are three key elements likely to affect the sensitivity of TSR pathway:

1. The muscle spindle sensitivity
2. Intrinsic excitability of the alpha motorneuron
3. Interneuronal processing of the Ia afferent information within the spinal cord

Where it was previously believed that the muscle spindle caused the increase in muscle tone due to enhanced fusimotor drive, more recent work has shown that there is no increase in this. It has been shown that it is the processing of Ia afferent information that is enhanced (Sheean 1998).

As well as changes in descending input and its effect upon spasticity, the role of neuroplastic change as a result of pathology or injury has to be considered. Heckman (1994) described subjects with spasticity as suffering from two movement deficits: transmission of voluntary movement commands are impaired, and commands which do reach the spinal cord encounter abnormal and hyperexcitable circuitry. This suggests both a change in descending input and in alterations at a spinal level occurring concurrently.

2.3.c.i Changes in neural inhibitory mechanisms following neurological injury

Much has been written about the spinal mechanisms controlling stretch reflex excitability. Kandel, Schwartz & Jessell (2000) stated that inhibitory interneurones played important roles in the co-ordination of reflex activity and therefore normal control of movement. Loss of such inhibition is believed to lead to the development of spasticity and other positive, or overactivity, features (see table 2.2) of the UMNS. This section considers the effects that damage to the CNS has upon the function of specific interneurones.

Although many complex and poorly understood mechanisms have been implicated (see section 2.3.a), current literature concentrates particularly upon the activity of the Ia inhibitory interneurone. This mechanism is involved with the control of reciprocal inhibition of muscle agonist-antagonist activity and therefore in the degree of co-contraction around joints during movement.

Ia fibres from muscle spindles excite motor nerves from that muscle and also those with a similar action. At the same time Ia fibres inhibit antagonistic muscles via Ia inhibitory interneurones (Figure 2.8A). This is the basis for reciprocal inhibition. This system is of importance to the production of controlled voluntary movement. Inhibition can be increased or decreased to allow freer movement (increased reciprocal inhibition) or to increase stability (co-contraction or co-activation) at a joint. Ia inhibitory interneurones also receive both inhibitory and excitatory information from descending pathways.

Studies investigating the activity of the Ia inhibitory interneurone have shown (Morita, *et al*, 2001, Crone, *et al*, 1994) that subjects with neurological injury are less able to control co-contraction of the soleus muscle in response to active dorsiflexion of the ankle joint. Both authors found that the short-latency inhibition of the ankle planter flexors (antagonist muscle group), present in the normal subject group at the onset of ankle dorsiflexion (agonist muscle group), was not present in the group with spasticity. It was hypothesised that this lack of reciprocal inhibition added to functional movement deficits seen in subjects with neurological damage. Boorman *et al* (1996) investigated 'natural reciprocal inhibition' in patients with spasticity following incomplete spinal cord injury. The authors stated that reciprocal Ia inhibition and presynaptic inhibition of Ia afferents by higher centres both play a role in natural reciprocal inhibition.

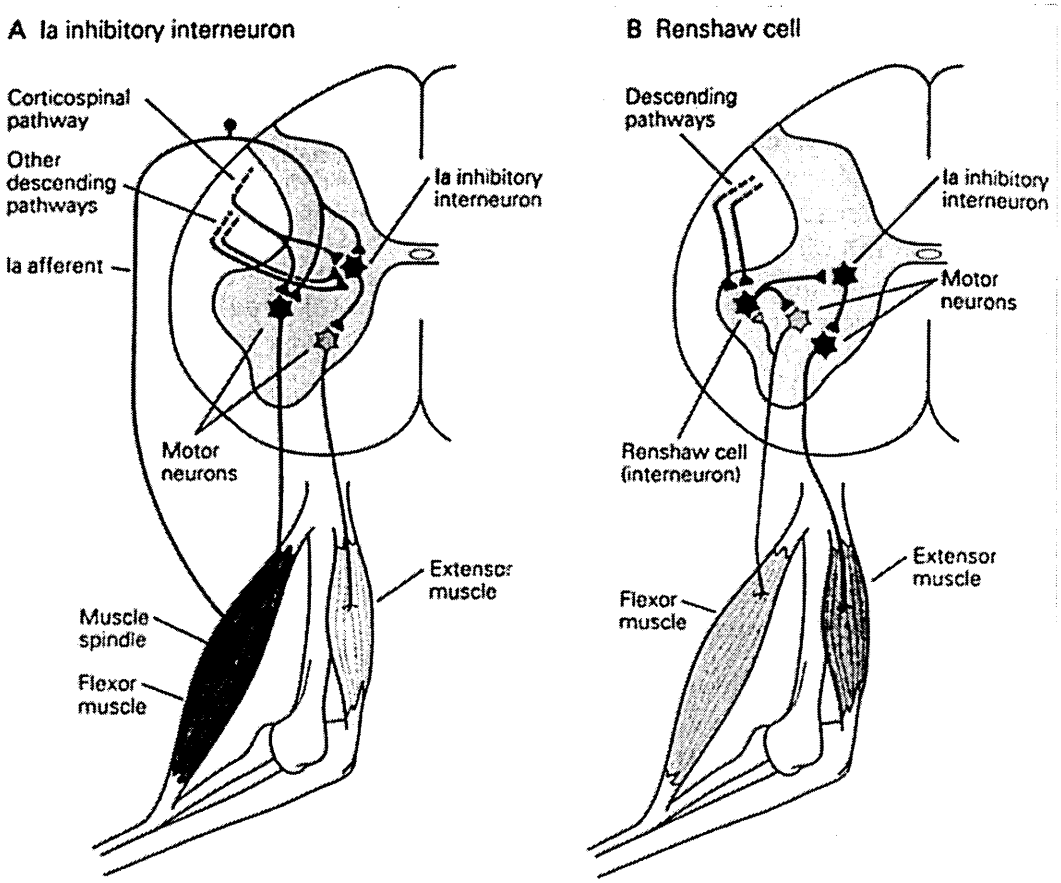


Figure 2.8: Spinal inhibitory interneurons
A – Ia inhibitory interneuron
B – Renshaw cell (Rf Kandel, Schwartz & Jessel, 2000)

They found that, compared to their control group of normal subjects, the subjects with ISCI demonstrated impaired reciprocal inhibition and a related large degree of co-activation of soleus during dorsiflexion. This effect was particularly active during fast, alternating ankle movement, such as those seen during walking.

Faist *et al* (1994) also investigated the effect of changes in Ia presynaptic inhibition upon spasticity development. They found that the subject group with SCI demonstrated a decreased level of presynaptic inhibition. They did not however find a correlation between this and their clinical measure of spasticity – the Ashworth Scale (Ashworth 1964). This led them to deduce that the changes in presynaptic inhibition did not have a substantial effect upon spasticity. This conclusion begs the question as to whether or not the Ashworth Scale can be considered as more of an analogue to true spasticity than electrophysiological testing of interneuronal activity. The discrepancy between research laboratory and clinical measures of spasticity is one which many authors highlight. This is an important issue and will be returned to in the section upon measurement of spasticity later in this chapter.

The part of Renshaw cells (RC) in regulating the activity of the Ia inhibitory interneurone also needs consideration. RC's are spinal interneurones that produce recurrent inhibition of motor neurons. They are excited by collaterals from motorneurones and form a negative feedback loop to inhibit those same motorneurones thus regulating their excitability and stabilising firing rates. These cells also send collaterals to synergist motor neurons and Ia inhibitory interneurones. They therefore exert an inhibitory influence upon all the motorneurones around a joint by their links to agonist, antagonistic and synergistic muscle groups (Figure 2.8B). Mazzocchio & Rossi (1997) studied the activity of the Renshaw cell (RC) in subjects with spasticity. They stated that these subjects lack in task dependent modulation of RC activity. During normal movement, descending commands provide a variable regulation of RC activity dependent on the motor task. RC activity is maintained by the reticulospinal systems, working in parallel with the corticospinal tracts. A lesion of the reticulospinal tract would lower the level of RC excitability, the result of which is inappropriate co-activation of muscles around a joint. The net result of these changes is again believed to have an effect upon patient function.

This section has summarised the role of the Ia inhibitory interneurone in reciprocal inhibition and therefore co-contraction of muscle groups during active movement in normal subjects and those with spasticity. The role of the Renshaw cell and presynaptic inhibition upon Ia interneuronal functioning has also been considered.

2.3.c.ii Plasticity of the spinal cord

Immediately following spinal cord injury a period of spinal shock is seen. Hiersemenzel *et al* (2000) investigated the development of upper motor neurone syndrome features with patients in the acute stages of spinal cord injury. They undertook a series of clinical and electrophysiological tests. Three phases were described:

Spinal Shock: this phase lasted up to three weeks. It was identified clinically by loss of tendon reflexes and hypotonia.

Transition Phase: this lasted for 3-8 weeks in the group studied. Clinically identified by increasing excitability of tendon tap reflexes, increasing muscle tone and frequency of spasms.

Spastic State: clinically shows as exaggerated tendon taps, increased muscle tone and involuntary muscle contractions.

The authors stated that there was a smooth transition from one state to the next. Chapman & Wiesendanger (1982) saw this period as the time in which plastic adaptation of the nervous system took place.

Where higher centres have long been accepted as being capable of plastic adaptation to injury the spinal cord has not been considered as such (Wolpaw & Tennissen, 2001). However research into the recovery of spinal cord function suggest the presence of four mechanisms active in this process:

- Sprouting
- Synaptogenesis
- Restoration of function to uninjured and uncrossed fibres
- Remyelination of demyelinated injured fibres, as well as restoration of the ability to conduct impulses through injured fibres in the absence of myelin (Dimitrijevic, 1988)

Muir & Steeves (1997) concurred with the above mechanisms. These authors stated that spinal cord circuits are capable of significant reorganisation in the form of both activity-

dependent and injury-induced plasticity. There was evidence that spinal circuitry undergoes significant and widespread alterations after spinal injury. These changes include an increase in responsiveness and amplitude of both mono- and polysynaptic stretch reflexes. However, not all injury-induced physiological changes are detrimental. These authors believed that it was possible for plastic change to be guided by activity, even in the damaged spinal cord, and that to modify spinal circuitry for a specific task movement performed during rehabilitation should be executed as normally as possible.

Wolpaw and Tennissen's (2001) article reviewing the plasticity of the spinal cord reiterated the above points. The authors also stated that the spinal cord is capable of activity-dependent plasticity. The guidance of positive plastic change following spinal cord injury is important in maximising function.

There is therefore a growing body of evidence to support the plastic capabilities of the spinal cord. The spinal cord is capable of both neural and synaptic plasticity. Higher centre and peripheral inputs can direct this plasticity. Physiotherapists aim to maximise positive change via mainly peripheral inputs directed towards producing goal-orientated movement in as normal a manner as possible. It may be that the use of electrical stimulation in a functional setting such as used in this study, gait enhancement, may bring about positive plastic change within the spinal cord.

2.3.c.iii Summary of pathophysiological changes

Insult to the spinal cord results in a variable degree of damage to segmental spinal circuitry, and to suprasegmental and supraspinal control mechanisms. A period of spinal shock follows with a gradual progression to the features of the upper motor neurone syndrome. It may not be possible to gain a true picture of the severity of the spinal injury until this period of shock is over. These features are due to loss of both descending, especially inhibitory, control and to plastic changes of spinal circuitry. Loss or disruption of normal control mechanisms leads to adaptive plastic changes in interneuronal functioning, not necessarily always for the worst. Whereas it was once believed that spinal cord circuitry was 'hard wired', research evidence has shown that it is modified in response to activity- or injury-induced changes.

2.3.d Measurement of spasticity

The complexity of the underlying neurophysiological mechanisms, the gaps in our knowledge of some of these systems, and the lack of correlation between laboratory and clinical measures (e.g. Priebe *et al* 1996, Hiersemenzal *et al* 2000) make the measurement of spasticity problematic. However the quantification of this substantially disabling phenomenon is seen as important by those working in research and clinical fields so that efficacy of treatment can be ensured.

Haas (1994) undertook a postal questionnaire in an attempt to survey current clinical practice of healthcare professionals involved in the management of spasticity. The main pathologies involved included stroke, spinal cord injury and multiple sclerosis. Over 94% of all respondents agreed or strongly agreed that it was important to measure spasticity as a part of treatment. Over 94% of respondents also said that physiotherapy should be the profession to measure spasticity. However the number of physiotherapists who actually did measure spasticity was low (less than 40%). Haas suggested some reasons for this disparity: subjective and unreliable outcome measures, complexity of some measures making them unrealistic in a clinical setting and the need for improved education at undergraduate and postgraduate levels.

Krebs (1987) suggested another possibility:

> *'quantitative spasticity data have eluded physiotherapists because the concepts and constructs have not been operationalised, which in turn...is because we cannot agree on what to detect'*

This echoes both Sheean's (1998) and Carr & Shepherd's (1998) plea for clarity of definition when the term is used, to ensure that clinicians can communicate with each other and appropriate treatment can be instigated. The definition of spasticity in the literature and in clinical practice can be far from obvious and may consist of a variety of the phenomena of the upper motor neuron syndrome (UMNS).

In spite of, or perhaps because of, this apparent confusion, measures of spasticity are plentiful. Table 2.3 lists some of those referred to in the literature. Measures vary from simple clinical assessment scales (such as the Ashworth Scale) to highly technical neurophysiological and biomechanical measures. Pierson's (1997) review article

discussed a variety of aspects related to the use of outcome measures in spasticity. The author stated that no one test is superior to another. Richardson (1998) said that there is no definitive, clinical measure of spasticity that meets the requirements of a test to be valid, sensitive (responsive) and reliable. Both authors suggested choosing a variety of appropriate measures to attempt to compensate for the deficiencies of any one test. Some authors (e.g. Skold, 1999) also discuss the need for patients' perceptions of the severity of their spasticity and its effect on function to be taken into consideration. From a clinician's viewpoint the patients' perception of the problem is of great importance in any intervention. Some individuals may live with substantial levels of spasticity that they do not perceive as a problem: others (with what a clinician may assess as a minor increase in tone) that this has a serious affect on their level of functioning on a daily basis. Treatment should be aimed at alleviating the individual's problem.

Table 2.3 Examples of outcome measures used in spasticity management

Neurophysiological Measures	Biomechanical Measures	Clinical Scales	Functional Scales
H-Reflex	Pendulum Test	Ashworth Scale & Modified Ashworth Scale	Clinical Gait Scores (e.g. 10m timed walk test)
Electromyography	Torque Measures	Oswestry Scale	Functional Ambulation Classification
F-Wave Amplitude		Penn Spasm Frequency Score	Barthel Activities of Daily Living Index
Vibration Inhibitory Index		Simple Grading Scales (e.g.+,++,+++)	Functional Independence Measures

There are a number of studies that report a lack of correlation between laboratory and clinical measures of spasticity (Priebe *et al*, 1996, Pierson 1997).

Priebe *et al* (1996) investigated a variety of clinical scales purporting to measure spasticity. Those considered were the Modified Ashworth Scale (MAS), the Penn Spasm Frequency Scale, planter stimulation response and tendon tap reflexes. They found poor correlation between the scales and suggested that they measured different aspects of spasticity. It may have been that their initial definition of spasticity, which was not stated in the paper, was not sufficiently clear. Tests investigated included measures of spasms, hypertonia and tendon hyperreflexia. These are varied symptoms of an upper motor neurone lesion, not classically spasticity.

Some of the more complex electrophysiological measures such as the H-reflex have no proven links to the actual clinical state of the patient (Pierson 1997). Hiersemenzel *et al*

(2000) found similar issues in their in-depth exploration of spasticity following spinal cord injury. These authors investigated changes in the H-reflex, M and F wave and electromyography immediately following SCI. They looked at links between these electrophysiological measures and their supposedly correlating clinical scales – the MAS, the Penn Spasm Frequency Scale, and tendon tap reflexes. It was recommended that care be taken in the direct extrapolation of electrophysiological tests results when making references regarding the clinical state of patients:

> *'clinical signs of increasing spasticity, such as muscle tone and spasms, can hardly be related to the electrophysiological recordings'*
>
> Hiersemenzel *et al* (2000)

The combination of variable definitions and lack of correlation between measures highlights the need for clarity in the use of the term 'spasticity'. It would appear that the clinical tests used for both papers address different aspects of the UMNS, not specifically spasticity. The lack of correlation between clinical and laboratory measures may be one of the reasons that physiotherapists seldom attempt to measure spasticity in clinical practice. A test may show an increase in spasticity but unless this is definitively linked to a negative effect on a patient's ability to function or quality of life, it has no relevance to clinical practice.

A variety of issues may act as variables in the measurement of spasticity. Those potential confounds specific to this study are considered more fully in Chapter 4. Other, more general, issues that have been identified include non-reflex mediated hypertonia and the critical velocity for initiating spasticity. These are issues that need to be considered in test methodology.

Spasticity is described as hypertonia, that is, an increased resistance to movement of a body part. Spasticity however, is only one part of hypertonicity. Resistance to movement is also produced by inertia of the part to be moved and by soft tissue changes. Many authors (e.g. Carey & Burghardt 1993, Goldspink & Williams 1990, Hufschmidt & Mauritz 1985) have documented the effect of soft tissue changes on tone. As well as changes in the non-contractile elements of muscle, ligaments and joints of limbs immobilised completely or partly as a result of an UMNL, muscle displays thixotropic change. Thixotropy relates to the formation of abnormal crossbridge

connections between actin and myosin filaments. The result of these connections is an abnormal stiffness in the muscle upon attempted movement. It is generally recognised that these peripheral changes may play a substantial part in perceived hypertonicity. Definitive testing for reflex-initiated hypertonicity rather than that from non-reflex is dependent upon the velocity of testing. Resistance felt at slow rates of movement is said to be due to soft tissue changes, those at greater velocities due to spasticity (Sheean 1998).

Lance's (1980) definition of spasticity states that it is velocity dependent. Where no movement is present, or where it is present at low velocities, there is no spasticity (Sheean 1998). The critical velocity of movement however is not so clear. Some authors suggest angular velocities as low as 40° per second (Powers *et al,* 1988), others as high as 100° per second (Burke *et al,* 1970) being needed to trigger spasticity. Whilst the actual velocity is unclear, it is obvious that the velocity at which tests are undertaken is of importance in recognising spasticity.

All of the above points to potential problems with the validity of both tests (clinical and technical) as measures of spasticity; to the need for clarity in definition of spasticity to address this issue; and to the actual effects of spasticity upon function. Whilst electrophysiological nerve testing may give information about the activity of the tonic stretch reflex, the use of clinical or functional activity scales can seldom be linked directly to the effects of spasticity alone. The factors that may act as potential confounds in clinical testing are many. Wherever possible they should be considered and addressed in test methods, but realistically may need to be accepted as present and uncontrolled.

2.3.e Spasticity and Physiotherapy

Spasticity is an impairment that physiotherapists who work in the field of neurology spend much time in attempting to alter and control. The therapeutic goal of physiotherapy is to limit its effects on patient function, in an attempt to improve recovery following such damage.

Historically physiotherapists working with the neurologically disabled concentrated on maximising the patients remaining abilities. Little, if any, attempt was made to facilitate recovery. Emphasis on treatment was rather aimed at teaching compensation for

neurological loss. Over time there have been substantial changes to this method of treatment. Compensation for neurological loss is still taught where appropriate, but is far from being the initial treatment of choice. Two of the current main treatment concepts in the management of this patient group are those following the Bobath Concept (Bobath, 1990) and Carr & Shepherds Motor Relearning Concept (Carr & Shepherd, 1998).

In the 1950s, Karl and Berta Bobath, working in the UK, devised a treatment concept with the intent of controlling the development of spasticity and facilitating more normal movement patterns. The Bobath approach to the treatment of neurologically damaged patients is the most frequently used and taught at both undergraduate and postgraduate level in this country. Bobath stated that spasticity 'creates a major problem in the management of the patient' with CNS damage, and adds that spasticity must be held responsible for much of the patient's motor deficit. This approach emphasises the need to control the positive features (due to excessive motor activity) of the UMNS. However, in Bobath's book from 1990 the term spasticity seems to be used as an umbrella term for these positive features. The Bobath Concept advocates the '*inhibition of abnormally released patterns of co-ordination and the facilitation of the higher integrated automatic reactions of normal postural control and those of more voluntary activity*' i.e. the inhibition of abnormal reflex activity following CNS damage and the facilitation of normal patterns of movement. More recently the Bobath Centre has clarified its definition of spasticity as **one part of**, not synonymous with, the UMNS (Lynch-Ellerington, 2001, Mayston, 2000). Whilst motor overactivities are still seen as causing main problems following UMN damage the Bobath Centre (Mayston, 2001) now puts an increasing emphasis upon the management of the negative features (due to reduced motor activity) of the UMNS. The use of normal movement is promoted to ensure optimal recovery of function.

Many other authors (e.g. Edwards, 1996, Kidd, Lawes & Musa, 1992) have also advocated the control of the positive features of UMNS in the facilitation of normal movement.

Carr & Shepherd's (1998) Motor Relearning concept places the emphasis on treatment of the negative features of the UMNS, which they describe as 'weakness, slowness of movement, loss of dexterity and fatigability'. They believe that these features are far

more disabling than changes in muscle tone or hyperreflexia. The negative features are said to result from loss of descending fibres to the motor neurone population, meaning that there is not enough innervation to allow complex movements by graded activation of co-ordinating muscles, or the high frequency discharges needed for tetanic contraction strength. They postulate that many of the positive signs of the UMNS can be mistakenly identified changes in muscle rheology, or as behavioural adaptations to the negative signs.

All current forms of physiotherapy treatment would claim to bring about positive plastic changes to the CNS by the manipulation of peripheral and higher centre (where possible) input to enhance patient recovery. Mayer (1997) summarised the need for therapy to address *'the balance of positive and negative symptoms'* according to the needs of the individual patient. The use of functional electrical stimulation is one treatment option available to physiotherapists in the treatment of neurologically damaged patients. Given the emphasis, in the UK, on treatment of the effects of motor overactivites this treatment option may not be considered due to the dogma that FES will increase 'muscle tone'. In spite of the emphasis on the management and control of spasticity in physiotherapy treatment, Haas's (1994) study shows that therapists apparently seldom measure it.

2.4 Measures for this Study

Given the number of potential confounding factors in any attempt to 'measure' spasticity, and the underlying and critical issue with the concepts and constructs of spasticity, one must question whether or not it is possible to measure that which Wade (1991) describes as an 'epiphenomenon'. This description may be more of a reflection on the fact that spasticity is so difficult to measure, and to link to function, rather than it being an irrelevant by-product of an upper motor neurone lesion. Krebs' (1987) suggested a paradigmatic approach to measurement. Table 2.4 attempts to give a structure and background to the process of measurement choice for this study through the operationalisation of spasticity. Lance's (1980) definition is used as the theoretical basis for spasticity.

As previously stated, this project was closely linked to a larger study – 'Clinical Rehabilitation by Electrical Stimulation via Telematics' (CREST). Two of the measures

for this study were dictated by the CREST project. The Modified Ashworth Scale (Bohannon & Smith, 1987) an ordinal clinical grading scale, was to be used as a measure of spasticity. The Modified Ashworth Scale (MAS) is one of the most frequently used clinical scales for grading spasticity. The Rancho Los Amigos Observational Gait Analysis system was used as a measure of walking ability.

Table 2.4: Schematic Illustration of Paradigmatic Approach to Quantitative measurement of Spasticity – after Krebs (1987)

General Description	**abstract thinking** ◄——————►			**concrete measurement**
Formal Description	theory	concept	construct	operationalised variable
Thought Process	What ideas and physiological evidence relate to spasticity?	What variables should I measure?	How should I measure them?	What units of measurement should be used?
Behaviour	Velocity related hypertonia – resistance to movement	Velocity related resistance to movement	Clinical scale measures Biomechanical force/torque measures	Ordinal scale measures Torque in Newtonmetres Velocity in °/second
	Results from increase in tonic stretch reflex activity	Changes in reflex threshold	Electrophysiological nerve testing	Voltage
	Functional deficit in ADL related to increased resistance to movement	Choose an appropriate ADL to the individual	Define necessary ADL parameters (scales may already exist)	Compare individual function to norm

This author chose two further measures – resistance to passive movement using isokinetic dynamometry and TELER Gait Indicators. Isokinetic dynamometric measurement of spasticity has been used by many authors (e.g. Akman *et al,* 1999, Perell *et al,* 1996, Firoozbakhsh *et al,* 1993). The author chose this measure of spasticity to give quantitative, instrumented data about passive resistance to movement, as it was known that the Modified Ashworth Scale had been criticised for its subjectivity. TELER® Normal Gait Indicators were developed in response to the perceived problems with the feasibility and analysis of the Observational Gait Analysis data.

No neurophysiological measurement of spasticity was used in either the CREST project or for this study. The CREST study proposed to investigate the effects of functional electrical stimulation used in a 'clinical' setting to improve walking ability, therefore

clinical or functional scales were chosen. Equipment, expertise and funding for neurophysiological measures were not available. Also, as previously stated (Hiersemenzel *et al,* 2000), there may also be concerns regarding the correlation between some electrophysiological and clinical tests.

Using Krebs' (1987) paradigm as a template for choice of measures, the MAS and isokinetic dynamometry measurements of torque were used as measures of velocity related hypertonicity during passive limb movements. The functional deficit in question was walking ability, the Rancho Los Amigos Observational Gait Analysis system and TELER Normal Gait Indicators were used to measure gait deficit.

Many issues with measurement of spasticity have been raised in this review of the literature; variable or unclear definitions, lack of correlation between measures, a perceived need to measure in clinical practice but a failure to do so. A critique of the validity of the measures chosen for this study will therefore be presented in the chapter dealing with measurement (Chapter 3).

2.5 Functional Electrical Stimulation and Spasticity

There is a large body of evidence in the literature relating to electrical stimulation and its effect upon spasticity. Studies from the early 1980s by Alfieri (1982) and Bajd *et al* (1985), upon hemiplegic and SCI subjects respectively, reported decreases in spasticity following electrical stimulation. Since that time many other authors have also investigated spasticity and electrical stimulation. The articles vary hugely in the pathology of the subjects, in the stimulation parameters used, in their methods of application and in their choice of measures for spasticity. Relatively few studies consider the effects of stimulation upon spasticity in a truly functional setting. Some authors have studied stimulation at low intensity levels (sub-muscle contraction levels) (e.g. Potisk *et al*, 1995), some the effects of stimulation for exercise purposes (e.g. Skold *et al*, 2002), some the effects of alternating agonist-antagonist muscle stimulation (e.g. Shindo, 1987) as treatments for spasticity. The variation of possible applications undoubtedly adds to the conflicting reports of improvements, deteriorations and 'no change' in this impairment. Vodovnik (1981), Yarkony *et al* (1992) and Daly *et al* (1996) have all reviewed the therapeutic effects of electrical stimulation, including its effects on spasticity, and proposed possible mechanisms for changes.

The following is a review of articles relating to FES applied to the lower limb and spasticity. As well as the variation in applications and methods of measurement discussed above, definitions of spasticity vary. Lance's definition from 1980 is most often used, but some definitions include flexor and extensor spasms and clonus.

Stefanovska *et al* (1989) reviewed the long-term effects of FES on spasticity in a group of eight hemiplegic subjects. The subjects had implanted drop foot stimulators. Electromyographic and torque measurements of tibialis anterior and triceps surae activity were undertaken over a six-month period. The authors found that, for each subject, the tonic component of spasticity in the calf muscle decreased significantly when the anterior tibial muscles were stimulated over the testing period, whereas phasic activity increased. No control group was used and subjects were considered individually, with measures being repeated over time. The authors concluded that the use of FES decreases the tonic component of the stretch reflex. They also suggested that articles that report FES as increasing spasticity may be measuring the phasic component of the stretch reflex. It is the tonic stretch reflex that is mainly implicated in spasticity.

Seib *et al* (1994) investigated the use of electrical stimulation on a combined group of spinal cord injured and head injured subjects. Stimulation was applied cutaneously to tibialis anterior with the subject sitting. The stimulation parameters were set to 'mimic the gait cycle'. The authors developed their own measurement tool, the Spasticity Measurement System, which included electromyography and torque measurements of anterior and posterior calf muscles. Subjects acted as their own controls – only one leg was stimulated. They found reductions in the levels of spasticity in the spinal cord injured group. The authors' hypothesised that reciprocal inhibition was possibly responsible for the decrease in spasticity. There may be a problem in the use of subjects as their own controls – any data gained cannot be truly independent - which may affect the statistical validity of their study.

Burridge *et al* (1997b) undertook one of the largest studies of hemiplegic patients treated with functional stimulation. 32 subjects were split into control and treatment groups. FES in the form of a cutaneously applied drop-foot stimulator was the intervention for the treatment group. Spasticity of the quadriceps was assessed using the Pendulum Test (Bajd & Vodovnik, 1984). Results showed a significant reduction in

spasticity in the treatment group. They hypothesised that this reduction may be due to a number of factors:

1. Reciprocal inhibition of the quadriceps via hamstring Ia inhibitory interneurones and Renshaw cell activity (the hamstrings are activated during drop-foot stimulation if the flexor withdrawal response is recruited to improve hip and knee control). Over time this repeated inhibition may lead to neuroplastic changes causing a decrease in quadriceps spasticity.
2. Improved foot position during walking which allowed for better lower limb alignment through the stance phase of gait, may have had an indirect effect on spasticity
3. Decreased effort in walking (which was measured by Physiological Cost Index) may also have had an indirect effect in the reduction of spasticity

Burridge & McLellan (2000) studied the effects of drop-foot stimulation in a group of subjects with hemiplegia. Their comprehensive investigations, which included EMG and biomechanical measurements, concluded that the sub-group of subjects who most benefited from stimulation demonstrated poor control of ankle movement and spasticity. Gait parameters measured included speed and Physiological Cost Index. As results for the entire group varied (those with a mechanical resistance to movement responded less well to stimulation), the authors hypothesised that stimulation of the tibialis anterior muscle via the common peroneal nerve led to inhibition of the antagonistic calf muscles.

In 1993, Granat *et al* studied the effects of multi-channel FES-assisted-gait in six subjects with incomplete spinal cord injury. A single subject experimental design was used with multiple baselines pre- and post- intervention. Aspects of gait, voluntary muscle contraction and spasticity were investigated. Spasticity was measured using the Ashworth Scale (Ashworth 1964) and the Pendulum Test (Bajd & Vodovnik 1984). No significant change was identified with the Ashworth Scale results. It is not clear from the paper if the lower limb as a whole was graded, or just one muscle group. The Pendulum Test, which quantifies quadriceps muscle spasticity, showed a significant decrease in spasticity when subjects were analysed as a group. When considered individually one subject presented with a significant increase. Unfortunately, no explanation was given for the spasticity increase in this subject. In spite of the spasticity increase in this subject, functional gait measures improved. All subjects received

peroneal stimulation, with most also receiving at least one other channel of stimulation – usually of the quadriceps muscle group.

Papers by Swain (1992) and Robinson *et al* (1988) reported finding increases in spasticity due to the use of electrical stimulation. Swain found increasing 'spasms' problematic in some subjects with spinal cord injury. At this point further intervention was stopped. No information was given as to type or duration of stimulation or how the 'spasms' were assessed. Stimulation was being applied to condition muscle. Swain believed that the increase in spasticity was due to increased 'strength' of the stimulated muscles. In this case the term 'spasms' might have been being used interchangeably with spasticity. Flexor and extensor spasms are other positive features (see table 2.2) of the UMNS, not spasticity.

Robinson *et al* (1988) studied 31 subjects with complete and incomplete spinal cord injury. Electrical stimulation was used to recondition the quadriceps muscle. Quadriceps spasticity was again assessed by the Pendulum Test and by torque measurements. Repeated initial baseline measurements were undertaken followed by regular testing throughout the intervention then final repeated baselines. Only eight of the subjects completed the eight-week training schedule. The authors stated that they did not have enough data for meaningful statistical analysis but described an increasing trend in spasticity for the group. The electrical stimulation was applied for muscle conditioning, not functionally. They recommended that caution should be used in the use of electrical stimulation.

Crone *et al* (1994), whilst studying disynaptic reciprocal inhibition of the ankle planterflexors in normals and subjects with spasticity discovered that four of the spastic subjects had relatively more normal inhibition of this muscle group during active dorsiflexion. All four of these subjects regularly used a drop foot stimulator. The authors theorised that the use of such stimulation may enhance spinal inhibitory networks responsible for reciprocal inhibition.

An article by Daly *et al* (1996) is relevant as it reviews the effects of FES on neural plasticity and 'learning'. The authors studied conditioning of the Hoffman reflex (H-reflex) (Brown, 1984) in animal experiments and concluded that two phases of change occurred. The H-reflex is evoked when Ia afferents from intrafusal muscle fibres are

stimulated at low intensities. The monosynaptic, or phasic, stretch reflex is activated causing a contraction of extrafusal fibres. This muscle activation is measured by electromyography. Phase I was a short-term change that responded to task dependent modulation. Phase II developed gradually and was believed to result from persistent altered neuronal activity in response to phase I. Increases and decreases in Ia excitatory post synaptic potentials were noted to occur dependent upon the task imposed. The authors hypothesised that changes in interneuron activity resulted in the changes they found. They believed that this reinforces the fact that the spinal cord demonstrates some ability to plastically adapt to tasks. Observations by Muir & Steeves (1997) that the spinal cord is capable of task-dependent plasticity would suggest that using electrical stimulation in a functional setting might encourage more normal movement.

Comparison of the existing literature is made difficult by the lack of clarity in definition of spasticity and due to the variety of measures used. The majority of the literature (Stefanovska *et al*, 1989, Seib *et al*, 1994, Burridge *et al*, 1997, Burridge & McLellan 2000,Crone *et al*, 1994) supports the hypothesis that spasticity is more likely to be decreased rather than increased by FES due to the reciprocal inhibition of spastic antagonistic planterflexor muscle groups when the ankle dorsiflexors are active. The two articles (Swain 1992, Robinson *et al*, 1988) which found an increase in spasticity used stimulation for conditioning muscle rather than functionally. In both cases quadriceps muscles were being stimulated and assessed for their level of spasticity. For the effects of possible reciprocal inhibition the hamstring (antagonistic) muscle group should have been assessed, but this did not appear to have been done.

Few articles addressed the effect of stimulation and changes in spasticity upon gait by including a measure of gait within their studies. Those that did included Burridge *et al* (1997), Burridge & McLellan (2000) and Granat *et al* (1993). The following section summarises the literature relating to FES and its effects on gait.

2.6 Functional Electrical Stimulation and Gait

Liberson *et al* (1961) first used a simple one-channel stimulator to enhance ankle dorsiflexion during the gait cycle of a patient who had suffered a hemiplegia. Since that time systems have been developed for production of 'synthetic' gait in complete injuries both with (e.g. Isakov *et al*, 1992, Thoumie *et al*, 1995), and without (e.g. Bajd *et al*,

1983, Graupe & Kohn, 1994), the use of orthoses. In recent years the emphasis has been more upon systems for gait enhancement in ISCI. In this country teams based in Salisbury and Glasgow have been very active in the research and clinical fields. Salisbury in particular have been involved in the development and use of a wide variety of FES systems for subjects with spinal cord injury. This team have experience in the application of fully implanted and cutaneous systems for gait production or enhancement.

A number of gait outcomes have been studied following the use of FES for gait enhancement. Reported changes in temporal parameters such as step length, swing to stance ratios and step symmetry appear to be inconclusive with Granat *et al* (1993) and Stein *et al* (1993) reporting little change. Improvements in walking speed were however reported by Granat (op.cit.), Stein *et al* (op.cit), Taylor *et al* (1999) and Burridge & McLellan (2000).

Burridge & McLellan (2000), Taylor *et al* (1999) and Stein *et al* (1993) assessed the effort involved in walking with and without FES. Burridge & McLellan and Taylor *et al* used the Physiological Cost Index. Stein *et al* studied oxygen consumption values. All authors found a decrease in the energy required to walk in their respective subject groups, suggesting that walking takes less effort when FES is used.

Granat *et al* (1996) considered the effects of FES intervention upon quality of gait and upon activities of daily living. The quality of gait was assessed by the incidence of heel strike at initial contact and the presence or otherwise of inversion during swing phase. A clear heel strike being a positive outcome, inversion through swing phase being negative. The Barthel ADL Index was used to measure global disability. Results for both outcome measures improved for all six subjects.

Taylor *et al* (1999) and Stein *et al* (1993) also considered the 'carry-over' effects of FES upon gait. Gait was assessed without FES to see if there were improvements when compared to the initial baseline measures. Stein *et al* found little improvement. Taylor *et al* found that even walking without stimulation showed significant improvement for their patient group. These differences may be due to differing pathologies of subject groups – Stein *et al* studied a small group of subjects with incomplete spinal cord injuries, the other group in the main had sustained hemiplegia following a stroke. Taylor

et al interestingly hypothesised that the use of FES may enhance the activity of the gait central pattern generator.

Consideration of time since injury needs to be considered for all groups of subjects. The study involving ISCI recruited subjects who were a minimum of one-year post-injury. Granat *et al* (1996) and Taylor *et al* (1999) investigated subjects relatively soon after their injury. Natural recovery may have played a part in these two studies.

In summary, the use of FES would appear to improve many aspects of walking ability in subjects with a variety of disabilities. The underlying mechanisms for these improvements may include:

- Direct orthotic benefit – the FES effectively works as a dynamic splint allowing the subject to produce movement they would otherwise be unable to, or have difficulty in being able to produce voluntarily. This means that a more normal gait pattern can be achieved, with more normal limb alignment and reduced effort of walking.
- Control of movement may be improved by increases in muscle strength either through direct or indirect stimulation (Granat *et al,* 1993, Stefanovska *et al,* 1989, Daly *et al,* 1996). Granat *et al* noted improvements in hip flexor muscle power even though these muscles had not been directly stimulated. They hypothesised that the repeated motor activity gained by stimulating the flexor withdrawal response actually strengthened the hip flexor muscle.
- Muscle phenotype has also been shown to change as a result of long-term stimulation. SCI subjects have relatively fewer slow oxidative motor units in their muscles than the norm, with a preponderance of fast glycolytic fibres. Stimulation has been shown to reverse this trend (Mohr *et al*, 1997, Pette & Vrbova, 1999), which would suggest that muscle develops a more fatigue-resistant profile.
- Improvements in reciprocal inhibitory mechanisms decrease spasticity allowing the production of better movement (e.g. Burridge *et al* 1997, Burridge & McLellan, 2000).

It is the final one of these points that is core to this study – alterations in levels of spasticity caused by the use of FES and their effects on the functional abilities of the individual. In this case, walking ability. The effects of spasticity upon gait therefore need to be considered.

2.7 Spasticity and Gait

The effect of spasticity upon gait and other functional abilities remains a debated topic. Some authors (Ada *et al,* 1998, Carr & Shepherd, 1998, Wade, 1990) have stated that it has no effect upon the functional abilities of patients. However there is a growing body of evidence (Morita *et al,* 2001, Knuttson *et al*, 1997, Crone *et al,* 1994, Corcus *et al,* 1986) that spasticity will negatively affect voluntary movement and therefore function. 'Spastic restraint', caused by inappropriate activity of antagonistic muscle groups, has been shown to occur during activity in subjects with spasticity. Studies of calf muscle activity for these subjects during active dorsiflexion of the ankle joint have shown a decrease in reciprocal inhibition of the soleus, with this muscle being active when in the normal subject it would be at rest (Morita *et al*, 2001).

Gait assessment measures effects, not causes (Rose, 1983). Wade (1992) echoes this with his observations about activity of daily living (ADL) indices. The fact that ADL scales have been developed in response to a 'perceived clinical need' enhances their validity, however they do not address the underlying cause as to why a subject fails to achieve a goal. Gait analysis cannot therefore be seen as measure of spasticity, but of a function that may be negatively affected by spasticity.

Individuals with incomplete spinal cord injuries may present with a variety of the features of the upper motor neurone syndrome. These features include positive and negative features such as spasms, clonus, spasticity, decreased selectivity of movement, muscle weakness due to inadequate activation, and fatigue. As Perry (1993) highlighted all the above are likely to have a negative effect on gait.

Untangling the effects of spasticity upon an activity as complex as walking from the other aspects of the UMNS is unlikely to be simply answered. If gait is affected by spasticity, a spasticity measure should correlate with an independent measure of gait. The issue with the outcome measures chosen in this study is that both measures of spasticity (the MAS and isokinetic dynamometry) are passive tests. As stated earlier, the effect of spasticity during passive movement is not the same as that during voluntary movement (McLellan, 1977, Knuttson & Martensson, 1980). Spastic restraint during active, especially fast active movement was found to be substantially greater than during passive movement. As the physiotherapist is interested in the effects of spasticity

upon function (in this case walking), a passive test that does not correlate to function becomes redundant for this purpose.

The issue of walking speed also needs to be addressed when considering the effects of spasticity upon gait. Spasticity is velocity dependent; velocities of limb movement in the subject group may not be fast enough to trigger the tonic stretch reflex. The subjects chosen for this study displayed a variety of walking abilities, some walked everywhere; others were very limited in their abilities and walked only for exercise. These subjects therefore may never walk at velocities fast enough to actually trigger spasticity. In 'normal' walking the human knee joint travels through 60° of movement in about 0.2 seconds. This gives an approximate velocity of 300° per second. All of the study participants walked at speeds substantially slower than 'normal'. The range of velocities above which spasticity is supposedly triggered was previously discussed as likely to be between 40°-100° per second. Knuttson *et al* (1997) found that 'spastic restraint' of agonist activity in concentric knee extension increased with increasing velocity of movement. Theoretically subjects with spasticity attempting to walk more quickly are likely to increase the resistance to leg movement and therefore slow their walking speed, or to use an increasing number of compensatory movement strategies in an attempt to maintain their speed. If spastic restraint was reduced by the use of FES, due to improved reciprocal inhibition between antagonistic muscle groups, more normal movement may be possible leading to improved walking speeds.

It is not possible to use gait as a direct measure of spasticity. There are many other factors which may affect walking ability and which may also be changed by FES.

2.8 Summary

The initial intent of this study was to investigate the effects of FES upon spasticity. FES is the use of electrical stimulation to produce functional movement. In this case FES was being used as an intervention to improve gait in individuals with incomplete spinal cord injury therefore gait measures were to be used as one of the outcomes. The measures of spasticity used were the Modified Ashworth Scale (MAS) and resistance to passive lower limb movement using an isokinetic dynamometer to give objective data about spasticity levels. The measures of gait were the Rancho Los Amigos Observational Gait Analysis System and TELER Gait Indicators.

Review of the literature relating to FES, spasticity and gait can be summarised as follows:

- FES may decrease spasticity – most probably via the reciprocal inhibitory mechanisms that play a role in the activity of the tonic stretch reflex.
- FES improves many aspects of gait – there are many ways in which this may occur. Gait may be improved by the orthotic effect, training effect or due to the changes in reciprocal inhibitory mechanisms as stated above.
- Spasticity is a hugely complex phenomenon that has repeatedly proven to be difficult to measure. Although many measures exist there is apparently little or poor correlation between them.
- The measures chosen for this study can be split into passive measures (MAS and isokinetic dynamometry) and active measures (gait). The response of spastic muscles in passive and active situations is different.
- Gait cannot be considered as a measure of spasticity but rather needs to be considered as a function that may be affected by it.

Although the possible link between gait and spasticity has been discussed, the measures chosen for this study can offer no direct link. The effect of disordered reciprocal inhibition upon a passive system has been shown to be substantially different to that of an active system. Gait may be affected by inappropriate co-contraction but a large number of other factors will also affect gait speed and quality. The ultimate importance of spasticity is its effect upon the functional abilities of the individual – does it prevent one walking, dressing or performing personal care?

The research direction therefore had to change from what the effects of FES intervention were upon spasticity for the individual with ISCI, using gait as a measure of this, to separately considering the effects of FES upon spasticity and upon gait for these subjects.

Given the issues raised in this Chapter with the measurement of spasticity, and with the importance of measurement validity to study validity, Chapter 3 will present a comprehensive review of the measures used in this study.

Chapter 3: Measurement

Review of the literature raised questions regarding the valid measurement of spasticity and highlighted the importance of appropriate measuring tools in research. This Chapter reviews the two measures of spasticity, the Modified Ashworth Scale and isokinetic dynamometry, and the two measures of gait, the Rancho Los Amigos Observational Gait Analysis System and TELER Gait Indicators, used in this study.

