LOCOMOTOR CHANGES ASSOCIATED WITH FUNCTIONAL ELECTRICAL STIMULATION-ASSISTED GAIT TRAINING IN PERSONS WITH INCOMPLETE SPINAL CORD INJURY

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New treatments such as functional electrical stimulation (FES) have been developed that allow people with spinal cord injury (SCI) the ability to stand and walk. This study investigated the use of FES-assisted gait training for two subjects with incomplete spinal cord injury in a single subject, repeated measures A-B design. Average walking velocity, cadence and stride length were determined while walking with and without FES at baseline and post-treatment evaluations. Changes in parameters were analyzed statistically and explained in biomechanical terms. FES-assisted gait training affected modifications in the gait parameters. One subject, initially a non-reciprocal walker, was able to walk overground at a faster velocity, cadence and longer stride length. Both subjects showed gains in these parameters over time. This study provided positive evidence for the use of FES-assisted gait training for these individuals with incomplete SCI. This may indicate that FES is a potentially useful rehabilitative tool as a gait aid for persons with SCI.

Des neuveax traitements tel que la stimulation éléctrique fonctionnelle (SEF) on été récemment dévelopés, permettant aux blessés medullaires incomplet (BMI) d'assumer la position débout ainsi que de marcher. Le but de cette étude était l'utilization du programme d'entraînement à la marche assistée par SEF. Deux sujets ont participé à l'étude employant un paradigm experimental simple. Les moyennes des paramètres de marche tel que la vitesse, la cadence et la longueur de deux pas consecutifs ont été mésurées avant et après le traitement, ainsi qu'à un suivi de 26 semaines. Les mesures avec et sans la SEF ont été prises lors de chaque évaluation. Le programme d'entraînement à la marche assistée par SEF a amélioré tous les paramètres de marche mentionnés ci-haut. Un sujet qui se déplocait de foçon non-réciproque avant le traitement, a augmenté sa vitesse de march, sa cadence ausi que sa longueur de pas suite à l'entraînement avec SEF. Egalement, les deux sujets ont été capable de maintenir l'amélioration des ces paramètres de marche pendant une période de 26 semaines. Cette étude a démontré que le programme d'entrainement à la march assistée par SEF peut avoir des effects positifs sur certain paramètres de march chez des blessés médulaires incomplet. Nos résultets peuvent indiquer que le SEF est une théropeutique favourable à la réadaptation de la marche des personnes ayant subi une lésions incomplètes à la moëlle épinière.

My time at McGill has been an adventure that I will appreciate all of my life. I have leaned many things, met many interesting people and enjoyed many wonderful experiences while completing my graduate studies.

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To all those people who have lived beyond a spinal cord injury.

I remember,

Dancing in my living room,
Holding hands at the movies,
Dangling my feet in water,
Running.

I remember,

The brush of your leg against mine as we slept,
A deep, deep embrace,
Long walks under a moonlit sky,
Making Love.

I remember,

Sitting in any chair I want,
Talking to someone at their eye level,
Leaving a room gracefully,
Holding my grandson.

I remember,

The feel of the carpet on my toes,
The cold bit of winter on my nose,
Holding my own cup of hot chocolate
by the warmth of the fireplace.

I remember,

Life before the injury.

I remember,

All that defines me.
The love that surrounds me.
The courage that enables me
to Live,
Beyond the injury.

Lucy Chilco

APPENDICES:

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Spinal cord injury (SCI) is a devastating condition that dramatically effects almost every aspect of one's life. Approximately 1,000 new cases of SCI occur per year in Canada alone leaving literally millions of people worldwide needing assistance in most areas of daily living. Many people with incomplete SCI endure spasticity, weakness, fatigue and loss of voluntary motor control, which prevents them from recovering the ability to stand and walk. Consequently, these people spend most of their day seated in a wheelchair. The subsequent deconditioning that may occur due to the lack of mobility further complicates the recovery of gait related functions.