Measurement theory is 'the conceptual foundation of all scientific decisions' (Krebs 1987). If a measurement is flawed, analysis and interpretation based on that measurement would be wrong. In short, in clinical practice, inappropriate treatment may be given. Krebs described measurement as *'the assignment of numbers to events according to rules'*. Events are measured in healthcare practice and research in an attempt to show that a treatment has had a beneficial, or otherwise, effect over and above the expected outcome of a disease process. Pierson (1997) stated that the goal of an outcome measure is to allow the quantification of physical status and change in a *'standardised and reproducible way'*. Wade (1991) however noted that, in the context of neurological rehabilitation, *'measurement in the pure scientific sense is rarely possible'*. Few aspects of neurological rehabilitation are easily quantifiable, standard units are generally absent. In spite of this, outcome measures proliferate in the literature relating to neurology (e.g. Pierson, 1997). With the promotion of evidence-based decision-making to direct clinical practice coming from both Government and Professional bodies, the need for good quality outcome measures, which meet the psychometric properties necessary for such scales, is ever important. An understanding of the level of measurement data being collected - nominal, ordinal, interval or ratio - is of importance in the construction of measures, final analysis of results and therefore the validity of conclusions drawn from study results. The properties necessary for any measure are described slightly differently in the literature, however the main issues that need to be assessed and considered can be summarised as validity, reliability, responsiveness and feasibility.

3.1 Criteria of measuring scales

Any measurement can be considered as consisting of the true measure plus the level of error and bias contained in the measurement (Le Roux, 2002). A truly valid measure

will give as exact a value as possible to the object or event under consideration. The chosen measure will be capable of measuring the said event. It needs to give consistently reliable results when used repeatedly or by different observers - sources of error and bias will be decreased to a minimum. The effects of possible confounding factors that may alter outcomes will be controlled. Valid measures are gained from valid measuring instruments. A measuring instrument consists of a translating medium and a calibrated scale. A translating medium translates the extent of an attribute from an object to a point on a measuring scale. Each calibrated point of a measurement scale needs to be unambiguous and clearly defined, to have a unique meaning (McKenzie & Charleson, 1986). Each point on a scale must also assess the same phenomenon and be organised in a reasonable hierarchical manner. There also needs to be a logical chain of reasoning if the object is not to be measured directly – e.g. the effects of the upper motor neurone syndrome upon function, spasticity upon gait. This occurs in many clinical scales where the effects of a pathology or impairment upon function are being considered.

Validity relates to the ability of a measure to measure that which it purports to measure (Gould, 1994, Seale & Barnard, 1998). In this section, validity refers to the measures rather than the methodological validity of the study. Validity and reliability are interlinked concepts. They are of vital importance in data collection to ensure that the conclusions being drawn from them are 'true'. Validity is a complex issue that includes many different components. There are four main types of generally recognised validity: face, content, construct and criterion validity. Face validity is perhaps the simplest form – the subjective assessment of the measurement tool to ensure that it is relevant and unambiguous. That is, it can measure the dimension in question and all the points on the scale are clearly defined and discrete. The last point is of particular importance to ordinal scales, which are often used in physiotherapy practice. If one is uncertain as to which rank an observation should be classified, errors will occur in results. Content validity requires more objective assessment of the concepts behind the tool, ensuring that it has the ability to measure the phenomena in question. Construct validity also relates to content validity and the theoretical concepts that underlie the test, a logical chain of reasoning from the concept to the measure needs to be explicit. Criterion validity consists of two parts: the ability of the test to correlate with other similar measures (concurrent validity) and the ability to predict outcomes (predictive validity).

Reliability is the extent to which a measure will give consistent results – both intra- and inter-observer. The concepts of error and bias are also encompassed within reliability. These issues need to be addressed within measurement. Error is a random or variable deviation from the true value and is due to the observer. Bias is a constant deviation from the true value and may result from the measuring instrument or from the observer.

Responsiveness relates to the ability of a scale to detect the change you are attempting to measure, if measurement points are too gross then clinically meaningful change may go undetected. Guyatt *et al* (1987) stated that responsiveness also had a direct link to validity and reliability. The scale used should be capable of detecting the observed value. If not, it is not likely to be a valid or reliable measure.

Feasibility addresses issues of simplicity of use and ease of incorporation into practice. This is of particular importance if a tool is to be used in a busy clinical setting.

Clinical significance is also a recurrent theme in measurement within a clinical setting. Hicks (1997) described clinical significance as 'the degree to which a set of results have clinical meaning or relevance'. The example that is given related to training for pelvic floor muscles. Training may show a statistically significant increase in muscle strength but if the patient remained incontinent, the results would show no clinical benefit to the patient. Other authors (Testa, 1995, Le Roux, 1993, Bain & Dollaghan, 1991) emphasised the need for measurement scales to be responsive to clinically significant change. All research findings should be considered in terms of their clinical significance to the subject group.

The following sections will critique the four measures used for this study in relation to the above criteria.

3.2 The Modified Ashworth Scale (MAS)

The MAS (Table 3.1) is a six-point ordinal scale that describes increasing levels of resistance to passive movement of a limb. Bohannon & Smith first described this scale in 1987. It was a modification of Ashworth's 1964 scale (Table 3.2) that was used to give a simple clinical quantification of the effects of a drug intervention in patients with multiple sclerosis. The authors introduced a further point on the scale (1+) due to what

they in their clinical experience considered the ambiguity of grade 1 on the original scale. Although this scale is much maligned for its subjectivity it is very frequently used and referred to in the neurological literature. It is a quick and simple test that costs nothing to apply, needs no complex equipment and can be simply applied at the 'bedside' – from this it can be seen that feasibility in terms of ease of use is good. The measuring mechanism transfers level of resistance to movement to a measuring scale via the therapist's perception of changes in resistance to passive limb movement.

Table 3.1: Modified Ashworth Scale for Grading Spasticity

GRADE	DESCRIPTION
0	No increase in muscle tone
1	Slight increase in muscle tone, manifested by a catch and release, or by minimal resistance at the end of the range of motion when the affected part is moved in flexion or extension
2 (1+)	Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM
3	More marked increase in muscle tone through most of the ROM, but affected parts easily moved
4	Considerable increase in muscle tone, passive movement difficult
5	Affected part rigid in flexion or extension

Table 3.2: The Ashworth Scale

GRADE	DESCRIPTION
0	No increase in muscle tone
1	Slight increase in tone giving a catch when the limb is moved into flexion or extension
2	More marked increase in tone but limb easily moved
3	Considerable increase in tone but limb easily flexed
4	Limb rigid in flexion or extension

3.2.a. Validity

Issues of validity relating to the Modified Ashworth Scale were comprehensively addressed by Pandyan *et al* (1999). They queried the construct and content validity of the scale as a measure of spasticity. The authors described these types of validity as relating to the underlying assumptions and the theoretical basis on which a scale is created. They rightly stated that resistance to passive movement is not an exclusive measure of spasticity. Changes in the viscoelastic properties of joints and soft tissues, the weight of the limb and the participation, intentionally or otherwise, of the subject will all affect resistance to passive movement. Thixotropic changes in muscle with repeated movements during the test may also confound. There is, therefore, an issue with whether or not the scale is truly a measure of spasticity. The authors suggested that the MAS is a valid measure of resistance to passive movement but not specifically of

spasticity. It does not therefore measure a single phenomenon, but possibly two. Their suggestion that test velocities should be kept low would appear to be in direct contradiction to the findings of other authors (e.g. Sheean, 1998, Knutsson & Martensson, 1980) who stress the fact that spasticity is velocity dependent, not being elicitable at low velocities. Resistance to passive movements undertaken at low velocities is unlikely to be due to spasticity – in fact this is more likely to exclude spasticity as a factor. Bohannon & Smith (1987) recommended that the elbow joint be moved from full flexion to full extension in one second i.e. approximately 150° per second. Velocity of testing should be at a level to provoke spasticity in an attempt to distinguish between it and other confounding factors. If this is not done the MAS cannot be considered as a valid test for spasticity.

Criterion validity – comparison of the measured scales with other related measures – was also addressed. A number of authors have considered the Modified Ashworth Scale in relation to other measures of spasticity (e.g. Vattanasilp & Ada, 1999, Skold, 1998, Priebe *et al*, 1996, Katz & Rymer, 1989). Results from these studies vary in their claims as to whether or not the MAS correlated with other tests. Part of the problem is that there is no recognised 'gold standard' test for the measurement of spasticity, so the MAS may be being compared to other measures that may have substantial flaws and issues with validity of their own. Skold (1998), investigating EMG recordings and the MAS in the upper limb of tetraplegic subjects, found a substantial level of correlation. Vattanasilp & Ada (1999) suggested that the MAS was a 'reasonable' way to quantify hypertonia in the clinic. However, they expressed reservations that the scale cannot distinguish between spasticity and other factors affecting resistance to movement. In testing however they graded 'slow' passive movements. So to date, the issue of criterion validity has not been fully answered in the literature.

Bohannon & Smith addressed the issue of face validity in 1987. Their concern with the original Ashworth test was that the grade 1 was, in their clinical experience, 'indiscrete'. They added an extra grade in an attempt to address this issue. Face validity relates to subjective assessment of the measurement tool to ensure that it is relevant and unambiguous. There is a hierarchy to the resistance described, but not a unique, discrete, meaning to each rank. It is difficult to give definitions to what is effectively a continuum. Subjectivity is a major issue. One therapist's definition of a 'considerable'

increase in spasticity may differ substantially from another's, or indeed may differ in the same therapist from day-to-day.

3.2.b Reliability

A small number of articles have addressed both intra and inter-rater reliability issues. One of the problems with the MAS scale is the lack of a clear test method in either of the definitive articles. For this thesis all subjects were tested in supine on a treatment plinth. All subjects could lie fully supine with just a pillow under their head for comfort. The testing sequence started at the hip and finished at the ankle joint. A number of practice sessions with other CREST physiotherapists and advisors were undertaken to standardise test procedure. All the physiotherapists involved were senior staff with substantial experience in the treatment of spinal cord injury. In this way, consistency of test method was addressed. Gregson *et al* (1999) undertook studies into the inter- and intra-rater reliability of the MAS. They found very good levels of both types of reliability. Bohannon & Smith (1987) also found good inter-rater reliability of the test in the assessment of upper limb muscle tone. However Haas *et al* (1996) investigated the inter-rater reliability of the MAS in assessment of lower limb spasticity in spinal cord injured subjects, and found poor levels of reliability. Most authors attempted to address issues of reliability prior to undertaking testing by discussion of test method with the parties involved, attempting to ensure consistency. Although it is of interest to note issues with inter-rater reliability, this was not an issue for this thesis as the author was the only assessor. This in itself may cause issues with bias. In an attempt to combat this, the author did not review previous test results prior to retesting.

3.2.c Responsiveness

Responsiveness is not an issue that papers relating to the MAS have addressed. The scale is fairly crude, but given its subjectivity, breaking it down further may be unrealistic and lead to increased problems with face validity – in particular issues with ambiguity - and reliability.

3.2.d Feasibility

The MAS is a very simple test to apply in a clinical setting. No special equipment is needed and it takes only a few minutes to complete.

3.2.e Summary

Whilst the Ashworth and Modified Ashworth Scales undoubtedly have their detractors they are also very frequently used in research as a measure of spasticity. There are reservations with the validity of the MAS as a measure of true spasticity. It is useful as a measure of resistance to passive movement. Aspects of velocity of testing should be addressed appropriately in the test technique in an attempt to distinguish between reflex and soft tissue resistance to movement. The clinical significance of such a passive test of the impairment spasticity is not clear.

3.3 Isokinetic Dynamometry

The isokinetic dynamometer used in this case was the Kin-Com®125 AP, manufactured by the Chattanooga Group Inc. (Figure 3.1) The Kin-Com® is an expensive and complex piece of equipment that in this case was used to provide interval level data relating to resistance to movement in units of torque. Nuyens *et al* (2001) stated that dynamometry provides *'quantitative, sensitive and objective measurements of resistance against joint movements'*. Torque data were collected through ten continuous repetitions of passive knee flexion and extension at two velocities (60° per second and 120° per second). Quadriceps resistance to movement was quantified as a unit of torque. The method used for gaining torque data from the isokinetic dynamometer had previously been used by a number of other authors (e.g. Akman *et al*, 1999, Franzoi *et al*, 1999, Firoozbakhsh *et al,* 1993). The peak torque for five consecutive knee flexion repetitions was statistically analysed by these authors.

3.3.a Validity

Some of the basic issues relating to the validity of the use of the Kin-Com® as a measure of spasticity are the same as those which applied to the MAS.

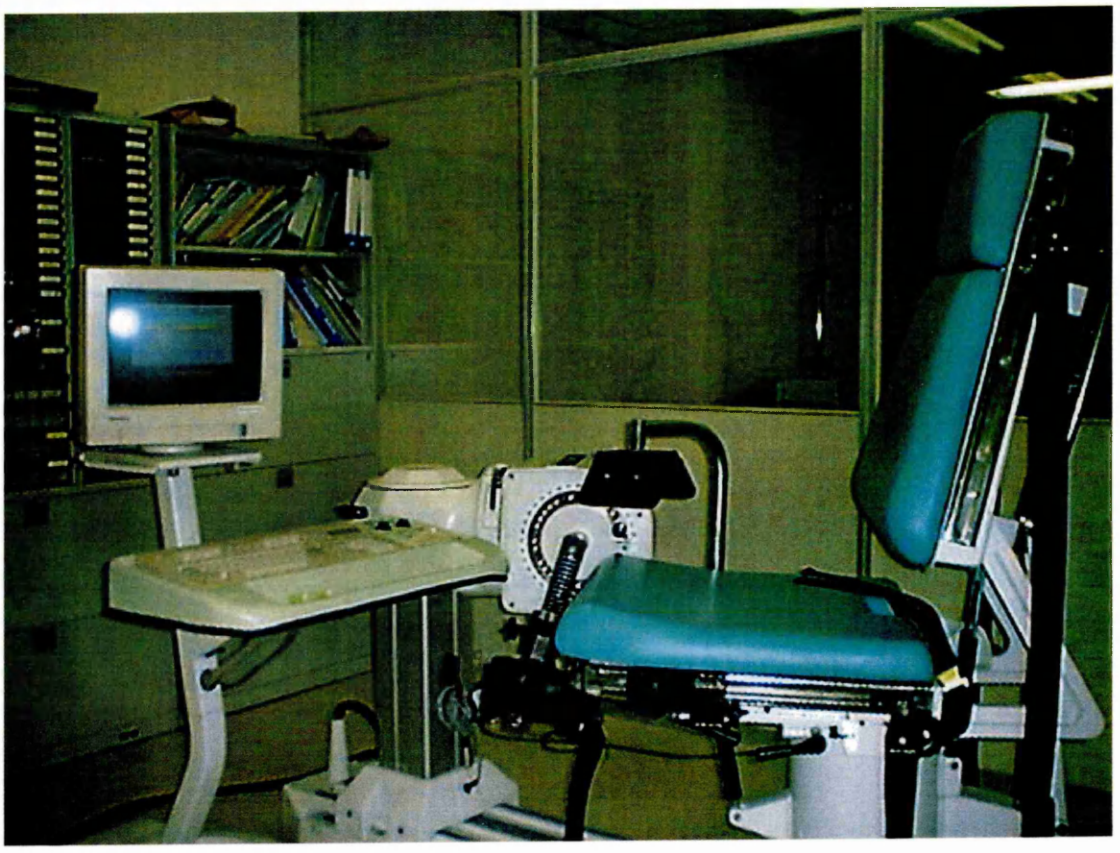


Figure 3.1: The Kin-Com Isokinetic Dynamometer

Whilst the Kin-Com® gives very objective, quantifiable information regarding resistance to passive movement, how much that resistance is a result of spasticity is questionable. The potentially confounding issues of joint and soft tissue rheological changes, limb inertia, velocity of testing and subject involvement are all as relevant to content validity as they are for the relatively subjective MAS (face validity).

Subjects were tested in the seated position through a range of 25°-85°of knee flexion. This range of movement was chosen to avoid the confounding issue of possible soft tissue tightness at the end of joint range. Some concerns however have to be expressed as to what the peak torque is actually measuring. In almost every instance it occurs very early in the flexion phase of the movement. At the end of range there is a rapid change of direction as the machine quickly decelerates, then accelerates into the new phase. Choices of three 'turning' accelerations are offered by this dynamometer. Initially a rapid change was chosen but it was found that the momentum of the limb, in particular in subjects with large limbs, was activating the safety cut-out feature and stopping the machine. The moderate change option was therefore chosen. The machine no longer cut out following this. This issue emphasises the effect momentum due to the rapid deceleration then acceleration in a new direction has upon the torque measurement. It may also be possible that the phasic part of the stretch reflex is being activated at this stage as a protective mechanism due to the sudden rapid change in direction of movement, even though the muscle is never actually on stretch due to the chosen joint ranges. Firoozbakhsh *et al* (1993) in their discussion query whether the maximum torque value seen is due to the inertia of the limb and its 'compliant coupling to the lever arm of the dynamometer'. Other authors who have copied his technique however have found statistically significant differences in peak torque measurements between subjects with spasticity due to spinal cord injury and normals (Akman *et al,* 1999, Franzoi *et al,* 1999, Perell *et al,* 1996).

Two velocities of movement were chosen in an attempt to differentiate between resistance due to soft tissue compliance and spasticity. Initially the speeds of 60° and 180° per second were chosen to give a substantial gap between high and low velocities of testing. However the 180° per second speed was very difficult to tolerate, even in normal subjects, and remain 'relaxed'. Perell *et al* (1996) found significant differences

between groups tested at 60° and 120° per second. The second test velocity was therefore changed to 120° per second, which all subjects tolerated comfortably.

Little appears to have been written as to the criterion validity of the isokinetic dynamometry measurement of spasticity. Interestingly some of the few articles that have addressed this issue (e.g. Akman *et al,* 1999, Franzoi *et al*, 1999) compare it to the Ashworth Scale. Both studies found a positive correlation between Ashworth scores and peak torque values. It was noted that subjects presenting lower Ashworth grades (1&2) did not appear significantly different from the 'normal' control groups in terms of torque measurements. Franzoi *et al* (*op. cit.*).

3.3.b Reliability:

The reliability of such a technical test lies inherently within the ability of the instrument to provide repeatable, reliable information and in the reliability of the test method. In an attempt to address issues with tester error and bias, an extended period of training in the use of the machine was undertaken under the supervision of a physiotherapy clinical specialist.

The test procedure was reviewed and standardised. Ten test sessions on 'normal' volunteers were performed using the test protocol prior to testing subjects. Franzoi *et al* (1999) reinforce the importance of standardised positioning if results are to be compared. Particular care was taken in lining the lever arm with the centre of the knee joint and with the positioning of the load cell above the malleoli. This was of particular importance as torque is defined as the turning force about a joint – the Kin-Com makes its calculations relative to the movement and position of the load cell.

Mayhew *et al* (1994) found that in testing that the Kin-Com® dynamometer was very reliable in a variety of situations. Davies *et al* (1996) however found that their torque data results at speeds above 30°/s were too 'contaminated' by noise to be analysed. Gleeson & Mercer (1996) discuss a number of methodological issues that may affect reliability and some aspects of validity. 'Human' issues - 'time-of-day effects' and learning from the test are raised as possible confounds. As the test used in this case was a passive one, learning from the machine was not considered as a problem.

3.3.c Responsiveness

Whilst the dynamometer may be very sensitive to small changes in torque, the point at which this change in torque becomes clinically significant to an individual's functional abilities, is not clear.

3.3.d Feasibility:

As previously stated, this type of dynamometer is a technically complex and expensive piece of equipment. Such items of equipment do not tend to be found within physiotherapy departments. The Kin-Com needs to be frequently calibrated and tested. To test quadriceps and hamstring resistance to passive movement for one subject took approximately 40 minutes. The seat of the machine was very high. One of the subjects could not access the Kin-Com as the seat was too high for them – a hoist would have been needed. However the size and shape of the base of the machine would have meant that a ceiling mounted tracking hoist would have been the only option. One other subject had to transfer onto a height adjustable plinth from their wheelchair and shuffle across onto the Kin-Com seat. Whilst the Kin-Com undoubtedly gives quantifiable information about resistance to movement in a research setting, it is not an easy piece of equipment to use and would not be feasible as an outcome measure in clinical practice.

3.3.e Summary

Isokinetic dynamometry has been used in many research studies to quantify muscle activity. Its advantage over the MAS is that it produces quantitative data; the disadvantage is that it is complex and time-consuming to set up. Consideration needs to be given to speed of testing and other possible confounding factors as for the MAS.

3.4 Observational Gait Analysis

Gait analysis is an important part of daily practice in physiotherapy. It plays a substantial part in our clinical decision-making and choice of treatment options for patients with movement disorders. The assessment of gait is a complex process with a variety of movements occurring in quick succession over a variety of limb segments. It involves many phases. Gait laboratories provide highly detailed, objective, 'gold

standard' data regarding gait but are costly, highly sophisticated and seldom accessible to most therapists. It can perhaps also be questioned how valid they are in the assessment of the very poor walkers often seen within physiotherapy departments. To ensure quality data from force plates and videotape subjects often have to make repeated walks along a walkway. Detailed analysis is usually made of one step. Subjects who fatigue quickly, whose gait is variable from step to step and who support a substantial amount of weight through walking aids are all difficult to analyse in a gait laboratory setting. In the clinical setting however most gait analysis is observational, and done in a very subjective manner (Coutts, 1999). This, in turn, leads to issues with assessing efficacy of treatment. For the purposes of this study the Rancho Los Amigos Observational Gait Analysis (OGA) form (Figure 3.2) was used to standardise the collection of gait data. Gait analysis played a substantial part in the FES strategies chosen for the study subjects. The OGA form provided a methodical way of assessing gait abnormalities within each phase of gait and at each joint of the lower limb. It provides nominal data about gait abnormalities. A mark is made on the form to indicate where and when a gait abnormality is present.

3.4.a Validity:

There has been little written as to the validity of observational gait analysis. In terms of face validity the Rancho Los Amigos OGA form gives a comprehensive breakdown of the phases of gait (as described by Perry (1992)) and of the joint ranges of the pelvis and the lower limb. The Rancho Los Amigos physical therapy department developed the form using normative gait data that was collated from 'gold standard' gait lab findings. Gait has been studied in great detail by many authors over many years (e.g. Perry, 1992, Sutherland, 1988, Inman, 1981). There is a substantial quantity and quality of objective quantitative data relating to normal human gait collated from computerised studies. For this thesis, gait was analysed from video recordings of subjects walking along a 10m walkway. It is recognised that this is an 'unnatural' setting and that the use of video may in itself affect the subjects' gait (Mulder, 1998).

Greenberg *et al* (1996) addressed the concurrent validity of the Rancho Los Amigos OGA form and computerised kinematic data from the Vicon gait analysis system. All of the scorers were senior clinicians with substantial experience in the field of gait analysis. They found a poor correlation between data from the observational data and

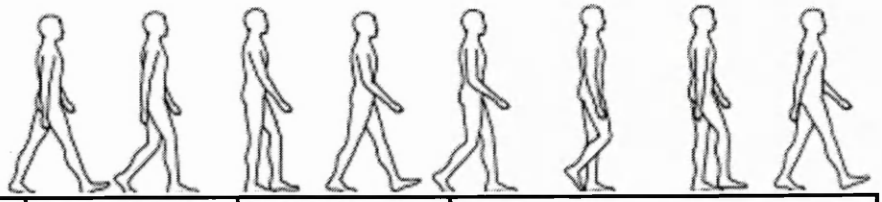
PHYSICAL THERAPY DEPARTMENT

CREST

GAIT ANALYSIS: FULL BODY

Patient ID.....

Reference Limb:
L ☐ **R** ☐



	Weight Accept		Single Limb Support		Swing Limb Advancement			
Major Deviation / Minor Deviation	IC	LR	MSt	TSt	PSw	ISw	MSw	TSw
Trunk Lean: B/F								
Lateral Lean: R/L								
Rotates: B/F								
Pelvis Hikes								
Tilt: P/A								
Lack Forward Rotation								
Lacks Backward Rotation								
Excess Forward Rotation								
Excess Backward								
Ipsilateral Drop								
Contralateral Drop								
Hip Flexion: Limited								
Excess								
Inadequate Extension								
Past Retract								
Rotation: IR/ER								
Ad/Abduction: Ad/Ab								
Knee Flexion: Limited								
Excess								
Inadequate Extension								
Wobbles								
Hyperextends								
Extension Thurst								
Varus/Valgus: Vr/Vl								
Excess Contralateral Flex								
Ankle Forefoot								
Foot-Flat Contact								
Foot Slap								
Excess Plantar Flexion								
Excess Dorsiflexion								
Inversion/Eversion:Iv/Ev								
Heel Off								
No Heel Off								
Drag								
Contralateral Vaulting								
Toes Up								
Inadequate Extension								
Clawed								

Major Problems:
Weight Acceptance Single limb Support Swing Limb Advancement

the Vicon data leading them to question the validity of the observations from the therapists.

There are undoubtedly many issue unresolved in the area of validity relating to OGA. The following section on reliability also raises issues that impact upon validity. If data is unreliable, carries a large degree of random error, it may not give valid (true) measures.

3.4.b Reliability:

There are a small number of studies that address the issue of reliability of OGA. None of them specifically address the Rancho Los Amigos system. Substantial concerns were voiced by all three reviewed articles regarding the lack of reliability found in their studies.

Krebs *et al* (1985) and Eastlack *et al* (1991) both found only moderate to poor inter- and intra-rater reliability in their studies. Coutts (1999) went so far as to state that at present, OGA on its own was insufficiently reliable to be clinically acceptable, echoing Krebs' (1985) observations regarding measurement error in gait analysis. The extent of any such measurement errors should be addressed before conclusions can be drawn from any test. Caution is suggested in analysis and generalisation of results. Sim & Arnell (1993), in their article on measurement validity in physical therapy research, used the problems with OGA reliability as an example of the importance of the links between reliability and validity. For conclusions drawn from data to be valid, the data itself must be reliable.

The preceding articles all draw similar conclusions to improve the reliability of OGA data:

1. The need for the use of a standardised form - clinicians seldom do, relying on highly subject assessment (Coutts, 1999)
2. Therapists must be familiar with normative gait data
3. Terminology used in the description of gait (to describe both phases and abnormalities) should be clearly understood

4. Video should be used wherever possible in OGA, preferably with freeze-frame and single-frame-forward options. This would give time for the analysis of multiple joint movements over multiple phases of gait and remove the issue of subject fatigue.

The Rancho Los Amigos system addresses the first three of these issues. The author underwent a period of training in the use of the form and in the terminology used with other CREST project members. This OGA system comes with a substantial training pack. The use of video and PC combined allowed for good quality freeze-frame and single-frame-advance assessment.

In spite of all the concerns regarding the reliability and validity, the author believes that there is a value in the use of OGA. Undoubtedly, care must be taken with any conclusions drawn from such data and limitations with reliability and validity must be addressed. As previously stated, visual analysis of gait, as part of the patient assessment is a common part of physiotherapy practice. Means of analysis without a standardised form are very subjective, with no indicator of outcome other than the therapist's opinion and with no evidence base. The other extreme is the use of highly sophisticated gait lab equipment, which in most cases is unrealistic, and which may still not give valid information regarding poorer walkers within a spinal cord injuries setting.

3.4.c Responsiveness:

One of the issues with the responsiveness of this form is that a huge number of data points are collected in any one assessment. The form only applies to one leg. If analysing both limbs another form must be completed. The gait improvement that effects a clinically important change for the individual may be lost in a welter of 'unimportant' information. The form provides nominal data about gait deviation i.e. an abnormality is either present or absent. There is no mechanism for noting improvement in performance if the normal is not achieved. Sensitivity to change is therefore low and clinical meaningfulness may be lost (Holden, 1984).

3.4.d Feasibility:

The Rancho Los Amigos form is complex. A substantial degree of knowledge/training is needed to recognise the different phases of gait, be familiar with normative gait

values and to have a comprehensive understanding of the described gait deviations. The form took approximately 30 minutes to complete even after the assessor improved their skills and became familiar with it. The use of video enhanced analysis of gait, in particular giving the ability to freeze frame and slow motion down. In the clinical setting such a lengthy assessment process would be a luxury. Not every physiotherapy department has access to a video camera, or to a video player that can provide a quality freeze frame or slow motion option from which to analyse movement.

3.4.e Summary

The Rancho Los Amigos analysis system is based upon gold standard gait laboratory measures so should have good validity as a measure of gait. Unfortunately its reliability appears to be poor – possibly due to the complex nature of gait. Reliability is an issue with observational analysis of gait. There appears to be little, if anything, published regarding the use of this system. This may be an indication of the potential problems with analysis of the data.

3.5 TELER® Gait Indicators

TELER is an acronym for Treatment Evaluation by A Le Roux's method. Le Roux (1993) developed the TELER system in response to the needs of physiotherapy services for a measurement tool that would measure effects of treatment in terms of goal attainment in the individual. As therapists seldom offer a 'rote' treatment, but rather, treatment adapted for the needs of the individual, a flexible system that actually measured the outcome of the process of rehabilitation was necessary. The system is based upon the assessment of the individual patient's needs and the development of treatment indicators from such.

The mechanism of measurement used by the TELER method is observation. This translating medium transfers observed activity to a measuring scale. The calibrated scale, or TELER Indicator, comprises six ranked, observable and clinically significant codes. These codes trace change, or lack of change, in a patient's abilities. The non-standard unit of measurement is clinically significant change. The TELER Indicator is an ordinal scale. Before an ordinal scale can be considered as the defined codes of a

TELER Indicator, seven conditions relating to the theory of measuring scales must be satisfied (Le Roux, 1999):

1. An intermediate outcome is an essential component of the desired outcome
2. All the intermediate outcomes are essential components of the desired outcome
3. The preceding intermediate outcome is an essential component of an intermediate outcome
4. All the preceding intermediate outcomes are essential components of the desired outcome
5. Each outcome is clinically significant
6. The progression from one outcome to the next is clinically significant
7. The outcomes reflect what is actually happening to the patient, as seen by the clinician, patient or carer.

An outcome is a TELER code. An intermediate outcome is a point on the hierarchical TELER Indicator scale. The first four concepts are linked to the need for each code to have a unique meaning in a hierarchy. This relates to the measurement properties of connectiveness, asymmetry and transitivity. These properties define the hierarchical relationship between codes. An outcome can be considered to be clinically significant when it can be justified by clinical or other knowledge, when the change between two successive outcomes can be explained with clinical knowledge, and when the time needed for change to occur can be explained by clinical or other knowledge. Outcomes are defined from the therapists' clinical and theoretical knowledge of the event under consideration; therefore current knowledge of the field is vital to the construction of valid indicators. For the outcomes to reflect what is actually happening to the patient the title of the TELER Indicator must reflect goals that are important to the patient. Each code is effectively a short-term treatment objective towards the stated goal. These goals must be understandable to the patient or anyone else reading them. The use of jargon should be avoided so that anyone reading the Indicator can understand it.

Another unique feature of the TELER system is that it is capable of showing attribution for the individual subject, that is that the observed change was due to the intervention chosen. It can only do so however when used in conjunction with a research method which controls for possible confounding variables. In a poorly defined measuring scale the random error of any measure is unknown and uncontrolled, therefore it is not

possible to know whether before and after differences are real or an artefact of the scale. In research this is allowed for by the use of groups of subjects, preferably as large as possible, so that any error is averaged out. In clinical practice the therapist needs to know the effect of an intervention upon the individual, not the 'average'. The TELER Indicator is a well-defined measuring scale which follows the above seven rules. The minimum of six discrete ranks with five clinically significant change intervals is also an important part of the attribution process. It is not possible to attribute a difference in before and after treatment scores for a single subject to a particular cause. If a series of intermediate scores between the before and after ones are considered attribution is possible. The minimum number of necessary changes is five.

The attribution of TELER Indicators is of particular importance to this study design where it is the individual who is under consideration.

TELER is a system of clinical note-taking that provides clinical information that can be used to establish the effectiveness of treatment. The TELER Indicator is an ordinal scale that traces the effects of an intervention through observable, clinically significant change in an individual patient's, or group of patients', abilities.

For this study TELER Normal Gait Indicators were developed in response to problems with the feasibility of applying the Rancho Los Amigos system within a clinical setting, with the problematic responsiveness of the tool and with the analysis issues that will be discussed in Chapter 6.

3.5.a Validity

A calibrated TELER Indicator is always valid (Le Roux, 1999) The level of validity will vary dependent upon the level of knowledge used to construct it and upon the number of therapists in agreement over its content and construction. The larger and more experienced the group the more valid the indicator.

The eight main phases of gait as described by Perry (1992), e.g. initial contact, mid swing, were used as the basis for the development of the TELER Normal Gait Indicators (Appendix I). TELER Indicators for trunk activity and foot contact through the gait cycle were also developed. Each Normal Gait Indicator consists of five

component parts that described normal limb movement in the saggital plane at the pelvis and at the hip, knee, ankle and metatarsophalangeal joints for each phase of movement. The saggital view was initially chosen for analysis due to its better reliability (Krebs, 1985) when compared to frontal or transverse planes. The components have no inherent hierarchy to them, so component rather than functional indicators were developed. The structure of a component indicator is shown in figure 3.3. The use of the codes 0-5 gives a hierarchical structure in keeping with points 1-4 of the conditions needed for a TELER Indicator. Each component is a discrete, clinically significant and observable feature of that phase of normal gait. The Indicators are based upon clinical and theoretical knowledge of the gait cycle. A review of the literature regarding normative gait data was undertaken by the author to give a basis for normal gait upon which to base the indicators. Normative gait data from 'gold standard' gait lab studies (Inman, 1981, Sutherland, 1988, Perry, 1992) were used to compile the Indicators. Dr Susan Mawson, Senior Lecturer in Physiotherapy, Wendy Dickens, Senior Physiotherapist in Gait Analysis, and the author of this thesis collaborated in the development of the Indicators. The indicators were therefore based upon both experiential and academic knowledge.

Figure 3.3: Format of a Component Indicator

Title

Components	***Treatment objective***
•	
•	
•	
•	
•	
0.	Unable to complete any of the required activities
1.	Able to complete one of the required activities
2.	Able to complete two of the required activities
3.	Able to complete three of the required activities
4.	Able to complete four of the required activities
5.	Able to complete all five of the required activities

Wade (1992) argued that activity of daily living (ADL) scales were inherently valid as they address a perceived disability. The TELER indicators point of origin is the patient's assessment of their problem. As an example 'I catch my toes and trip' on further assessment could be defined in terms of an inability to dorsiflex the ankle

sufficiently. The therapist may then describe this as a lack of dorsiflexion through the swing phase of gait. In this manner Indicators that are clinically relevant to the individual subject's problems are chosen.

The above addresses issues of face and content validity. TELER indicators also need to demonstrate construct and concurrent validity. A small group of senior physiotherapists from the Spinal Cord Injury Unit and Gait Laboratory at the Northern General Hospital was convened to trial and critique the Indicators. Although this was a very small pilot, the indicators were considered by this group as acceptable measures of normal gait and usable for the assessment of patients. Further work with larger groups of clinicians with expertise in the field of observational gait analysis would need to be undertaken before construct and concurrent validity could be shown.

3.5.b Reliability

The reliability of the indicators is linked to their validity. If found to be valid, they should also be reliable. The small pilot study described above in part addressed reliability. The group analysed videotape of a subject with a spinal cord injury walking. Further work would need to be undertaken following this preliminary study to further consider both inter- and intra-rater reliability of the indicators.

3.5.c Responsiveness

TELER indicators should demonstrate a high level of responsiveness to clinically important change. The indicators are chosen for the individual patient and are based upon their own analysis of their problem. Each TELER code should be based upon a clinically significant, observable outcome. The indicators were developed in relation to the parameters needed for normal gait. The relatively small number of data points also means that a significant change should not be easily overlooked.

3.5.d Feasibility

When compared to forms such as that from the Rancho Los Amigos, the TELER indicators are far easier to apply in a clinical setting. A small number of indicators appropriate to the subject being assessed are chosen for scoring, focusing on the key

aspects of gait being treated. The time taken to complete the chosen indicators is therefore far less than that of the Rancho Los Amigos, and can easily be incorporated into clinical practice.

3.5.e Summary

The TELER system is capable of producing valid, reliable and clinically significant data. The Indicators have been developed to provide a more clinically feasible method of analysing gait.

3.6 Chapter Summary

This Chapter has considered the criteria it is necessary for measuring scales to demonstrate. These were identified as validity, reliability, responsiveness and feasibility. The issue of clinical significance was also introduced and its importance in giving real meaning to results gained from measures highlighted.

The four measures chosen for this study were reviewed against these criteria. Those measures are the Modified Ashworth Scale, isokinetic dynamometry measurement of resistance to passive movement of a limb, the Rancho Los Amigos Observational Gait Analysis System and the newly developed TELER Normal Gait Indicators.

Despite questions being raised as to aspects of the measurement criteria of some of these tools, they are all accepted measurement techniques. The following Chapters expand upon the application of these measures and present and discuss the results from them.

The intent of this study was to investigate the effects of the clinical application of functional electrical stimulation upon spasticity in the individual with incomplete spinal cord injury, and in turn the effects of this change in spasticity upon gait. However, following a review of the literature and of the chosen measures it was clear that it would not be possible within the remit of this study to determine the effects of FES upon spasticity in dynamic activity i.e. gait. Consequently it is necessary to replace the original research questions with the following:

1. What changes in spasticity does an individual who receives FES as a treatment experience?
2. What changes in gait does an individual who receives FES as a treatment experience?

This study will consider both questions separately.

This chapter is split into two parts. The first includes the research hypothesis, study design and study validity. The overall validity of the study should not be confused with measurement validity, which was addressed in Chapter 3. Measurement validity is one aspect of methodological validity, along with internal, external and statistical validity, which can affect the veracity of conclusions drawn from the study results. The second part details the research process: the pilot study, subject selection, details of the data collection process, and of the FES strategies and decision-making process. Finally the analysis methods are introduced.

Ethics Committee approval for this study was gained from the Northern General Hospital Trust prior to starting.

4.1 Study Design

A single subject experimental design (SSED) was chosen. The main features of SSED design are the sequential application and withdrawal of treatment and the use of repeated measures of the dependent variable. Data were collected during initial and then final baselines giving an AB design. This type of design is described as quasi-experimental (Seale & Barnard, 1998) as it does not meet the full rigor of a true

experimental design. The reasoning behind this choice of design, rather than a more conventional group design, is as follows:

- The aim of the study was to look at the effects of FES on spasticity in the individual subject. A clinician is interested in the individual, rather than the group response to treatment. Whilst large group studies may give valid information regarding the average subject by evening out the effects of random error, the SSED is capable of giving information about the individual's response. If Sackett's (1996) definition of evidence based practice as 'the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients' is considered valid then this type of design is perhaps more likely to help in answering such clinical questions.
- The small group of subjects used was non-homogenous. Each subject had sustained an incomplete spinal cord injury. However, clinical presentations and problems were all different. All received FES as an intervention for gait problems but the parameters and applications were different.
- The incidence of spinal cord injury is very small – approximately 600-900 new injuries per annum in this country. Incomplete injuries capable of ambulating are obviously a smaller subsection of this group. Obtaining a large enough group to give meaningful data from both control and treatment groups was not practical. Rather than undertaking research based on an inappropriate group method upon a small subject group, it was seen as more valid to use a SSED. This type of design uses the individual subject as their own 'control' by the use of repeated measures.
- The conditions in which the study was carried out was closer to a clinical setting than a research setting.

4.2. Study Validity

To avoid drawing unjustifiable conclusions from a study, aspects of methodological and measurement validity and the control of possible confounding factors must be addressed. Black (1999) outlines four types of validity that need to be considered – construct, internal, external and statistical. Construct validity relates to the ability of the measures used to measure what they are supposed to. This was addressed in Chapter 3. Statistical validity relates to the choice of appropriate statistical tests. The statistical tests for this study will be introduced at the end of this chapter.

4.2.a. Internal validity

The literature states that, for a study to have strong internal validity, the effects of error, bias and potentially confounding factors need to be controlled wherever possible. The issue of extraneous variables, that is, variables which may act as competing independent variables and which may confound results, should be addressed. Quasi-experimental designs have been recognised as not demonstrating the same strength of evidence of a causal link between dependent and independent variables as true experimental designs. Black (1999) argued that whilst the above may be true, the advantage of this type of design is that it can reflect real-life situations more closely than those conducted under more experimental conditions. This is likely to be of interest to therapists working in a clinical setting who regularly deal with a complex combination of potentially confounding factors.

Ottenbacher (1986) highlighted two main issues relating to internal validity to which special consideration needs to be given in SSEDs: testing and instrumentation. Where repeated measures are used, error related to instrumentation can become a major issue. The behaviour of an individual or group is likely to be altered simply by the process of being measured (Hawthorne effect). Where repeated measurements are used, as in multiple baselines, there is obviously an increased risk of this occurring. Individuals are likely to learn from the test itself and therefore improve in their performance. Potential problems with instrumentation are also likely to be highlighted by the use of repeated measures. The reliability of results become paramount in ensuring that baselines show genuine change and not machine or measuring tool instability.

For this study baselines were kept to a minimum. This was in part to address the issue Black (1999) described as 'learning from the instrument'. Doing so also had a practical purpose – many subjects worked and/or had a 100 mile round trip to attend for sessions. Other issues with testing relate to the tester/assessor. The researcher was the assessor for all measures used. This may obviously leave the study open to experimenter bias. In an attempt to address this, a second blinded assessor was used for the Observational Gait Analysis section. Other more general assessor issues may play a part e.g. increased experience over time may affect measurements, more rigorous or relaxed testing method over time may also be an issue.

4.2.a.i Competing Independent Variables

It can be argued that competing independent variables are not an issue in answering the new research questions. The intention is to determine whether there is an association between the changes that occurred and FES. It is not the intention to establish a causal link between the changes that occurred and FES.

Consideration is however given to some of the many issues, other than FES, that may affect spasticity and gait. If these potentially confounding variables are not, wherever possible, recognised and controlled there is a risk of drawing invalid conclusions from data that may be a result of these variables rather than the one under observation. Spasticity in particular is notoriously variable and may be affected by a number of issues. Figure 4.1 highlights some of the main identified variables liable to affect spasticity in this study. The following section addresses each of these issues and indicates how the researcher attempted to address each with the intent of avoiding confounding outcomes.

- **Disease**: This is cited by many authors (e.g. Kirschblum, 1999) as a possible cause for increased tone or 'spasticity' and should be assessed for prior to commencing any treatment. Typical causes include bladder infections, pressure sores, and syringomyelia cyst formation. Two subjects (one identified as 014, the other unidentified), who were initially assessed as possible candidates for the project developed medical complications of spinal cord injury prior to starting baseline measurements. They therefore discontinued their involvement with the project.
- **Medication for spasticity**: Many of the subjects were taking the antispasmodic Baclofen. Any medication was noted at initial assessment. Subjects were asked to inform the researcher of any changes in their normal medication. No changes were reported.
- **Physiotherapy treatment**: Some subjects attended local outpatient physiotherapy departments for maintenance routines. This was again noted and subjects were asked to inform their therapists of their involvement in this project. Subjects were also asked to inform the researcher of any substantial changes in their therapy routines. No changes were reported.
- **Test position**: Many authors (e.g. Edwards, 1996) state the importance of a standardised testing position in the measurement of spasticity; pattern of tone can

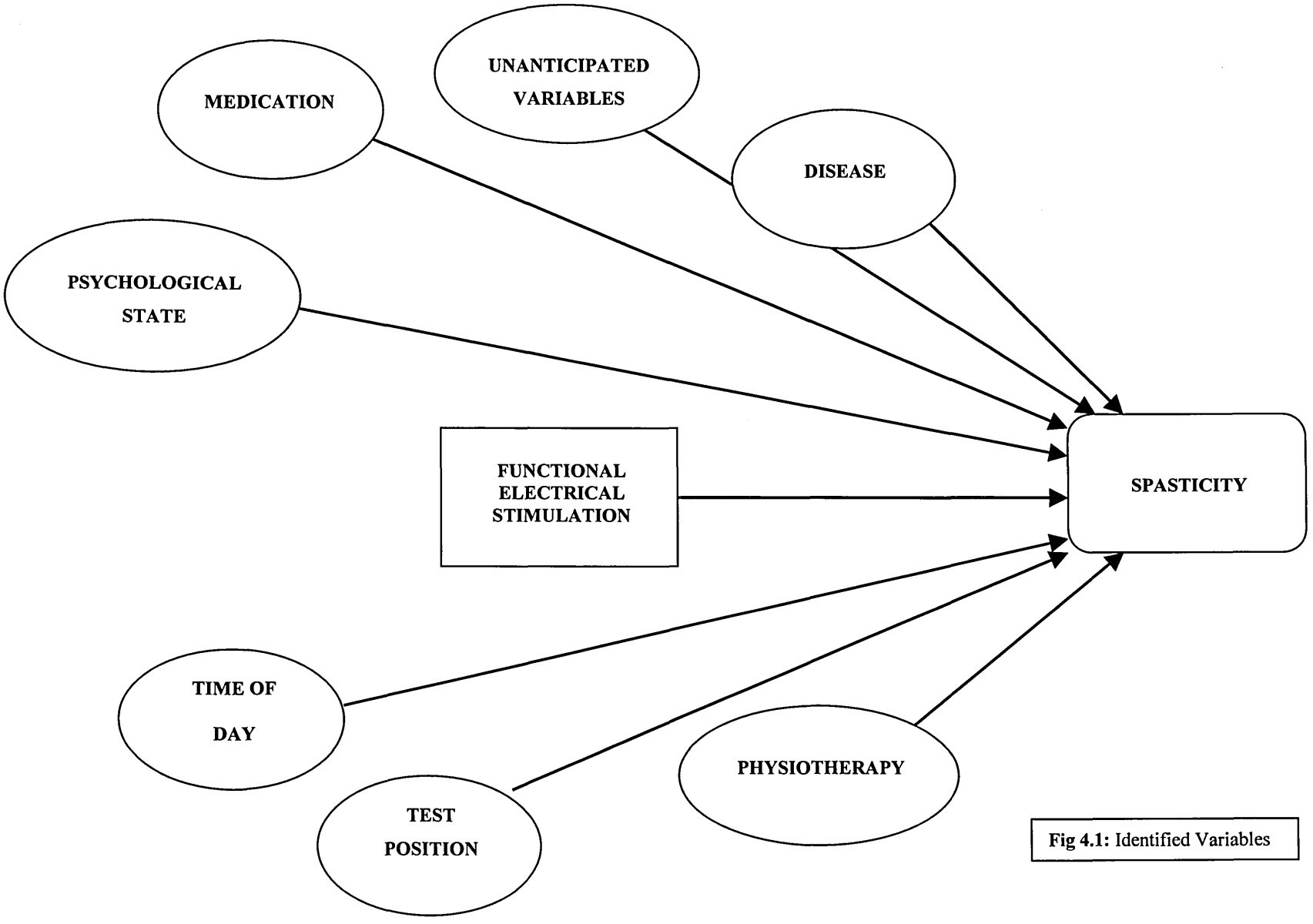


Fig 4.1: Identified Variables

depend upon the subject's position. This was addressed in the testing procedures that are detailed in section 4.5 of this Chapter.

- **Psychological state**: This can also be considered a possible confounding issue. Anxiety and depression are both believed to have a negative influence on spasticity. This was noted but no steps were taken to address this with the subject group.
- **Time of day for testing**. Wherever possible subjects were kept to either morning or afternoon sessions. As a variety of outcome measures were used, which may have impacted upon each other the sequence of tests was always constant i.e. Modified Ashworth Score, gait analysis and then isokinetic dynamometry.

'Unanticipated variables' have also been added as potential competing variables. Whilst the researcher has attempted to consider all possible issues in this complex field it is possible that some have been overlooked.

Walking ability may have been altered by increased physiotherapy input. Although gait re-education did not formally take place, training in the use of the FES system had a component of gait re-education within it.

4.2.b External validity

External validity relates to the extent to which results from an experiment can be generalised to other subjects and populations. The mechanisms used to ensure this relate to sampling and the conditions under which the study is carried out. They should be representative of the populations and situations to which the results are to apply.

Ottenbacher (1986) argued that SSEDs might address external validity better than true experimental research in that they address the individual rather than the 'average'. This study used subjects as their own controls. Each FES intervention was tailored to the individual dependent upon the physical examination and subjective assessment of the subjects needs. In this manner, the intervention avoided being described as an 'unnatural' treatment. In the author's opinion this is undoubtedly a possible threat to external validity in many areas of physiotherapy research – to be effective treatment must be appropriate to the individual, rather than a set 'recipe'. There are, perhaps, few examples within the field of neurological physiotherapy where a 'set' treatment can be appropriately applied. This gives rise to issues with measurement and research

methodology in this field. Le Roux's (1993) article highlighted the crux of the matter: we should look for appropriate measures and methodologies that investigate what physiotherapists do, not adapt practice to suit measures.

The subjects for this study were not sampled as such. Senior physiotherapists audited casenotes to produce a list of candidates who met the inclusion criteria. These individuals were then contacted as possible subjects.

External validity is not however an issue in answering the new research questions. The intention of this study is to obtain data on which to base an hypothesis for the effects of FES on spasticity and upon gait. It is not the intention to generalise the findings of the study beyond the individuals involved.

4.3 Pilot study

The pilot study for the CREST project, in part, covered the pilot study for this study. Five Spinal Cord Injury Units from across Europe participated. Initial meetings were held to identify outcomes for the CREST project and then to formalise test procedures. These meetings included the protocols for the Modified Ashworth Scale and the Rancho Los Amigos Observational Gait Analysis system. Expert external advisors were present at these sessions. As research therapist for one of the centres of expertise, this author was responsible for the 'roll-out' of education in these protocols and in the application of the FES systems following these sessions. Meetings were held in Denmark and Spain for all clinicians to be involved with the assessment of subjects and the application of FES systems. These involved practical sessions to ensure, as much as possible for subjective tests, a common understanding and application of the test protocols, and familiarity with the application of FES systems.

For the isokinetic dynamometry test procedure the researcher undertook a period of education in the use of the equipment from a senior clinician with expertise in the use of the Kin-Com. Advice was also taken from the Sports Science and Physiotherapy Departments at Sheffield Hallam University regarding data analysis. Ten tests were undertaken on 'normal' subjects at both test speeds. Data from these tests were imported as ASCII data to Microsoft Excel, where they were graphed for data analysis. Data were collected from only one test for each subject. Data were also collected from a

patient volunteer prior to that from the test subjects. Unfortunately repeated data was not collected from any of the above volunteers.

The TELER Normal Gait Indicators were developed from 'gold standard' gait laboratory data regarding normal gait parameters, from clinical experience and from experience of observational gait data. As explained in Chapter 3 they were developed in conjunction with senior physiotherapists who have substantial experience in the use and development of the TELER system and in gait analysis. Practical sessions were undertaken involving a group of senior physiotherapists. Video of a patient walking was analysed using the Indicators.

The above addressed the consistent application of the test protocols. Extra training in the use of the Odstock stimulators was undertaken. The other research groups within the CREST project also undertook practical sessions in the application of the FES systems.

4.4 Subject Selection

Possible subjects for the study were identified during a review of physiotherapy records. The researcher and a senior physiotherapist from the Spinal Injuries Unit audited all records for a ten-year period from 1987-1997. Those meeting the inclusion criteria for the project were short listed.

Inclusion criteria were as follows; capable of ambulating – ASIA C and D categories (functional or for exercise purposes), injuries above T12 spinal level i.e. upper motor neurone lesions, minimum of one year post-injury, stable neurological condition (no recent improvement or deterioration), no medical complications, no substantial lower limb joint laxity.

Two staff were involved in the short-listing of potential subjects for the project. The selected subjects (see Table 5.1) grossly mirrored the general statistical population for individuals with spinal cord injury (see Figures 2.1-4). There were two main age groups - the first with a mean of 22.2 years, the second with a mean of 46.5 years. The ratio of pathological to traumatic causes was 3:7. There were three paraplegic and seven tetraplegic subjects. Two out of the ten subjects were female.

Letters were sent to this group explaining the purpose and duration of the study and inviting them to reply if interested in participating. This letter also briefly outlined the commitment required from them in terms of time and activity. Respondents were asked to attend for an initial assessment. This assessment included a physical examination (muscle power, joint range of movement, sensation and muscle tone), a brief functional electrical stimulation test to see if subjects responded to stimulation and found the stimulation acceptable, and gait analysis. Subjects were also questioned as to what it was they wanted to improve about their walking, and their understanding of the uses and limitations of FES. Ten subjects were accepted. Informed consent was gained. All travel expenses were paid.

4.5 Process

4.5.a An Overview

Table 4.1 Summary of subject attendance and intervention

Attendance	Session content
Week 1-2	**Initial Baseline Measurements:** • **Modified Ashworth Scale – repeated x3** • **Observational; Gait Analysis** • **TELER Normal Gait Indicators** • **Isokinetic Dynamometry – repeated x3**
Weeks 3-10	**'Intervention' Phase – maximum of ten sessions** • **Application and adjustment of FES systems** • **Subject education in safe application and fine adjustment of FES systems** • **Gait assessment – TELER system** • **Gait re-education with FES systems**
Weeks 11-12	**Final Baseline Measurements – as per initial baselines**

Once enrolled upon the programme, all subjects attended for assessment then initial baseline testing, intervention and final baseline testing with and without FES. Initial baseline testing was repeated over three sessions. The purpose of taking baseline measurements is to produce a base against which later changes may be evaluated (Sjoden, 1987). Initial baseline data illustrates the extent and stability of the patient's problem prior to intervention. This can assist in concluding whether 'spontaneous recovery' or placebo effects have had substantial effects on results. Measures taken at initial and final baselines included all those detailed in the previous chapter. The Modified Ashworth Scale and Isokinetic torque data were recorded on three occasions

at initial baselines and final baselines (without stimulation) respectively. Saggital and frontal plane video was taken on each day of testing at initial and final baselines (with and without stimulation). Observational gait analysis and TELER Gait Indicator analysis was undertaken once at initial and final baselines both with and without stimulation. TELER assessment was also undertaken during the intervention phase. Table 4.1 shows timescales for when subjects attended assessment and intervention phases following initial assessment and recruitment.

4.5.b Test Protocols

The methods used to ensure that valid measures were obtained was in part addressed in the 'Pilot Study' section above. Consensus in the methods of test application was gained through discussion and practical sessions with groups of therapists and volunteer subjects. These sessions resulted in standardised test protocols used by the CREST group, and by a refining of the tests used specifically for this study. This was done in an attempt to minimise random error and bias in the measurements undertaken. The ability of the measures to give valid data about spasticity and gait abnormality was discussed in Chapter 3.

The effects of assessor bias were addressed wherever possible. The author was the only assessor in all but the Rancho Los Amigos Observational Gait Analysis. The Modified Ashworth Scale data was collected on three separate sessions at both initial and final baselines. Scores were entered into the CREST personal computer by the project bioengineer. The assessor did not see the previous test session results. The MAS is undoubtedly a very subjective test, bias may always play a part in the outcomes. Once the Kin-Com tests were in progress it was not possible to further affect the results. Any issues with observer bias or error occurred at the point of setting the machine up. For the Observational Gait Data a senior physiotherapist from the Spinal Cord Injuries Unit who had experience in gait assessment provided inter-observer test data for four randomly chosen subjects. This tester was told which sessions to assess but did not know whether the FES system was on or off for the final baseline sessions, subjects wore the FES systems for both sessions. Only the author collected the TELER data. Ideally another observer would also have collected this data to check for bias. Bias in the choice of possible Indicators was avoided; the chosen indicators are treatment goals negotiated with the individual subject and based upon objective and subjective clinical

assessment. As the researcher collected and analysed all data a blinded observer also assessed gait using the OGA form in an attempt to address observer bias. The second assessor chose four subjects at random for analysis. Given the large number of data points and the known issues with inter-rater reliability of observational gait analysis only the 'swing limb advancement' phase of the gait cycle was analysed in the saggital plane for the hip, knee and ankle joints. This also addressed some of the issues with uniqueness of the OGA. For all subjects the FES intervention was intended to facilitate specific movements through specific parts of the gait cycle, in considering the entire lower limb and pelvic activity the 'real' effect of the intervention can be lost. It is however recognised that the improvement of one part of the gait cycle may have an effect on other aspects of gait. This effectively gave 39 points for scoring.

4.5.b.i The Modified Ashworth Scale:

The Modified Ashworth Scale (Bohannon & Smith, 1987) was the first test applied on each day of testing. The subject was positioned in supine upon a height adjustable plinth with a pillow under their head. Subjects were asked to 'relax' and not attempt to move the limb being tested. Passive movement of each limb was undertaken at a brisk pace. Each muscle group in the lower limb was individually graded. The data collection sheet is shown in Figure 4.2

4.5.b.ii Torque Measurements Using Isokinetic Dynamometry:

Isokinetic dynamometry was undertaken using the Kin-Com® 125 AP manufactured by the Chattanooga Group, Inc. The method used by Firoozkbakhsh *et al* (1993) and later by Perell *et al* (1996) and Franzoi *et al* (1999) was used as the basis for this study. The purpose of this test is to measure the amount of torque generated during passive movement on repeated passive flexion and extension of the knee joints with a defined subject group. Tests were undertaken on each of the three initial and final baseline sessions. Test speeds of 60° and 120° per second were chosen to allow consideration to be given to the effects of different velocities of movement upon spasticity.

Subject Position:

The subject was asked to sit on the seat and to ensure that they were comfortable. The back rest angle was 78°, the seat tilt angle 15° and the seat depth set so that there was

Figure 4.2: Data Collection Sheet – Modified Ashworth Scale

Patient Name: _____ Date: _____

ASHWORTH SPASTICITY SCORE

	RIGHT	LEFT
Hip flexors	☐	☐
Hip extensors	☐	☐
Hip abductors	☐	☐
Hip adductors	☐	☐
Knee extensors	☐	☐
Knee flexors	☐	☐
Dorsiflexors	☐	☐
Planterflexors	☐	☐

0 No increase in muscle tone.
1 Slight increase in muscle tone, manifested by a catch and release, or by minimal resistance at the end of the range of motion when affected part(s) is moved in flexion or extension.
2 **(1+)** Slight increase in muscle tone, through most of range of movement, but affected part easily moved.
3 More marked increase in muscle tone, passive movement difficult.
4 Considerable increase in muscle tone, passive movement difficult.
5 Affected part(s) rigid in flexion or extension.
NT Not tested.

Conduct of Test

Nature of Spasm

approximately 3cm between the back of the knee and the seat with the lower leg hanging free. Once in a comfortable seating position with hip and knee in 90° of flexion, the thigh was held in place to prevent unwanted movement using a stabiliser.

The pre-set position for testing the chosen side was attained then fine adjustments to align the Kin-Com's centre of rotation with that of the individual's knee joint laterally was performed. The double pad attachment was positioned 4cm above the lower border of the lateral malleolus so that the ankle was allowed free movement. The lever arm length was taken as that level with lower border of the load cell. The lever arm was aligned with the tibia. Passive testing of the amount of movement of the double pad around the lower end of the tibia was performed to ensure that the centre of the dynamometer's axis of rotation and that of the knee joint was aligned. If there was no movement of this pad the alignment was taken as correct.

Test Protocol:

The Kin-Com® programme was entered and the 'Evaluation' option was chosen from the main menu. New subject details were entered as prompted by the programme. The Passive Mode was chosen from the next menu, with the knee joint and the muscle group for flexion/extension identified. The 'Handle Jog' procedure was undertaken to ensure that the load cell adapted to read the force in the direction from which it was being produced. If first one limb then the other is tested without this procedure being undertaken the load cell will read force as if it were still the opposite side or inverted position. Gravity correction was performed for each test so that the dynamometer could calculate the weight of the leg during each test.

The range of movement to be produced at the knee joint was 60° between 25° and 85° of knee flexion. This range was chosen in an attempt to prevent soft tissue tightness at full knee extension or in flexion confounding results. Impingement of the seat on the back of the knee also was to be avoided. The horizontal was determined by the use of a spirit level. Range of movement was gauged from this point by the Kin-Com. As well as the computer settings for the limits to the range of movement, the mechanical stops were set as a safety back up. Subjects were asked to relax prior to movement, and throughout the tests.

Medium acceleration at the change of direction to reach the test velocity was used. A maximum cut out force of 200N was set to allow for any unexpected resistance to movement to prevent any possible damage to the subject's limb during unexpected movement. Should that force be overridden the machine automatically cuts out. The subject was also given an over-ride 'panic button' which would stop the test should they become uncomfortable

Tests were performed at two velocities – 60° per second and 120° per second. A warm up was performed for each test. This consisted of a set of ten repetitions of flexion followed by extension at the speed in degrees per second of the test that was to follow. After this one group of ten-repetitions at 60°/s was undertaken. This test was saved. The same process was then followed for the test at 120°/s.

When tests had been completed for one leg the machine was set up for the other leg and the above process was repeated.

4.5.b.iii Rancho Los Amigos Observational Gait Analysis

Observational gait analysis (OGA) was undertaken once at initial baselines and then once at final baselines both with and without stimulation.

Subjects were asked to walk along a ten-metre walkway. Sagittal and frontal plane video was taken of the subject walking at a their own speed. The video cameras were in fixed positions. These were filed on the CREST software on a personal computer. The computer had a 'frame-grabber' and programme that allowed the video to be slowed or stopped at any stage during the gait cycle.

The data capture form used was that devised by the team at the Rancho Los Amigos (Figure 3.2). A separate form was filled in for each of the three assessment sessions (once at initial baseline and once at final baseline – both with and without stimulation). Only the leg to be stimulated was assessed for each subject. The video session numbers used for each assessment were noted on the OGA form.

4.5.b.iv TELER® Gait Indicators

On initial assessment each subject was asked to identify what he or she would like to improve about the way they walked. Physiotherapy assessment included joint range of movement, muscle power, degree of spasticity and observational gait analysis. From the clinical and subjective assessments a list of each individual's problems were identified and negotiated.

From the identified problem list appropriate TELER® Normal Gait Indicators chosen for each individual subject. From saggital plane video, gait was monitored against the chosen indicators on four occasions:

- Initial assessment
- Within the treatment process
- Final baselines – without FES
- Final baselines – with FES

The TELER Normal Gait Indicators developed for this study are shown in Appendix I. The bibliography used in the development of these Indicators is included.

4.5.c Intervention

Intervention for each subject was defined from the objective baseline measurements and from subjective information from the individuals involved. Intervention included muscle training programmes where appropriate, application and adjustment of FES systems, and gait re-education. The FES systems were refined throughout the intervention phase so that the timing and intensity of stimulation correlated with the individuals gait speed and pattern. This was done to ensure as normal a gait as possible and that stimulation parameters were comfortable. Subjects attended for up to a maximum of 10 intervention sessions before undertaking final baseline assessments. The following is an example of the assessment and intervention process for one subject. Appendix II gives a breakdown of the individual interventions by subject.

Subject 005

45-year-old male with a pathological lesion incomplete at T10. Brown-Sequard lesion. ASIA grade D.

Problems Identified

- Catches toes of right foot whilst walking – unable to 'shorten' leg adequately during swing phase of gait due to decreased hip knee and ankle flexion
- Frequently 'goes over' his right ankle when walking
- Occasionally falls when his right knee gives way – has quadriceps weakness

Aims of treatment

- To instigate a strengthening regime for quadriceps and ankle evertors
- To provide a stable right ankle during stance
- To provide a stable right knee during stance
- To increase dorsiflexion of the right ankle during swing
- To increase right hip and knee flexion during swing

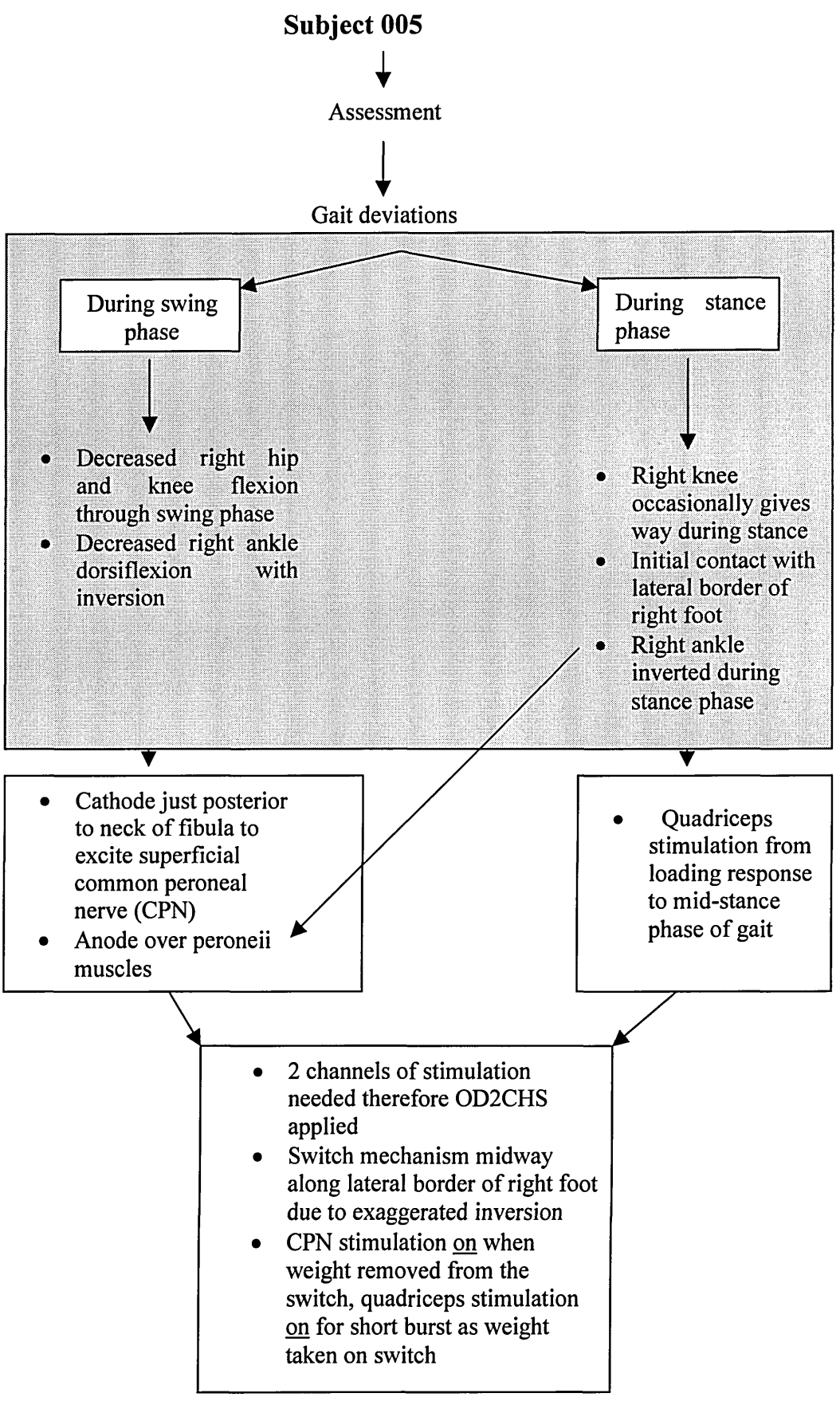
Treatment:

- Exercise regime for quadriceps and ankle evertors
- Gait re-education with elbow crutches
- FES strategy decision tree see figure 4.3

The electrical stimulators used were the Odstock one (ODFS III) and two channel stimulators (OD2CHS – Figure 4.4), and the CRESTim three channel stimulator (Figure 4.5). A team of therapists and bio-engineers based in the Medical Physics Department, Salisbury District General Hospital, developed both Odstock stimulators. The CREStim is a computer programmable stimulator developed for the CREST project by the Medical Physics Department at the Royal Hallamshire Hospital in Sheffield. This stimulator allowed for a high degree of flexibility in adjustment of stimulation parameters. Pals self adhesive electrodes were used.

Final baseline testing was repeated over three days both with and without FES.

Figure 4.3 Decision Tree for FES Strategy



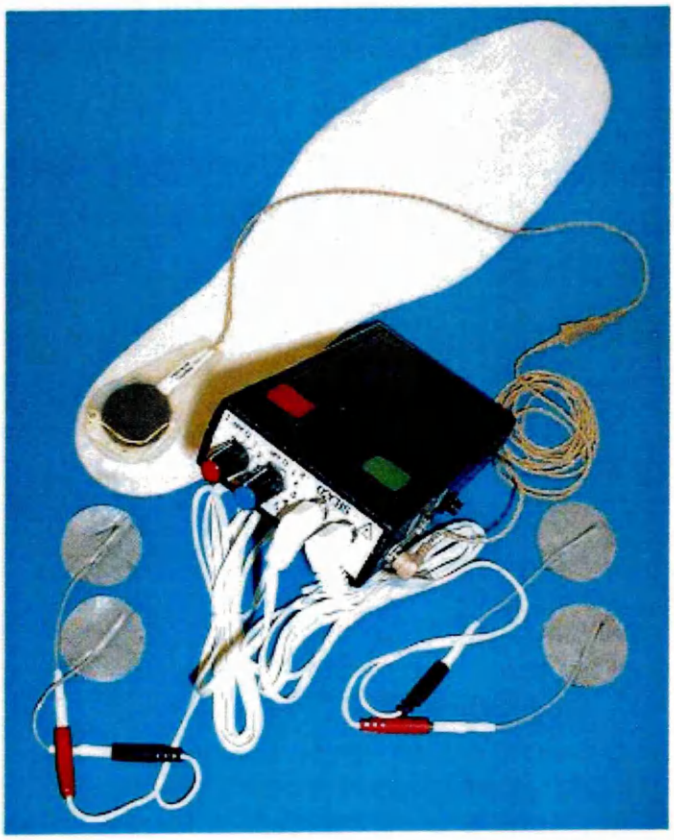


Figure 4.4 Odstock 2-channel stimulator

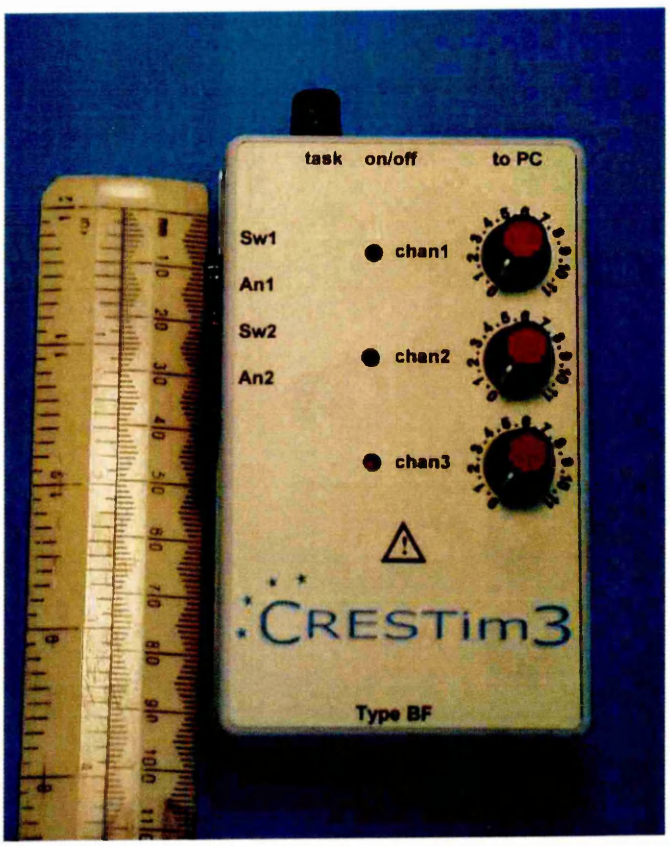


Figure 4.5 CREST Stimulator

4.6 Statistical Analysis

Analysis of single subject experimental design is a debated area. For the purposes of this study data were initially graphed or tabulated for ease of descriptive analysis. Statistical analysis was then undertaken in all cases other than that of the isokinetic data. Visual analysis in itself may present some particular problems, as there is no theoretical framework to guide interpretation of results. It is the most commonly recognised method of analysing information from SSEDs. There is discussion as to the appropriateness of statistical analysis of such data because statistical tests were developed for group studies and were based on assumptions about the data, which in turn may not be applicable to single case studies. However, some authors (e.g. Ottenbacher, 1986, Sjoden, 1987) have suggested that after initial visual analysis, it may be appropriate to perform statistical analysis on the data as a supplement to visual analysis where weak treatment effects are seen. Ottenbacher (*op. cit.*) also suggested the use of statistical analysis where baselines are unstable, or where there are relatively small visual changes. Both authors also point to the likelihood that visual analysis that shows a strong treatment effect is likely to demonstrate clinical significance - that is, show a clinically important change due to the intervention.

Given the two research questions there are two statistical test hypotheses:

1. $\mathbf{H_0}$ - there is no association between the changes in spasticity experienced by an individual and the use of FES

   $\mathbf{H_1}$ – there is an association between the changes in spasticity experienced by an individual and the use of FES

This gives a two-tailed statistical hypothesis – the association between spasticity and FES may be positive or negative.

2. $\mathbf{H_0}$ - there is no association between improvements in gait experienced by an individual and the use of FES

   $\mathbf{H_1}$ - there is an association between improvements in gait experienced by an individual and the use of FES

This gives a one-tailed statistical hypothesis – gait will improve with FES treatment.

The level of significance is set at $p< 0.05$ for both hypotheses. Possible links between spasticity and function were addressed at the end of Chapter 2, and will be returned to in Chapter 6: Discussion.

There were problems with the independence of data from the MAS – both in terms of repeated testing and testing of different muscle groups from the same limb. A limitation in one muscle group is likely to impose a corresponding limitation in another muscle group. Measurement of the output of the different muscle groups are therefore unlikely to possess the statistical independence required by conventional tests of statistical significance, which therefore are likely to produce meaningless results. Before and after measurements of the same groups of muscles are also unlikely to possess the statistical independence required by conventional tests of statistical significance, with the same consequences.

Using the median of a group of measurements eliminates any lack of statistical independence between the measurements in the group. A lack of statistical significance on the median test invalidates the null hypothesis, as its cause is unlikely to be the lack of statistical independence between the before and after measurements. On the other hand, statistical significance on the Median test shows that a lack of statistical independence between the before and after measures did not contribute to the result of the test, such in so far as it inhibited achievement of the result.

Fisher's exact test was used to test for an association between MAS grades pre- and post-FES intervention. The median test was initially used to quantify the number of grades above and below the median score pre and post-intervention. Fisher's exact test was chosen rather than the Chi^2 test, as the number of results was small so the 'rule of five' applied. The rule of five states that 80% of cells in a frequency table should have expected values of at least five. This was not the case in this instance.

Due to the inconsistencies in the Kin-com data no statistical analysis was performed upon it. Data were graphed and analysed descriptively.

Observational Gait Analysis data were analysed for the subjects as a small group. Data collected using the Rancho Los Amigos System could not be analysed for individual subjects as the data lacked independence. The paired t-test was used to analyse the data

for the subjects as a group. Data were collected at initial baselines without stimulation and at final baselines with stimulation. The number of gait deviations when walking with and without FES was calculated for each individual. The test result was calculated from the mean difference between the paired values (number of gait deviations with and without FES) for each individual. As the researcher collected all data, a blinded assessor also analysed a random selection of the OGA data. Spearman's rank correlation coefficient was used to assess the association between blinded and non-blinded assessors scores. The scores were again based on the changes between subjects walking with and without FES.

TELER data were analysed for individual subjects and then for the subjects as a group. Data were initially tabulated for the individual subject then descriptively analysed. The table itself shows which individual indicators show statistically significant change. A probability tree analysis was then performed upon three of the most clinically important indicators to the subject. The TELER indices Deficit Index, Improvement Index and Health Gain Index were calculated. These indices respectively give a measure of the overall effect of the presented problems on the individual, the improvement in function and the extent to which a subject is free from residual or chronic disability.

The Chi-squared test was applied to the TELER data collected for the subjects as a group. The observed values in each cell were tested for association against the expected values in each cell.

4.7 Chapter Summary

This Chapter has:

- Stated the research questions to be answered by the study.
- Addressed aspects of study design and validity
- Outlined the pilot work undertaken prior to the start of full data collection.
- Described the study process; including subject selection, the test protocols and data collection processes, the intervention and decision-making process this was based on and the equipment used.
- Stated the statistical test hypotheses and introduced the statistical tests used.

Chapter 5 presents the results from these processes.

CHAPTER 5: RESULTS

Results from the four outcome measures used for the study will be presented in this chapter. The chosen methodology is that of a repeated single subject experimental design. Due to this results are, wherever possible, initially presented and discussed for each subject (n = 8). The two research questions, what are the effects of functional electrical stimulation (FES) upon spasticity and upon gait, will be considered separately. Data will be presented for visual or descriptive analysis, then, where appropriate, for statistical analysis. The level of significance for all statistical analysis was set at $p<0.05$. Data for each subject are presented only for the limb that was treated with FES. The untreated limb was not used as a 'control' as the results do not satisfy the criteria of independence required by tests of statistical significance, therefore conclusions drawn from such results are likely to be flawed. Data will initially be presented for each individual test.

5.1 Subjects for this Study

Table 5.1: Subject Demographics

	Subject ID	Age	Sex	Level of injury	Cause	Time since injury✶	ASIA Grading	Incomplete Syndrome
1	005	45	M	T10	Pathological	3	D	Brown-Sequard
2	006	19	M	C4/5	Diving	2	C	Brown-Sequard
3	007	25	F	C6	RTA	6	C	Brown-Sequard
4	008	23	F	C6	RTA	3	D	Brown-Sequard
5	009	49	M	C7	Fall	18 months	D	Brown-Sequard
6	010	41	M	T4	Pathological	13	C	Brown-Sequard
7	011	28	M	C6	Diving	7	D	Brown-Sequard
8	012	61	M	C5	Sport	5	D	Central Cord
9	013	43	M	C6	Pathological	1	D	Incomplete
10	014	38	M	T7	RTA	10	D	Brown-Sequard

✶ = Time since injury in years unless otherwise stated

The method of subject selection was detailed in Chapter 4. Table 5.1 details the subjects selected for the study. Age of subjects on recruitment to the study ranged from 19 to 61, with a mean of 37 years. Two were female, eight male. Seven subjects presented with an incomplete tetraplegia, three with incomplete paraplegia. Seven subjects had spinal cord damage resulting from traumatic injuries, three as a result of pathological change.

The mean time from injury on recruitment to the study was 5.2 years (range 1 to 13 years). Subjects 006 and 007 had the most substantial degree of paralysis and were classified ASIA C grades, all others were ASIA D. Eight presented as Brown-Sequard lesions, one as central cord syndrome, and one with an unclassified incomplete injury. Subject 007 did not complete the study, subject 014 was taken ill before initial baseline measurements were undertaken and therefore did not participate. This meant that the total number of subjects to complete the study was eight (N=8).

5.2 FES and Spasticity

The Modified Ashworth Scale (MAS) was used as an outcome measure to give ordinal data regarding resistance to passive movement of the lower limb. The isokinetic dynamometer was used to give interval data relating to resistance to passive movement of the knee joint.

5.2.a The Modified Ashworth Scale

MAS data were first analysed descriptively then statistically using Fisher's exact test based upon the median score. Data for one subject are shown below to demonstrate the analysis process. That for all other subjects is shown in Appendix III

5.2.a.i MAS Results for Subject 005

FES was applied to the right leg therefore the results shown relate to this limb.

Table 5.2 Modified Ashworth Scale (MAS) Data by Grade pre- and post-FES

MAS Grade	0	1	2	3	4	5	Total
R Pre	0	9	13	2	0	0	24
R Post	0	21	3	0	0	0	24
Total	0	30	16	2	0	0	48

The analysis on Table 5.2 shows an improvement from 15 readings at grade 2 and 3 pre-FES to only 3 readings on grade 2 post-FES. As a result the concentration of 13 readings on grade 2 pre-FES improved to a concentration of 21 readings on grade 1.

The situation post-FES therefore is, firstly, an increase in the concentration on the median from 54% on grade 2 pre-FES to 88% on grade 1 post-FES, and, secondly, an improvement of 1 grade in the median.

Analysis of the MAS pre- and post-FES changes on the individual readings (Table 5.3) shows that 14 pre-FES readings improved by 1 grade, 10 pre-FES readings did not change, and no pre-FES readings deteriorated.

Table 5.3 Number and nature of change episodes post FES intervention

	Nature of Change		
	Improvement	**No Change**	**Deterioration**
	1	1	
	1	1	
	1	1	
	1	1	
	1	1	
	1	1	
	1	1	
	1	1	
	1	1	
	1	1	
	1		
	1		
	1		
	1		
Total	**14**	**10**	**0**

These improvements suggest that subject 005 did not suffer a deterioration in spasticity, and may even have demonstrated an improvement, following FES. The suggestion becomes a conclusion if the changes could not have occurred by chance.

Assuming that there is no co-variation between pre- and post-FES readings the following statistical hypotheses are tested:

$\mathbf{H_0}$ - there is no difference between the pre- and post-FES deviations from the pooled median

$\mathbf{H_1}$ – there is a difference between the pre- and post-FES deviations from the pooled median

The pooled median = the grade of the 24th reading. From table 5.2 it can be seen that the number of grade 1 readings = 30, therefore the 24th ordered reading = 1. Fisher's exact test was then used to calculate the probability that the differences between pre- and post-FES deviations from the pooled median were due to chance.

Table 5.4: Subject 005 - MAS grades above and below the pooled median

	Pre	Post	Total
No of readings below Median code	0	0	0
No of readings above Median code	15	3	18
Total	15	3	18

$$P = \frac{(A+B)!(A+C)!(B+D)!(C+D)!}{N!A!B!C!D!}$$
$$= \frac{(0+0)!(0+15)!(0+3)!(15+3)!}{18!0!0!15!3!} = 1$$

Therefore for subject 005, $p > 0.05$. For this individual the null hypothesis is accepted and the alternative rejected. There is no statistically significant difference between pre- and post-FES deviations from the pooled median. The validity of this conclusion is dependant upon the assumption that co-variance between pre- and post-FES results had no effect and that there are a sufficient number of MAS changes to justify acceptance of the null hypothesis.

It is not possible to draw conclusions regarding clinical significance for the individual from the results of the Modified Ashworth Scale, which measures impairment rather than disability or handicap. This is an issue that will be expanded upon in discussion in Chapter 6.

5.2.a.ii Summary of MAS results for all subjects

Table 5.5 Summary of descriptive and statistical analysis of MAS data for all subjects

Subject	Descriptive analysis summary	Statistical analysis summary
005	Suggested decrease in MAS grades post FES	Null accepted
006	Suggested increase in MAS grades post FES	Null rejected – deterioration shown
008	Suggested increase in MAS grades post FES	Null accepted
009	Suggested decrease in MAS grades post FES	Null rejected – improvement shown
010	Inconclusive	Null accepted
011	Inconclusive	Null accepted
012	Suggested decrease in MAS grades post FES	Null accepted
013	Suggested increase in MAS grades post FES	Null accepted

Table 5.5 shows that, on descriptive analysis, three subjects show an increase, three a decrease and two inconclusive results when assessed by the MAS following FES intervention. On statistical analysis the null hypothesis is accepted in six out of eight cases. Subject 006 shows a statistically significant deterioration in MAS grades from the median. Subject 009 shows a statistically significant improvement in MAS grades from the median.

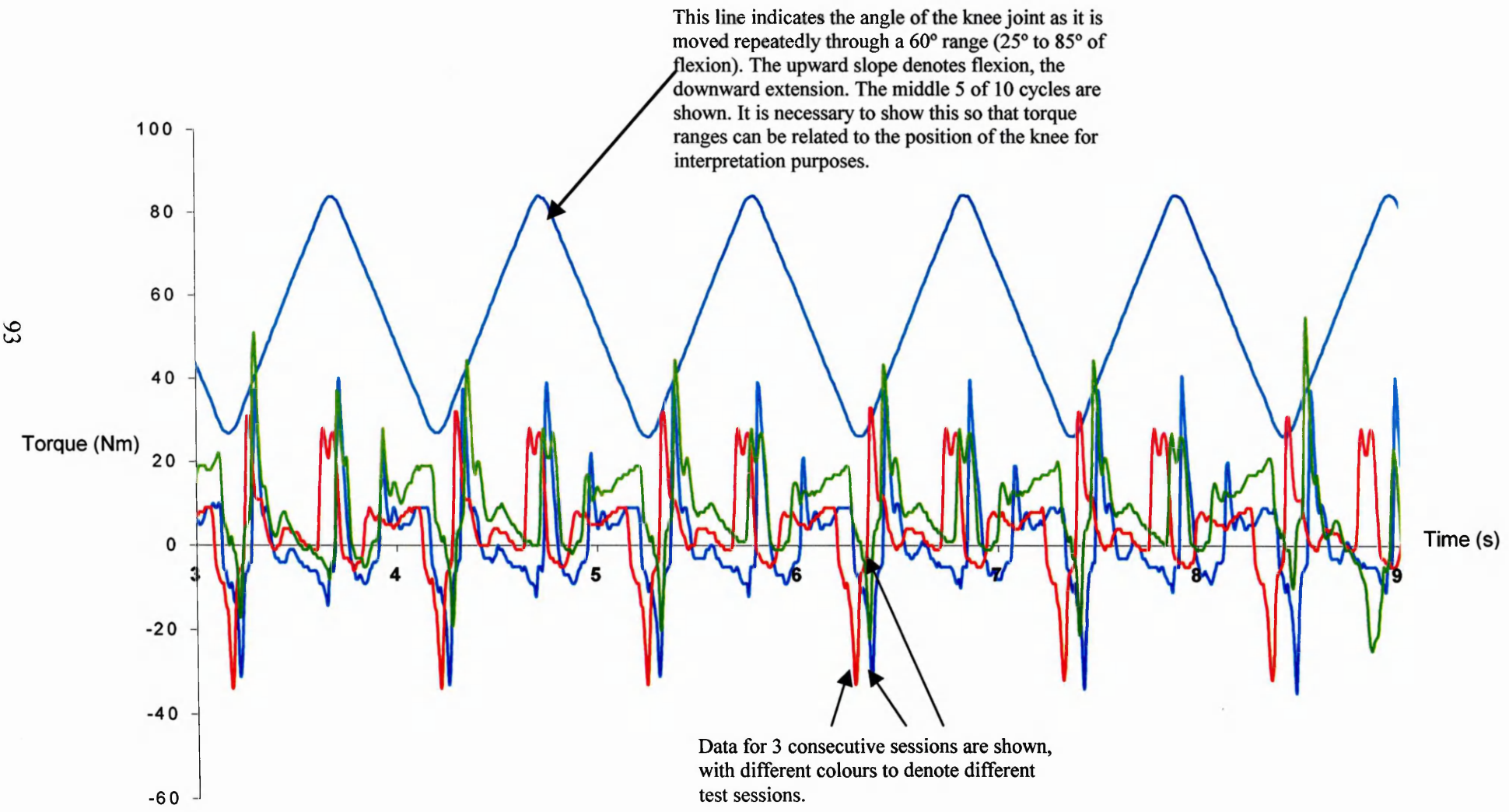
5.2.b Isokinetic dynamometry

Test data were collected at initial and final baselines (without stimulation). Test data for each subject were collated as ASCII data. This was imported from the Kin-Com to Microsoft Excel for analysis. Data for each subject and for the 'normal' test group were graphed. A graph was produced for each of the four test conditions – pre- and post-FES intervention at velocities of 60° per second and 120° per second. Each graph plots data for three consecutive initial or final baseline test sessions. Figure 5.1 shows an example of graphed torque data for one subject (005) pre-FES intervention at 60° per second. This graph has been annotated to highlight the key points it features. Graphed data for all other test subjects are shown in Appendix IV for information only. On observation of the graphs it was found that the data displayed substantial errors. Torque data for any one subject, at any one test speed, varied hugely along the y-axis. The reliability of the data therefore has to be questioned.

Whilst variation along the y-axis was in some cases substantial, the excursion and shape of graphs was often very similar to visual inspection. The author therefore calculated range of torque for each test. The middle five repetitions were analysed for each data set. This was to avoid any initial or final effects of repeated movements. The intra-test ranges are very consistent, to within a few Newton metres, even at the faster velocity of 120° per second. This suggests a uniformity of resistance to passive movement within any one test period. The two exceptions occur within the graphs for subject 005, where a substantial increase in torque can be seen in the 'pre 60°per second' and 'post 60°per second' data. In both cases the subject presented with episodes of spasm during the test.

Data were only collected for six subjects. One subject (012) could not transfer onto the seat due to his poor upper limb function combined with the height of the seat. The other (008) could not commit the time for this final test of the day. For subjects 010, 011 and

Figure 5.1 Subject 005: Graphed Torque Data for three consecutive test sessions pre-FES intervention at 60° per second



013 data were only collected for two sessions – again due to time constraints on the part of the subjects.

Figures 5.2.a and 5.2.b show mean peak torque values for subject 005 at initial and final baseline sessions at 60° and 120° per second respectively. At a velocity of 60° per second the mean torque value increased by 16 Newton metres, from 18 pre-FES to 34 post-FES. At a velocity of 120° per second the mean torque value increased by 3 Newton metres, from 71 pre-FES to 74 post-FES. In both cases therefore, resistance to movement, when measured by the isokinetic dynamometer, increased following FES

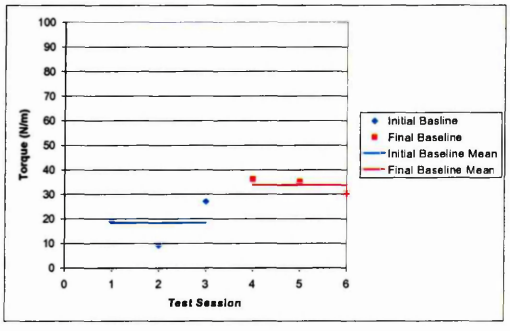


Figure 5.2.a **Torque data details Subject 005 60° per second**

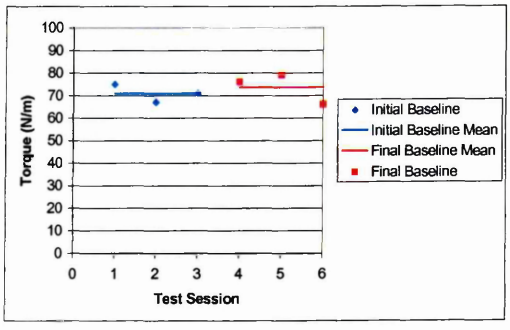


Figure 5.2.b **Torque data details Subject 005 120° per second**

intervention. The increase at 120° per second, however, was very small. Graphs for all other subjects are shown in Appendix V. As with the MAS data it is not possible to draw conclusions regarding the clinical significance to the subjects of changes in measured torque.