In an effort to prevent deconditioning from occurring, while at the same time offering people with SCI the opportunity to enjoy life to its' fullest, many researchers have provided evidence that the benefits of exercise are applicable and attainable in this population (Glaser, 1994; Gordon & Mao, 1994; Hooker et al., 1992; Krauss et al., 1993). Arm and leg crank ergometry exercise protocols have shown favourable results in reversing and / or preventing deconditioning, increasing productivity and improving psychosocial functioning. Further benefits from daily standing and walking have also been documented but generally the task of walking following SCI carries a high cost of energy and requires the use of cumbersome ambulatory assistive devices.

The goal of providing a less cumbersome yet efficient and safe walking aid brought the focus of many researchers worldwide to the use of functional electrical stimulation (FES). Surface FES can be applied to sites on the skin which overly peripheral nerves and / or motor end plates within muscle. With the lower motor neuron and spinal reflex loop components intact, the stimulation will activate the muscle or muscle group to achieve a functional contraction. By applying FES to antigravity muscles or to nerve sites that will induce the flexor reflex, FES can be used to provide the support and impulse necessary to assist gait.

The feasibility and benefits of such assisted gait have been demonstrated (Kralj & Bajd, 1989). However, there are issues concerning the design and use of FES systems remaining that hold it to carefully controlled experimental settings. Three important issues that require further investigation are as follows: 1) the use of FES as a tool in conjunction with extensive gait training, not just as a walking aid to better demonstrate how it can assist the recovery of walking following SCI; 2) the establishment of treatment effectiveness through a large scale clinical trial; and, 3) the study of the longitudinal effects of FES-assisted gait training. Addressing these issues may provide the evidence required that would allow the use of FES as part of SCI rehabilitation to cross the bridge from the research laboratory into the clinic.

2.1 SPINAL CORD INJURY

2.1.1 Overview of Spinal Cord Injury

Traumatic spinal cord injury (SCI) affects approximately 35 per million Canadians each year (Canadian Paraplegic Association Annual Report, 1993). There is no organized registration of persons living with a SCI, therefore it is difficult to know the current prevalence of SCI in Canada. An estimate based on membership in the Canadian Paraplegic Association numbers approximately 10,000 new cases between 1982 and 1994. The main causes of SCI in Canada can be attributed to accidents: motor vehicle 40%; falls 17%; sports 7%; industrial 5%; and, diving 5%. Other causes such as falling objects and medical or surgical procedures account for the remaining 10 and 15% of all SCI cases. A similar demographic picture of SCI can be seen in the United States however, and unfortunately, there exists a category of violent acts, mostly due to gunshot wounds, that accounts for 15% of their SCI cases each year (Gutierrez et al., 1993).

There are four times more men than women who sustain a SCI with the highest incidence of injury occurring between the ages of 16 and 24 years. There are approximately an equal number of paraplegics and quadriplegics resulting from SCI with an equal division of those with a complete injury as opposed to an incomplete injury (Canadian Paraplegic Association Annual Report, 1993; Gutierrez et al., 1993; Parsons and Lammertse, 1991). The injury is said to be *complete* when there is a complete loss of sensory and motor function below the level of injury and *incomplete* when there is some sparing of motor and / or sensory function below the level of the injury. The degree of damage may be graded according to the ASIA Impairment Scale as seen in Table 2.1. Classification of a SCI may also be made according to the level of the injury. Usually, the vertebral level of the injury at which there is intact functional motor power and sensation is reported.

Table 2.1: The ASIA Impairment Scale for Classification of SCI

A	Complete	No sensory or motor function is preserved in the sacral segments S4-S5.
B	Incomplete	Sensory but not motor function is preserved below the neurological level and extends through the sacral segments S4-S5.
C	Incomplete	Motor function is preserved below the neurological level, and the majority of key muscles below the neurological level have a muscle grade less than 3.
D	Incomplete	Motor function is preserved below the neurological level, and the majority of key muscles below the neurological level have a muscle grade greater than or equal to 3.
E	Normal	Sensory and motor function is normal.

Despite the level and degree of damage, the effects of SCI are devastating. Virtually all the systems of the body may be affected resulting in altered physiologic, physical and psychosocial functioning (Buchanan & Nawczenski, 1987; Closson et al., 1991; Murray, 1984). Movement following SCI is complicated by symptoms of spasticity (e.g., increased muscle tone, clonus, abnormal reflexes and spasms), weakness, fatigue and decreased voluntary motor control. Consequently, the spinal cord injured person may require assistance with many activities of daily living (ADL) such as eating, dressing, toileting, transferring and ambulating. Furthermore, the clinical manifestations resulting from SCI often lead to secondary complications that may ultimately cause death. The leading causes of premature death among persons with SCI include cardiovascular disease, respiratory disease, septicaemia due to pressure sores or urinary tract or respiratory infections, accidents and suicide (DeVivo et al, 1991; Lammertse & Yarkony, 1991; Sanko, 1994).

Four important issues should be pointed out concerning the population of persons with SCI as follows: i) Improvements in transfer techniques and acute care have increased the survival rate following SCI thereby increasing the number of people needing unique lifelong health care; ii) The elimination of the top three causes of death among people with SCI would bring their mortality rate close to that for the spinally intact population; iii) These leading causes of death may be directly related to the deconditioning effects resulting from the consequences associated with SCI; and, iv) Exercise, standing and walking programs have been shown to be feasible in the SCI population and have proven to be beneficial in reversing certain deconditioning effects (DeVivo et al., 1991; Ragnarsson, 1992; Sanko, 1994; Tator et al., 1993, 1995). Therefore, with proper care and attention paid to his special needs, a person with a SCI could expect to live a long, happy, healthy life. Rehabilitation following SCI should include the prevention of secondary complications, the preservation of any remaining function, and the development of an active, health conscious lifestyle that includes regular physical exercise.

2.1.2 The Importance of Exercise and SCI

As introduced above, the complications associated with SCI may interfere with the recovery of voluntary movement, including walking, resulting in a considerable amount of time being spent seated in a wheelchair. The daily maneuvering into, out of and with a wheelchair to perform the ADL requires a high degree of effort that may cause great physical strain (Janssen et al., 1994).

Consequently, many people with SCI reduce their activity level and become sedentary. This lifestyle leads to deconditioning which has detrimental effects on many systems of the body as well as impedes one's functional independence and psychosocial status (Glaser, 1994; Kavanagh, 1984; Krauss et al., 1993; Ragnarsson, 1992). Ragnarsson (1992) outlines the effects of deconditioning as follows: reductions in cardiovascular fitness, respiratory function, serum high density lipoproteins, lean body mass (obesity), bone density (osteoporosis), muscle bulk, strength and endurance, endorphin production, self image, stress tolerance and insulin sensitivity with alterations in both autonomic and somatic reflex activity leading to changes in muscle tone, bowel and bladder function and vasomotor responses.

The physical strain involved in the daily manipulation of a wheelchair is one important consideration in maintaining some amount of physical strength following SCI. Janssen et al. (1994) used heart rate recordings (HRR) during the ADL of 43 male subjects with SCI for one day to assess the physical strain associated with manipulating the wheelchair in his own environment. They found significant differences for each category of subjects between their resting and peak HRR ($p<0.01$). While the subjects differed in terms of level of injury and amount of daily physical activity, the results indicate that all subjects experienced times of great strain during the performance of regular ADL. They suggest that improvement in physical capacity through an exercise training program could lessen the physical strain of daily life in a wheelchair and would potentially improve mobility and independence for this population.

While the effects of deconditioning are not exclusive to people with SCI, neither, fortunately, are the proven reconditioning effects of regular physical exercise. The wheelchair, therefore, need not prohibit an individual from being active. In fact, many forms of exercise exist (e.g., arm and leg ergometry) that allow a person with SCI to maintain a healthy level of physical fitness while seated. Exercise protocols using functional neuromuscular stimulation of leg muscles either alone or in conjunction with upper arm training have shown improvements in muscle strength, endurance and size as well as in cardiorespiratory function (Glaser, 1994; Gordon & Mao, 1994; Hooker et al., 1992; Krauss et al., 1993).