Table 5.6 summarises the changes in torque data pre-and post-FES for all subjects. There is no obvious pattern to any of the changes in torque values pre- and post-FES.

Table 5.6: Summary of visual analysis of mean Torque data by subject:

Subject	Torque 60°s $^{-1}$	Torque 120°s $^{-1}$
005	++	+
006	+	++
008	No data	No data
009	-	+
010	++	-
011	++	++
012	No data	No data
013	--	--

Key

++	Substantial increase from initial to final baseline
+	Minor increase from initial to final baseline
-	Minor decrease from initial to final baseline
--	Substantial decrease from initial to final baseline

Given the substantial flaws in the data no further analysis was undertaken.

5.3 FES and Gait

The Rancho Los Amigos Observational Gait Analysis System and TELER Normal Gait Indicators were the measures used to consider the effects of FES upon gait.

5.3.a Rancho Los Amigos Observational Gait Analysis

The Rancho Los Amigos Observational Gait Analysis (OGA) form presents data, relating to gait abnormality within the different phases of gait, as nominal data. An abnormality is either present or absent. The total number of gait deviations for each subject was totalled for the initial test and the final test with stimulation (Table 5.7).

OGA data were also collected at final baselines without stimulation. These data were not analysed for the purposes of this study, as the intent was to investigate the effects of walking with stimulation upon the individual. Data collection sheets are shown in Appendix VI. The summed data were initially graphed for ease of visual analysis (Figure 5.3). The 'equality' line shows where gait deviation scores would be the same both with and without FES. All of the subjects fall below this line, showing a decrease in gait deviations for all when walking with FES.

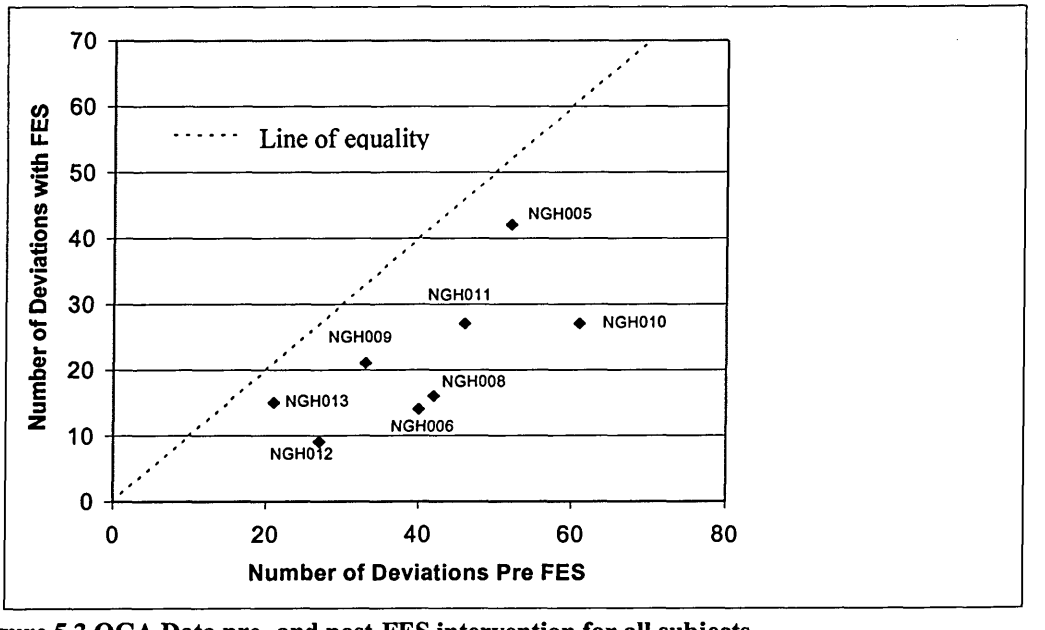


Figure 5.3 OGA Data pre- and post-FES intervention for all subjects

Whilst visual analysis shows a decrease in gait deviations for all subjects when using FES a statistically significant change must be shown before this change can be attributed to this intervention.

The following statistical hypotheses were therefore tested using the paired t-test:

$\mathbf{H_0}$ - there is no decrease in the number of gait deviations when walking with FES

$\mathbf{H_1}$ – there is a decrease in gait deviations when walking with FES

Table 5.7 Paired t-test: data analysis

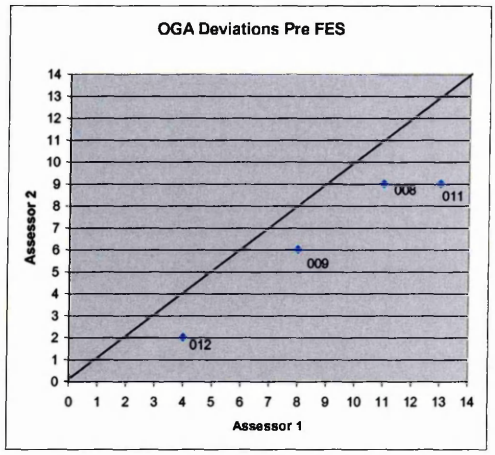
Subject	OGA Results		Calculations	
	Pre-FES (A)	With FES (B)	(A-B)=d	d^2
005	52	42	10	100
006	40	14	26	676
008	42	16	26	676
009	33	21	12	144
010	61	27	34	1156
011	46	27	19	361
012	27	9	18	324
013	21	15	6	36
Σ	322	171	151	3473
mean	40.25	21.378	$(\Sigma d)^2$=22801	

From Table 5.7 the calculated t-value was 5.65, degrees of freedom = 7. The results were found to be significant at $p < 0.05$, for a one tailed test. The null hypothesis was therefore rejected and the alternative hypothesis accepted. The mean value of the OGA deviations when walking with FES was less than that when walking without FES. There was therefore a statistically significant improvement in gait, attributable to FES intervention for this subject group.

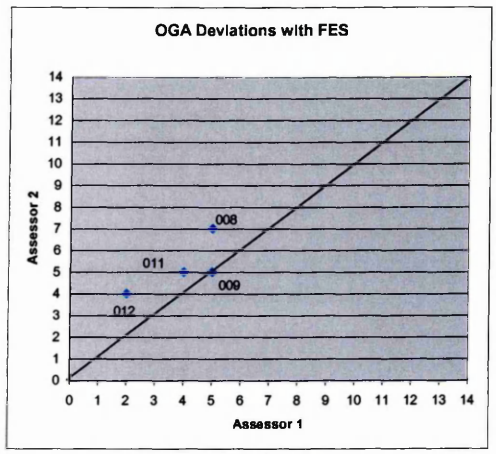
5.3.a.i Results from Inter-observer Testing of OGA Data

Figures 5.4.a and 5.4.b show the number of gait deviations as noted by both assessors. Assessor 1 was the author, assessor 2 the blinded tester. Data collection sheets for the blinded assessor are shown in Appendix VI.

From visual analysis of these graphs it can be seen that Assessor 1 noted more deviations at initial baseline than the blinded assessor did, and less at final baseline. There may therefore be an issue with bias in the initial testers scores.



5.4.a. Pre-FES



5.4.b. With FES

Figure 5.4 **Observed Gait data from Assessors 1 and 2: a- pre-FES, b- with FES**

Spearman's rank correlation coefficient was the used to analyse the degree of correlation between the two scorers' results (Table 5.8). The null hypothesis states that there is no correlation between the two sets of data, such that as assessor 1 scores increase Assessor 2's scores also increase. The alternative hypothesis is therefore that there is a correlation between the two sets, such that as assessor 1 scores increase assessor 2's scores also increase.

Table 5.8 **Spearmans Rank Correlation Coefficient: Data analysis**

	Assess 1	Assess 2 (blinded)				
Subject	**A**	**B**	**Rank A**	**Rank B**	**d (A-B)**	**d^2**
008 pre	11	9	7	7.5	0.5	0.25
008 post	5	7	4.5	6	-1.5	2.25
009 pre	8	6	6	5	1	1
009 post	5	5	4.5	3.5	1	1
011 pre	13	9	8	7.5	0.5	0.25
011 post	4	5	2.5	3.5	-1	1
012 pre	4	2	2.5	1	1.5	2.25
012 post	2	4	1	2	-1	1
						$\Sigma d^2 = 9$

Using Spearman's test on the data $r_s = + 0.893$. Where N = 8, $p < 0.05$ for a two-tailed hypothesis. This means that there is a positive correlation between the scores from Assessor 1 and 2. The strength of the relationship is 0.893^2 x 100 = 79.9%. This strong positive relationship shows that the two assessors largely agreed on the direction of the

changes. However, the data in table 5.8 shows that they disagree on the size of changes. The average pre- to post FES change was –5 for Assessor 1, and –1.25 for Assessor 2. The reason for this is that Assessor 1 noted higher pre-FES scores than Assessor 2, and lower post-FES scores than Assessor 2. In other words, the assessors disagreed upon where the subjects started and where they ended. As a result the effects of FES found by Assessor 1 was higher than that found by Assessor 2. This discrepancy may be a result of assessor bias, may relate to the problem of reliability with observational gait analysis, or may be suggestive of problems with the Rancho Los Amigos gait analysis system. This will be further considered in the following chapter.

5.3.b TELER® Gait Indicators

The TELER Indicators were developed as a result of the issues with both analysis of results and the feasibility of the Rancho Los Amigos OGA system. Indicators for each subject were chosen from the problems identified by the individual. From these physiotherapy aims were identified. The appropriate TELER Indicators to monitor change were identified for each subject.

TELER data was first tabulated and analysed descriptively. A probability tree was then used to test the statistical significance of the data. Deficit, Improvement and Health Gain Indices were then calculated for all subjects (Le Roux, 2003). The analysis for subject 005 is shown below, that for all other subjects can be found in Appendix VII.

5.3.b.i Analysis of TELER data: subject 005

Analysis is split into two sections: the first being that of analysis of change in each indicator, the second being that of analysis of the indicators as a group. Analysis of individual indicators is of interest to the clinician in identifying the specific results of treatment, the group analysis shows the overall effect of treatment, which gives both a clinicians and a patient's perspective on the outcome of FES intervention for that individual.

Individual Indicators:

Table 5.9 is a summary of the indicator scores for subject 005. The TELER data collection sheet for this is shown in Appendix VII.

Table 5.9 Subject 005: TELER codes pre- and post-intervention

Number of indicators by code pre (before) and post (after) intervention						
	Code before					
Code after	0	1	2	3	4	Total
0						
1						
2		1				1
3	2		2			4
4						
5						
Total	2	1	2			5

Key: -------- **Area under dashed line shows clinically significant change**
▬▬▬ Area under which indicators show statistically significant improvements at the 95% confidence level

Table 5.9 shows that the admission codes for subject 005 ranged from 0 to 2, with a median code of 1, and a mode of 0 or 2, both of these codes occurring twice on initial assessment. The admission code of two (40%) of the five indicators was 0, one indicator (20%) was graded at code 1, and two (40%) were graded at code 2.

The discharge or outcome codes ranged from code 2 to 3, with a median of 3 and a mode of 3. The discharge outcome code on four (80%) of the five indicators was 3, the other discharge code was 2 (20%).

From the table it can be seen that all the indicators showed some improvement in their code gradings. All entries showed clinically significant improvements. The magnitude of these improvements ranged from 1 to 3 clinically significant stages, with two indicators improving by three codes and three improving by one code. None of the individual indicators in Table 5.9 showed a statistically significant improvement at the 95% confidence level.

Indicators as a Group:

Whilst the above analysis of the data shows a clinically significant improvement in walking outcomes following the application of FES it is necessary to show a statistically

significant improvement if these are to be attributable to the intervention. The indicators were analysed as a group to consider the overall effects of FES for this subject. The following statistical hypotheses were tested using a probability tree analysis (Le Roux, 2003):

$\mathbf{H_0}$ – there is no improvement in TELER Gait Indicator grades with FES intervention

$\mathbf{H_1}$ – there is an improvement in TELER Gait Indicator grades with FES intervention

To ensure maximum independence between indicators and what they measure, and therefore to minimise co-variance, a maximum of three were selected for analysis. The three chosen were considered to be of most clinical significance to this subject. These indicators were mid-swing, loading response and initial contact. From Table 5.10 it can be seen that these indicators had a combined score of 2 on initial assessment (2,0,0 respectively), there were 7 clinically significant changes by the time of discharge, giving an outcome score of 9. The results were therefore found to be statistically significant at the 5% one-tailed level. The null hypothesis was rejected and the alternative accepted. There was an improvement in TELER gait indicator grades for this subject, apparently attributable to the FES intervention.

Table 5.10 shows a decrease in Deficit Index by nearly half from 80 to 44 percentage points. The Improvement Index was calculated as 45, meaning that there was an improvement in this subject's identified problems during treatment. The Health Gain Index was 36 and therefore smaller than the Improvement Index, denoting a chronic disability.

Table 5.10: Worksheet for the TELER Index for Subject 005

Item	Expected Outcome	Visit	
		1	2
Pre-swing	5	1	2
Mid-swing	5	2	3
Loading response	5	0	3
Initial contact	5	0	3
Mid-stance	5	2	3
Total number of missing scores			
Deficit Index		80	44
Improvement index			45
Health Gain Index			46

The clinical significance of these improvements is inherent within the structure of the indicators. Each code is a clinically significant outcome needed for 'normal' gait.

5.3.b.ii Summary of TELER Analysis for all subjects

Table 5.11 Summary of TELER Data Analysis for all Subjects

Subject	No. of clinically significant changes	Statistically significant at 95% confidence level	Deficit Index (improvement by percentage points)	Improvement Index	Health Gain Index
005	7	Yes	36	45	36
006	4	No	24	40	24
008	2	No	7	22	13
009	3	No	15	25	15
010	7	Yes	40	50	40
011	4	No	20	31	20
012	3	No	20	27	20
013	6	No	35	44	35

From Table 5.11 it can be seen that all subjects showed clinically significant improvements in their outcomes. Only two, 005 and 010, showed a statistically significant improvement allowing for the changes to be attributable to FES. These two subjects had Deficit Indices of 36 or more. Subject 013 had a Deficit Index of 35, but changes were not statistically significant at the 95% confidence level. So for subjects 005 and 010 an improvement in 36 or more percentage points in the Deficit Index was found to be statistically significant. All subjects showed a positive Improvement Index, denoting an improvement during treatment. In the case of subject 008 however, this was minimal at 7 percentage points. In all cases the Health Gain Index was less than the Improvement Index, indicating that all subjects still had a 'chronic' disability.

5.3.b.iii TELER Data: group analysis

Table 5.12 TELER codes pre- and post-intervention for subjects as a group

Number of indicators by code pre (before) and post (after) intervention						
Code after	Code before					Total
	0	1	2	3	4	
0						
1						
2	2	6	2	1		11
3	3	4	4	1		12
4		1	1	4		6
5						
Total	5	11	7	6		29

Table 5.12 shows that the admission codes for this group of subjects ranged from 0 to 3, with a median code of 1, the mode was also 1. The admission code of five (17%) of the 29 indicators was 0, eleven (38%) were coded 1, seven (24%) were coded 2 and six (21%) were coded 3.

Discharge or outcome codes ranged from 2 to 4, with a median and mode of 3. The outcome code on 11 (38%) of the 29 indicators was 2, 12 (41%) were coded 3, and 6 (21%) were coded 4.

Visual analysis of results shows that one indicator showed a deterioration from code 3 to 2, three showed no change and 26 showed clinically significant improvements. The magnitude of these improvements ranged from 1 to 3 clinically significant stages.

Whilst the above descriptive analysis shows clinically significant change in walking outcomes for the subjects as a group following the application of FES, it is necessary to show a statistically significant improvement if these are to be attributable to the intervention. The following statistical hypotheses were tested using the Chi^2 test.

H_0 – there is no difference in TELER Gait Indicator grades with FES intervention for the subjects as a group

H_1 – there is a difference in TELER Gait Indicator grades with FES intervention for the subjects as a group

The expected values for the Chi^2 test were calculated as shown in table 5.13 (TELER Newsletter, Jan 2003).

Table 5.13: Calculation of Chi^2 expected values for subjects as a group

Expected Values [(Probability) x (Number of subjects)] by code before and after						
Code after	**Code before**					**Chi^2 expected values**
	0	**1**	**2**	**3**	**4**	
0	0.278x5	0.247x11	0.130x7	0	0	**5.02**
1	0.351x5	0.340x11	0.241x7	0.111x6	0	**7.85**
2	0.225x5	0.229x11	0.259x7	0.222x6	0	**6.79**
3	0.106x5	0.128x11	0.222x7	0.333x6	0	**5.49**
4	0.034x5	0.048x11	0.111x7	0.222x6	0	**2.81**
5	0.006x5	0.012x11	0.037x7	0.111x6	0	**1.09**
Total	5	11	7	6	0	**29.05**

The combined expected value for codes 4 and 5 on discharge (after) is less than 4. The values of codes 3,4 and 5 were therefore combined to give a single outcome, "Code 3 or larger" on discharge. This was done in compliance with the 'rule of five'.

Table 5.14 Chi^2 Analysis of TELER data for subject group

Discharge outcome code	Observed cases (O)	Expected cases (E)	O-E	$(O-E)^2/E$
0	0	5.02	-5.02	5.02
1	0	7.85	-7.85	7.85
2	11	6.79	4.21	2.61
3 or more	18	9.39	8.61	7.89
Total				**23.4**

The null hypothesis states that FES will have no effect upon TELER outcomes. The alternative hypothesis is that the use of FES will improve TELER outcomes. This is therefore a one-tailed hypothesis. Calculated $X^2 = 23.4$, degrees of freedom = 6. Results were therefore found to be significant at $p < 0.05$. The results show a statistically significant improvement in TELER outcomes therefore the null hypothesis is rejected and the alternative accepted. The group of subjects demonstrated a statistically significant improvement in TELER Gait Indicators, attributable to FES intervention.

5.4 Chapter Summary

- Analysis of the Modified Ashworth Scale data for the individual was problematic due to the data's lack of independence. Fisher's exact test, based upon the Median test, was used to analyse this data. Overall results were inconclusive.
- Descriptive analysis of the isokinetic dynamometry data, based upon the individual range of torque differences, was presented. No further analysis was undertaken as the data was flawed.
- Lack of independence of the Rancho Los Amigos Observational Gait Analysis data resulted in the data being analysed for the subjects as a group. The paired t-test was used to analyse the data. Substantial statistically significant improvement was shown for the subjects as a group.
- Inter-observer testing of the Observational Gait Analysis data using Spearman's rank correlation co-efficient demonstrated a strong positive correlation between the two assessors. On visual and descriptive analysis there was a difference in the magnitude of change in gait deviations noted by assessors.

- TELER data were analysed for subjects individually and as a group. Although all individual subjects showed some improvement in the scored TELER indicators, only two showed statistically significant improvement on probability tree analysis. TELER Deficit, Improvement and Health Gain Indices were calculated for all subjects. The Chi-squared test was used to analyse the data from the subjects as a group. A substantial statistically significant improvement was shown.

These results will be discussed in detail and related to the existing literature in the following Chapter.

Chapter 6: Discussion

This chapter will address the development of the study, relating this to the changed research aims. The results presented in Chapter 5 will be further discussed. As the chosen methodology was that of single subject experimental design these results are initially considered for the individual subject. Not all measurements could be validly analysed for the individual, so there follows a section on analysis for the subjects as a group. Findings from this study will be compared, where possible, with results from previously published literature. The theoretical basis for changes in spasticity and in gait following FES will also be considered. Limitations of this study will be discussed prior to final conclusions being drawn.

6.1 Thesis Development

During the course of this study the initial aims of the thesis altered. These were to investigate the effects of functional electrical stimulation (FES) on spasticity in the individual with incomplete spinal cord injury (ISCI). The measures to be used included those which would give data regarding resistance to movement (the Modified Ashworth Scale and isokinetic measurement of torque) and to changes in walking abilities (the Rancho Los Amigos Observational Gait Analysis System and TELER® Gait Indicators). However, following a review of the literature and analysis of the chosen measures it was found that it was not possible to draw direct conclusions regarding the effect of spasticity change upon gait within the remit of this study. The initial research questions were therefore changed to:

1. What changes in spasticity does an individual who receives FES as a treatment experience?
2. What changes in gait does an individual who receives FES as a treatment experience?

Whilst no correlational analysis was undertaken, possible links between the changes in spasticity upon gait were discussed in Chapter 2 and will be returned to later in this Chapter.

6.2 Individual Results by Subject

A single subject experimental design (SSED) was chosen so that the effects of the intervention could be considered upon the individual. This methodology can give the clinician information regarding outcomes of treatment for specific patients, rather than the results of an intervention for the 'average' patient, which is the information gained from randomised control trials. In this manner the SSED has the potential capacity for enhancing clinical decision making for the individual, for enhancing the clinician's use of evidence based practice (*'the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients'* Sackett et al, 1996).

Only the data for the MAS and TELER were analysed for the individual. A brief summary of the individual and the chosen FES strategy are presented before the findings are discussed.

6.2.a.i Subject 005

Subject 005 was a 45-year-old male who sustained a Brown-sequard pattern ISCI at T10 level three years prior to enrolling on the project. He was a community walker who used a right long leg splint (KAFO) and elbow crutches to ambulate.

The chosen FES intervention strategy was that of stimulation to his right quadriceps during the stance phase of gait and to his right common peroneal nerve during swing phase of gait to enhance limb flexion.

Descriptive analysis of the MAS showed that a majority (14) of grades improved, with ten showing no change and none showing deterioration. On statistical analysis no significant change was detected at the 5% two-tailed level. So although there was a tendency for the MAS grades to show a decrease following FES intervention this could not be attributed to that intervention. The raw MAS data showed a concentration of grades at the lower end of the MAS (grades 1 and 2). It may have been that this individual highlighted the lack of sensitivity of the Modified Ashworth Scale.

TELER Gait Indicator data showed an improvement in all five indicators. None of the single indicators showed a statistically significant improvement, but when the three

most clinically significant were subjected to a probability tree analysis they demonstrated a statistically significant improvement attributable to the use of FES. The Deficit Index, which shows the overall effect of the presented problems on the individual, showed a decrease by nearly half from 80 to 45 percentage points. The Improvement Index, whose values range from -100 to +100 (with 0 denoting no change), showed a substantial improvement score of 45 percentage points. The Health Gain Index, which shows the extent to which a subject is free from residual or chronic disability, was, at 36, lower than the Improvement Index. This score shows that this individual still had a substantial degree of disability following treatment. This subject, as all others, had a 'stable' spinal cord injury, in that there had been little or no obvious change in his neurological condition for a substantial time prior to his enrollement onto the study. The immediate effects of FES are that of a dynamic orthosis. FES produces movement that the individual is unable to perform, either at all or adequately. Over time FES may improve volitional control of movement through its potential therapeutic effects. The timescales for this project (approximately two-months for an individual subject) may not have been adequate for such changes to be obvious. So whilst FES may be capable of bringing about a decrease in chronic disability, in this case it was not apparent as shown by the Health Gain Index.

The clinical significance of FES intervention for this individual was that he discarded the KAFO and used the stimulator for all ambulation.

6.2.a.ii Subject 006

Subject 006 was a 19-year-old male who sustained a Brown-Sequard pattern ISCI at C4/5 level two years prior to enrolling on the project. He walked with elbow crutches for exercise purposes only, either during physiotherapy sessions or at home with carers.

The chosen FES intervention strategy was that of stimulation to his right quadriceps from terminal swing to midstance phase of gait and to his right common peroneal nerve during swing phase of gait to enhance limb flexion.

Descriptive analysis of the MAS showed a deterioration in 12 of the 24 grades, with 11 showing no change and one showing improvement. On statistical analysis a significant

change was detected at the 5% two-tailed level. There was therefore a statistically significant increase in MAS grades following FES intervention for this individual.

TELER Gait Indicator data showed an improvement in four of the five indicators, one showed no change. None of the single indicators showed a statistically significant improvement. When the three most clinically significant were subjected to a probability tree analysis no statistically significant improvement at the 5% one-tailed level was found. The Deficit Index showed a decrease by nearly half from 60 to 36 percentage points. The Improvement Index showed a substantial improvement score of 40. The Health Gain Index was, at 24, lower than the Improvement Index. This score shows that this individual still had a substantial degree of disability following treatment.

The MAS results were indicative of an increase in spasticity following FES intervention. Whilst this must be considered as a possibility and would need monitoring for this subject, the validity of the MAS as a measure of spasticity has been questioned. It may also be that, due to the timescales of this project, this subject was still learning to use the stimulator efficiently when final baseline measurements were undertaken. Burridge *et al* (1997a) found that an initial increase in spasticity whilst subjects were learning to use the stimulator was followed by a decrease as the subjects became familiar with its use. This subject was a poor walker prior to commencing the project, walking only for exercise purposes. Although some decrease in gait abnormality was achieved during the study, this subject continued to walk only for exercise purposes in the house and with assistance.

6.2.a.iii Subject 007

Subject 007 was a 25-year-old female who sustained a Brown-Sequard pattern ISCI at C6 level six years prior to enrolling on the project. She walked at home for exercise purposes with a KAFO in parallel bars. She needed assistance to don and doff the KAFO. This subject had the poorest walking ability on admission to the study. Unfortunately she found walking with the stimulator too difficult. Habituation was a substantial problem and it was found that her right knee joint hyperextended on weightbearing without the KAFO causing discomfort. She did not complete the project and therefore no results are presented.

6.2.a.iv Subject 008

Subject 008 was a 23-year-old female who sustained a Brown-Sequard pattern ISCI at C6 level three years prior to enrolling on the project. She was a community walker who walked using bilateral walking sticks.

The chosen FES intervention strategy was that of stimulation to her right common peroneal nerve during swing phase of gait to enhance limb flexion.

Descriptive analysis of the MAS showed that a majority (14) of grades deteriorated, with nine showing no change and one showing deterioration. On statistical analysis no significant change was detected at the 5% two-tailed level. So although there was a tendency for the MAS grades to show an increase following FES intervention this could not be attributed to that intervention. It may again have been that this individual highlighted the lack of sensitivity of the Modified Ashworth Scale in detecting change.

TELER Gait Indicator data showed an improvement in two indicators, with a deterioration in one. None of the single indicators showed a statistically significant change. When all three were subjected to a probability tree analysis they demonstrated no statistically significant improvement attributable to the use of FES. The Deficit Index showed a small decrease from 60 to 53 percentage points. The Improvement Index showed a small improvement with a score of 22. The Health Gain Index was, at 13, lower than the Improvement Index. This score shows that this individual still had a substantial degree of disability following treatment. All of the TELER Index scores show a minimal improvement.

In spite of being a functional walker this subject used the stimulation only whilst attending outpatient physiotherapy sessions, never functionally as a part of her daily routine. This was her personal choice, the reasons for which were not made clear. It may have been that the gait improvements achieved during stimulation were not considered of enough benefit when compared to the time needed to don and doff the system.

6.2.a.v Subject 009

Subject 009 was a 49-year-old male who sustained a Brown-Sequard pattern ISCI at C7 level eighteen months prior to enrolling on the project. He was a community walker who used a rollator to ambulate.

The chosen FES intervention strategy was that of stimulation to his right common peroneal nerve during swing phase of gait to enhance limb flexion.

Descriptive analysis of the MAS showed that a majority (13) of grades improved, with 11 showing no change and none showing deterioration. On statistical analysis a significant change was detected at the 5% two-tailed level. There was therefore a statistically significant decrease in MAS grades following FES intervention for this individual.

TELER Gait Indicator data showed an improvement in three indicators, one showed no change. None of the single indicators showed a statistically significant improvement. When the three most clinically significant were subjected to a probability tree analysis no statistically significant improvement at the 5% one-tailed level was found. The Deficit Index showed a decrease from 60 to 45 percentage points. The Improvement Index showed an improvement with a score of 25. The Health Gain Index was, at 15, lower than the Improvement Index. This score shows that this individual still had a substantial degree of disability following treatment.

Whilst MAS grades demonstrated a statistically significant decrease post-FES intervention, TELER Indicators and Indices showed a relatively minimal improvement for this subject. This subject continued to use the stimulator on a daily basis when walking with the rollator. It may have been that the improvement in toe clearance was of enough benefit to offer a real improvement in walking ability for this individual.

6.2.a.vi Subject 010

Subject 010 was a 41-year-old male who sustained a Brown-Sequard pattern ISCI at T4 level thirteen years prior to enrolling on the project. He used elbow crutches to walk in the house and to and from the car, but was otherwise dependent upon his wheelchair for mobility.

The chosen FES intervention strategy was that of stimulation to his left quadriceps from terminal swing to midstance to enhance stability on weightbearing and to his left common peroneal nerve during swing phase of gait to enhance limb flexion.

Descriptive analysis of the MAS showed that a majority (14) of grades did not change, with seven showing an improvement and three showing deterioration. On statistical analysis no significant change was detected at the 5% two-tailed level.

TELER Gait Indicator data showed an improvement in all four indicators. None of the single indicators showed a statistically significant improvement, but when the three most clinically significant were subjected to a probability tree analysis they demonstrated a statistically significant improvement attributable to the use of FES. The Deficit Index decreased by half from 80 to 40 percentage points. The Improvement Index showed a substantial improvement of 50. The Health Gain Index was, at 40, lower than the Improvement Index. This score shows that this individual still had a substantial degree of disability following treatment.

This subject used the stimulator for both exercise and functional purposes in and around the house.

6.2.a vii Subject 011

Subject 011 was a 28-year-old male who sustained a Brown-Sequard pattern ISCI at C6 level three years prior to enrolling on the project. He walked short distances in the house and to and from the car.

The chosen FES intervention strategy was that of stimulation to his left quadriceps during the stance phase of gait and to his left common peroneal nerve during swing phase of gait to enhance limb flexion.

Descriptive analysis of the MAS showed that a majority (15) of grades did not change, with four showing an improvement and five showing deterioration. On statistical analysis no significant change was detected at the 5% two-tailed level.

TELER Gait Indicator data showed an improvement in three indicators, one showed no change. None of the single indicators showed a statistically significant improvement. When the three most clinically significant were subjected to a probability tree analysis no statistically significant improvement at the 5% one-tailed level was found. The Deficit Index showed a decrease from 65 to 45 percentage points. The Improvement Index showed an improvement of 31. The Health Gain Index was, at 20, lower than the Improvement Index. This score shows that this individual still had a substantial degree of disability following treatment.

This subject made relatively small gains in TELER codes and did not continue to use the stimulator following the study. He used his wheelchair for the majority of his mobility during the day whilst at work, walking to and from the car to the house and round the house in the evenings. The small benefits gained in using the stimulator were not perceived as beneficial enough to continue its use.

6.2.a.viii Subject 012

Subject 012 was a 61-year-old male who sustained a central cord pattern ISCI at C5 level five years prior to enrolling on the project. He walked for exercise purposes using an elbow support rollator with assistance from one.

The chosen FES intervention strategy was that of stimulation to his right quadriceps during the stance phase of gait and to his right common peroneal nerve during swing phase of gait to enhance limb flexion.

Descriptive analysis of the MAS showed that a majority (18) of grades did not change, with six showing an improvement and none showing deterioration. On statistical analysis no significant change was detected at the 5% two-tailed level. The raw MAS data again showed a concentration of grades at the lower end of the scale (grades 1 and 2). It may have been that this individual, as with subject 005, highlighted the lack of sensitivity of the Modified Ashworth Scale.

TELER Gait Indicator data showed an improvement in all three indicators. None of the single indicators showed a statistically significant improvement. When these three were subjected to a probability tree analysis they demonstrated no statistically significant

improvement. The Deficit Index showed a decrease from 73 to 53 percentage points. The Improvement Index showed an improvement of 27. The Health Gain Index was, at 20, lower than the Improvement Index. This score shows that this individual still had a substantial degree of disability following treatment.

In spite of the minimal gains in TELER Indicator scores this subject continued to use the stimulator at home following the project.

6.2.a.ix Subject 013

Subject 013 was a 43-year-old male who sustained a ISCI at C6 spinal level one year prior to enrolling on the project. He walked in the house and short distances outside the house with elbow crutches.

The chosen FES intervention strategy was that of stimulation to his left quadriceps from terminal swing to midstance phase of gait and to his left common peroneal nerve during swing phase of gait.

Descriptive analysis of the MAS showed that a majority (12) of grades deteriorated, with seven showing no change and five improving. On statistical analysis no significant change was detected at the 5% two-tailed level. So although there was a tendency for the MAS grades to show an increase following FES intervention this could not be attributed to that intervention.

TELER Gait Indicator data showed an improvement in all four indicators. None of the single indicators showed a statistically significant improvement. When the three most clinically significant were subjected to a probability tree analysis they did not demonstrate a statistically significant improvement. The Deficit Index showed a decrease by nearly half from 80 to 45 percentage points. The Improvement Index showed a substantial improvement score of 44. The Health Gain Index was, at 35, lower than the Improvement Index. This score shows that this individual still had a substantial degree of disability following treatment.

This subject continued to use the stimulator at all times following the study.

6.2.a.x Subject 014

Subject 014 was a 38-year-old male who sustained a Brown-Sequard pattern ISCI at T7 level ten years prior to enrolling on the project. He was a community walker who used a walking stick. Unfortunately this subject was taken ill prior to starting the study and therefore was unable to participate.

6.2.b The Modified Ashworth Scale – general observations

The results from the MAS (Table 5.5) show a typically random pattern, both descriptively and statistically. There are an equal number of increases and decreases shown descriptively, three and three. Six out of the eight statistical analysis results support the null hypothesis. Of the two that show statistically significant change one shows a decrease, one an increase in MAS grades. It is therefore necessary to question what the MAS is actually measuring the effects of – it may be the effect of FES upon spasticity, but the evidence is insufficient. As was discussed in Chapter 3, the MAS may be useful as a subjective guide to the passive resistance offered to the movement of a limb, but not necessarily spasticity.

Analysis of the MAS data proved to be difficult due to the lack of independence of the data collected. Independence is an essential concept underpinning statistical analysis of data. The MAS data was compromised in a number of ways. Data were collected for different muscle groups in the same leg. There was therefore no independence between these data, spasticity seldom affects only one muscle group in a limb, but rather shows as an overall pattern, with some muscle groups being more affected than others. There was also the issue of measures being repeated over three days pre- and post-FES intervention. Each of the different days' measures were dependent upon each other.

Fisher's exact test assumes that the data in each cell of the table are independent of each other. As the potential degree of covariance of the number of readings below and above the Median code was not know these results had to be stated as dependent upon this being of no effect. It may be that the true meaning of the null hypothesis is that there is no evidence of an effect due to the potential size of the covariance, rather than genuine lack of an effect of the intervention.

Ordinal scales should have discrete codes, so that it is clear for the scorer as to which category a result falls into. The MAS is effectively a subjective continuum, leading to potential difficulties in scoring. There is a difference between the true extent of an attribute possessed by an object and the observer's measure of that extent. The smaller the difference between the two the better the validity of the measure. The lack of objectivity in the MAS coding is likely to increase the difference between observer's assessment and true extent of the attribute.

As demonstrated by subjects 005 and 012, floor or ceiling effects may occur due to the limited sensitivity of the MAS. Where results fall at one end of the scale it may be that potentially significant results are masked.

Spasticity is an impairment, that is, a symptom of an underlying neurological pathology. The clinical significance of both the MAS (and the isokinetic torque data) test results is not apparent. There are no direct functional correlates to an increase or decrease in grades. There is an assumption that a gravity 'eliminated' (due to test position), passively tested increased resistance to movement is an indicator of increased spasticity that may in turn have a negative effect upon some aspect of an individual's function. Research has shown (McLellan, 1977, Knuttson & Martensson, 1980) that the effect of spasticity during passive movement is not the same as that during voluntary movement. Spastic restraint during active, especially fast active movement was found to be substantially greater than during passive movement. This may in turn be why physiotherapists seldom attempt to measure spasticity in isolation in a clinical setting – physiotherapists deal with patients' clinical problems and are therefore considering the effects of a pathology at either a disability or handicap level.

6.2.c TELER Indicators – general observations

None of the chosen indicators showed a statistically significant change for the individual subjects. Many indicators that did show improvement did so by only one or two codes. There was not enough data collected for individual subjects, or enough data collected for individual indicators, to show statistical significance in most cases. Only subjects 005 and 010 demonstrated statistically significant improvements in their gait. It can therefore be argued that, for many of the subjects, walking ability improved only minimally with the FES intervention. Table 6.1 summarises the changes in TELER

Deficit Index for all subjects. Although all show a decrease in Deficit Index, all still show a substantial degree of residual problems when walking with FES.

Table 6.1: Range of TELER Deficit Index for all subjects with and without FES

Subject	Deficit Index Range In percentage points
005	80-45%
006	60-36%
008	60-53%
009	60-45%
010	80-40%
011	65-45%
012	73-53%
013	80-45%

Where the changes in TELER data are not attributable to FES i.e. are not statistically significant the reasons for the changes need to be considered. It may be that, within the timescales of the study, the full potential of FES for these subjects was not achieved. It may have been that the FES strategies were not optimal for the subjects. Frequency of use may also have played a part. The usage of the stimulators out-with the therapy environment was only measured subjectively. Subjects varied widely in their use, some stating that they used the stimulators functionally every day, some that they only used them when attending for treatment or test sessions. It would have been useful to have an objective measurement of how often the stimulators were used other than in study sessions. The reported subjective usage of the stimulation however did not always correspond with the lack of gain in TELER Indicator scores. For example subjects 009 and 012 continued in their use of the systems with apparently modest gains. It may have been that one small improvement, e.g. improved ankle dorsiflexion, was critical enough clinically to make a meaningful improvement for the individual. The TELER Gait Indicators denote normal gait. Where an improvement is seen but the normal not fully achieved in one code of an indicator, e.g. knee flexion of 60° during initial swing, this code would not be scored. This is of particular concern where subjects have a substantial degree of 'chronic' disability, such as those who have participated in this study where 'normal' may never be achieved. The Gait Indicators need further development work, in particular taking into account aspects of their sensitivity and reliability.

All of the above assume that FES was capable of producing an improvement in gait. Other factors that may have caused the clinical improvements seen may have included learning from the tests – this is a recognised problem in the use of repeated measures – or the fact that subjects received gait re-education as part of the process in learning to use the stimulators.

Again the issue of bias may be a concern as the researcher was the only assessor. Indicators may have been chosen which demonstrated greatest positive change. However, as can be seen from Appendix II, the process behind the choice of indicators was directly linked to the subjects' identification of their gait problems. In this way, the subjects' problems were converted to a treatment plan and the appropriate indicators were chosen from this process.

6.2.d Isokinetic Dynamometry

As was shown in Chapter 5 the data from the isokinetic dynamometer tests demonstrated substantial flaws. Due to this no descriptive or statistical conclusions for the subjects are drawn from these results. Consideration is however given to the problems highlighted by this data.

Problems with instrumentation are reported as one of the possible risks to the internal validity of SSED (Ottenbacher, 1986). Instrumentation may refer to a mechanical device being used for data collection or to the observational technique. The researcher needs to be certain that they are measuring the actual parameter in question and not an artefact of the machine or scale. In the case of repeated measures any issues with reliability of the measuring instrument are of extreme importance. Data were collected on three consecutive days at initial and final baselines. The Kin-Com should have given the most objective, quantitative data of all the tests used. In this study, it is obvious that there was either a problem with the calibration of the dynamometer, or operator error in the setting up of the machine.

The pilot study included training in the use of the Kin-Com dynamometer and the collection of data from 'normal' subjects and one subject with an incomplete spinal cord injury. Only one data set for each of these subjects was collected. The data was graphed for analysis, but was not subject to further statistical testing. Repeated tests for these

subjects would have shown potential flaws in data collection prior to formal testing of subjects being undertaken.

As with the MAS the clinical significance of such technical parametric data produced by the dynamometer has no direct link to functional abilities. The test in this instance was also passive.

6.3 Results for Subjects as a Group

The Rancho Los Amigos Observational Gait Analysis System data was analysed for the subjects as a group due to problems with the independence of the data. The TELER system allowed for data to be analysed for the individual or the group. The TELER data is analysed here for the subjects as a small group.

6.3.a Observational Gait Analysis

The Rancho Los Amigos Observational Gait Analysis (OGA) system was one of the chosen gait measures for the CREST European project. This author subsequently used this data but also developed TELER Gait Indicators. These were developed in response to the problems with feasibility and analysis of the Rancho Los Amigos form.

The OGA form covers all joints of the pelvis and lower limbs, for all phases of gait, and in all three planes of movement. Realistically, with an FES intervention only certain phases of gait and certain ranges of movement are being addressed. It may be that a useful treatment effect is being masked by collected data that the assessor was not attempting to alter, or was unable to alter, with the given intervention. Both of the above issues lead to questions regarding the clinical significance and uniqueness of this test, it may be that a useful clinical effect is being lost in a large amount of 'superfluous' data. The level of measurement data gained from the form is nominal i.e. an abnormality is either present or absent. No allowance can be made for improvement that does not achieve the 'normal'. The sensitivity of the system may therefore also need to be questioned, especially where the subjects being treated have a substantial degree of chronic disability.

Data were collected on three occasions: at initial assessment, and once at final baselines with stimulation and once without stimulation. The numbers of gait deviations at 'initial baseline' and 'final baseline with stimulation' phases were calculated. When pre and post-intervention data was graphed (figure 5.3) and visually analysed it could be seen that all subjects showed an improvement in their walking abilities in terms of gait deviations. 'Correctness' of gait is obviously only one parameter it is possible to analyse. Speed and energy efficiency are other aspects that have not been addressed in this study. Statistically significant improvement was found between gait deviations, when walking with and without FES, when the paired t-test was used to analyse the data.

Throughout this study, the author was researcher and assessor, a situation which could leave the study open to the accusation of bias. This possibility was addressed for this measure by the use of a blinded assessor in the analysis of gait. From the graphed data in figure 5.4 it can be seen that the blinded assessor gives relatively better scores (fewer deviations) at initial baselines and worse scores (more deviations) at final baselines. Correlation between the two assessors using Spearman's test was strongly positive, however the magnitude of the changes noted by the author were much greater than those noted by the blinded assessor. This could be the result of a variety of causes e.g. results from the first assessor were biased, differences in experience in using the measure. However, as discussed in Chapter 3, section 3.4.b, results from observational gait analysis have notoriously poor inter-rater reliability (Krebs *et al*, 1985, Eastlack *et al* 1991, and Coutts 1999). Steps were taken to minimise these issues prior to testing. Saggital and frontal plane video was taken and both assessors were trained in the use of the Rancho Los Amigos System. The video used for gait analysis purposes consisted of a short phase of the subject walking – approximately 4-5 steps. The subjects for this study varied greatly in their walking abilities. For some of the poorer walkers there could be substantial variation from step to step, therefore deciding which step is 'typical' for the subject could be problematic. In clinical practice, an overall picture of gait is built up through observing subjects walking over time. It was felt that for the purposes of this study a more valid result was to be gained by allowing the assessors to analyse the step they considered most typical for that subject. In this way a fuller picture of the subjects gait was gained rather than close analysis of one step that may or may not have been typical to the subject. This may also have meant that assessors analysed different steps.

Whilst it can be seen from graphical analysis (figure 5.4) of all eight subjects that they improved in terms of gait deviations, it must be remembered that visual observation suggests that experimenter bias may be an issue.

6.3.b TELER Gait Indicators

Analysis of TELER data for the subjects as a group showed that all but 3 of the 29 chosen indicators improved. Two of those that did not improve showed no change, the other showed a deterioration of one point. None of the individual indicators showed a statistically significant improvement at the 95% confidence level. When considered as a group, substantial statistical significance was found. This effectively meant that the improvements seen for individual indicators could not be attributed to FES, but when the indicators were considered as a group the changes could be attributed to FES.

6.3.c Group versus individual analysis

Both the above tests give data regarding the small group of subjects. It is not possible to make conclusions regarding individual subjects from this data. Due to this the results from the Rancho Los Amigos OGA System and the TELER data when considered as a group are of limited benefit to this study.

6.4 Clinical significance

Whilst statistically significant change has been shown in some of the results this is meaningless unless the real clinical effect of the changes can be seen as of significance for the individual.

Bain & Dollaghan (1991) attempted to objectify clinical significance by defining three dimensions that such a change should possess:

- Shown to result from treatment rather than maturation or other confounds
- Shown to be real rather than random
- Shown to be important rather than trivial – in terms of the size of change and its impact upon the subject

Maturation was a potential concern in this study due to the length of time between initial and final baselines for some subjects. However all subjects were a minimum of one year post- injury and in a stable physical state. Other potential confounds (e.g. disease, medication) have been previously addressed in Chapter 4 (figure 4.1).