Hooker et al. (1992) studied the physiologic effects of leg cycle exercise for 18 subjects with SCI (10 quadriplegics; 8 paraplegics). Measurements of expired gas and cardiac response were taken during training sessions to evaluate power output, oxygen uptake, pulmonary ventilation, heart rate, stroke volume, cardiac output, arteriovenous oxygen difference, mean arterial pressure and total peripheral resistance. Exercise training consisted of 36 sessions of 30 minutes of electrical stimulation assisted pedaling (3 sessions per week). The external resistance of the cycle ergometer was originally set at 0.0 W and was increased by 6.1 W as tolerated. A one-way repeated measures ANOVA was used to determine whether differences between the pre- and post-training variables were greater than what would be expected by chance alone. Significant differences were found for all variables except stroke volume, arteriovenous oxygen difference and mean arterial pressure ($p<0.05$). These data indicate that a short term exercise training program utilizing electrical stimulation to assist lower limb cycling may increases cardiovascular and pulmonary functioning thereby contributing to the improvement and/or maintenance of physical fitness in persons with SCI.

Not only can the physiologic effects of deconditioning be reversed with regular exercise but improvements in psychosocial function may also be achieved. Noreau and Shephard (1992) studied a sample of 74 people with SCI to assess the association between fitness level and productive activities such as gainful employment and active leisure. They found a significant association ($R^2=0.64$, $p<0.05$) between physical fitness and productivity and suggest that the benefits of regular physical exercise may lead to better employment opportunity and enjoyment of leisure activities.

Further benefits have be observed such as improved joint range of motion, muscle tone, bone density, bladder pressure and circulation through upright exercise, even quiet standing for 2-3 hours per day (Jaeger et al., 1989; Kralj & Bajd, 1989). The ability to stand also allows for the freedom to reach for objects, enables smooth and safer transfers and is a precursor for the restoration of walking (Kralj et al., 1992).

The importance of preserving a healthy level of fitness in persons with SCI is apparent and may even be crucial when considering that the leading causes of death in this population can be related to their usually adopted sedentary lifestyle. Maintaining physical strength may reduce the strain of activities of daily living and may facilitate the potential to stand and walk following SCI. Regular physical exercise, be it in or out of a wheelchair, leads to improved physical fitness and allows for greater independence and general well-being.

2.1.3 Walking Following Spinal Cord Injury

The question of walking following spinal cord injury involves the consideration of many factors. Walking potential can be influenced by age, level and degree of injury, physical fitness, medical condition, mechanical factors such as heterotopic ossification, and psychosocial factors such as family support (Closson et al., 1991; Jaeger et al., 1989; Subbarao, 1991). Most people with SCI require the use of ambulatory assistive devices (AAD) such as braces, walkers or crutches to stand and walk which compensate for losses in strength and balance. To be successful, the process of walking demands proper training and a high level of motivation. An understanding of the movement impairments associated with SCI (as discussed on Page 4), the requirements of successful gait, and the proper application of AAD's should allow a rehabilitation specialist to develop a training program specific to each client's needs.

Waters et al. (1993) studied the gait performance of 36 people with SCI who, upon completion of their initial rehabilitation programme that included gait training, were all able to walk overground with various AAD's for at least five minutes. Subjects were evaluated on walking velocity and certain energy consumption variables. Results indicated that the physiological demands of walking were much greater for the patients as compared to a sample of normal subjects. They found for the SCI group that walking velocity was 52% slower, rate of oxygen consumption was 23% greater and oxygen cost per meter was 240% higher.

The research team Yakura et al. (1990) tested similar variables for 10 of the 36 subjects at their one year follow up examination. Significant improvement in ambulatory capacity ($p<0.007$) was seen for all subjects: nine out of 10 subjects were community walkers and of these nine, only four had increased their walking velocity to speeds approaching the community norm. All subjects continued to encounter high energy demands despite their improvement in strength and conditioning.