Dimension two relates to the validity and reliability of the measures used, these issues have been addressed in depth in Chapter 3. The final dimension is perhaps the one that holds most interest for clinicians. Both the MAS and the isokinetic data raise questions as far as clinical significance is concerned. The stage at which changes in MAS or torque values become of clinical significance to the subject, and how these relate to function, is not clear. The OGA data also has issues related to size of change and specificity. With such a large number of data points, the real effects of the intervention may be lost in a plethora of detail that may not be of importance to the individual. The TELER indicators demonstrate a number of 'givens' (Le Roux, 1993) that relate to clinical significance. Indicator codes are each a clinically significant, observable outcome of importance to the subject. The indicators were developed from a bibliography of 'normal' gait data. That is, each point is necessary for the production of that particular phase of gait. Indicators for each subject were chosen from their own identification of their gait problems and so addressed the issue of a personally important rather than a trivial change.

6.5 Valid and Reliable Measurement of Spasticity

Chapter 3 discussed the reliability, validity, responsiveness and feasibility of the four chosen measures for this study. Only the MAS and isokinetic data can be considered as measures of spasticity. The MAS is considered a relatively valid and reliable ordinal measure of resistance to movement, not specifically spasticity. Torque measurements for spasticity assessment in this case were unfortunately unreliable due to error. It may be that the same issues recur as with the MAS, resistance to movement is measured but may not be spasticity specific. Gait parameters are not measures of spasticity, but rather of a function that may be affected by spasticity. There are some questions in the literature as to whether true spasticity has a substantial effect upon gait. It can however be argued that, due to disordered reciprocal inhibition of muscle groups during activity, increased co-contraction can negatively affect function.

Whilst it was not the intent of this study to provide a comprehensive review of all possible measures of spasticity, review of the literature gave the author an overview of the wide variety of possible measures and the apparent discrepancies between them.

General comments regarding the choice of measures for spasticity include:

1. Clarity of definition in the clinical assessment of the different features of the upper motor neurone syndrome (UMNS) is important. The term spasticity should not be used as an umbrella term for these features as this leads to confusion in identification of the individual subject's movement disorder. Outcome measures appropriate to the problematic UMNS feature should be chosen.
2. An understanding of the theories, concepts and constructs underlying these features, and of measurement theory, should assist the therapist in the choice of valid and reliable measures.
3. Conclusions about the effects of spasticity upon function need to be made with care, potentially confounding factors, e.g. soft tissue stiffness, must be considered.

6.6 Comparison of results with published literature

Comparison of the results of this study with others is not straightforward due to the variety of measures used in different studies, to the differences in stimulation parameters and equipment used, and to the variety of pathologies which have been treated. Methodologies are also variable, from randomised controlled trials, to small group studies, or to single case studies. This study considers the results for individual subjects. Where analysis has not been possible for the individual due to problems with the independence of data, data have been analysed for the subjects as a small group.

Burridge *et al* (1997b) randomised 32 subjects with hemiplegia into treatment and control groups. A variety of measures were used. The Wartenberg pendulum test was used to assess quadriceps spasticity. Other assessments included walking speed and effort, and gait analysis. Spasticity was found to be reduced in the treatment group when compared to the control group. Gait parameters also improved. However, correlation was not found between change in spasticity, as measured by the pendulum test, and

change in functional parameters. Burridge assessed quadriceps spasticity, considering the effects of reciprocal inhibition of this muscle group in response to activity of the hamstrings through use of the drop-foot stimulator. The present study considered the overall effect of a variety of stimulation strategies upon spasticity of the main muscle groups of the lower limb.

In a more recent article Burridge & McLellan (2000) investigated the effects of common peroneal nerve stimulation upon spasticity levels and gait for subjects who had suffered a stroke. The electrical response of muscle to stimulation, the ability of subjects to control the activation of muscle groups, and the effort and speed of walking were investigated. They found that subjects with spasticity were likely to respond well to stimulation. Subjects with increased resistance to movement due to soft tissue stiffness responded less well. They also found that all subjects' walking improved with the use of FES. The present study did not use neurophysiological tests to consider the effects of stimulation upon nerve conduction.

Granat *et al* (1993) investigated the effects of FES for gait enhancement on 6 subjects with ISCI. A variety of FES strategies were used for this patient group. The Ashworth Scale and Pendulum test were used to measure spasticity. Gait measures included speed, cadence and Physiological Cost Index. Results were presented and discussed for both individual subjects and as a small group. A statistically significant improvement in relaxation index was found in the results from the pendulum test for all but one subject who demonstrated an increase. Results from the Ashworth Scale were stated as being inconclusive. All gait parameters again showed a statistically significant improvement. The inconclusive results in the MAS findings and the improvements in gait found in this present study are in keeping with the findings of Granat *et al* (op. cit.).

Robinson *et al* (1988) and Swain (1992) applied electrical stimulation for training purposes to subjects with SCI. Robinson *et al* (op. cit.) used the pendulum drop test to measure spasticity. These authors claimed that a 'tendency towards increasing spasticity' was found with their subject group. However only eight out of 31 subjects completed the eight-week course. The authors also noted that spasticity decreased after 8 weeks of training. Observations of an increase in tone were related to measurements taken at 4 weeks of stimulation. Swain (op. cit.) found a tendency for spasticity and spasms to increase when such stimulation was applied. In both cases stimulation was

applied to exercise muscle, rather than to improve walking ability. Whilst it is interesting to note the above findings, it is not possible to relate the results from the present study (where stimulation was applied to improve functional abilities) to the results of either of these studies.

Seib *et al* (1994) applied electrical stimulation to the tibialis anterior muscle of five subjects with traumatic brain injuries and five with SCI. Their measures included the Spasticity Measurement System. Results were presented for individual subjects. Spasticity was found to decrease post intervention for all subjects, but especially so for those with SCI.

Stefanovska *et al* (1989) investigated the effects of implanted stimulators on spasticity and gait in 8 subjects with hemiplegia. Studies of EMG and resistive torque at the ankle joint were undertaken. The authors found an increase in phasic stretch reflex activity and a decrease in tonic stretch reflex activity (spasticity) for all subjects.

The results of this study can, to a variable extent, be considered as in accordance with those previously published. Only one subject demonstrated a statistically significant increase in MAS results thus suggesting that FES has no significant negative effect on spasticity. However, only one subject presented with a statistically significant decrease in MAS scores, suggesting a decrease in spasticity levels. For the majority of subjects the null hypothesis was accepted. TELER Indicators showed clinically but not always statistically significant improvements for all subjects irrespective of an increase or decrease in MAS scores. Only subjects 005 and 010 demonstrated a statistically significant improvement in TELER scores. When the subjects were considered as a small group statistically significant improvement was found in both OGA and TELER Indicators. A general improvement in gait parameters was noted in all articles that addressed this (e.g. Burridge *et al*, 1997a&b, Granat *et al*, 1993).

Many authors also found little correlation between measures of spasticity, in particular passive (e.g. MAS, Pendulum and isokinetic torque) against functional (gait measures) tests. The lack of correlation between the many possible measures of spasticity has previously been discussed. Priebe *et al* (1996) related this to the fact that the different measures effectively address different aspects of the upper motor neurone syndrome.

The majority of reviewed articles discuss the statistical significance of the measures used. Few address the clinical significance of changes. Where a variety of gait measures are considered the clinical benefit to the subject is seldom made explicit.

The effects of FES are complex and incompletely understood. Whilst it is beyond the scope of this study to draw definitive conclusions as to the reasons behind the effects of FES on spasticity and upon gait, it is interesting to consider possibilities. Vodovnik & Stefanovska (1992) summarised the effects of electrical stimulation (Figure 2.7) in terms of its orthotic or restorative effects. If this figure is considered, spasticity and gait may be improved in a number of ways, at either a peripheral or central level.

Orthotic functional stimulation:

- Control of movement may be improved by increases in muscle strength either through direct or indirect stimulation (Granat *et al,* 1993, Stefanovska *et al,* 1989, Daly *et al,* 1996). Granat *et al* noted improvements in hip flexor muscle power even though these muscles had not been directly stimulated. They hypothesised that the repeated motor activity gained by stimulating the hip flexor withdrawal response actually strengthened the hip flexor muscle.
- Muscle phenotype has also been shown to change as a result of long-term stimulation. SCI subjects have relatively fewer slow oxidative motor units in their muscles than the norm, with a preponderance of fast glycolytic fibres. Stimulation has been shown to reverse this trend. (Mohr *et al*, 1997, Pette & Vrbova, 1999)
- Improved foot and limb position during gait improves alignment of limb segments allowing for more normal movement (Burridge *et al,* 1997b).
- Effort of walking has also been shown to decrease when assessed by Physiological Cost Index (Granat *et al,* 1993, Burridge *et al,* 1997a).

Restorative Functional Stimulation:

There are a number of theories relating to the effect of FES on spasticity reduction.

- Some authors have reported that stimulation of an agonist muscle group will have an inhibitory effect on the antagonist muscle group through the Ia inhibitory interneuron and Renshaw Cell mechanisms. (Burridge & McLellan, 2000)
- Stefanovska *et al* (1989) and Yarkony *et al* (1992) stated that FES decreases tonic stretch reflex activity.

- Dermatomal stimulation also has an effect on decreasing spasticity (Granat *et al,* 1993, Daly *et al*, 1996).
- FES can drive plastic change at spinal cord level (Daly *et al,* 1996), thus potentially improving and reinforcing spinal circuitry such as that of the Ia inhibitory interneurone.

Consideration has also to be given to the effect of FES on motor learning and relearning. Chronic deafferentation in SCI causes changes in the cortical somatosensory and motor representation maps (Topka *et al,* 1991). 'Chronic' FES has been shown to alter these cortical maps. Wolpaw & Tennissen (2001) reviewed research relating to plasticity of the spinal cord. They stated that the spinal cord is capable of activity-dependent plastic adaptation. This concurs with the findings of Muir & Steeves (1997) that the spinal cord was capable of plastic change, and that to modify spinal circuitry for a specific task, movements during rehabilitation should be executed as normally as is possible. It may be that FES, if used regularly enough, and in a functional manner, e.g. to produce more normal gait, will promote positive plastic change at both spinal and cortical level.

6.7 Limitations to this study

Some of the limitations of this study have been addressed in previous sections of this Chapter. These include issues with experimenter bias and with instrument reliability.

The choice of Single Subject Experimental Design posed some problems in analysis and conclusions from the data. The statistical independence of data can be threatened due to the use of repeated measures. The subject design was such that data was effectively collected pre- and post-intervention only, giving an AB design. The small number of data points collected may have had an effect on statistical significance. Short baselines pre- and post-intervention may have added to these problems. The chosen methodology does not allow for extrapolation of results to the wider community of people with incomplete spinal cord injury. The use of a SSED does however allow for results for individual subjects to be clarified and discussed in detail. Such information may be of direct benefit to the clinician considering such an intervention.

The lack of a blinded assessor for all of the tests may leave this study open to accusations of bias. This was in part addressed by the use of a blinded assessor for the Rancho Los Amigos OGA data.

Full analysis of the isokinetic data for the test subject prior to full data collection starting may have highlighted the problems with the reliability of this data. It may have been that these problems could have been addressed to give useable data.

No conclusions can be made about the effects of spasticity changes upon walking ability due to the effects of FES, as was the initial intent of this study. However the possible links have been discussed and assumptions that true spasticity negatively affects gait have been questioned.

6.8 Conclusions

Two research questions were posed:

1. What changes in spasticity does an individual who receives FES as a treatment experience?
2. What changes in gait does an individual who receives FES as a treatment experience?

Investigation of the effects of FES upon spasticity in the individual with ISCI demonstrated that the use of FES decreased or had no statistically significant effect on seven out of the eight subjects when assessed by the MAS. The null hypothesis was accepted for six out of the eight subjects. One subject showed a statistically significant decrease in MAS grades following stimulation, one an increase. Descriptive analysis of these six results has two sets of data suggestive of an increase in MAS grades, two a decrease and two sets inconclusive. The results demonstrated a typically random pattern. Changes in MAS grades may not have been due to the use of FES.

Results from the isokinetic passive torque tests are not considered in any conclusions drawn from this study.

A clinically applicable, valid and reliable measure of spasticity remains elusive. The chosen measures have strengths and weaknesses as tools to measure spasticity.

Appreciation of these should increase their usefulness to clinical practice. The author would suggest that clarity of definition in the clinical assessment of the different features of the UMNS is important. The term spasticity should not be used as an umbrella term as this leads to confusion in identification of the individual subject's movement disorder. Outcome measures appropriate to the problematic UMNS feature should be chosen. An understanding of the theories, concepts and constructs underlying these features, and of measurement theory, should assist the therapist in the choice of valid and reliable measures. The MAS may be a valid scale for measuring resistance to passive movement, its ability to measure spasticity change is debatable.

Measures of gait are not measures of spasticity, but rather of a function that may be affected by spasticity. This may be one of the reasons why physiotherapists rarely measure spasticity in a clinical setting, but tend consider functional abilities. Assumptions that spasticity directly affects function need to be made with care.

The degree of gait abnormality lessened for all eight subjects, irrespective of MAS results. However these improvements were often minimal for some subjects.

TELER Indicators could be analysed for the subjects as individuals or as a group. Although clinical improvements were seen in all subjects, statistically significant improvement was found in only two out of the eight. Reasons for this lack of attributable change may include:

- the improvements were not due to FES – other factors may be responsible
- project timescales may have been too short to allow for maximum possible improvements
- the chosen stimulation strategies may not have been optimal for the individual

When the subjects are considered as a group statistically significant improvement was found in both Rancho Los Amigos Observational Gait Analysis and in TELER gait indicators. However it is not possible to draw conclusions about the individual subjects from these results.

FES may work well for some subjects but not for others. The underlying reasons for this may be complex, encompassing a host of physical and psychological issues. In terms of service provision, optimal effect would be gained by the provision of an FES service

from specialist centres with a supporting network of physiotherapists trained in the assessment of potential users and the use of FES systems who can make appropriate referrals to such centres.

This study adds to the body of literature relating to the effects of FES upon spasticity and upon gait. It perhaps brings an extra dimension in that the single subject experimental design allows individual subjects to be considered. In this manner it is hoped that findings may have an increased clinical significance and meaning for the physiotherapist.

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APPENDIX I: *TELER® Gait Indicators*

The TELER Gait Indicators developed for this study are shown on the following pages. The bibliography used in the development of these Indicators is included.

TELER®

Normal Gait Component Indicators
Sue Mawson/Elaine Scott

Stance Phase **(R) & (L) leg**

- initial contact
- loading response
- mid stance
- terminal stance
- erect reciprocal trunk/pelvic rotation

See trunk in stance

Swing Phase ***(R) & (L)***

- preswing
- initial swing
- mid swing
- terminal swing
- erect reciprocal trunk/pelvic rotation

See trunk in swing

TELER® Stance Trunk

- pelvis rotates forwards (upper trunk reciprocal)
- pelvis returns to neutral (upper trunk reciprocal)
- pelvis rotates backwards (upper trunk reciprocal)
- anterior tilt increase then decreases
- pelvic obliquity increases, returns to neutral then increases

-

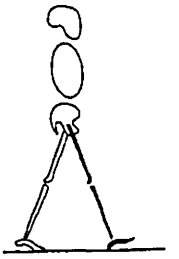
TELER ® Swing Trunk

- pelvis rotates backwards (upper trunk reciprocal)
- pelvis returns to neutral (upper trunk reciprocal)
- pelvis rotates forward (upper trunk reciprocal)
- anterior tilt decreases then returns to neutral
- pelvic obliquity drops, increases to neutral then drops again

Stance Phase

TELER ® Initial Contact

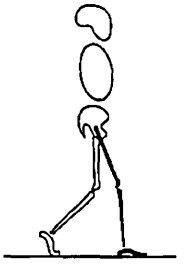
- Erect spine with forward rotation of pelvis
- Hip flexion 25-45°
- Knee fully extended
- Neutral dorsiflexion of ankle
- Toes in neutral alignment



Interval 0-2% GC

TELER® Loading Response

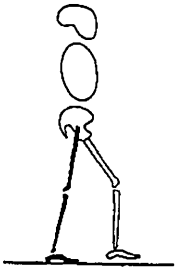
- Erect spine with forward rotation of pelvis
- Hip flexion 25-45°
- Knee flexes to 15-20°
- Ankle planterflexes to 10°
- Toes neutral alignment



Interval 0-10% GC

TELER® Mid Stance

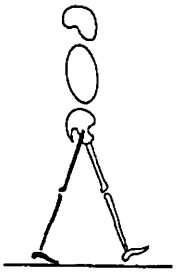
- Erect spine, pelvis returns to neutral
- Hip extends to neutral
- Knee in extends to neutral
- Ankle dorsiflexes 5°
- Toes in neutral



Interval 10-30% GC

TELER® Terminal Stance

- Erect spine, pelvis rotates backwards
- Hip extends to 20° apparent hyper-extension
- Knee in full extension
- Ankle continues to dorsiflex to 10°
- Toes extend to 30° MTP extension



Interval 30-50% GC

TELER® Foot Contact – Stance

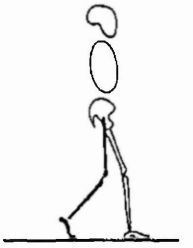
(Use with phases of stance)

- Heel contact
- Weight shift to lateral border of foot
- 5^{th} MT
- 1^{st} MT
- Toe off

Swing Phase

TELER® Pre Swing

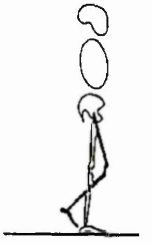
- Erect spine with backward rotation
- Hip returns to neutral
- Knee flexes to 40°
- Ankle planterflexes to 20°
- Toes extend to 60° MTP extension



Interval 50-60% GC

TELER® Initial Swing

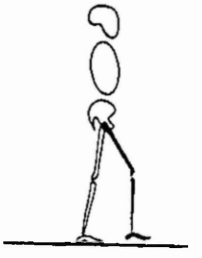
- Spine erect with pelvis in backward rotation
- Hip flexes to 15°
- Knee flexes to 60°
- Ankle returns to 10° planterflexion
- Toes return to neutral alignment



Interval 60-73% GC

TELER® Mid Swing

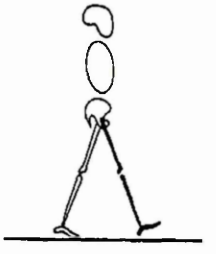
- Spine erect, pelvis returns to neutral
- Hip continues to flex to 25°
- Knee extends to 25° of flexion
- Ankle dorsiflexes to plantergrade
- Toes neutral



Interval 73-87% GC

TELER® Terminal Swing

- Spine erect, pelvis rotates forwards
- Hip flexion 25°
- Knee extends to neutral
- Ankle plantergrade
- Toes neutral



Interval 87-100%GC

PHASES OF HUMAN GAIT

Normal human gait consists of a repeated series of limb motions which progress the body along an intended path while maintaining weight-bearing stability, conserving energy and absorbing the shock of floor impact.
A gait cycle is defined as the time from heel strike to ipsilateral heel strike. The gait cycle can be divided into stance and swing phase. Stance is the whole period the limb is in contact with the ground, swing begins when the foot comes off the ground.
The gait cycle can be divided into eight phases.

Initial Contact (IC): The moment when the foot contacts the ground

Loading Response (LR): Weight is rapidly transferred onto the outstretched limb, the first period of double support.

Mid-Stance (MSt): The body progresses over a single, stable limb.

Terminal Stance (TSt): Progression over the stance limb continues. The body moves ahead of the limb and weight is transferred onto the forefoot.

Pre-Swing (PSw): A rapid unloading of the limb occurs as weight is transferred to the contralateral limb, the second period of double support.

Initial Swing (ISw): The thigh begins to advance as the foot comes off the floor.

Mid-Swing (MSw): The thigh continues to advance as the knee begins to extend: the foot clears the ground.

Terminal Swing (TSw): The knee extends; the limb prepares to contact the ground for Initial Contact.

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APPENDIX II: Treatment aims and interventions by subject

The following is a summary of the findings following baseline assessments, and identified by subjects, as issues to be addressed by the functional electrical stimulation interventions.

Subject 005

45-year-old male with a pathological lesion incomplete at T10. Brown-Sequard lesion. ASIA grade D.

Problems Identified

- Catches toes of right foot whilst walking – unable to 'shorten' leg adequately during swing phase of gait due to decreased hip knee and ankle flexion
- Frequently 'goes over' his right ankle when walking
- Occasionally falls when his right knee gives way – has quadriceps weakness

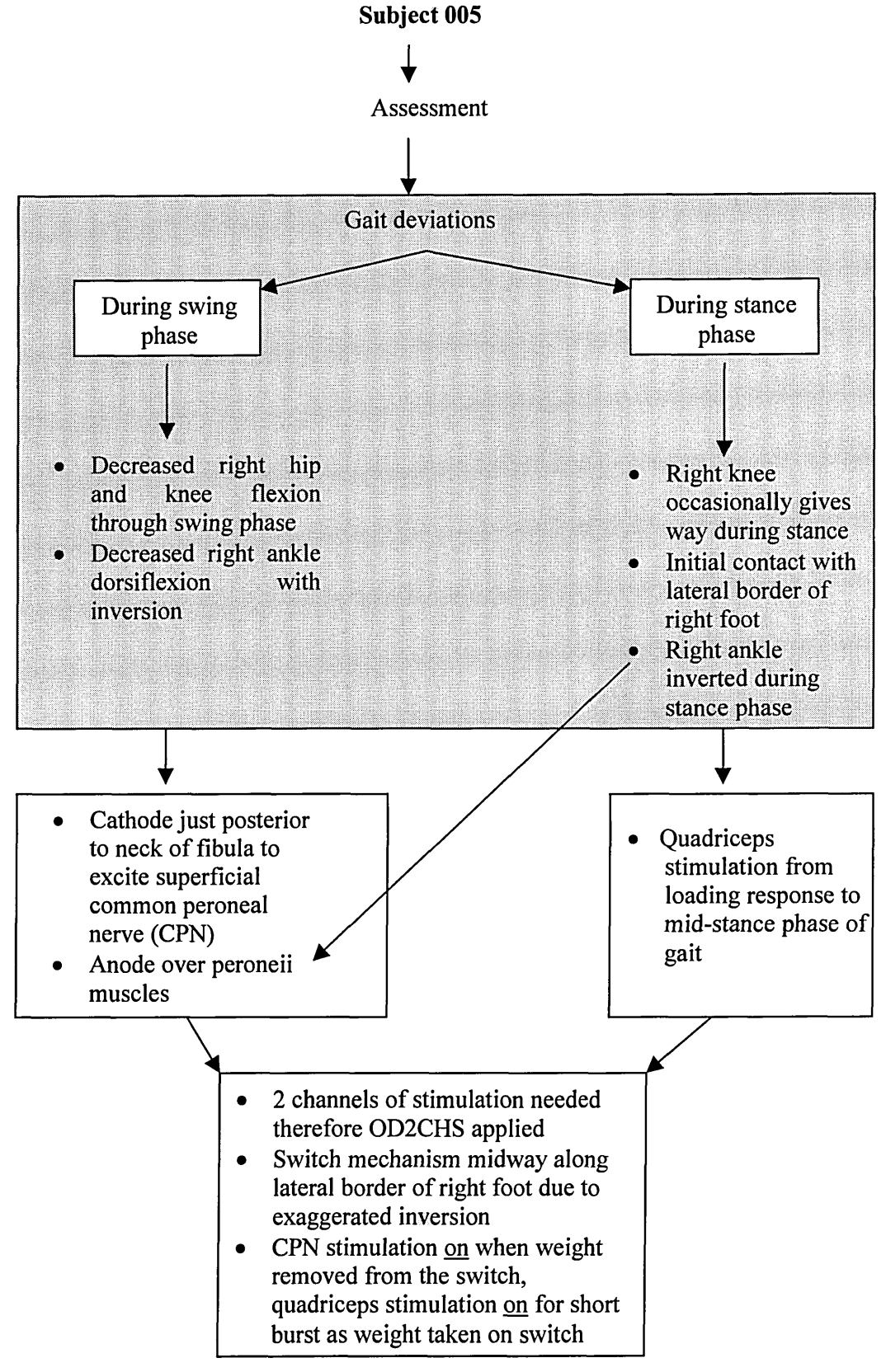
Aims of treatment

- To instigate a strengthening regime for quadriceps and ankle evertors
- To provide a stable right ankle during stance
- To provide a stable right knee during stance
- To increase dorsiflexion of the right ankle during swing
- To increase right hip and knee flexion during swing

Treatment:

- Exercise regime for quadriceps and ankle evertors
- Gait re-education with elbow crutches
- FES strategy decision tree see figure II.1

Figure II.1: Decision Tree for FES Strategy



Subject 006

19-year-old male with a C4/5 incomplete tetraplegia following a diving accident. Brown-Sequard lesion. ASIA grade C.

Problems Identified

- Catches toes of right foot when walking
- Takes a lot of effort to step through with right leg
- Step taken with right leg often short
- Right knee unsteady when takes weight on it

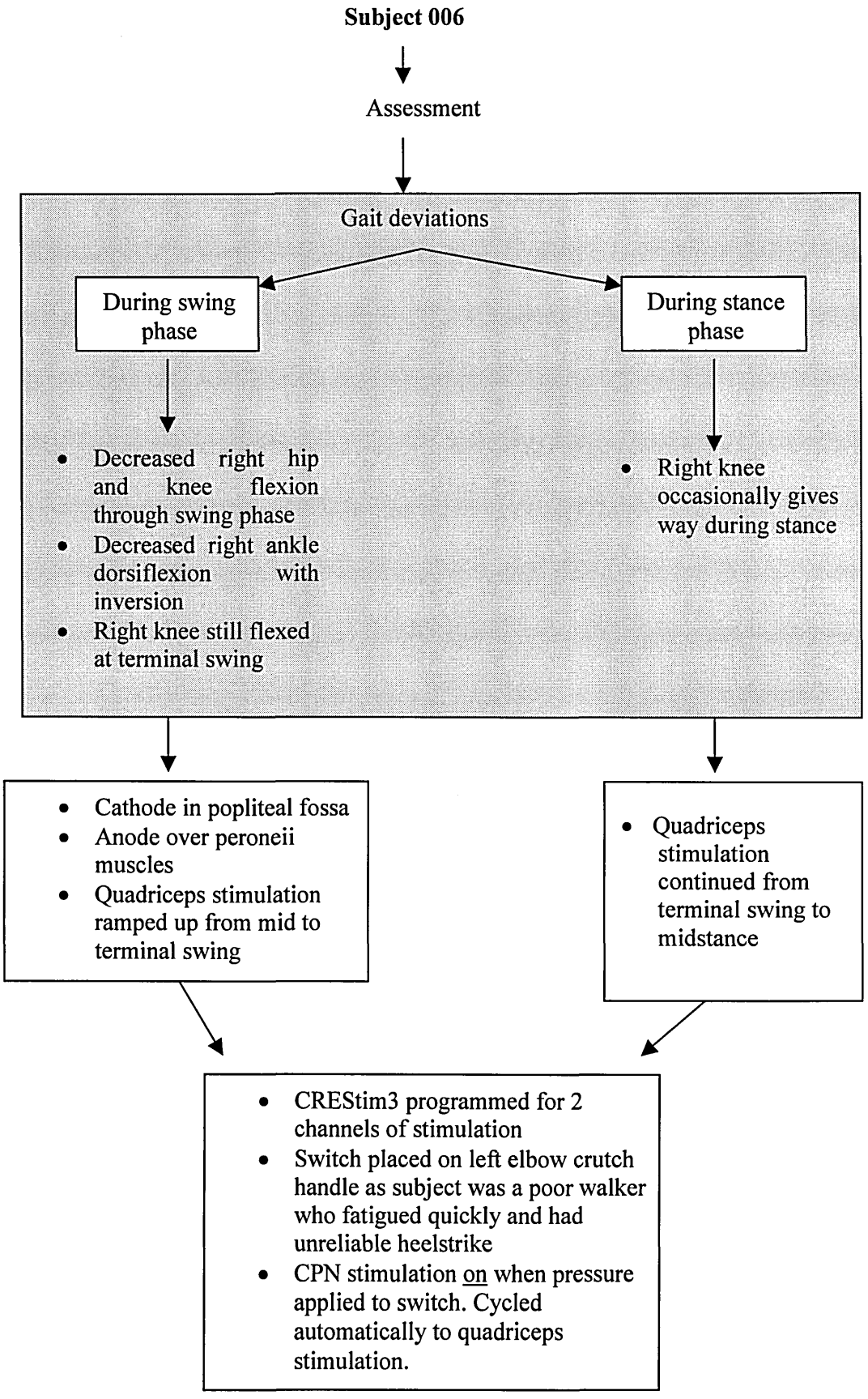
Aims:

- To instigate strengthening regime for quadriceps and ankle dorsiflexors bilaterally
- Top improve right leg flexion throughout swing
- To provide stability during stance
- To reduce the effort of walking

Treatment:

- CRESTim3 programmed for quads and dorsiflexor exercise programme
- Gait re-education with elbow crutches
- FES strategy decision tree see figure II.2

Figure II.2: Decision Tree for FES Strategy



Subject 007

25-year-old female with a C6 lesion following a road traffic accident. Brown-Sequard type lesion. ASIA grade C.

Problems Identified

- Wants to be able to walk for exercise without KAFO as cannot put it on or take it off herself.
- Has a lot of right leg weakness
- Is 'double jointed' – has general joint laxity

Aims:

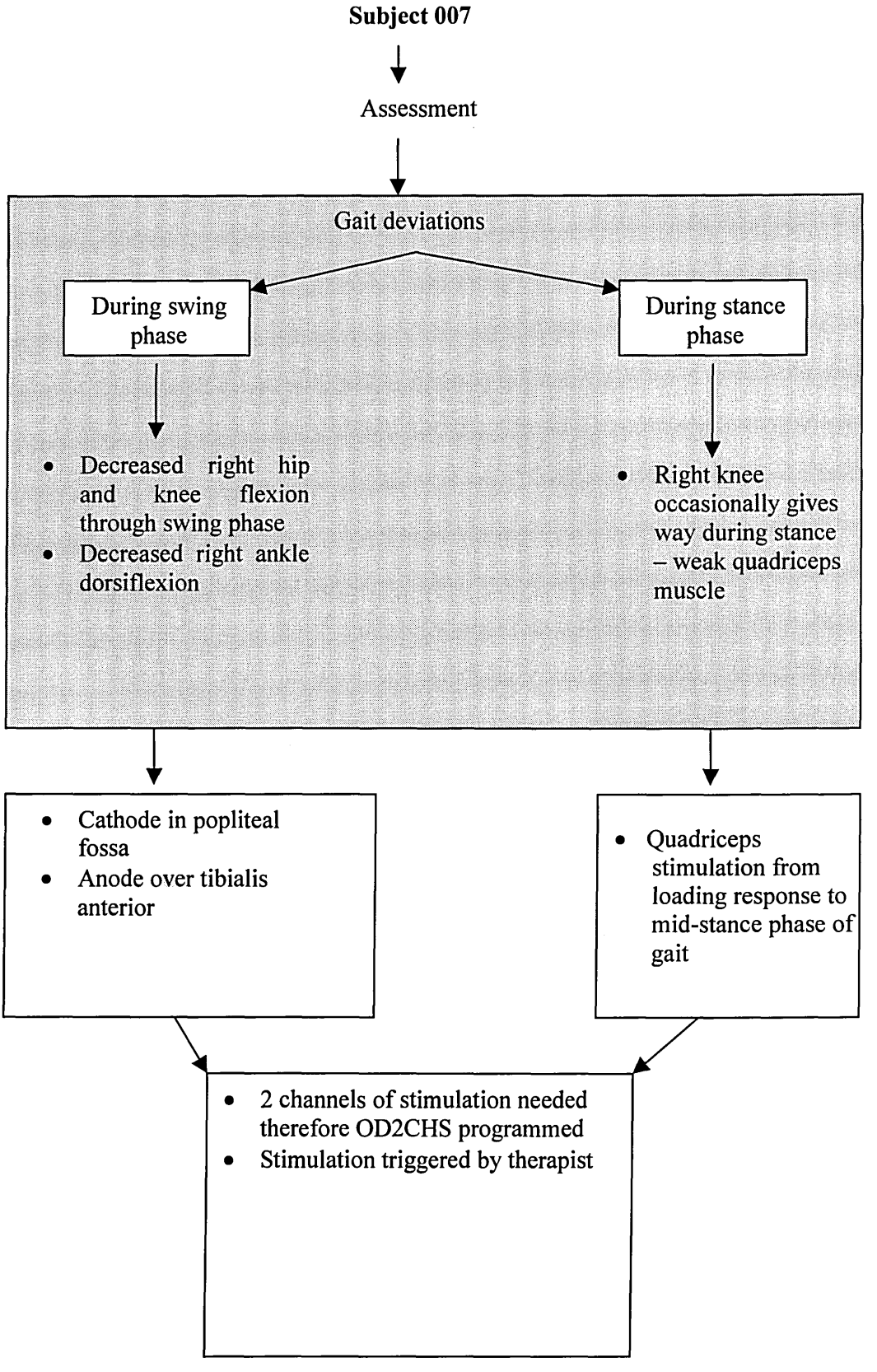
- To walk for exercise without KAFO as cannot don and doff independently
- To allow hip, knee and ankle flexion through swing
- To assist knee extension in stance
- To control knee hyperextension

Treatment:

- Home exercise programme to strengthen quadriceps and ankle dorsiflexors instigated
- Knee brace to control knee joint hyperextension
- Gait re-education in parallel bars
- FES strategy decision tree see figure II.3

Subject 007 did not finish the project. She was the most borderline walker of all those involved with the project. Ambulation was too difficult with the prescribed system. She continued to use electrical stimulation for a home training exercise programme.

Figure II.3: Decision Tree for FES Strategy



Subject 008

23-year-old female with a C6 injury following a road traffic accident. Brown-Sequard type lesion. ASIA grade D.

Problems identified

- Catches toes whilst walking – often trips
- Has large degree of spasticity which gives problems with knee not bending adequately when stepping

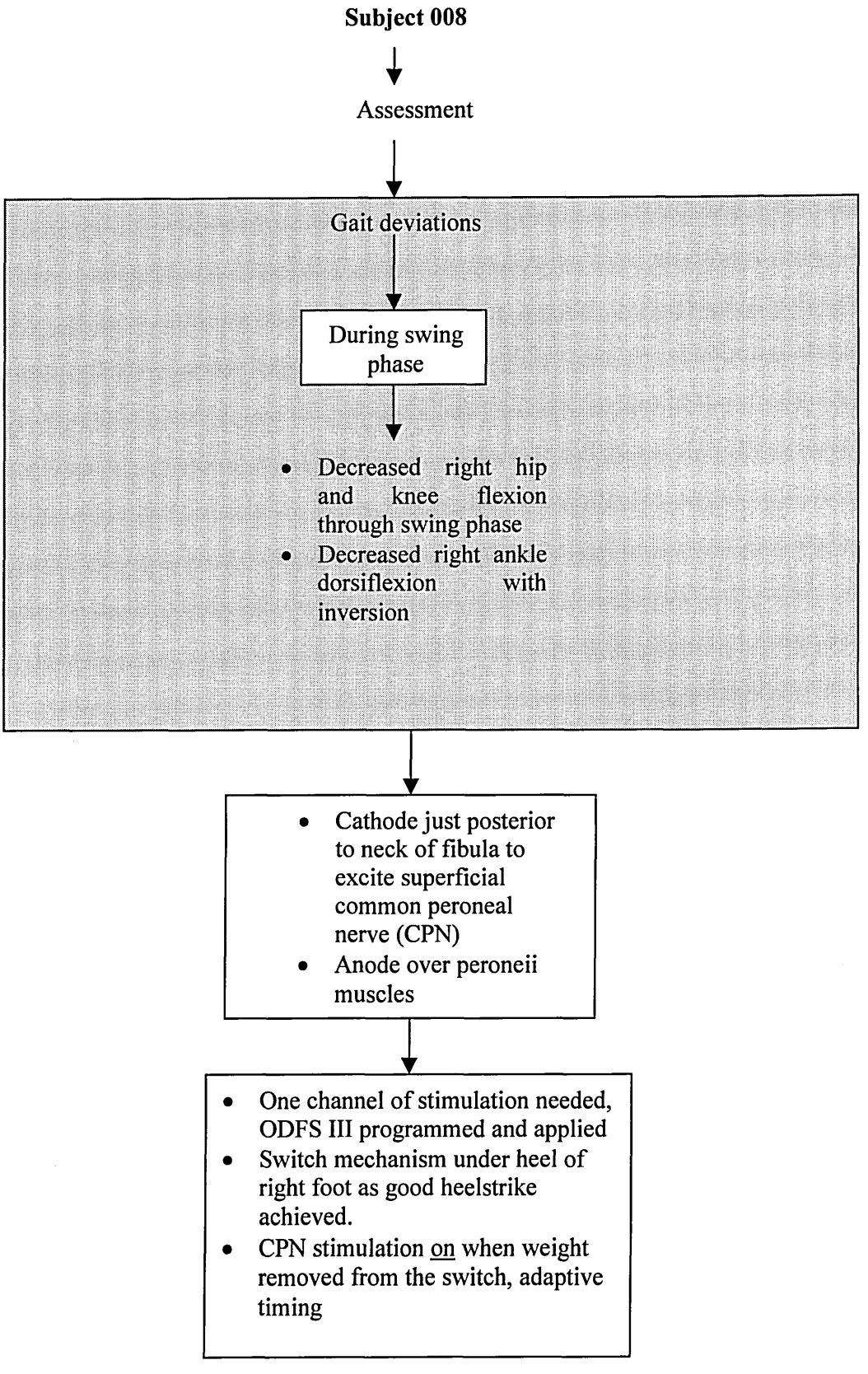
Aims:

- Increase flexion of right hip, knee and ankle during swing phase

Treatment:

- FES strategy decision tree see figure II.4
- Gait re-education with walking sticks

Figure II.4: Decision Tree for FES Strategy



Subject 009

49-year-old male with a C7 incomplete tetraplegia following a fall. Brown-Sequard type lesion. ASIA grade D.

Problems Identified

- Frequently catches toes and trips when walking. Has fallen.

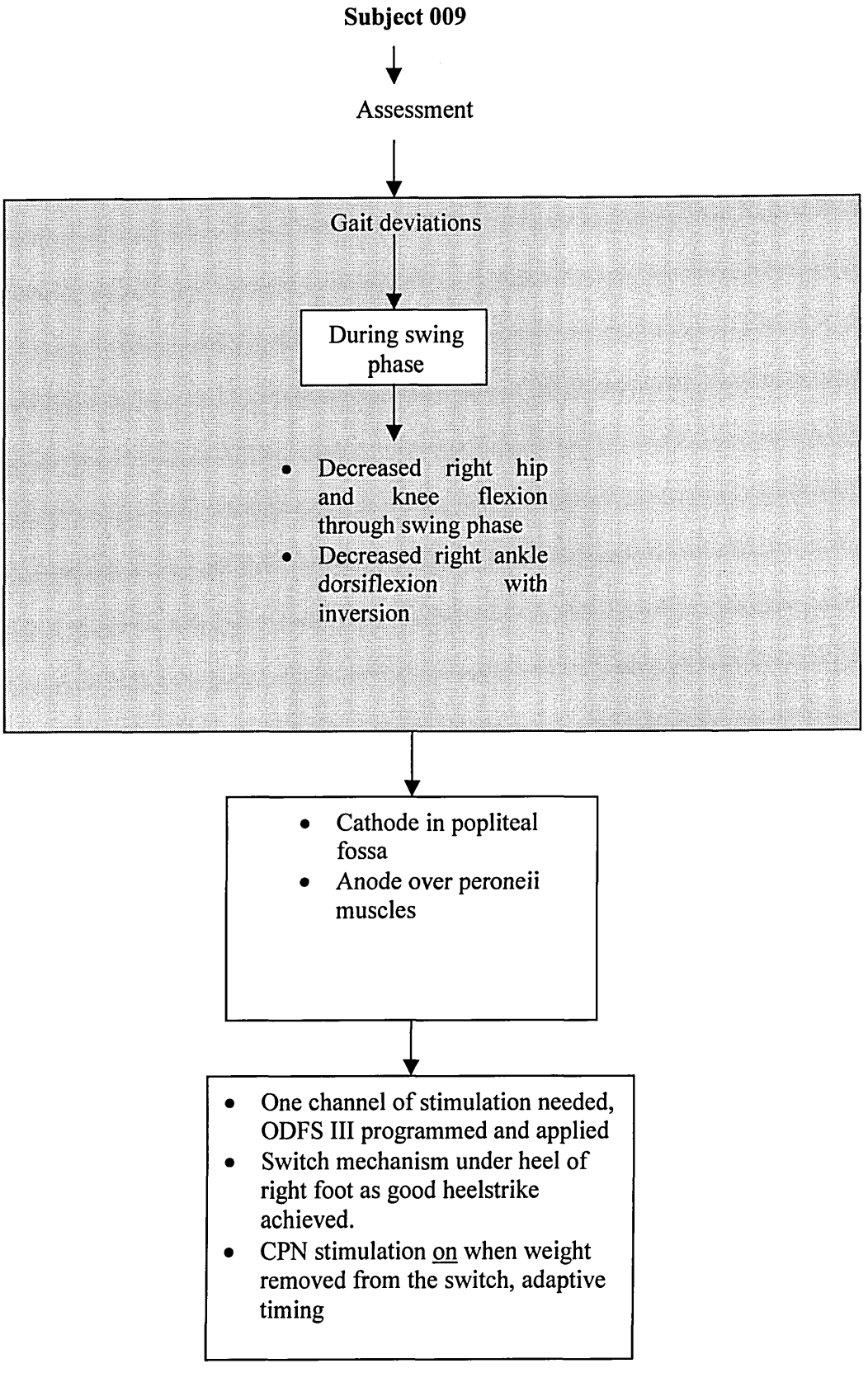
Aims:

- To increase right hip, knee and ankle flexion through swing
- To correct inversion through swing phase and at initial contact

Treatment:

- FES strategy decision tree see figure II.5
- Gait re-education with rollator.

Figure II.5: Decision Tree for FES Strategy



Subject 010

41 year old male with a T4 pathological lesion. Brown-Sequard type lesion. ASIA grade C.

Problems identified

- Very poor stepping ability due to left leg weakness
- Catches toes of left foot when walking
- Left leg sometimes gives way when walking

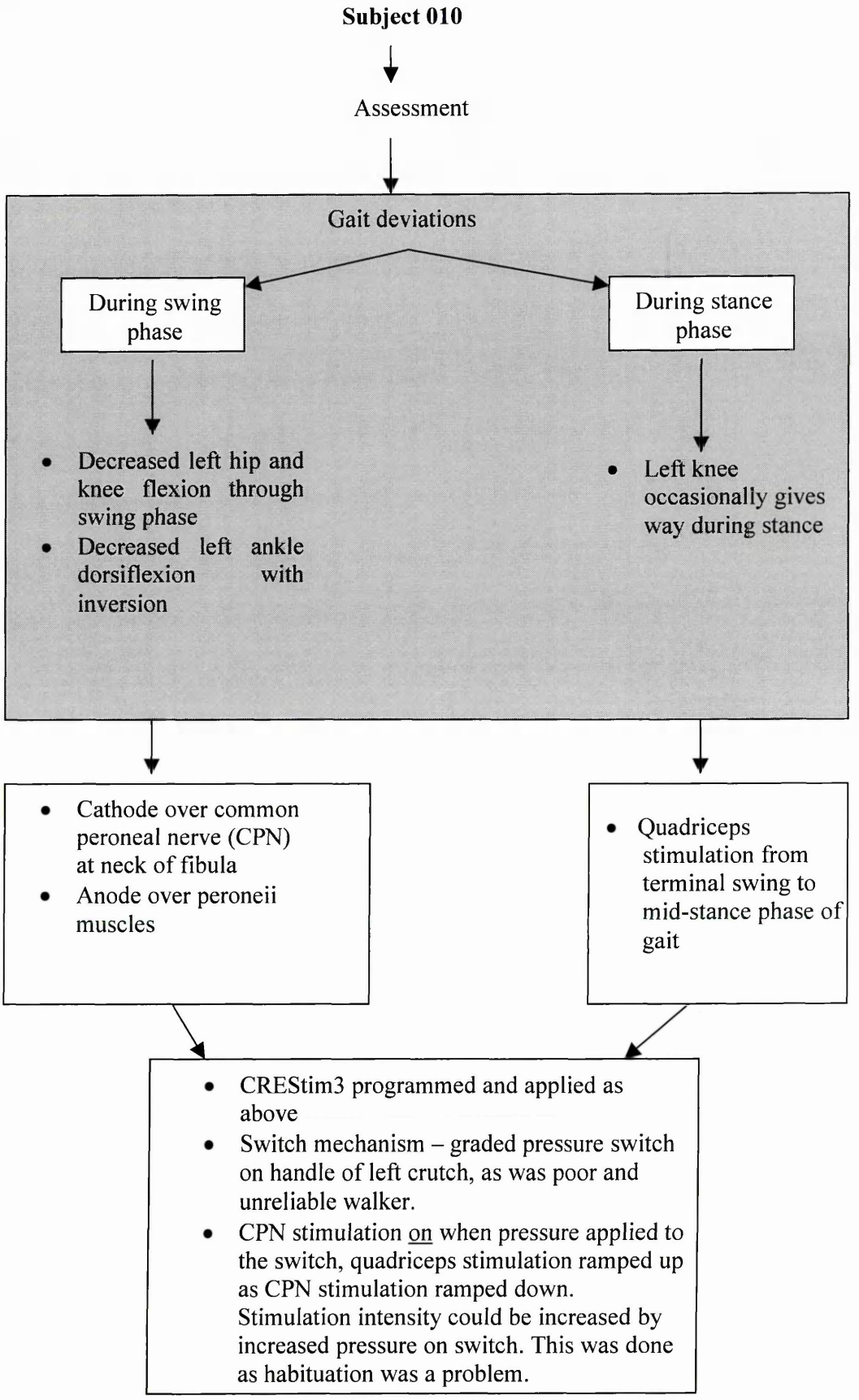
Aims:

- To set up home exercise plan for quads and dorsiflexors
- To increase flexion of left leg throughout swing phase
- To increase stability of left leg during stance.

Treatment:

- CRESTim3 set up with home exercise programme
- Gait re-education with elbow crutches
- FES strategy decision tree see figure II.6

Figure II.6: Decision Tree for FES Strategy



Subject 011

28-year-old male with a tetraplegia incomplete at C7 due to a diving accident. Brown-Sequard type lesion. ASIA grade D

Problems Identified

- Catches toes of left foot when walking.
- Frequently 'goes over' left ankle
- Has very tight ankle planterflexor muscles – cannot get heel to floor

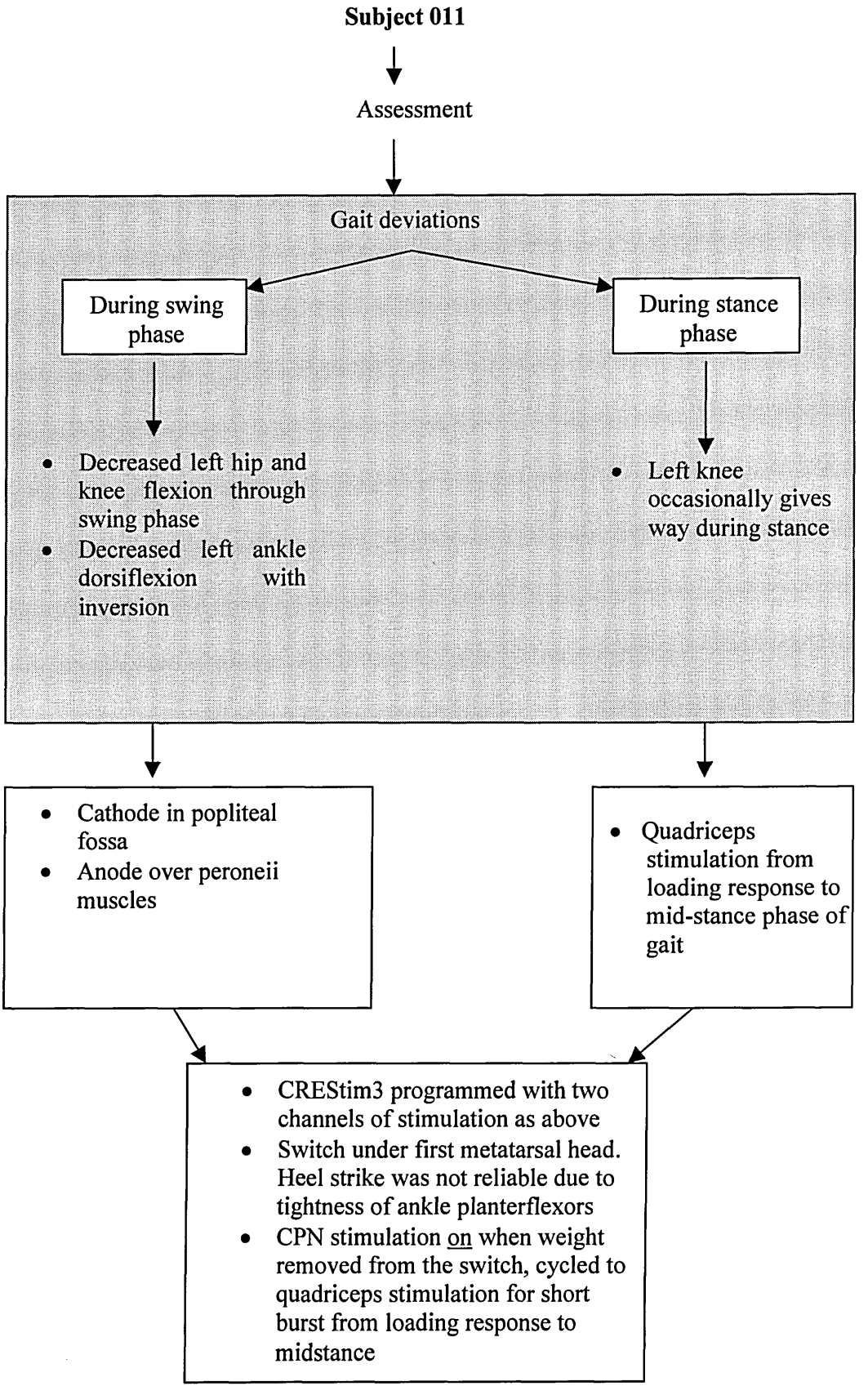
Aims:

- To increase flexion at left hip, knee and ankle joints during swing phase of gait
- To increase left knee extension at terminal swing and through early stance phase of gait to provide stability for weight bearing
- To correct left ankle inversion through swing phase of gait
- To decrease effort needed for swing phase

Treatment:

- Exercise programme prescribed for left quads and dorsiflexors
- Gait re-education with elbow crutches
- FES strategy decision tree see figure II.7

Figure II.7: Decision Tree for FES Strategy



Subject 012

61 year old male with a tetraplegia incomplete at C5 following a sports accident. Central cord syndrome. ASIA grade D.

Problems Identified

- Catches toes of right foot when stepping
- Right knee not reliable when stepping on it – sometimes gives way
- Walks in a slightly flexed posture

Aims:

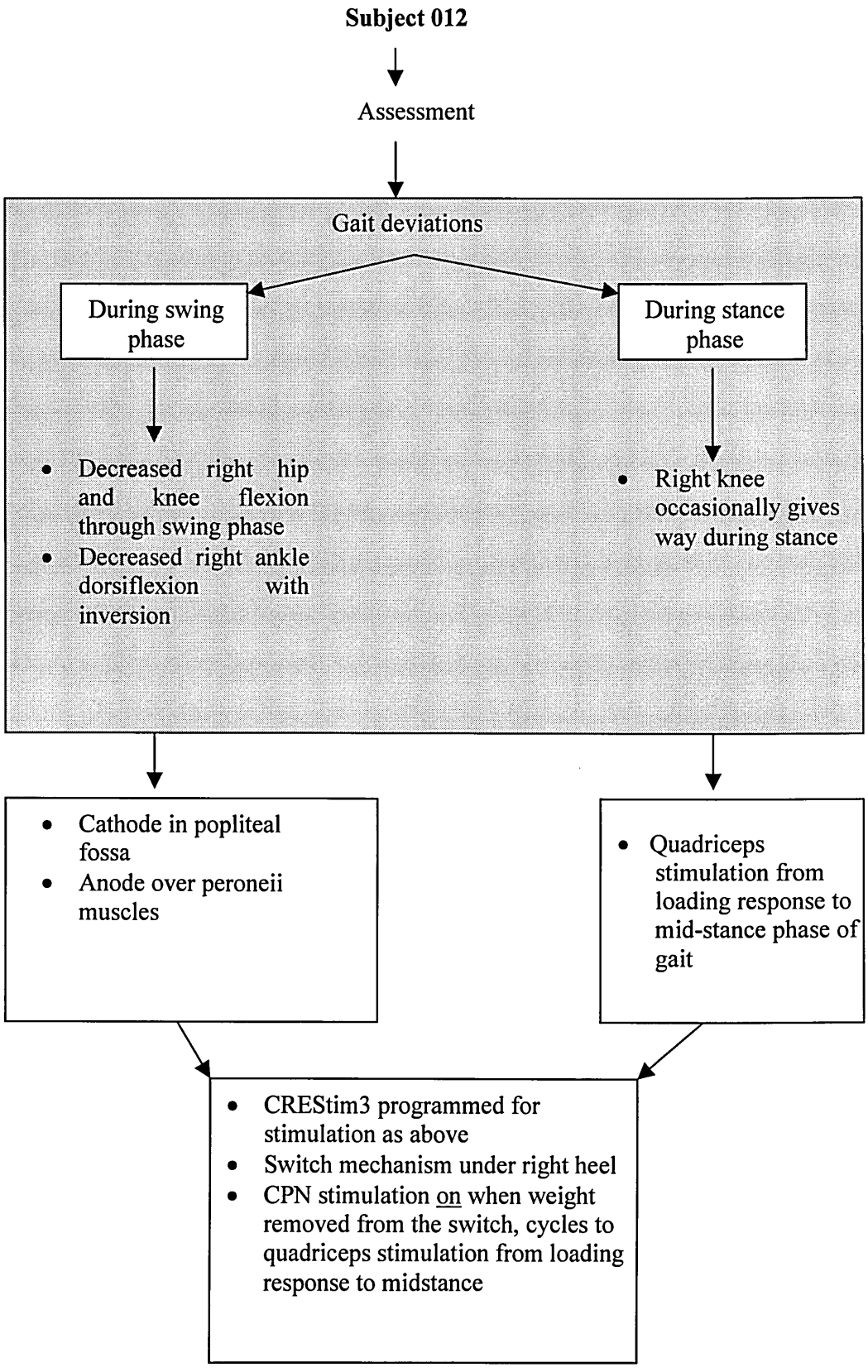
- To set up an exercise programme for home use
- To produce right heel strike at initial contact
- To correct right foot inversion throughout the gait cycle
- To gain right knee extension at terminal swing
- To improve right hip extension and stability during stance

Treatment:

- CRESTim3 programmed with exercise for bilateral quads and right evertors and dorsiflexors
- Gait re-education with elbow support rollator.
- FES strategy decision tree see figure II.8

A third channel was also set up for hip extension during stance. However this caused problems with knee flexion occurring as the hip was extending and so was discontinued.

Figure II.8: Decision Tree for FES Strategy



Subject 013

43-year-old male with a pathological tetraplegia, incomplete at C6. No typical spinal syndrome presentation. ASIA grade D.

Problems Identified

- Catches toes of left foot when walking
- Initial contact with left foot is made with forefoot
- Left knee does not straighten throughout the gait cycle

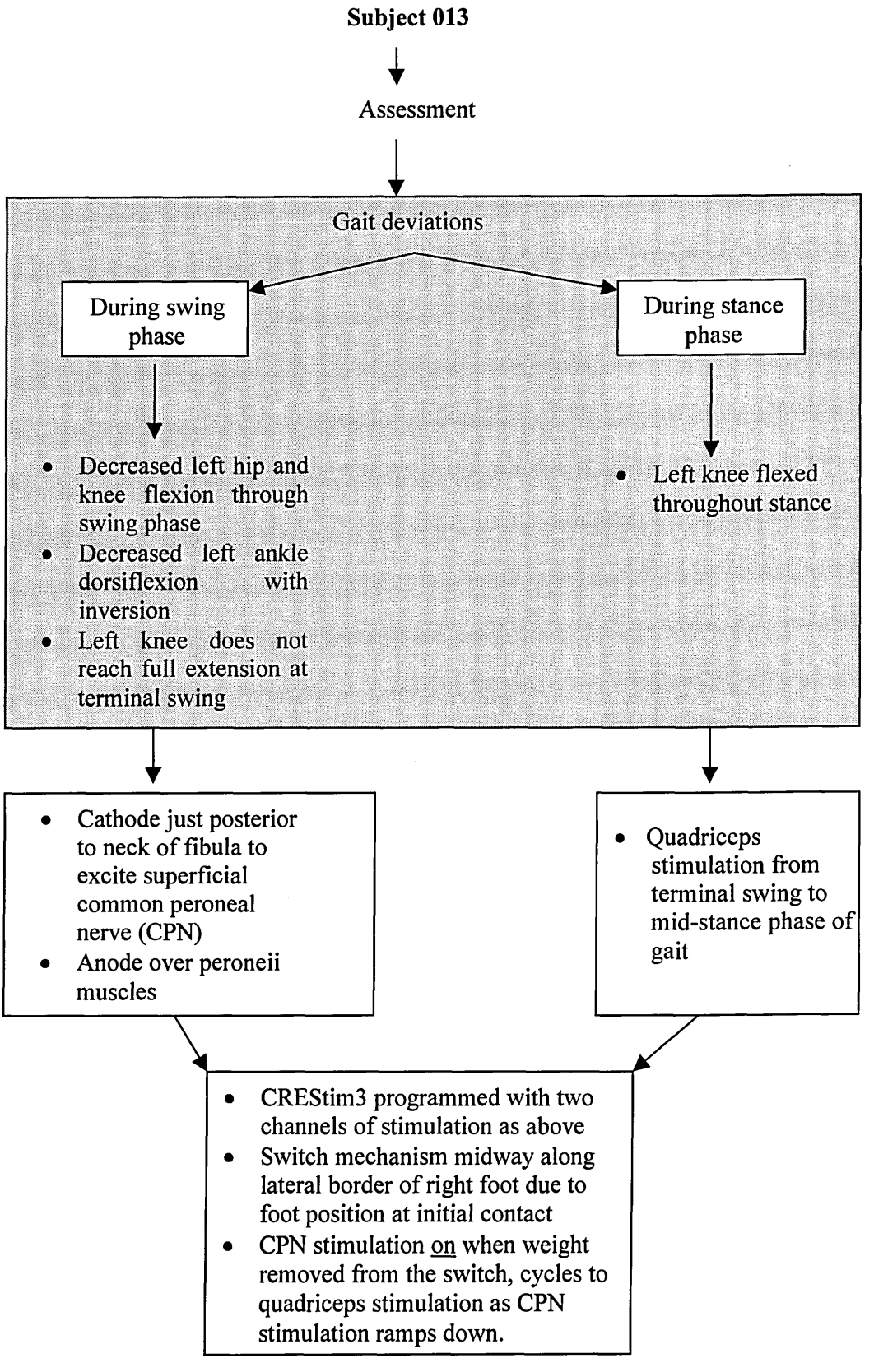
Aims:

- To produce a heel strike at initial contact of the left leg
- To improve flexion of the left leg during swing phase
- To gain knee extension of the left leg at terminal swing and through the first part of stance phase of gait
- To decrease the effort of walking

Treatment:

- FES strategy decision tree see figure II.9
- Gait re-education with elbow crutches

Figure II.9: Decision Tree for FES Strategy



APPENDIX III: Analysis of Modified Ashworth Scale Data

III.A: Subject 005

Table III.1: Subject 005 - Modified Ashworth Scale (MAS) Data by Grade pre- and post-FES

MAS Grade	0	1	2	3	4	5	Total
R Pre	0	9	13	2	0	0	24
R Post	0	21	3	0	0	0	24
Total	0	30	16	2	0	0	48

Analysis of Table III.1 shows an improvement from 15 readings at grade 2 and 3 pre-FES to only 3 readings on grade 2 post-FES. As a result the concentration of 13 readings on grade 2 pre-FES improved to a concentration of 21 readings on grade 1.

The situation post-FES therefore is, firstly, an increase in the concentration on the median from 54% on grade 2 pre-FES to 88% on grade 1 post-FES, and, secondly, an improvement of 1 grade in the median.

An analysis of the pre- and post-FES changes on the individual readings (Table III.2) shows that 14 pre-FES readings improved by 1 grade, 10 pre-FES readings did not change, and no pre-FES readings deteriorated.

Table III.2: Subject 005 - Number and nature of change episodes pre and post FES

Nature of Change		
Improvement	No Change	Deterioration
1	1	
1	1	
1	1	
1	1	
1	1	
1	1	
1	1	
1	1	
1	1	
1	1	
1		
1		
1		
1		
Total **14**	**10**	**0**

These improvements suggest that subject 005 did not suffer a deterioration in spasticity, and may even have demonstrated an improvement, following FES. The suggestion becomes a conclusion if the changes could not have occurred by chance.

Assuming that there is no co-variation between pre- and post-FES readings the following statistical hypotheses are tested:

$\mathbf{H_0}$ - there is no difference between the pre- and post-FES deviations from the pooled median

$\mathbf{H_1}$ – there is a difference between the pre- and post-FES deviations from the pooled median

The pooled median = the grade of the 24th reading. From table III.1 it can be seen that the number of grade 1 readings = 30, therefore the 24th ordered reading = 1. Fisher's exact test was then used to calculate the probability that the differences between pre- and post-FES deviations from the pooled median were due to chance.

Table III.3: Subject 005 - MAS grades above and below the pooled median

	Pre	Post	Total
No of readings below Median code	0	0	0
No of readings above Median code	15	3	18
Total	15	3	18

$$P = \frac{(A+B)!(A+C)!(B+D)!(C+D)!}{N!A!B!C!D!} = 1$$

Therefore for subject 005, $P > 0.05$. For this individual the null hypothesis is accepted and the alternative rejected. There is no statistically significant difference between pre- and post-FES deviations from the pooled median. The validity of this conclusion is dependant upon the assumption that co-variance between pre- and post-FES results had no effect and that there are a sufficient number of MAS changes to justify acceptance of the null hypothesis.

III.B: Subject 006

Table III.4: Subject 006 - Modified Ashworth Scale (MAS) Data by Grade pre- and post-FES

MAS Grade	0	1	2	3	4	5	Total
R Pre	0	13	5	6	0	0	24
R Post	0	5	9	9	1	0	24
Total	0	18	14	15	1	0	48

Analysis of Table III.4 shows a deterioration from 11 readings at grade 2 and 3 pre-FES to 19 readings on grade 2,3 and 4 post-FES. As a result the concentration of 13 readings on grade 1 pre-FES deteriorated to a concentration of 9 on each of grade 2 &3.

The situation post-FES therefore is, firstly, a decrease in the concentration on the median from 54% on grade 1 pre-FES to 75% on grades 2 & 3 post-FES, and, secondly, a deterioration of 1-2 grades in the median.

Analysis of the pre- and post-FES changes on the individual readings (Table III.5) shows that 1 pre-FES readings improved by 1 grade, 11 pre-FES readings did not change, and 12 pre-FES readings deteriorated.

Table III.5: Subject 006 - Number and nature of change episodes pre and post FES

Nature of Change		
Improvement	No Change	Deterioration
1	1	1
	1	1
	1	1
	1	1
	1	1
	1	1
	1	1
	1	1
	1	1
	1	1
	1	1
		1
Total **1**	**11**	**12**

These changes suggest that subject 006 suffered a deterioration in spasticity following FES. The suggestion becomes a conclusion if the changes could not have occurred by chance.

Assuming that there is no co-variation between pre- and post-FES readings the following statistical hypotheses are tested:

$\mathbf{H_0}$ - there is no difference between the pre- and post-FES deviations from the pooled median

$\mathbf{H_1}$ – there is a difference between the pre- and post-FES deviations from the pooled median

The pooled median = the grade of the 24th reading. From table III.4 it can be seen that the number of grade 1 readings = 18, the number of grade 2 readings = 14, therefore the 24th ordered reading = 2. Fisher's exact test was then used to calculate the probability that the differences between pre- and post-FES deviations from the pooled median were due to chance.

Table III.6: Subject 006 - MAS grades above and below the pooled median

	Pre	Post	Total
No of readings below Median code	13	5	18
No of readings above Median code	6	10	16
Total	19	15	34

$$P = \frac{(A+B)!(A+C)!(B+D)!(C+D)!}{N!A!B!C!D!} = 0.037$$

Therefore for subject 006 $P < 0.05$. For this individual the null hypothesis is rejected and the alternative accepted. There is a statistically significant difference between pre and post-FES deviations from the pooled median. The change is that of a deterioration in spasticity as there are an increased number of MAS grades above the median code following FES. The validity of this conclusion is dependant upon the assumption that the co-variance between pre- and post-FES results had no effect and that there are a sufficient number of MAS changes to justify rejection of the null hypothesis.

III.C: Subject 008

Table III.7: Subject 008 - Modified Ashworth Scale (MAS) Data by Grade pre- and post-FES

MAS Grade	0	1	2	3	4	5	Total
R Pre	0	7	11	5	1	0	24
R Post	0	3	9	8	4	0	24
Total	0	10	20	13	5	0	48

Analysis of Table III.7 shows a deterioration from 17 readings at grade 2, 3 and 4 pre-FES to 21 readings on grade 2,3 and 4 post-FES. As a result the concentration of 11 readings on grade 2 pre-FES deteriorated to a concentration of 9 on grade 2.

The situation post-FES therefore is a decrease in the concentration on the median from 46% on grade 2 pre-FES to 37.5% on grade 2 post-FES.

An analysis of the pre- and post-FES changes on the individual readings (Table III.8) shows that 1 pre-FES readings improved by 1 grade, 9 pre-FES readings did not change, and 14 pre-FES readings deteriorated.

Table III.8: Subject 008 - Number and nature of change episodes pre and post FES

Nature of Change		
Improvement	No Change	Deterioration
1	1	1
	1	1
	1	1
	1	1
	1	1
	1	1
	1	1
	1	1
	1	1
		1
		1
		1
		1
		1
Total	**1**	**9**	**14**

These changes suggest that subject 008 suffered a deterioration in spasticity following FES. The suggestion becomes a conclusion if the changes could not have occurred by chance.

Assuming that there is no co-variation between pre- and post-FES readings the following statistical hypotheses are tested:

$\mathbf{H_0}$ - there is no difference between the pre- and post-FES deviations from the pooled median

$\mathbf{H_1}$ – there is a difference between the pre- and post-FES deviations from the pooled median

The pooled median = the grade of the 24th reading. From table III.7 it can be seen that the number of grade 1 readings = 10, the number of grade 2 readings = 20, therefore the 24th ordered reading = 2. Fisher's exact test was then used to calculate the probability that the differences between pre- and post-FES deviations from the pooled median were due to chance.

Table III.9: Subject 008 - MAS grades above and below the pooled median

	Pre	Post	Total
No of readings below Median code	7	3	10
No of readings above Median code	6	12	18
Total	13	15	28

$$P = \frac{(A+B)!(A+C)!(B+D)!(C+D)!}{N!A!B!C!D!} = 0.0595$$

Therefore for subject 008 $P > 0.05$. For this individual the null hypothesis is accepted and the alternative rejected. There is no statistically significant difference between pre- and post-FES deviations from the pooled median. The validity of this conclusion is dependant upon the assumption that co-variance between pre- and post-FES results had no effect and that there are a sufficient number of MAS changes to justify acceptance of the null hypothesis.

III.D: Subject 009

Table III.10: Subject 009 - Modified Ashworth Scale (MAS) Data by Grade pre- and post-FES

MAS Grade	0	1	2	3	4	5	Total
R Pre	0	14	9	1	0	0	24
R Post	5	16	3	0	0	0	24
Total	5	30	12	1	0	0	48

Analysis of Table III.10 shows an improvement from 10 readings at grade 2 and 3 pre-FES to only 3 readings on grade 2 post-FES. As a result the concentration of readings remained at grade 1, but 5 scores were graded at 0, where none had been before.

The situation post-FES therefore shows a small increase in the concentration on the median from 58% on grade 1 pre-FES to 67% on grade 1 post-FES.

An analysis of the pre- and post-FES changes on the individual readings (Table III.11) shows that 13 pre-FES readings improved by 1 grade, 11 pre-FES readings did not change, and no pre-FES readings deteriorated.

Table III.11: Subject 009 - Number and nature of change episodes pre and post FES

	Nature of Change		
	Improvement	No Change	Deterioration
	1	1	
	1	1	
	1	1	
	1	1	
	1	1	
	1	1	
	1	1	
	1	1	
	1	1	
	1	1	
	1	1	
	1		
	1		
Total	13	11	0

These improvements suggest that subject 009 did not suffer a deterioration in spasticity, and may even have demonstrated an improvement, following FES. The suggestion becomes a conclusion if the changes could not have occurred by chance.

Assuming that there is no co-variation between pre- and post-FES readings the following statistical hypotheses are tested:

$\mathbf{H_0}$ - there is no difference between the pre- and post-FES deviations from the pooled median

$\mathbf{H_1}$ – there is a difference between the pre- and post-FES deviations from the pooled median

The pooled median = the grade of the 24th reading. From table III.10 it can be seen that the number of grade 0 readings = 5, the number of grade 1 readings = 30, therefore the 24th ordered reading = 1. Fisher's exact test was then used to calculate the probability that the differences between pre- and post-FES deviations from the pooled median were due to chance.

Table III.12: Subject 009 - MAS grades above and below the pooled median

	Pre	Post	Total
No of readings below Median code	0	5	5
No of readings above Median code	10	3	13
Total	10	8	18

$$P = \frac{(A+B)!(A+C)!(B+D)!(C+D)!}{N!A!B!C!D!} = 0.0065$$

Therefore for subject 009 $P < 0.05$. For this individual the null hypothesis is rejected and the alternative accepted. There is a statistically significant difference between pre and post-FES deviations from the pooled median. The change is that of an improvement in spasticity as there are an increased number of MAS grades below the median code following FES. The validity of this conclusion is dependant upon the assumption that the co-variance between pre- and post-FES results had no effect and that there are a sufficient number of MAS changes to justify rejection of the null hypothesis.

III.E: Subject 010

Table III.13: Subject 010 - Modified Ashworth Scale (MAS) Data by Grade pre- and post-FES

MAS Grade	0	1	2	3	4	5	Total
L Pre	0	2	11	6	5	0	24
L Post	0	7	7	3	7	0	24
Total	0	9	18	9	12	0	48

Analysis of Table III.13 shows a slight improvement from 22 readings at grade 2, 3 and 4 pre-FES to 17 readings on grade 2, 3 and 4 post-FES. The concentration of 11 readings at grade 2 pre-FES decreased to 7 readings on grade 1 and 2 respectively post-FES.

The situation post-FES therefore shows a small increase in the concentration on the median from 46% on grade 2 pre-FES to 58% on grade 1 and 2 post-FES.

An analysis of the pre- and post-FES changes on the individual readings (Table III.14) shows that 7 pre-FES readings improved by 1 grade, 14 pre-FES readings did not change, and 3 pre-FES readings deteriorated.

Table III.14: Subject 010 - Number and nature of change episodes pre and post FES

	Nature of Change		
	Improvement	No Change	Deterioration
	1	1	1
	1	1	1
	1	1	1
	1	1	
	1	1	
	1	1	
	1	1	
		1	
		1	
		1	
		1	
		1	
		1	
		1	
Total	7	14	3

These changes suggest that subject 010 showed little alteration in spasticity following FES. Fisher's exact test was used to confirm this finding.

Assuming that there is no co-variation between pre- and post-FES readings the following statistical hypotheses are tested:

$\mathbf{H_0}$ - there is no difference between the pre- and post-FES deviations from the pooled median

$\mathbf{H_1}$ – there is a difference between the pre- and post-FES deviations from the pooled median

The pooled median = the grade of the 24th reading. From table III.13 it can be seen that the number of grade 1 readings = 9, the number of grade 2 readings = 18, therefore the 24th ordered reading = 2. Fisher's exact test was then used to calculate the probability that the differences between pre- and post-FES deviations from the pooled median were due to chance.

Table III.15: Subject 010 - MAS grades above and below the pooled median

	Pre	Post	Total
No of readings below Median code	2	7	9
No of readings above Median code	11	10	21
Total	13	17	30

$$P = \frac{(A+B)!(A+C)!(B+D)!(C+D)!}{N!A!B!C!D!} = 0.106$$

Therefore for subject 010 $P > 0.05$. For this individual the null hypothesis is accepted and the alternative rejected. There is no statistically significant difference between pre- and post-FES deviations from the pooled median. The validity of this conclusion is dependant upon the assumption that co-variance between pre- and post-FES results had no effect and that there are a sufficient number of MAS changes to justify acceptance of the null hypothesis.

III.F: Subject 011

Table III.16: Subject 011 - Modified Ashworth Scale (MAS) Data by Grade pre- and post-FES

MAS Grade	0	1	2	3	4	5	Total
L Pre	0	7	9	4	4	0	24
L Post	0	8	5	8	3	0	24
Total	0	15	14	12	7	0	48

Analysis of Table III.16 shows a very slight improvement from 17 readings at grade 2, 3 and 4 pre-FES to 16 readings on grade 2, 3 and 4 post-FES. The concentration of 9readings at grade 2 pre-FES altered to 8 readings on grade 1 and 3 respectively post-FES.

The situation post-FES therefore shows a decrease in the concentration on the median from 37.5% on grade 2 pre-FES to 21% on grade 2 post-FES.

An analysis of the pre- and post-FES changes on the individual readings (Table III.17) shows that 4 pre-FES readings improved by 1 grade, 15 pre-FES readings did not change, and 5 pre-FES readings deteriorated.

Table III.17: Subject 011 - Number and nature of change episodes pre and post FES

	Nature of Change		
	Improvement	No Change	Deterioration
	1	1	1
	1	1	1
	1	1	1
	1	1	1
		1	1
		1	
		1	
		1	
		1	
		1	
		1	
		1	
		1	
		1	
		1	
		1	
Total	4	15	5

These changes suggest that subject 011 did showed little alteration in spasticity following FES. Fisher's exact test was used to confirm this finding.

Assuming that there is no co-variation between pre- and post-FES readings the following statistical hypotheses are tested:

$\mathbf{H_0}$ - there is no difference between the pre- and post-FES deviations from the pooled median

$\mathbf{H_1}$ – there is a difference between the pre- and post-FES deviations from the pooled median

The pooled median = the grade of the 24th reading. From table III.16 it can be seen that the number of grade 1 readings = 15, the number of grade 2 readings = 14, therefore the 24th ordered reading = 2. Fisher's exact test was then used to calculate the probability that the differences between pre- and post-FES deviations from the pooled median were due to chance.

Table III.18: Subject 011 - MAS grades above and below the pooled median

	Pre	Post	Total
No of readings below Median code	7	8	15
No of readings above Median code	8	11	19
Total	15	19	34

$$P = \frac{(A+B)!(A+C)!(B+D)!(C+D)!}{N!A!B!C!D!} = 0.262$$

Therefore for subject 011 $P > 0.05$. For this individual the null hypothesis is accepted and the alternative rejected. There is no statistically significant difference between pre- and post-FES deviations from the pooled median. The validity of this conclusion is dependant upon the assumption that co-variance between pre- and post-FES results had no effect and that there are a sufficient number of MAS changes to justify acceptance of the null hypothesis.

III.G: Subject 0012

Table III.19: Subject 012 - Modified Ashworth Scale (MAS) Data by Grade pre- and post-FES

MAS Grade	0	1	2	3	4	5	Total
R Pre	0	16	8	0	0	0	24
R Post	0	22	2	0	0	0	24
Total	0	38	10	0	0	0	48

Analysis of Table III.19 shows an improvement from 8 readings at grade 2 pre-FES to only 2 readings on grade 2 post-FES. As a result the concentration of 16 readings on grade 1 pre-FES improved to a concentration of 22 readings on grade 1.

The situation post-FES therefore is an increase in the concentration on the median from 67% on grade 1 pre-FES to 92% on grade 1 post-FES.

An analysis of the pre- and post-FES changes on the individual readings (Table III.20) shows that 6 pre-FES readings improved by 1 grade, 18 pre-FES readings did not change, and no pre-FES readings deteriorated.

Table III.20: Subject 012 - Number and nature of change episodes pre and post FES

Nature of Change		
Improvement	No Change	Deterioration
1	1	
1	1	
1	1	
1	1	
1	1	
1	1	
	1	
	1	
	1	
	1	
	1	
	1	
	1	
	1	
	1	
	1	
	1	
	1	
	1	
Total 6	**18**	**0**

These improvements suggest that subject 012 did not suffer a deterioration in spasticity, and may even have demonstrated an improvement, following FES. The suggestion becomes a conclusion if the changes could not have occurred by chance.

Assuming that there is no co-variation between pre- and post-FES readings the following statistical hypotheses are tested:

$\mathbf{H_0}$ - there is no difference between the pre- and post-FES deviations from the pooled median

$\mathbf{H_1}$ – there is a difference between the pre- and post-FES deviations from the pooled median

The pooled median = the grade of the 24th reading. From table III.19 it can be seen that the number of grade 1 readings = 38, therefore the 24th ordered reading = 1. Fisher's exact test was then used to calculate the probability that the differences between pre- and post-FES deviations from the pooled median were due to chance.

Table III.21: Subject 012 - MAS grades above and below the pooled median

	Pre	Post	Total
No of readings below Median code	0	0	0
No of readings above Median code	8	2	10
Total	8	2	10

$$P = \frac{(A+B)!(A+C)!(B+D)!(C+D)!}{N!A!B!C!D!} = 1$$

Therefore for subject 012 $p>0.05$. For this individual the null hypothesis is accepted and the alternative rejected. There is no statistically significant difference between pre- and post-FES deviations from the pooled median. The validity of this conclusion is dependant upon the assumption that co-variance between pre- and post-FES results had no effect and that there are a sufficient number of MAS changes to justify acceptance of the null hypothesis.

III.H: Subject 013

Table III.22: Subject 013 - Modified Ashworth Scale (MAS) Data by Grade pre- and post-FES

MAS Grade	0	1	2	3	4	5	Total
L Pre	0	5	10	9	0	0	24
L Post	0	7	6	3	8	0	24
Total	0	12	16	12	8	0	48

Analysis of Table III.22 shows a change from 19 readings at grade 2 and 3 pre-FES to 17 readings on grade 2,3 and 4 post-FES. As a result the concentration of 10 readings on grade 2 pre-FES altered to a wider spread across grades 1 to 4, with a substantial increase in grade 4's from 0 to 8.

The situation post-FES therefore is a decrease in the concentration on the median from 42% on grade 2 pre-FES to 25% on grade 2 post-FES.

An analysis of the pre- and post-FES changes on the individual readings (Table III.23) shows that 5 pre-FES readings improved by 1 grade, 7 pre-FES readings did not change, and 12 pre-FES readings deteriorated.

Table III.23: Subject 013 - Number and nature of change episodes pre and post FES

Nature of Change		
Improvement	No Change	Deterioration
1	1	1
1	1	1
1	1	1
1	1	1
1	1	1
	1	1
	1	1
		1
		1
		1
		1
		1
Total **5**	**7**	**12**

These changes suggest that subject 013 suffered a deterioration in spasticity following FES. The suggestion becomes a conclusion if the changes could not have occurred by chance.

Assuming that there is no co-variation between pre- and post-FES readings the following statistical hypotheses are tested:

$\mathbf{H_0}$ - there is no difference between the pre- and post-FES deviations from the pooled median

$\mathbf{H_1}$ – there is a difference between the pre- and post-FES deviations from the pooled median

The pooled median = the grade of the 24th reading. From table III.7 it can be seen that the number of grade 1 readings = 10, the number of grade 2 readings = 20, therefore the 24th ordered reading = 2. Fisher's exact test was then used to calculate the probability that the differences between pre- and post-FES deviations from the pooled median were due to chance.

Table III.24: Subject 013 - MAS grades above and below the pooled median

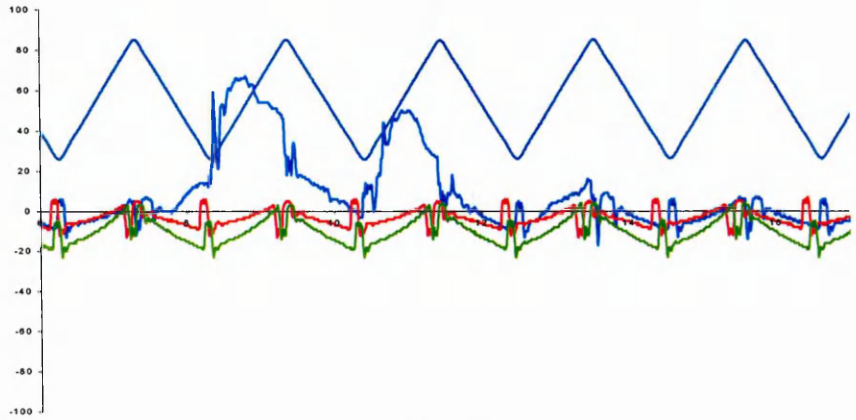
	Pre	Post	Total
No of readings below Median code	5	7	12
No of readings above Median code	9	11	20
Total	14	18	32

$$P = \frac{(A+B)!(A+C)!(B+D)!(C+D)!}{N!A!B!C!D!} = 0.282$$

Therefore for subject 013 $P > 0.05$. For this individual the null hypothesis is accepted and the alternative rejected. There is no statistically significant difference between pre- and post-FES deviations from the pooled median. The validity of this conclusion is dependant upon the assumption that co-variance between pre- and post-FES results had no effect and that there are a sufficient number of MAS changes to justify acceptance of the null hypothesis.

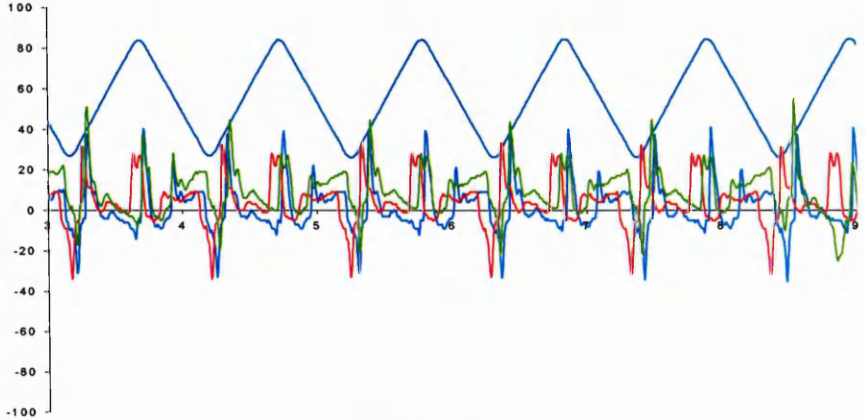
Subject 005 Isokinetic Torque Data

R60°/s Pre-FES



Time (s)

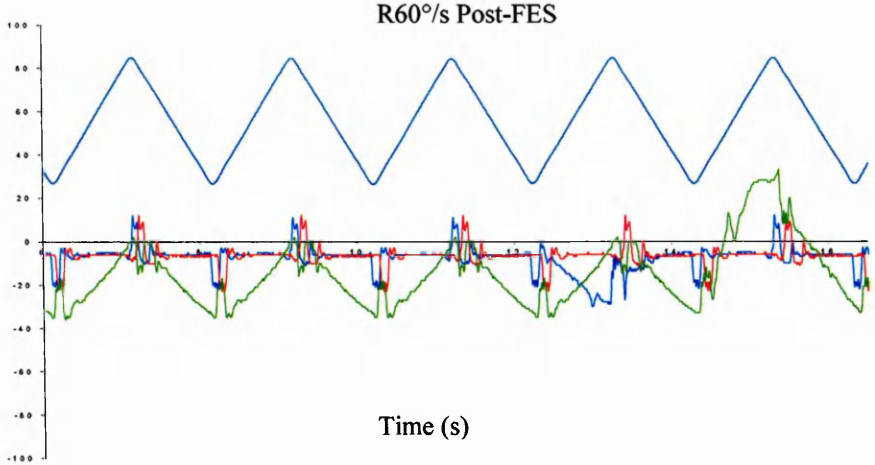
R120°/s Pre-FES



Time (s)

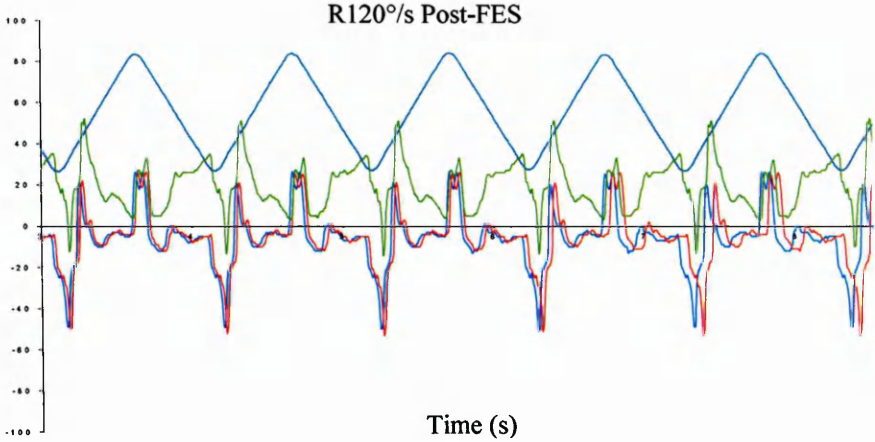
Angle of the knee joint in degrees
Torque (Nm) Test Session 1
Torque (Nm) Test Session 2
Torque (Nm) Test Session 3

R60°/s Post-FES



Time (s)

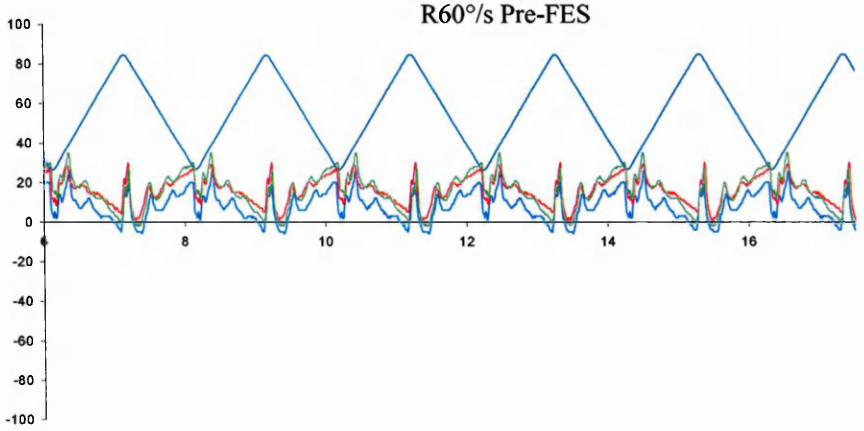
R120°/s Post-FES



Time (s)

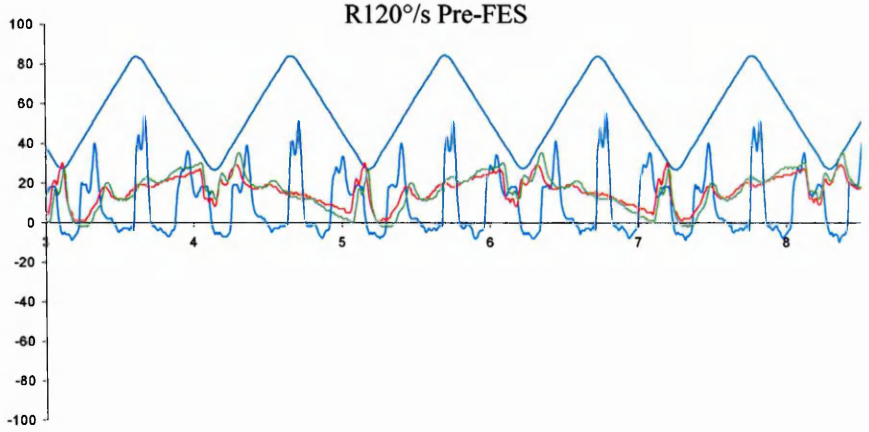
Subject 006 Isokinetic Torque Data

R60°/s Pre-FES



Time (s)

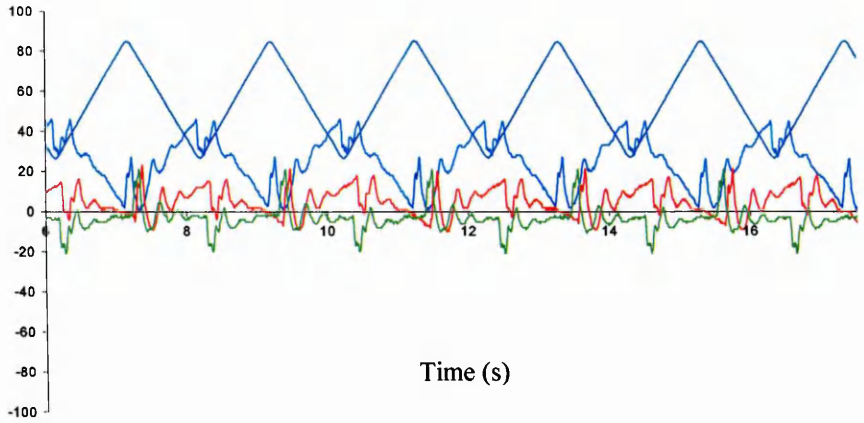
R120°/s Pre-FES



Time (s)

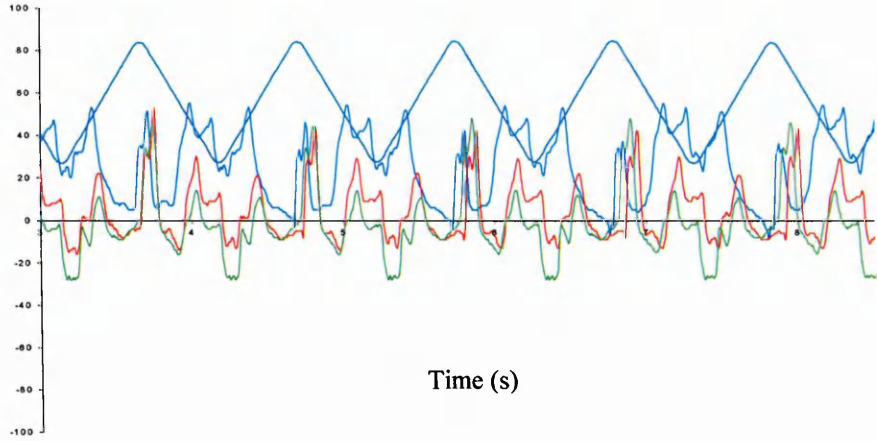
Angle of the knee joint in degrees
Torque (Nm) Test Session 1
Torque (Nm) Test Session 2
Torque (Nm) Test Session 3

R60°/s Post-FES



Time (s)

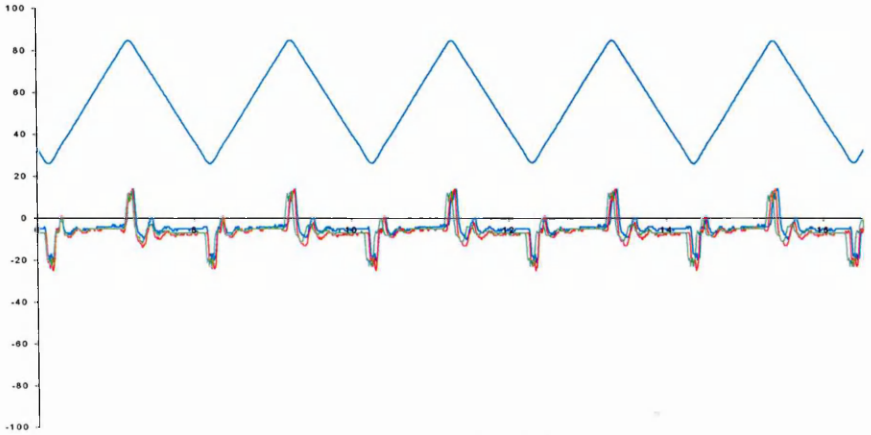
R120°/s Post-FES



Time (s)

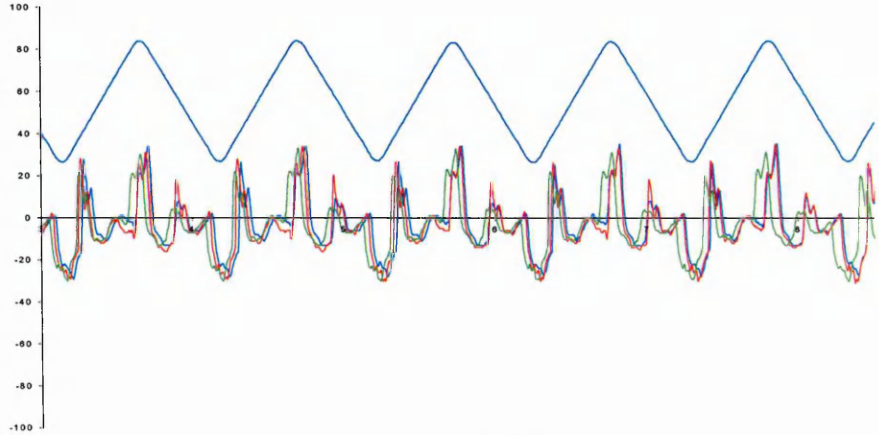
Subject 009 Isokinetic Torque Data

R60°/s Pre-FES



Time (s)

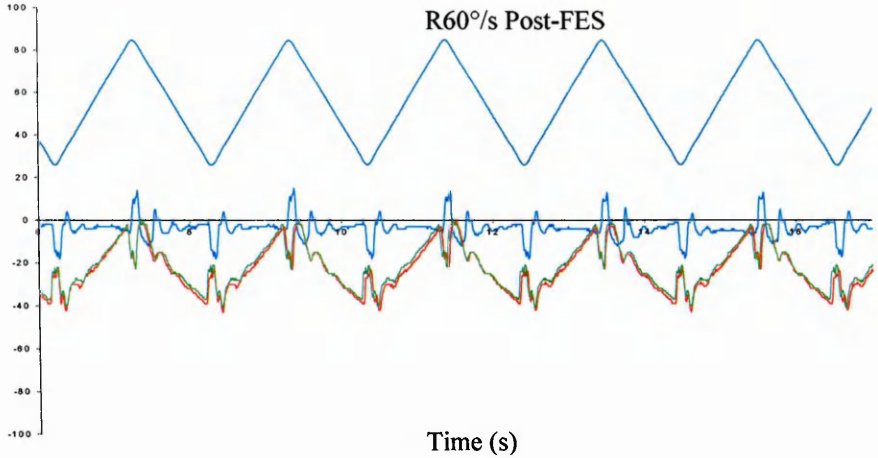
R120°/s Pre-FES



Time (s)

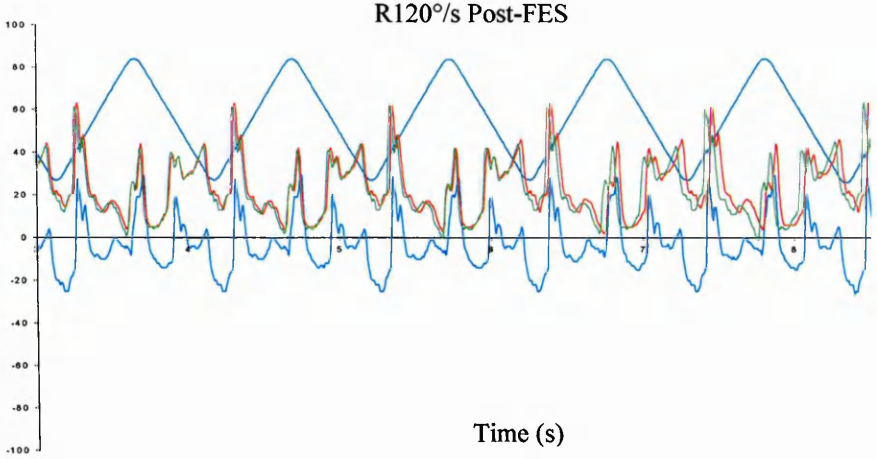
Angle of the knee joint in degrees
Torque (Nm) Test Session 1
Torque (Nm) Test Session 2
Torque (Nm) Test Session 3

R60°/s Post-FES



Time (s)

R120°/s Post-FES

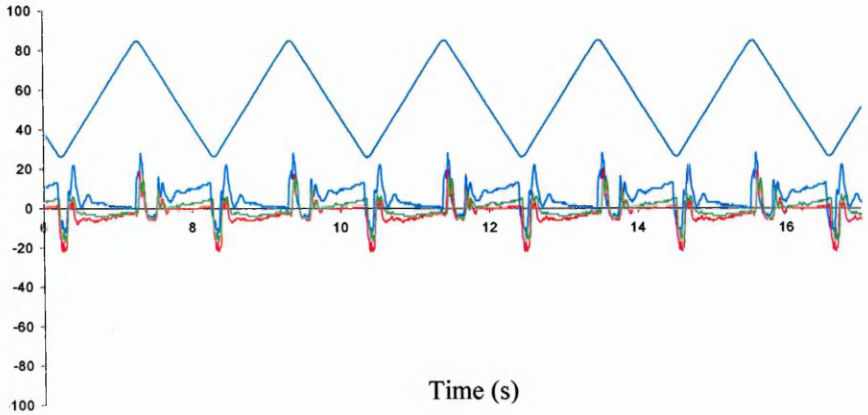


Time (s)

Appendix IV.4

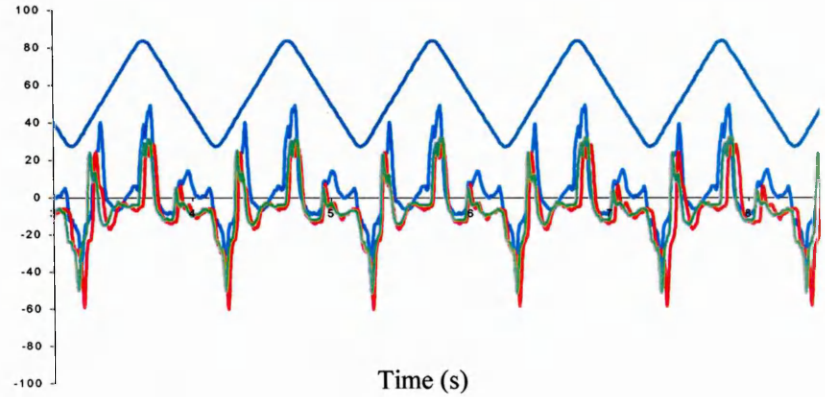
Subject 010 Isokinetic Torque Data

R60°/s Pre-FES



Time (s)

R120°/s Pre-FES

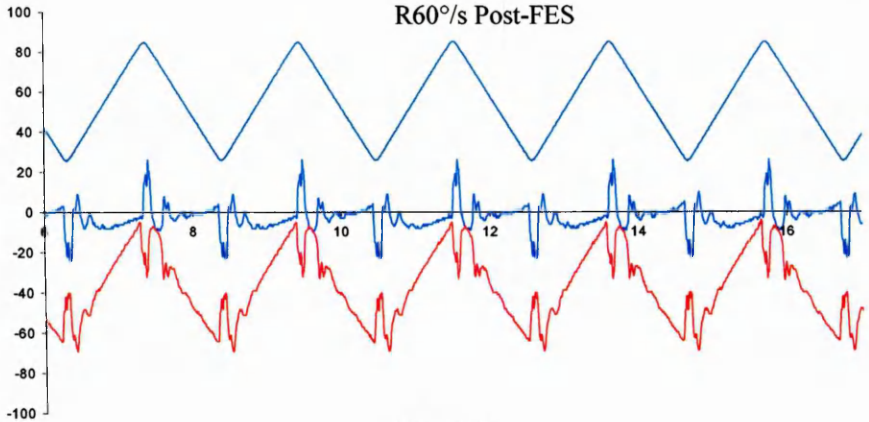


Time (s)

Angle of the knee joint in degrees
Torque (Nm) Test Session 1
Torque (Nm) Test Session 2
Torque (Nm) Test Session 3

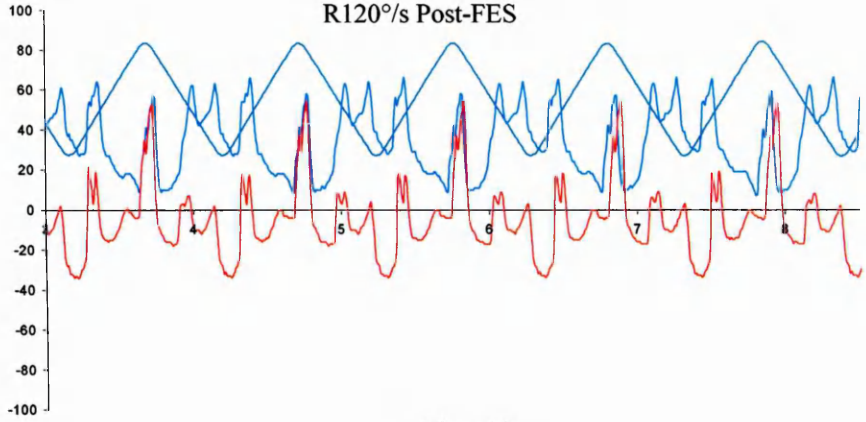
NB: Only 2 test sessions Post-FES

R60°/s Post-FES



Time (s)

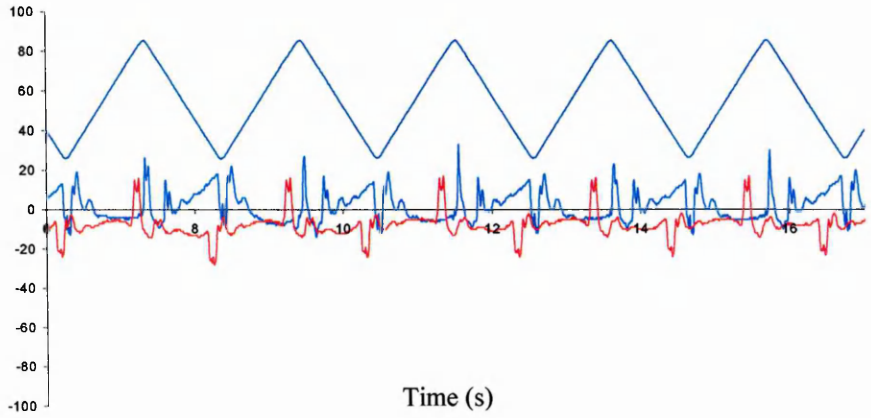
R120°/s Post-FES



Time (s)

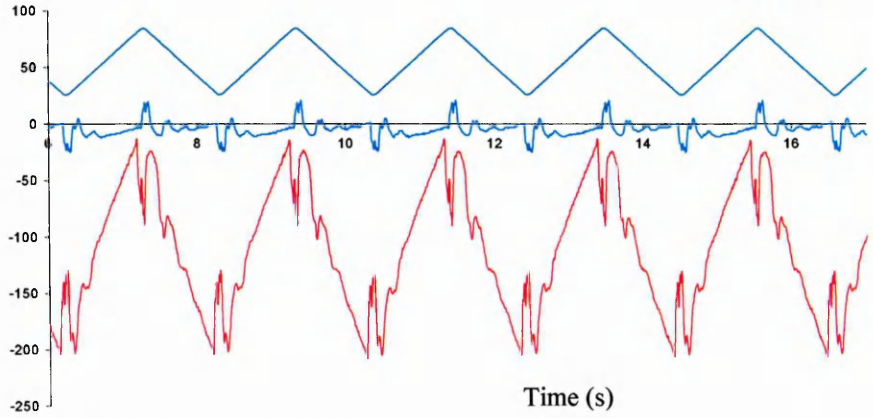
Subject 011 Isokinetic Torque Data

R60°/s Pre-FES



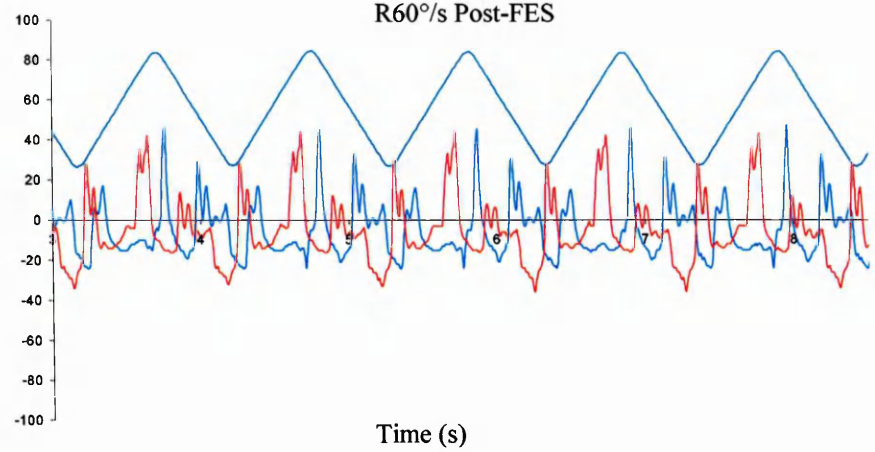
R120°/s Pre-FES

* Note scale



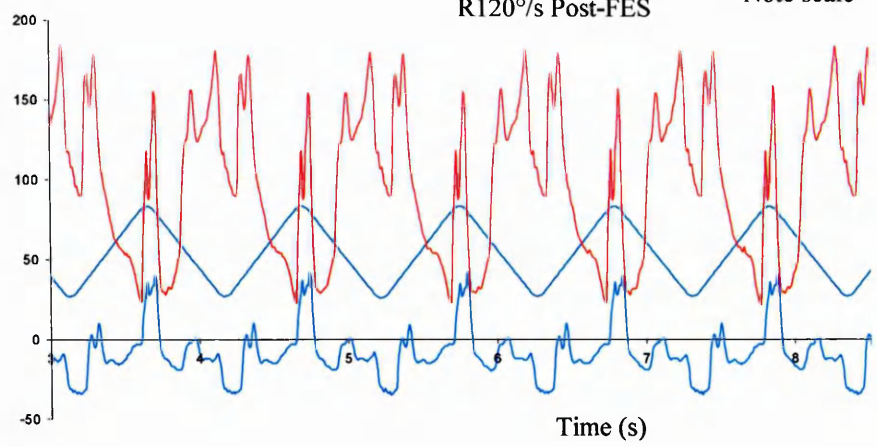
Angle of the knee joint in degrees
Torque (Nm) Test Session 1
Torque (Nm) Test Session 2

R60°/s Post-FES



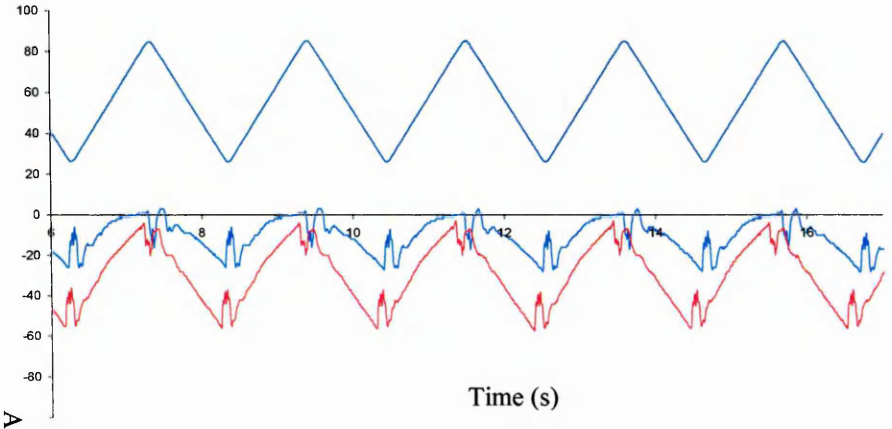
R120°/s Post-FES

* Note scale

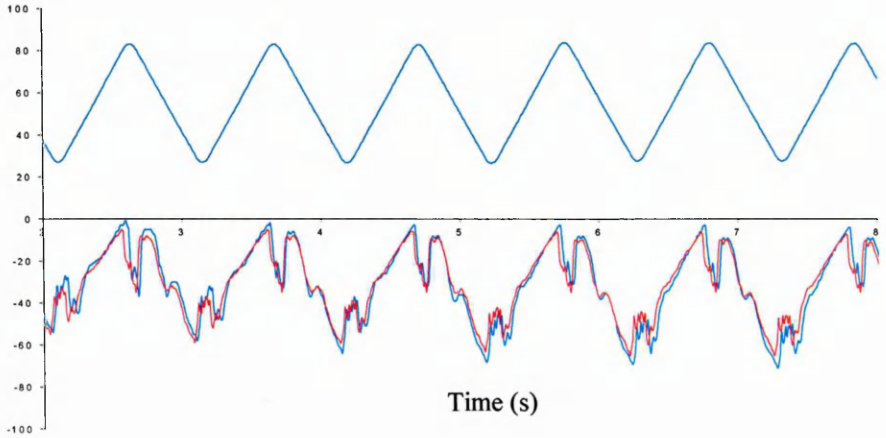


Subject 013 Isokinetic Torque Data

R60°/s Pre-FES



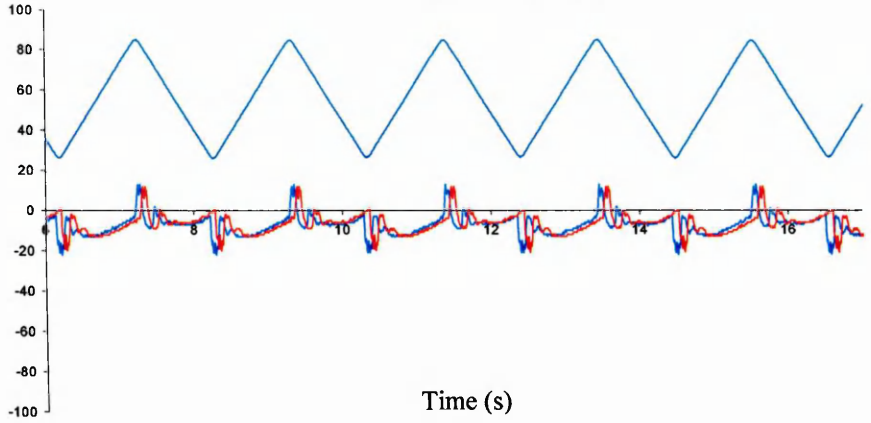
R120°/s Pre-FES



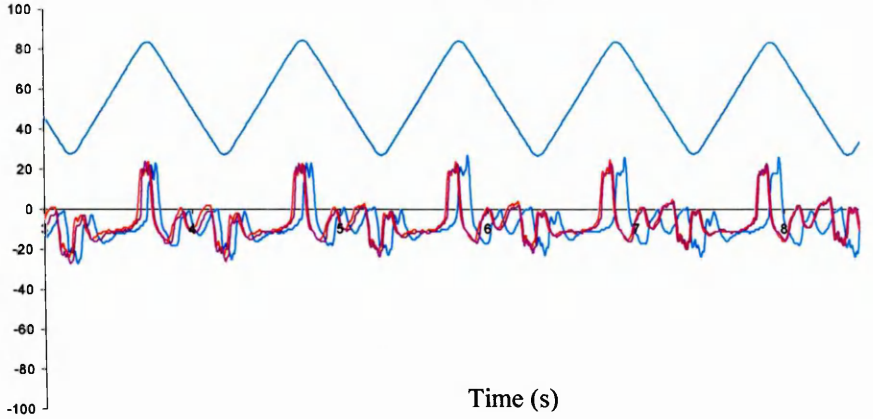
Appendix IV.7

Angle of the knee joint in degrees
Torque (Nm) Test Session 1
Torque (Nm) Test Session 2

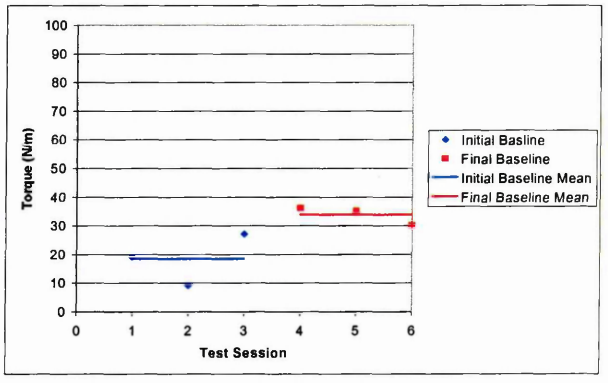
R60°/s Post-FES



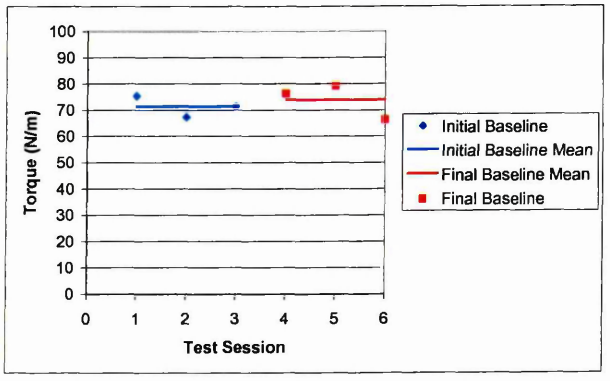
R120°/s Post-FES



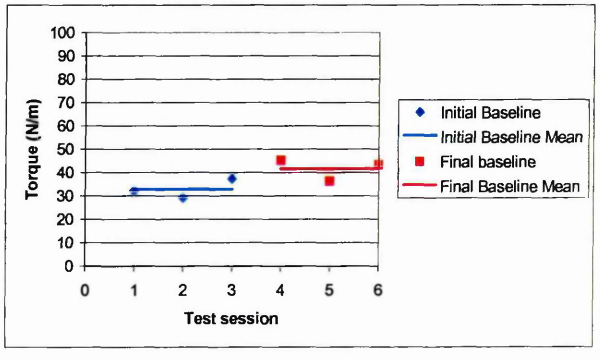
APPENDIX V: Summary of Torque Range data



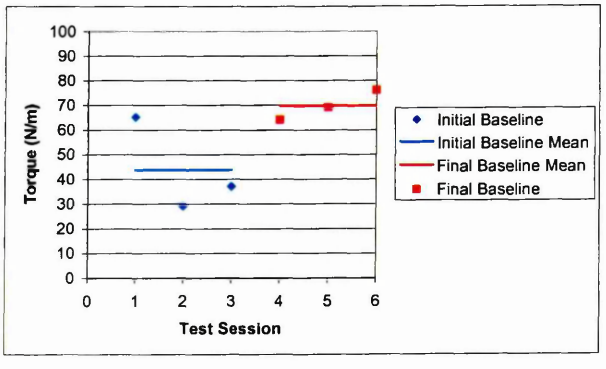
1. Subject 005 60°s



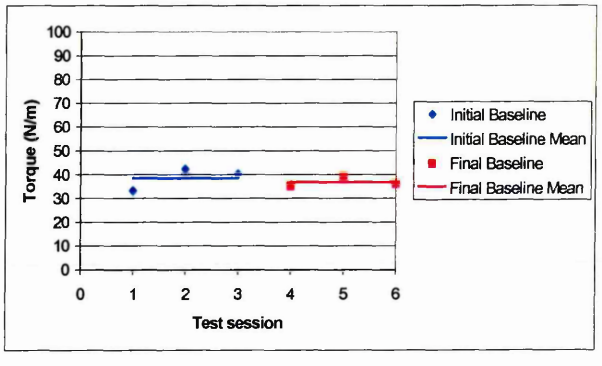
2. Subject 005 120°s



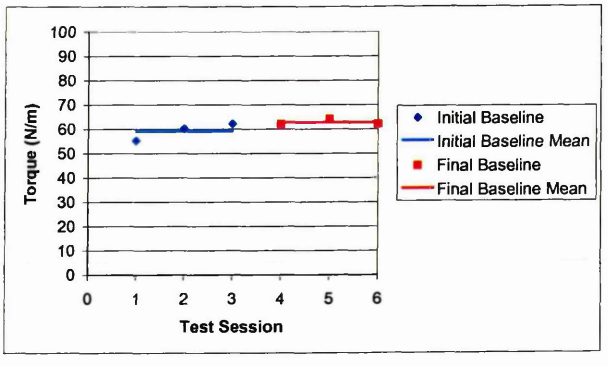
3. Subject 006 60°s



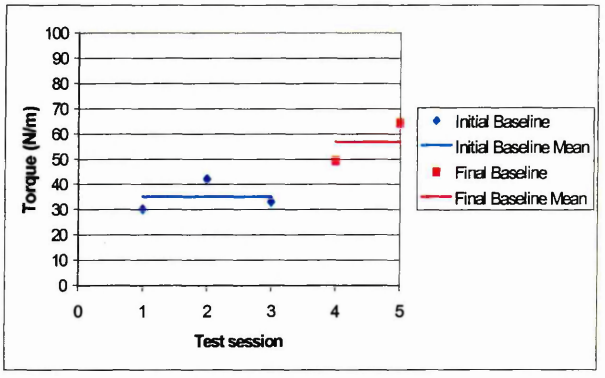
4. Subject 006 120°s



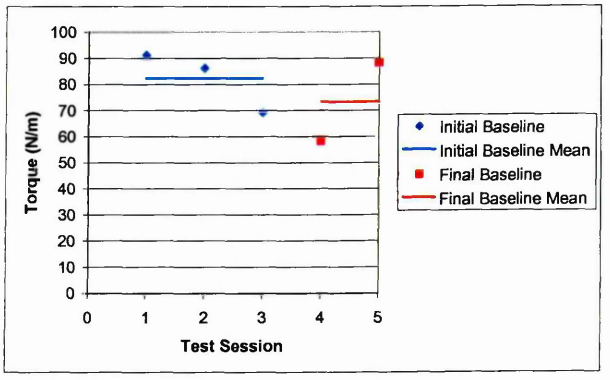
5. Subject 009 60°s



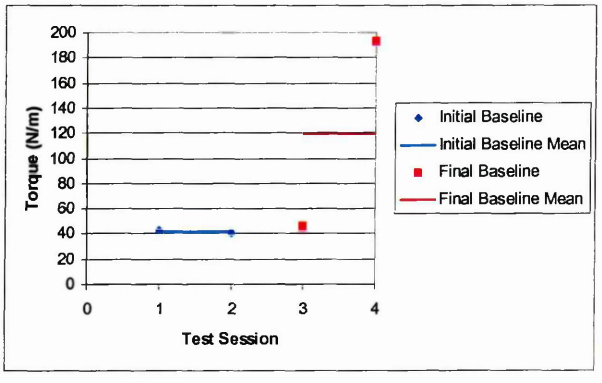
6. Subject 009 120°



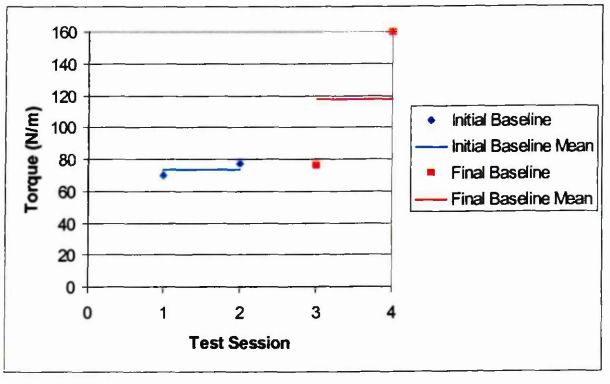
7. Subject 010 60°s



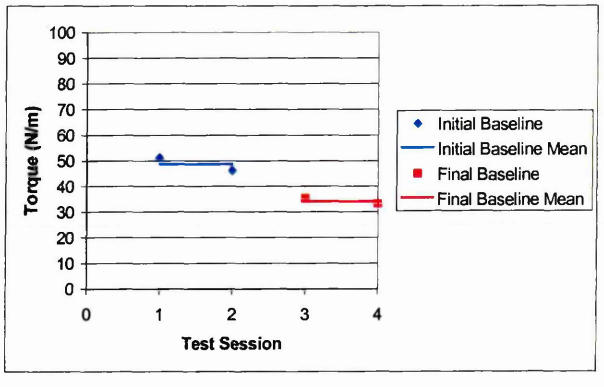
8. Subject 010 120°s



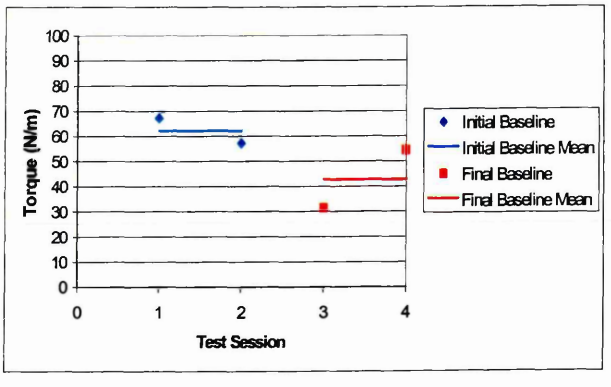
9. Subject 011 60°s



10. Subject 011 120°s



11. Subject 013 60°s



12. Subject 013 120°s

Appendix VI: Rancho Los Amigos Observational Gait Analysis Data

The first eight forms are data from the original assessor; the final four are data collected by the blinded assessor.

1 = initial test session without stimulation

2 = final test session without FES

3 = final test session with FES

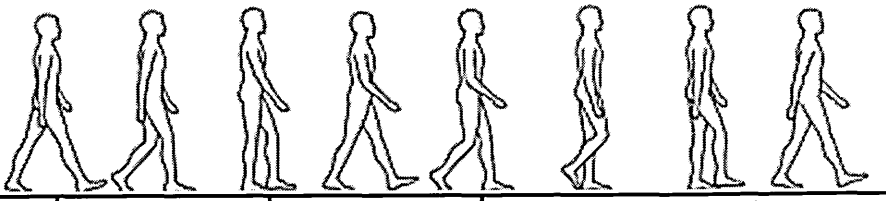
RANCHO LOS AMIGOS MEDICAL CENTRE
PHYSICAL THERAPY DEPARTMENT

CREST

GAIT ANALYSIS: FULL BODY

Patient ID...005

Reference Limb:
L ☐ R ☐



	Weight Accept		Single Limb Support		Swing Limb Advancement			
Major Deviation / Minor Deviation	IC	LR	MSt	TSt	PSw	ISw	MSw	TSw
Trunk Lean: B/F		1,2,3	1,2,3	1,2,3	1,2,3	1,2,3	1,2	1,2,3
Lateral Lean: R/L		1,2,3	1,2,3	1,3	1,2,3	1,2,3	1,2,3	1,2,3
Rotates: B/F					2			
Pelvis Hikes					1,2,3	1,2,3	1,2,3	1,2,3
Tilt: P/A								
Lack Forward Rotation		2,3						2,3
Lacks Backward Rotation								
Excess Forward Rotation		1						1
Excess Backward			2			2		
Ipsilateral Drop		3	2,3	3				
Contralateral Drop								
Hip Flexion: Limited		1			1	1,2,3	1,2,3	1
Excess								
Inadequate Extension			1,2,3	2				
Past Retract								
Rotation: IR/ER					1	1	1,2,3	1
Ad/Abduction: Ad/Ab		2			1,2,3	1,2,3	1,2,3	1,2,3
Knee Flexion: Limited		1,2			1,2,3	1,2,3		
Excess								
Inadequate Extension								
Wobbles								
Hyperextends								
Extension Thurst								
Varus/Valgus: Vr/Vl								
Excess Contralateral Flex								
Ankle Forefoot	1,2							
Foot-Flat Contact								
Foot Slap								
Excess Plantar Flexion		1,2	1	1	1	1,2,3	1,2,3	1,2
Excess Dorsiflexion				3				
Inversion/Eversion:Iv/Ev		1,2,3	1,2,3	1,2,3	1,2,3	1,2,3	1,2,3	1,2,3
Heel Off								
No Heel Off								
Drag								
Contralateral Vaulting								
Toes Up								
Inadequate Extension								
Clawed								

Major Problems:
Weight Acceptance Single limb Support Swing Limb Advancement

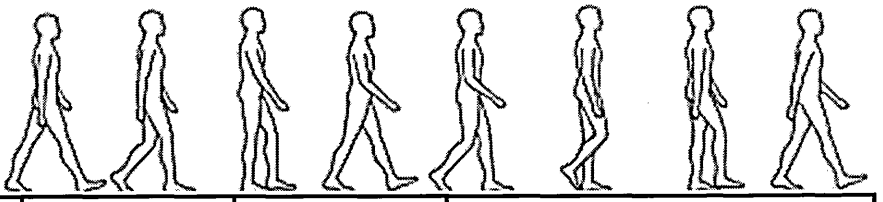
RANCHO LOS AMIGOS MEDICAL CENTRE
PHYSICAL THERAPY DEPARTMENT

CREST

GAIT ANALYSIS: FULL BODY

Patient ID...006

Reference Limb:
L ☐ R ☐



☐ Major Deviation / ▒ Minor Deviation	Weight Accept		Single Limb Support		Swing Limb Advancement			
	IC	LR	MSt	TSt	PSw	ISw	MSw	TSw
Trunk Lean: B/F		1,2,3	2	1	1,2	1	1,2	1,2,3
Lateral Lean: R/L		1,2	1,2,3	1,2	1,2,3	1,2,3	1,2,3	1,2,3
Rotates: B/F		1			1			1
Pelvis Hikes								
Tilt: P/A						1	1	2
Lack Forward Rotation		2						2,3
Lacks Backward Rotation								
Excess Forward Rotation		1	1					
Excess Backward								
Ipsilateral Drop						3		
Contralateral Drop								
Hip Flexion: Limited						1	1,2	1,2,3
Excess		1						
Inadequate Extension								
Past Retract								
Rotation: IR/ER					1		1,3	
Ad/Abduction: Ad/Ab			3		1		1,2,3	
Knee Flexion: Limited					1	1		
Excess							1	
Inadequate Extension								1,2,3
Wobbles		2						
Hyperextends		1						
Extension Thurst		2	2					
Varus/Valgus: Vr/Vl								
Excess Contralateral Flex								
Ankle Forefoot	1,2							
Foot-Flat Contact								
Foot Slap								
Excess Plantar Flexion		1,2,3				1,2	1	1
Excess Dorsiflexion								
Inversion/Eversion:Iv/Ev								
Heel Off								
No Heel Off								
Drag						1,2	1,2	2
Contralateral Vaulting								
Toes Up								
Inadequate Extension								
Clawed								

Major Problems:
Weight Acceptance Single limb Support Swing Limb Advancement

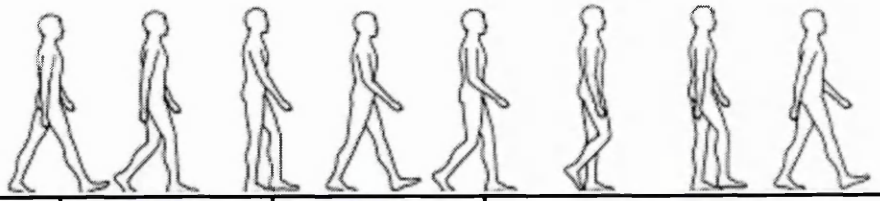
RANCHO LOS AMIGOS MEDICAL CENTRE
PHYSICAL THERAPY DEPARTMENT

CREST

GAIT ANALYSIS: FULL BODY

Patient ID…008

Reference Limb:
L ☐ R ☐



	Weight Accept		Single Limb Support		Swing Limb Advancement			
Major Deviation / Minor Deviation	IC	LR	MSt	TSt	PSw	ISw	MSw	TSw
Trunk Lean: B/F		1,2	1	2	1,2,3	1,2,3	1,2,3	1,2,3
Lateral Lean: R/L		1	1,3	1,2	1,2,3	1,3	1,2,3	1,2
Rotates: B/F								1
Pelvis Hikes					1	1	1,2	1
Tilt: P/A		1			1	1		
Lack Forward Rotation		1						1
Lacks Backward Rotation					1	1		
Excess Forward Rotation								
Excess Backward								
Ipsilateral Drop		3	1,3	1				
Contralateral Drop								
Hip Flexion: Limited						1	1	
Excess								
Inadequate Extension			2		1			
Past Retract								
Rotation: IR/ER								
Ad/Abduction: Ad/Ab		1						
Knee Flexion: Limited					1,2,3	1,2		
Excess								
Inadequate Extension								1,2,3
Wobbles								
Hyperextends								
Extension Thurst			3					
Varus/Valgus: Vr/Vl								
Excess Contralateral Flex								
Ankle Forefoot								
Foot-Flat Contact	1,2							
Foot Slap								
Excess Plantar Flexion					1	1,2	1,2	
Excess Dorsiflexion								
Inversion/Eversion: Iv/Ev			2	2	2	1,2	1,2	2
Heel Off								
No Heel Off								
Drag								
Contralateral Vaulting						1,2,3	1,2,3	3
Toes Up								
Inadequate Extension								
Clawed								

Major Problems:
Weight Acceptance Single limb Support Swing Limb Advancement

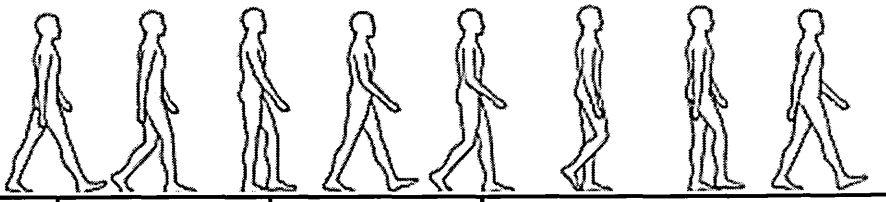
RANCHO LOS AMIGOS MEDICAL CENTRE
PHYSICAL THERAPY DEPARTMENT

CREST

GAIT ANALYSIS: FULL BODY

Patient ID...009

Reference Limb:
L ☐ R ☐



	Weight Accept		Single Limb Support		Swing Limb Advancement			
Major Deviation / Minor Deviation	IC	LR	MSt	TSt	PSw	ISw	MSw	TSw
Trunk Lean: B/F		1,2,3	1,2,3	1,2,3	1,2,3	1,2,3	1,2,3	1,2,3
Lateral Lean: R/L		1,2	1,2,3	1,2,3	1,2	1,2	1,2,3	1,2,3
Rotates: B/F								
Pelvis Hikes					1,2	1,2,3	1,2,3	1,2
Tilt: P/A								
Lack Forward Rotation		2						
Lacks Backward Rotation								
Excess Forward Rotation								
Excess Backward								
Ipsilateral Drop			2					
Contralateral Drop								
Hip Flexion: Limited					1	1,2,3	1,2,3	
Excess								
Inadequate Extension			1,2,3					
Past Retract								
Rotation: IR/ER						2		
Ad/Abduction: Ad/Ab		2			2	1	1	
Knee Flexion: Limited		1,2,3			1,2,3	1,2,3		
Excess								
Inadequate Extension								1
Wobbles								
Hyperextends			1,2,3					
Extension Thurst								
Varus/Valgus: Vr/Vl								
Excess Contralateral Flex								
Ankle Forefoot								
Foot-Flat Contact	1							
Foot Slap								
Excess Plantar Flexion			1,2,3			1,2,?3	1,2	
Excess Dorsiflexion								
Inversion/Eversion:Iv/Ev								
Heel Off								
No Heel Off								
Drag								
Contralateral Vaulting								
Toes Up								
Inadequate Extension								
Clawed								

Major Problems:
Weight Acceptance Single limb Support Swing Limb Advancement

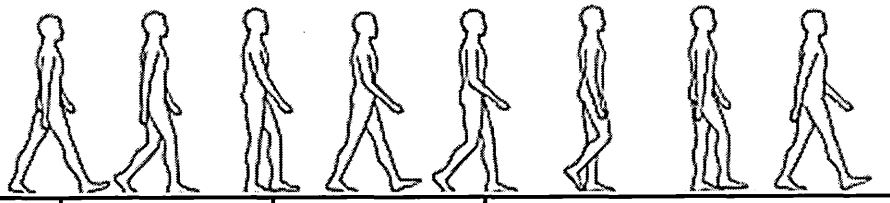
RANCHO LOS AMIGOS MEDICAL CENTRE
PHYSICAL THERAPY DEPARTMENT

CREST

GAIT ANALYSIS: FULL BODY

Patient ID 010

Reference Limb:
L ☐ R ☐



☐ Major Deviation / ▨ Minor Deviation	Weight Accept		Single Limb Support		Swing Limb Advancement			
	IC	LR	MSt	TSt	PSw	ISw	MSw	TSw
Trunk Lean: B/F		1,2,3	1,2,3		1,2,3	1,2,3	1,2,3	1,2,3
Lateral Lean: R/L		1,2	2,3	1	1,2,3	?2	1,2	1
Rotates: B/F		1	1	1	1	1	1,2	
Pelvis Hikes							2	
Tilt: P/A			1	1	1	1		
Lack Forward Rotation								1
Lacks Backward Rotation								
Excess Forward Rotation							1,2	
Excess Backward				1	2	2		
Ipsilateral Drop					1,2	1,2,3	1,3	2
Contralateral Drop								
Hip Flexion: Limited					2	1,2,3	1	
Excess		1						
Inadequate Extension			1,3					
Past Retract								1
Rotation: IR/ER		2	2	1,2,3	1,2,3	1,2,3	1,2	
Ad/Abduction: Ad/Ab		2			1	1,2	2	2
Knee Flexion: Limited					1,2,3	1,2,3		
Excess								
Inadequate Extension								1,2,3
Wobbles		1,2						
Hyperextends		1,2,3	1,2,3	1				
Extension Thurst		1						
Varus/Valgus: Vr/Vl								
Excess Contralateral Flex								
Ankle Forefoot	1,2							
Foot-Flat Contact								
Foot Slap								
Excess Plantar Flexion		1,3	1,2,3	1,3	1	1,2,3	1,2	2
Excess Dorsiflexion								
Inversion/Eversion:Iv/Ev							1,2	1
Heel Off			1					
No Heel Off								
Drag						1,2,3	1,2	2
Contralateral Vaulting						1	1,2,3	1,2,3
Toes Up								
Inadequate Extension								
Clawed								

Major Problems:
Weight Acceptance Single limb Support Swing Limb Advancement

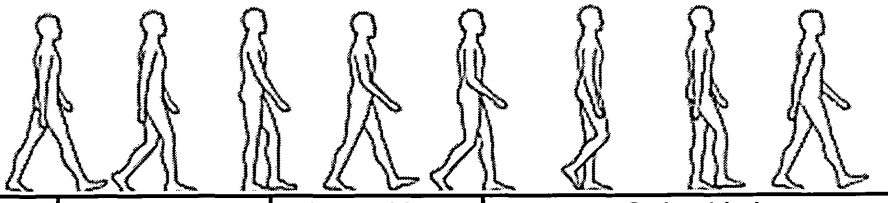
RANCHO LOS AMIGOS MEDICAL CENTRE
PHYSICAL THERAPY DEPARTMENT

CREST

GAIT ANALYSIS: FULL BODY

Patient ID...011

Reference Limb:
L ☐ R ☐



	Weight Accept		Single Limb Support		Swing Limb Advancement			
Major Deviation / Minor Deviation	IC	LR	MSt	TSt	PSw	ISw	MSw	TSw
Trunk Lean: B/F		1,2,3	1,2,3	2	1,2,3	1,2,3	1,2	2
Lateral Lean: R/L		1	1,2,3	1,2,3	2,3	1,2,3	1,2,3	1,3
Rotates: B/F		1,2,3				2	1,2	1,2,3
Pelvis Hikes						1,2,3	1,2,3	1
Tilt: P/A								
Lack Forward Rotation		1,2,3						1,2
Lacks Backward Rotation								
Excess Forward Rotation								
Excess Backward						1,2,3	2	
Ipsilateral Drop				2	2			
Contralateral Drop							2,3	
Hip Flexion: Limited					1	1,2	1	
Excess								
Inadequate Extension			1,2,3					
Past Retract								
Rotation: IR/ER							1,2	1,2,3
Ad/Abduction: Ad/Ab				2		1	1	1
Knee Flexion: Limited					1,2,3	1,2,3		
Excess								
Inadequate Extension								1,2,3
Wobbles								
Hyperextends			1,2					
Extension Thurst								
Varus/Valgus: Vr/Vl								
Excess Contralateral Flex								1
Ankle Forefoot								
Foot-Flat Contact	1,2,3							
Foot Slap								
Excess Plantar Flexion			1		2,3	1,2	1,2	1
Excess Dorsiflexion								
Inversion/Eversion:Iv/Ev					1	1	1	1
Heel Off								
No Heel Off								
Drag								
Contralateral Vaulting						1,2,3	1,2,3	1,2,3
Toes Up								
Inadequate Extension								
Clawed								

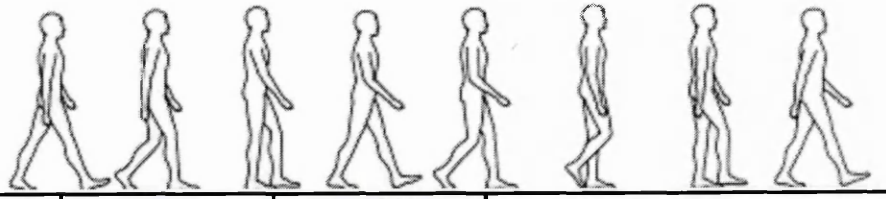
Major Problems:
Weight Acceptance Single limb Support Swing Limb Advancement

CREST

GAIT ANALYSIS: FULL BODY

Patient ID…012

Reference Limb:
L ☐ **R** ☐



	Weight Accept		Single Limb Support		Swing Limb Advancement			
Major Deviation / Minor Deviation	IC	LR	MSt	TSt	PSw	ISw	MSw	TSw
Trunk Lean: B/F		1,2,3	1,2,3	1,2,3	1,2,3	1,2,3	1,2,3	1,2
Lateral Lean: R/L					1	1	1	1
Rotates: B/F					1			
Pelvis Hikes								
Tilt: P/A								
Lack Forward Rotation								
Lacks Backward Rotation								
Excess Forward Rotation								
Excess Backward								
Ipsilateral Drop								
Contralateral Drop								
Hip Flexion: Limited								
Excess								
Inadequate Extension			1,2,3	2	1			
Past Retract								1
Rotation: IR/ER					1			
Ad/Abduction: Ad/Ab								
Knee Flexion: Limited								
Excess		1						
Inadequate Extension								1,2,3
Wobbles								
Hyperextends								
Extension Thurst		1	1					
Varus/Valgus: Vr/Vl								
Excess Contralateral Flex								
Ankle Forefoot								
Foot-Flat Contact	1,2							
Foot Slap								
Excess Plantar Flexion						2,3		
Excess Dorsiflexion							1	
Inversion/Eversion: Iv/Ev		1	1	1	1		1	2
Heel Off								
No Heel Off								
Drag								
Contralateral Vaulting								
Toes Up								
Inadequate Extension								
Clawed								

Major Problems:
Weight Acceptance Single limb Support Swing Limb Advancement

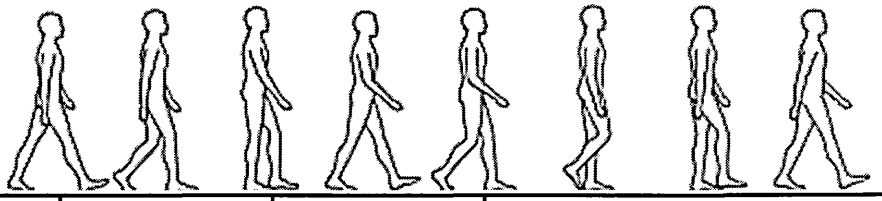
RANCHO LOS AMIGOS MEDICAL CENTRE
PHYSICAL THERAPY DEPARTMENT

CREST

GAIT ANALYSIS: FULL BODY

Patient ID...013

Reference Limb:
L ☐ R ☐



☐ Major Deviation / ▒ Minor Deviation	Weight Accept		Single Limb Support		Swing Limb Advancement			
	IC	LR	MSt	TSt	PSw	ISw	MSw	TSw
Trunk Lean: R/F			2,3	1	3	1,2,3	1,2,3	1,2
Lateral Lean: R/L		2			1,2,3	1,3		1,2
Rotates: B/F		1,2					2,3	1,2
Pelvis Hikes								
Tilt: P/A								
Lack Forward Rotation								
Lacks Backward Rotation								
Excess Forward Rotation								
Excess Backward								
Ipsilateral Drop					2	2		
Contralateral Drop								
Hip Flexion: Limited							1,3	
Excess		1						
Inadequate Extension			1					
Past Retract								
Rotation: IR/ER								
Ad/Abduction: Ad/Ab								
Knee Flexion: Limited					1,2,3	1,2,3		
Excess								
Inadequate Extension			1	1,3				1,2,3
Wobbles								
Hyperextends								
Extension Thurst								
Varus/Valgus: Vr/Vl								
Excess Contralateral Flex								
Ankle Forefoot								
Foot-Flat Contact	1,2,3							
Foot Slap								
Excess Plantar Flexion						2		
Excess Dorsiflexion			1					
Inversion/Eversion:Iv/Ev								
Heel Off								
No Heel Off								
Drag								
Contralateral Vaulting						2	1,2,3	1,2,3
Toes Up								
Inadequate Extension								
Clawed								

Major Problems:
Weight Acceptance Single limb Support Swing Limb Advancement

☐

RANCHO LOS AMIGOS MEDICAL CENTRE
PHYSICAL THERAPY DEPARTMENT

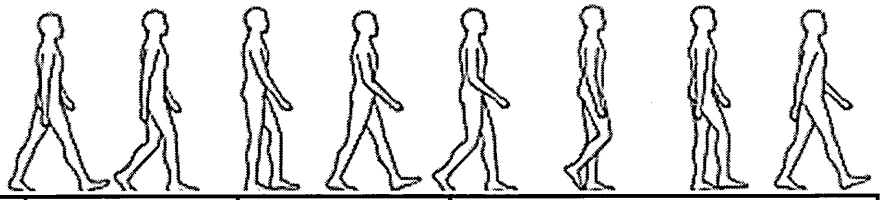
Appendix VI

CREST

GAIT ANALYSIS: FULL BODY

Patient ID...008.....

Reference Limb:
L ☐ R ☐



Major Deviation
Minor Deviation

	Weight Accept		Single Limb Support		Swing Limb Advancement			
	IC	LR	MSt	TSt	PSw	ISw	MSw	TSw
Trunk Lean: B/F		3	1,3		1,3	1,3	1,3	1
Lateral Lean: R/L		1,1	3	1	1	1,3	3	3
Rotates: B/F								
Pelvis Hikes					1	1,3	1,3	
Tilt: P/A		1	1		1			
Lack Forward Rotation								
Lacks Backward Rotation								
Excess Forward Rotation								
Excess Backward						3	3	
Ipsilateral Drop								
Contralateral Drop		1,3	1	1				
Hip Flexion: Limited								
Excess								
Inadequate Extension					3			
Past Retract								
Rotation: IR/ER		1	1			1,3		1
Ad/Abduction: Ad/Ab		1	1,3	1,3	1		1	1,3
Knee Flexion: Limited					1	1		
Excess								
Inadequate Extension								1,3
Wobbles								
Hyperextends			1,3	1,3				
Extension Thurst								
Varus/Valgus: Vr/Vl			3					
Excess Contralateral Flex								1
Ankle Forefoot								
Foot-Flat Contact								
Foot Slap								
Excess Plantar Flexion		1					1	1
Excess Dorsiflexion					3	3		
Inversion/Eversion:Iv/Ev		3	1,3	1,3	1	1	1	1
Heel Off								
No Heel Off								
Drag								
Contralateral Vaulting						1,3	1,3	1,3
Toes Up								
Inadequate Extension								
Clawed								

Major Problems:
Weight Acceptance Single limb Support Swing Limb Advancement

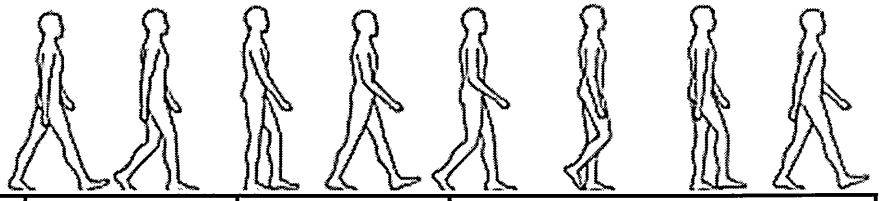
RANCHO LOS AMIGOS MEDICAL CENTRE
PHYSICAL THERAPY DEPARTMENT

CREST

GAIT ANALYSIS: FULL BODY

Patient ID 009.....

Reference Limb:
L ☐ R ☐



☐ Major Deviation
▒ Minor Deviation

	Weight Accept		Single Limb Support		Swing Limb Advancement			
	IC	LR	MSt	TSt	PSw	ISw	MSw	TSw
Trunk Lean: R/F		3	1,3	1	1,3	1,3	1,3	
Lateral Lean: R/L		3	1,3	1,3				
Rotates: B/F		▒	▒	▒	▒	▒	▒	▒
Pelvis Hikes		■	■	■	1	1,3	1,3	▒
Tilt: P/A		▒			▒			▒
Lack Forward Rotation		▒	■	■	■	■	■	
Lacks Backward Rotation		■			▒	▒	■	■
Excess Forward Rotation		▒	▒	■	■	■	▒	▒
Excess Backward		■	▒	▒	▒	▒	▒	■
Ipsilateral Drop		▒	▒	▒				
Contralateral Drop					▒	▒	▒	▒
Hip Flexion: Limited			■	■	1,3	1,3	1,3	
Excess		■	■	■	■	▒	▒	▒
Inadequate Extension		■	3		▒	■	■	■
Past Retract		■	■	■	■	■	■	
Rotation: IR/ER		▒	▒	▒	▒	3	1	▒
Ad/Abduction: Ad/Ab		3	▒	▒	▒	1,3	1	3
Knee Flexion: Limited			■	■	1,3	1,3	■	■
Excess		■	■	■	▒	▒	▒	■
Inadequate Extension		■			■	■	■	
Wobbles					■	■	■	■
Hyperextends		1,3	1,3	1,3	1	■	■	▒
Extension Thurst					▒	■	■	▒
Varus/Valgus: Vr/Vl		1,3	1,3	1,3	3	■	■	■
Excess Contralateral Flex	■	■	■	■				
Ankle Forefoot		■	■	■	■	■	■	■
Foot-Flat Contact	1	■	■	■	■	■	■	■
Foot Slap	■		■	■	■	■	■	■
Excess Plantar Flexion	■	3	3		▒			
Excess Dorsiflexion	■					▒	▒	▒
Inversion/Eversion:Iv/Ev	■			3	1,3	1	1	
Heel Off	■			■	■	■	■	■
No Heel Off	■	■	■			■	■	■
Drag	■	■	■	■	■			
Contralateral Vaulting	■	■	■	■				
Toes Up	■							
Inadequate Extension	■	■	■			■	■	■
Clawed	■							

Major Problems:
Weight Acceptance Single limb Support Swing Limb Advancement

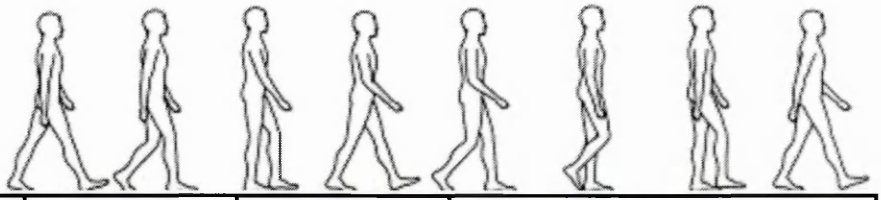
RANCHO LOS AMIGOS MEDICAL CENTRE
PHYSICAL THERAPY DEPARTMENT

CREST

GAIT ANALYSIS: FULL BODY

Patient ID 011.....

Reference Limb:
L ☐ R ☐



Major Deviation
Minor Deviation

	Weight Accept		Single Limb Support		Swing Limb Advancement			
	IC	LR	MSt	TSt	PSw	ISw	MSw	TSw
Trunk Lean: B/F			1	1	1,3	1	1	
Lateral Lean: R/L				1	3	1	1,3	1,3
Rotates: B/F						1	1	1
Pelvis Hikes					1	1	1	1
Tilt: P/A			1		1			
Lack Forward Rotation								1
Lacks Backward Rotation								
Excess Forward Rotation								
Excess Backward					1	1?		
Ipsilateral Drop							3	
Contralateral Drop								
Hip Flexion: Limited					1,3	1,3		
Excess								
Inadequate Extension								
Past Retract								
Rotation: IR/ER						3	3	1
Ad/Abduction: Ad/Ab		3	3	3	1,3			1,3
Knee Flexion: Limited					1,3	1,3		
Excess								
Inadequate Extension								1,3
Wobbles								
Hyperextends				3?				
Extension Thurst								
Varus/Valgus: Vr/Vl								
Excess Contralateral Flex								
Ankle Forefoot								
Foot-Flat Contact	1,3							
Foot Slap								
Excess Plantar Flexion								1
Excess Dorsiflexion								
Inversion/Eversion:Iv/Ev					3		3	
Heel Off								
No Heel Off								
Drag								
Contralateral Vaulting						1	1,3	1,3
Toes Up								
Inadequate Extension								
Clawed								

Major Problems:
Weight Acceptance Single limb Support Swing Limb Advancement

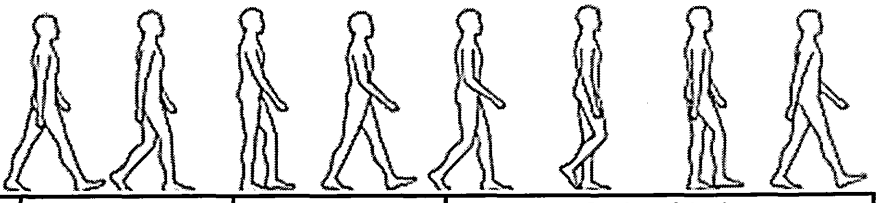
RANCHO LOS AMIGOS MEDICAL CENTRE
PHYSICAL THERAPY DEPARTMENT

CREST

GAIT ANALYSIS: FULL BODY

Patient ID.....012...

Reference Limb:
L ☐ R ☐



Major Deviation
Minor Deviation

	Weight Accept		Single Limb Support		Swing Limb Advancement			
	IC	LR	MSt	TSt	PSw	ISw	MSw	TSw
Trunk Lean: B/F		1,3	1,3	1,3	1,3	1,3	1,3	1,3
Lateral Lean: R/L								
Rotates: B/F								
Pelvis Hikes					1	1	1	1
Tilt: P/A		?1	?1		1			
Lack Forward Rotation								
Lacks Backward Rotation								
Excess Forward Rotation								
Excess Backward								
Ipsilateral Drop								
Contralateral Drop								
Hip Flexion: Limited								
Excess								
Inadequate Extension			1,3		1			
Past Retract								
Rotation: IR/ER					1	1,3	1,3	3
Ad/Abduction: Ad/Ab						1		3
Knee Flexion: Limited								
Excess								
Inadequate Extension								1,3
Wobbles								
Hyperextends			1??,3?					
Extension Thurst								
Varus/Valgus: Vr/Vl					1?			
Excess Contralateral Flex								
Ankle Forefoot								
Foot-Flat Contact	1,3							
Foot Slap								
Excess Plantar Flexion								
Excess Dorsiflexion					3			
Inversion/Eversion:Iv/Ev				1	1,3	3	3	1
Heel Off								
No Heel Off								
Drag							3	
Contralateral Vaulting								
Toes Up								
Inadequate Extension								
Clawed								

Major Problems:
Weight Acceptance Single limb Support Swing Limb Advancement

Appendix VII: TELER Data Analysis

1. Subject 005

Table 1 Subject 005: TELER codes pre- and post-intervention

Number of indicators by code pre (before) and post (after) intervention						
	Code before					
Code after	0	1	2	3	4	Total
0						
1						
2		1				1
3	2		2			4
4						
5						
Total	2	1	2			5

Key: -------- **Area under dashed line shows clinically significant change**
Area under which indicators show statistically significant improvements at the 95% confidence level

Table 1 summarises the data from the original TELER data collection form (following page). It shows that the admission codes for subject 005 ranged from 0 to 2, with a median code of 1, and a mode of 0 or 2, both of these codes occurring twice on initial assessment. The admission code of two (40%) of the five indicators was 0, one indicator (20%) was graded at code 1, and two (40%) were graded at code 2.

The discharge or outcome codes ranged from code 2 to 3., with a median of 3 and a mode of 3. The discharge outcome code on four (80%) of the five indicators was 3; the other discharge code was 2 (20%).

From the table it can be seen that all the indicators showed some improvement in their code gradings. All entries showed clinically significant improvements. The magnitude of these improvements ranged from 1 to 3 clinically significant stages, with two indicators improving by three codes and three improving by one code. None of the individual indicators in Table 1 showed a statistically significant improvement at the 95% confidence level.

MASTER FORM

Treatment Record

INITIAL ASSESSMENT

GAIT RE-ED WITH FES

FINAL ASSESSMENT - NO FES

FINAL ASSESSMENT - WITH FES

17·1	16·1	30·9	30·9	
✓				
	✓			
		✓		
			✓	

Performance Record

Indicators:

	17·1		16·1		30·9		30·9	
PSw	1		3		0		2	
MSw	2		3		2		3	
LR	0		3		0		3	
IC	0		3		0		3	
MSt	2		3		3		3	
Number of 0 code	2				3			
1 code	1							
2 code	2				1		1	
3 code			5		1		4	
4 code								
5 code								

Indicators as a Group:

Whilst the above analysis of the data shows a clinically significant improvement in walking outcomes following the application of FES it is necessary to show a statistically significant improvement if these are to be attributable to the intervention. The indicators were analysed as a group to consider the overall effects of FES for this subject. The following statistical hypotheses were tested using a probability tree analysis (Le Roux, 2003):

$\mathbf{H_0}$ – there is no improvement in TELER Gait Indicator grades with FES intervention

$\mathbf{H_1}$ – there is an improvement in TELER Gait Indicator grades with FES intervention

To ensure maximum independence between indicators and what they measure, and therefore to minimise co-variance, a minimum of three were selected for analysis. The three chosen were considered to be of most clinical significance to this subject. These indicators were mid-swing, loading response and initial contact. From Table 2 it can be seen that these indicators had a combined score of 2 on initial assessment (2,0,0 respectively), there were 7 clinically significant changes by the time of discharge, giving an outcome score of 9. The results were therefore found to be statistically significant at the 5% one-tailed level. The null hypothesis was rejected and the alternative accepted. There was an improvement in TELER gait indicator grades for this subject, apparently attributable to the FES intervention.

Table 2 shows a decrease in Deficit Index by nearly half from 80 to 44. The Improvement Index was calculated as 45; meaning that there was an improvement in this subjects identified problems during treatment. The Health Gain Index was 36 and therefore smaller than the Improvement Index, denoting a chronic disability.

The clinical significance of these improvements is inherent within the structure of the indicators. Each code is a clinically significant outcome needed for 'normal' gait.

Table 2: Worksheet for the TELER Index (recovery) for Subject 005

Item	Expected Outcome	Visit	
		1 Pre-FES	2 With FES
Pre-swing	5	1	2
Mid-swing	5	2	3
Loading response	5	0	3
Initial contact	5	0	3
Mid-stance	5	2	3
Total number of missing scores			0
Deficit Index		80	44
Improvement index			45
Health Gain Index			36

2. Subject 006

Table 3 Subject 006: TELER codes pre- and post-intervention

Number of indicators by code pre (before) and post (after) intervention						
Code after	Code before 0	1	2	3	4	Total
0						
1						
2		1	1			2
3						
4		1	2			3
5						
Total		2	3			5

Key: -------- **Area under dashed line shows clinically significant change**
Area under which indicators show statistically significant improvements at the 95% confidence level

Table 3 summarises the data from the original TELER data collection form (following page). It shows that the admission codes for subject 006 ranged from 1 to 2, with a median code of 2, and a mode of 2. The admission code of two (40%) of the five indicators was 1, three indicators (60%) were graded at code 2.

The discharge or outcome codes ranged from code 2 to 4, with a median of 4 and a mode of 4. The discharge outcome code on three (60%) of the five indicators was 4; two were coded 2 (40%).

From the table it can be seen that four of the five indicators showed some improvement in their code gradings. One showed no change. The magnitude of the improvements ranged from 1 to 3 clinically significant stages, with one indicator improving by three codes, two improving by two codes and one improving by one code. None of the individual indicators in Table 3 showed a statistically significant improvement at the 95% confidence level.

Indicators as a Group:

Whilst the above analysis of the data shows a clinically significant improvement in walking outcomes following the application of FES it is necessary to show a statistically significant improvement if these are to be attributable to the intervention. The indicators

MASTER FORM

Treatment Record

INITIAL ASSESSMENT
GAIT RE-ED WITH FES
FINAL BASELINE - NO FES
FINAL BASELINE - WITH FES

20.1	19.8	12.10	13.10
✓			
	✓		
		✓	
			✓

Performance Record

Indicators:
PSW
ISW
MSW
TSW
LR

3		4		3		4		
1		3		1		4		
3		4		3		4		
2		1		1		2		
1		3		1		2		
2		1		3				
1						2		
2		2		2				
		2				3		

Number of 0 code
1 code
2 code
3 code
4 code
5 code

were analysed as a group to consider the overall effects of FES for this subject. The following statistical hypotheses were tested using a probability tree analysis:

$\mathbf{H_0}$ – there is no improvement in TELER Gait Indicator grades with FES intervention

$\mathbf{H_1}$ – there is an improvement in TELER Gait Indicator grades with FES intervention

To ensure maximum independence between indicators and what they measure, and therefore to minimise co-variance, a minimum of three were selected for analysis. The three chosen were considered to be of most clinical significance to this subject. These indicators were initial swing, mid-swing and terminal swing. From Table 4 it can be seen that these indicators had a combined score of 6 on initial assessment (1,3,2 respectively), there were 4 clinically significant changes by the time of discharge, giving an outcome score of 10. The results were therefore not found to be statistically significant at the 5% one-tailed level. The null hypothesis was accepted and the alternative rejected. There was no statistically significant change in TELER gait indicator grades for this subject.

Table 4 shows a decrease in Deficit Index from 60 to 36. The Improvement Index was calculated as 40, meaning that there was an improvement in this subjects identified problems during treatment. The Health Gain Index was 24 and therefore smaller than the Improvement Index, denoting a chronic disability.

The clinical significance of these improvements is inherent within the structure of the indicators. Each code is a clinically significant outcome needed for 'normal' gait.

Table 4 Worksheet for the TELER Index (recovery) for Subject 006

Item	Expected Outcome	Visit	
		1 Pre-FES	2 With FES
Pre-swing	5	3	4
Initial swing	5	1	4
Mid-swing	5	3	4
Terminal swing	5	2	2
Loading response	5	1	2
Total number of missing scores			0
Deficit Index		60	36
Improvement index			40
Health Gain Index			24

3. Subject 008

Table 5 Subject 008: TELER codes pre- and post-intervention

Number of indicators by code pre (before) and post (after) intervention						
	Code before					
Code after	0	1	2	3	4	Total
0						
1						
2				1		1
3		1	1			2
4						
5						
Total		1	1	1		3

Key: -------- **Area under dashed line shows clinically significant change**

Area under which indicators show statistically significant improvements at the 95% confidence level

Table 5 summarises the data from the original TELER data collection form (following page). It shows that the admission codes for subject 008 ranged from 1 to 3, with a median of 2. The admission code of one (33.3%) of the three indicators was 1, one indicator (33.3%) was graded at code 2, the other at 3.

The discharge or outcome codes ranged from code 2 to 3, with a median of 3 and a mode of 3. The discharge outcome code on two (66.6%) of the three indicators was 3; one was coded 2 (33.3%).

From the table it can be seen that two indicators showed some improvement in code grading. One showed a deterioration. The magnitude of the improvements ranged from 1 to 2 clinically significant stages, with one indicator improving by two codes and one improving by one code. Neither of the individual indicators that improved showed a statistically significant improvement at the 95% confidence level. The indicator which showed a deterioration lost one code grade.

Indicators as a Group:

The above analysis of the data can be considered as showing some improvement in walking ability. The indicators were analysed as a group to consider the overall effects of FES for this subject. The following statistical hypotheses were tested using a probability tree analysis:

MASTER FORM

Patient: NGH 008

Treatment Record

17·2	28·7	9.12	9·12	
INITIAL ASSESSMENT	✓			
GAIT RE-ED WITH FES		✓		
FINAL BASELINE - NO FES			✓	
FINAL BASELINE - WITH FES				✓

Performance Record

Indicators:									
1 SW	1		2		1		3		
M SW	2		3		3		3		
L R	3		2		1		2		

Number of 0 code
1 code
2 code
3 code
4 code
5 code

H_0 – there is no improvement in TELER Gait Indicator grades with FES intervention

H_1 – there is an improvement in TELER Gait Indicator grades with FES intervention

All three of the chosen indicators were used for analysis. From Table 6 it can be seen that these indicators had a combined score of 6 on initial assessment (1,2,3 respectively), there were 3 clinically significant changes by the time of discharge, giving an outcome score of 8. The results were therefore not found to be statistically significant at the 5% one-tailed level. The null hypothesis was accepted and the alternative rejected. There was no statistically significant change in TELER gait indicator grades for this subject.

Table 6 shows a small decrease in Deficit Index from 60 to 53. The Improvement Index was calculated as 22, meaning that there was an improvement in this subjects identified problems during treatment. The Health Gain Index was 13 and therefore smaller than the Improvement Index, denoting a chronic disability.

The clinical significance of these improvements is inherent within the structure of the indicators. Each code is a clinically significant outcome needed for 'normal' gait.

Table 6 Worksheet for the TELER Index (recovery) for Subject 008

Item	Expected Outcome	Visit	
		1 Pre-FES	2 With FES
Initial swing	5	1	3
Mid-swing	5	2	3
Loading response	5	3	2
Total number of missing scores			0
Deficit Index		60	53
Improvement index			22
Health Gain Index			13

4. Subject 009

Table 7 Subject 009: TELER codes pre- and post-intervention

Number of indicators by code pre (before) and post (after) intervention						
	Code before					
Code after	0	1	2	3	4	Total
0						
1						
2		1	1			2
3			1			1
4				1		1
5						
Total		1	2	1		4

Key: -------- **Area under dashed line shows clinically significant change**
Area under which indicators show statistically significant improvements at the 95% confidence level

Table 7 summarises the data from the original TELER data collection form (following page). It shows that the admission codes for subject 009 ranged from 1 to 3, with a median code of 2, and a mode of 2. The admission code of one (25%) of the four indicators was 1, two indicators (50%) were graded at code 2, and one (25%) was grade 3.

The discharge or outcome codes ranged from code 2 to 4, with a median of 2 and a mode of 2. The discharge outcome code on one (25%) of the four indicators was 4; one (25%) was coded 3, and two were coded 2 (50%).

From the table it can be seen that three of the four indicators showed some improvement in their code gradings. One showed no change. The magnitude of the improvements was one clinically significant change in all cases. None of the individual indicators in Table 7 showed a statistically significant improvement at the 95% confidence level.

Indicators as a Group:

Whilst the above analysis of the data shows a clinically significant improvement in walking outcomes following the application of FES it is necessary to show a statistically significant improvement if these are to be attributable to the intervention. The indicators were analysed as a group to consider the overall effects of FES for this subject. The following statistical hypotheses were tested using a probability tree analysis:

MASTER FORM

Patient: NGH009

Treatment Record

INITIAL ASSESSMENT

FINAL ASSESSMENT - NO FES

FINAL ASSESSMENT - WITH FES

16·3	17·8	18·8		
✓				
	✓			
		✓		

Performance Record

Indicators: PSW
ISW
MSW
TSW

2			2		2				
1			2		2				
2			3		3				
3			2		4				
1									
2			3		2				
1			1		1				
					1				

Number of 0 code
1 code
2 code
3 code
4 code
5 code

H_0 – there is no improvement in TELER Gait Indicator grades with FES intervention

H_1 – there is an improvement in TELER Gait Indicator grades with FES intervention

To ensure maximum independence between indicators and what they measure, and therefore to minimise co-variance, a minimum of three were selected for analysis. The three chosen were considered to be of most clinical significance to this subject. These indicators were initial swing, mid-swing and terminal swing. From Table 8 it can be seen that these indicators had a combined score of 6 on initial assessment (1,2,3, respectively), there were 3 clinically significant changes by the time of discharge, giving an outcome score of 9. The results were therefore not found to be statistically significant at the 5% one-tailed level. The null hypothesis was accepted and the alternative rejected. There was no statistically significant change in TELER gait indicator grades for this subject.

Table 8 shows a decrease in Deficit Index from 60 to 46. The Improvement Index was calculated as 25, meaning that there was an improvement in this subjects identified problems during treatment. The Health Gain Index was 15 and therefore smaller than the Improvement Index, denoting a chronic disability.

The clinical significance of these improvements is inherent within the structure of the indicators. Each code is a clinically significant outcome needed for 'normal' gait.

Table 8 Worksheet for the TELER Index (recovery) for Subject 009

Item	Expected Outcome	Visit	
		1 Pre-FES	2 With FES
Pre-swing	5	2	2
Initial swing	5	1	2
Mid-swing	5	2	3
Terminal swing	5	3	4
Total number of missing scores			0
Deficit Index		60	45
Improvement index			25
Health Gain Index			15

5. Subject 010

Table 9 Subject 010: TELER codes pre- and post-intervention

Number of indicators by code pre (before) and post (after) intervention						
	Code before					
Code after	0	1	2	3	4	Total
0						
1						
2		1				1
3	1	1				2
4			1			1
5						
Total	1	2	1			4

Key: ------- **Area under dashed line shows clinically significant change**
Area under which indicators show statistically significant improvements at the 95% confidence level

Table 9 summarises the data from the original TELER data collection form (following page). It shows that the admission codes for subject 010 ranged from 0 to 2, with a median code of 2, and a mode of 2. The admission code of one (25%) of the four indicators was 0, two indicators (50%) were graded at code 1, and one (25%) was grade 2.

The discharge or outcome codes ranged from code 2 to 4, with a median of 2 and a mode of 2. The discharge outcome code on one (25%) of the four indicators was 4; two (50%) was coded 3, and one was coded 2 (25%).

From the table it can be seen that all the indicators showed some improvement in their code gradings. All entries showed clinically significant improvements. The magnitude of these improvements ranged from 1 to 3 clinically significant stages, with one indicator improving by three codes, two improving by two codes and one improving by one code. None of the individual indicators in Table 9 showed a statistically significant improvement at the 95% confidence level.

Indicators as a Group:

Whilst the above analysis of the data shows a clinically significant improvement in walking outcomes following the application of FES it is necessary to show a statistically significant improvement if these are to be attributable to the intervention. The indicators were analysed as a group to consider the overall effects of FES for this subject. The following statistical hypotheses were tested using a probability tree analysis:

TELER

MASTER FORM

Patient: NGH 010

Treatment Record

INITIAL ASSESSMENT
GAIT RE-ED WITH FES
FINAL BASELINE - NO FES
FINAL BASELINE - WITH FES

22-4	11-10	18-11	7-12	
✓				
	✓			
		✓		
			✓	

Performance Record

Indicators:
PSW
ISW
MSW
TSW

1			3		1		2		
0			3		3		3		
2			2		2		4		
1			3		2		3		
1									
1					1				
2			1		2		1		
			3		1		2		
							1		

Number of 0 code
1 code
2 code
3 code
4 code
5 code

H_0 – there is no improvement in TELER Gait Indicator grades with FES intervention

H_1 – there is an improvement in TELER Gait Indicator grades with FES intervention

To ensure maximum independence between indicators and what they measure, and therefore to minimise co-variance, a minimum of three were selected for analysis. The three chosen were considered to be of most clinical significance to this subject. These indicators were initial swing, mid-swing and terminal swing. From Table 10 it can be seen that these indicators had a combined score of 3 on initial assessment (0,2,1, respectively), there were 7 clinically significant changes by the time of discharge, giving an outcome score of 10. The results were therefore found to be statistically significant at the 5% one-tailed level. The null hypothesis was rejected and the alternative accepted. There was an improvement in TELER gait indicator grades for this subject, apparently attributable to the FES intervention.

Table 10 shows a decrease in Deficit Index by half from 80 to 40. The Improvement Index was calculated as 50, meaning that there was an improvement in this subjects identified problems during treatment. The Health Gain Index was 40 and therefore smaller than the Improvement Index, denoting a chronic disability.

The clinical significance of these improvements is inherent within the structure of the indicators. Each code is a clinically significant outcome needed for 'normal' gait.

Table 10 Worksheet for the TELER Index (recovery) for Subject 010

Item	Expected Outcome	Visit	
		1 Pre-FES	2 With FES
Pre-swing	5	1	2
Initial swing	5	0	3
Mid-swing	5	2	4
Terminal swing	5	1	3
Total number of missing scores			0
Deficit Index		80	40
Improvement index			50
Health Gain Index			40

6. Subject 011

Table 11 Subject 011: TELER codes pre- and post-intervention

Number of indicators by code pre (before) and post (after) intervention						
	Code before					
Code after	0	1	2	3	4	Total
0						
1						
2	1	1				2
3				1		1
4				1		1
5						
Total	1	1		2		4

Key: -------- **Area under dashed line shows clinically significant change**
Area under which indicators show statistically significant improvements at the 95% confidence level

Table 11 summarises the data from the original TELER data collection form (following page). It shows that the admission codes for subject 011 ranged from 0 to 3, with a median code of 2, and a mode of 3. The admission code of one (25%) of the four indicators was 0, one indicator (25%) was graded at code 1, and two (50%) were grade 3.

The discharge or outcome codes ranged from code 2 to 4, with a median of 2.5 and a mode of 2. The discharge outcome code on one (25%) of the four indicators was 4; one (25%) was coded 3, and two were coded 2 (50%).

From the table it can be seen that three of the four indicators showed some improvement in their code gradings. One showed no change. The magnitude of the improvements ranged from 1 to 2 clinically significant stages, with one indicator improving by two codes and two improving by one code. None of the individual indicators that improved showed a statistically significant improvement at the 95% confidence level.

Indicators as a Group:

Whilst the above analysis of the data shows a clinically significant improvement in walking outcomes following the application of FES it is necessary to show a statistically significant improvement if these are to be attributable to the intervention. The indicators

MASTER FORM

Patient: NGH 011

Treatment Record

18.5	10.11	25.11	25.11	
✓				
	✓			
		✓		
			✓	

INITIAL BASELINE
GAIT RE-ED WITH FES
FINAL BASELINE - NO FES
FINAL BASELINE - WITH FES

Performance Record

Indicators:									
ISw	0		0			0		2		
MSw	3		4			2		4		
TSw	1		2			3		2		
LR	3		4			4		3		
Number of 0 code	1		1			1				
1 code	1									
2 code			1			1		2		
3 code	2					1		1		
4 code			2			1		1		
5 code										

were analysed as a group to consider the overall effects of FES for this subject. The following statistical hypotheses were tested using a probability tree analysis:

$\mathbf{H_0}$ – there is no improvement in TELER Gait Indicator grades with FES intervention

$\mathbf{H_1}$ – there is an improvement in TELER Gait Indicator grades with FES intervention

To ensure maximum independence between indicators and what they measure, and therefore to minimise co-variance, a minimum of three were selected for analysis. The three chosen were considered to be of most clinical significance to this subject. These indicators were initial swing, mid-swing and terminal swing. From Table 12 it can be seen that these indicators had a combined score of 4 on initial assessment (0,3,1, respectively), there were 4 clinically significant changes by the time of discharge, giving an outcome score of 8. The results were therefore not found to be statistically significant at the 5% one-tailed level. The null hypothesis was accepted and the alternative rejected. There was no statistically significant change in TELER gait indicator grades for this subject.

Table 12 shows a decrease in Deficit Index from 65 to 45. The Improvement Index was calculated as 31, meaning that there was an improvement in this subjects identified problems during treatment. The Health Gain Index was 20 and therefore smaller than the Improvement Index, denoting a chronic disability.

The clinical significance of these improvements is inherent within the structure of the indicators. Each code is a clinically significant outcome needed for 'normal' gait.

Table 12 Worksheet for the TELER Index (recovery) for Subject 011

Item	Expected Outcome	Visit	
		1 Pre-FES	2 With FES
Initial swing	5	0	2
Mid-swing	5	3	4
Terminal swing	5	1	2
Loading response	5	3	3
Total number of missing scores			0
Deficit Index		65	45
Improvement index			31
Health Gain Index			20

7. Subject 012

Table 13 Subject 012: TELER codes pre- and post-intervention

Number of indicators by code pre (before) and post (after) intervention						
	Code before					
Code after	0	1	2	3	4	Total
0						
1						
2		2				2
3			1			1
4						
5						
Total		2	1			3

Key: ------- **Area under dashed line shows clinically significant change**
Area under which indicators show statistically significant improvements at the 95% confidence level

Table 13 summarises the data from the original TELER data collection form (following page). It shows that the admission codes for subject 012 ranged from 1 to 2, with a median code of 1, and a mode of 1. The admission code of two (66.6%) of the three indicators was 1, the other (33.3%) was grade 2.

The discharge or outcome codes ranged from code 2 to 3, with a median of 2 and a mode of 2. The discharge outcome code on one (33.3%) of the three indicators was 3; and two were coded 2 (66.6%).

From the table it can be seen that all three indicators showed some improvement in their code gradings. The magnitude of the improvements in all cases was only one clinically significant stage. None of the individual indicators that improved showed a statistically significant improvement at the 95% confidence level.

Indicators as a Group:

Whilst the above analysis of the data shows a clinically significant improvement in walking outcomes following the application of FES it is necessary to show a statistically significant improvement if these are to be attributable to the intervention. The indicators were analysed as a group to consider the overall effects of FES for this subject. The following statistical hypotheses were tested using a probability tree analysis:

MASTER FORM

Patient: [illegible]

Treatment Record

INITIAL BASELINE
GAIT RE-ED WITH FES
FINAL BASELINE - NO FES
FINAL BASELINE - WITH FES

19-10	9-11	10-12	10-12	
✓				
	✓			
		✓		
			✓	

Performance Record

Indicators: TSw
HR
ISw

1		3		2		2			
1		1		2		2			
2		3		3		3			
						1			
2		1							
1				2		2			
		2		1		1			

Number of 0 code
1 code
2 code
3 code
4 code
5 code

H_0 – there is no improvement in TELER Gait Indicator grades with FES intervention

H_1 – there is an improvement in TELER Gait Indicator grades with FES intervention

All three indicators were included in the analysis. From Table 14 it can be seen that these indicators had a combined score of 4 on initial assessment (1,1,2 respectively), there were 3 clinically significant changes by the time of discharge, giving an outcome score of 7. The results were therefore not found to be statistically significant at the 5% one-tailed level. The null hypothesis was accepted and the alternative rejected. There was no statistically significant change in TELER gait indicator grades for this subject.

Table 14 shows a decrease in Deficit Index from 73 to 53. The Improvement Index was calculated as 27, meaning that there was an improvement in this subjects identified problems during treatment. The Health Gain Index was 20 and therefore smaller than the Improvement Index, denoting a chronic disability.

The clinical significance of these improvements is inherent within the structure of the indicators. Each code is a clinically significant outcome needed for 'normal' gait.

Table 14 Worksheet for the TELER Index (recovery) for Subject 012

Item	Expected Outcome	Visit	
		1 Pre-FES	2 With FES
Terminal swing	5	1	2
Loading response	5	1	2
Initial swing	5	2	3
Total number of missing scores			0
Deficit Index		73	53
Improvement index			27
Health Gain Index			20

8. Subject 013

Table 15 Subject 013: TELER codes pre- and post-intervention

Number of indicators by code pre (before) and post (after) intervention						
	Code before					
Code after	0	1	2	3	4	Total
0						
1						
2	1					1
3		2	1			3
4						
5						
Total	1	2	1			4

Key: -------- **Area under dashed line shows clinically significant change**
Area under which indicators show statistically significant improvements at the 95% confidence level

Table 15 summarises the data from the original TELER data collection form (following page). It shows that the admission codes for subject 013 ranged from 0 to 2, with a median code of 2, and a mode of 2. The admission code of one (25%) of the four indicators was 0, two indicators (50%) were graded at code 1, and one (25%) was grade 2.

The discharge or outcome codes ranged from code 2 to 3, with a median of 3 and a mode of 3. The discharge outcome code on three (75%) of the four indicators was 3; one was coded 2 (25%).

From the table it can be seen that all the indicators showed some improvement in their code gradings. All entries showed clinically significant improvements. The magnitude of these improvements ranged from 1 to 2 clinically significant stages, with three indicators improving by two codes, and one improving by one code. None of the individual indicators in Table 15 showed a statistically significant improvement at the 95% confidence level.

Indicators as a Group:

Whilst the above analysis of the data shows a clinically significant improvement in walking outcomes following the application of FES it is necessary to show a statistically significant improvement if these are to be attributable to the intervention. The indicators

MASTER FORM

Patient: NGHUIS

Treatment Record

INITIAL ASSESSMENT
GAIT RE-ED WITH FES
FINAL BASELINE - NO FES
FINAL BASELINE - WITH FES

21-10	5-11	30-11	30-11
✓			
	✓		
		✓	
			✓

Performance Record

Indicators:
1SW
MSW
TSW
MSt

0		2		0		2	
1		3		1		3	
1		3		2		3	
2		3		4		3	

1				1			
2				1			
1		1		1		1	
		3				3	
				1			

Number of 0 code
1 code
2 code
3 code
4 code
5 code

were analysed as a group to consider the overall effects of FES for this subject. The following statistical hypotheses were tested using a probability tree analysis:

$\mathbf{H_0}$ – there is no improvement in TELER Gait Indicator grades with FES intervention

$\mathbf{H_1}$ – there is an improvement in TELER Gait Indicator grades with FES intervention

To ensure maximum independence between indicators and what they measure, and therefore to minimise co-variance, a minimum of three were selected for analysis. The three chosen were considered to be of most clinical significance to this subject. These indicators were initial swing, mid-swing and terminal swing. From Table 16 it can be seen that these indicators had a combined score of 2 on initial assessment (0,1,1, respectively), there were 6 clinically significant changes by the time of discharge, giving an outcome score of 8. The results were therefore not found to be statistically significant at the 5% one-tailed level. The null hypothesis was accepted and the alternative rejected . There was no statistically significant improvement in TELER gait indicator grades for this subject.

Table 16 shows a decrease in Deficit Index by nearly half from 80 to 45. The Improvement Index was calculated as 44, meaning that there was an improvement in this subjects identified problems during treatment. The Health Gain Index was 35 and therefore smaller than the Improvement Index, denoting a chronic disability.

The clinical significance of these improvements is inherent within the structure of the indicators. Each code is a clinically significant outcome needed for 'normal' gait.

Table 16 Worksheet for the TELER Index (recovery) for Subject 013

Item	Expected Outcome	Visit	
		1 Pre-FES	2 With FES
Initial swing	5	0	2
Mid-swing	5	1	3
Terminal swing	5	1	3
Mid-stance	5	2	3
Total number of missing scores			0
Deficit Index		80	45
Improvement index			44
Health Gain Index			35