While bipedal ambulation with SCI is possible, it is usually too slow to be functional in the community and it carries a high energy cost (Crosbie & Nicol, 1990; Waters et al., 1993; Yakura et al., 1990). Therefore, under conventional rehabilitation strategies, most people with SCI adopt wheelchair use as their main mode of ambulation and use walking for therapeutic rather than functional purposes (Closson et al., 1991; Jaeger et al., 1989; Subbarao, 1991).

2.1.4 A New Approach to Gait Therapy

The quest to restore functional walking following SCI continues to thrive in many research laboratories world-wide. New treatment strategies and devices aspiring to provide the assistance required to allow people with SCI to become successful community walkers are being developed and tested. As previously mentioned, an understanding of the associated complications, determinants of successful gait and use of ambulatory assistive devices should provide the basis for the development of potential compensatory mechanisms for walking with SCI (see Figure 2.1). Beyond the application of conventional AAD's (bracing, use of walkers, crutches, etc.), overcoming the consequences of SCI to satisfy the determinants of gait can be achieved by using a body weight support (BWS) system, drug therapy and functional electrical stimulation in conjunction with gait training (Barbeau & Rossignol, 1994).

The use of a BWS system to allow locomotor training in persons with SCI is currently being studied at many centres around the world including Montreal, Canada, Lund Sweden and Berlin, Germany (Barbeau & Rossignol, 1994). The BWS system entails strapping the subject into a harness that is suspended over a treadmill capable of advancing at very slow speeds. A system of pulleys allows the body weight of the subject to be support from 0% up to 100%. The support mechanism of the harness system allows for a regulated increase and / or decrease in BWS by the subject as he / she progresses in training. Regardless of whether the question being studied concerns the recovery of walking, the early application of locomotor training or the mechanism behind spinal walking, the notion of using BWS following SCI has shown promising results (Barbeau & Blunt, 1991; Barbeau et al., 1993; Wernig & Muller, 1992).

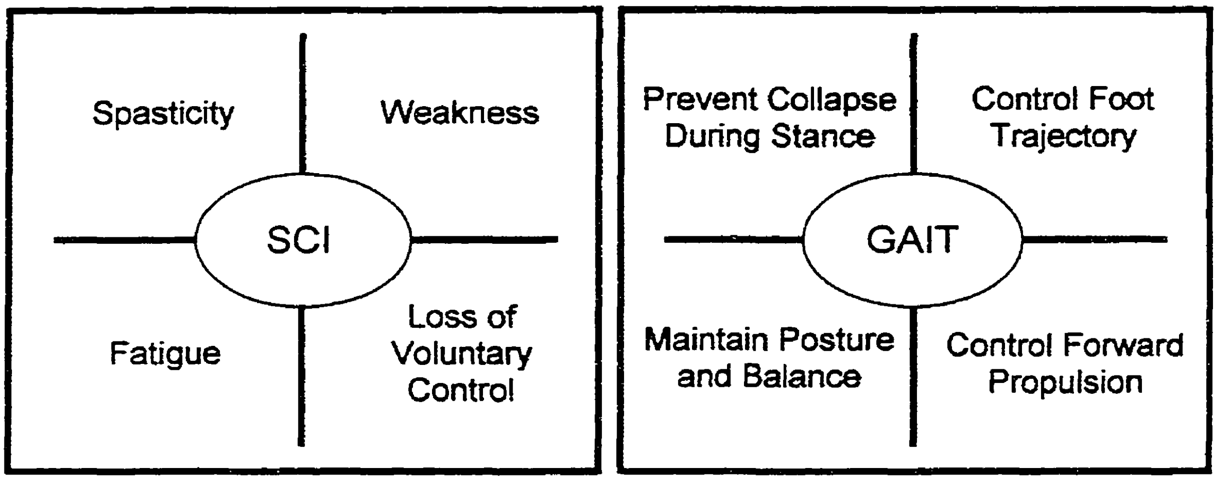


FIGURE 2.1 MOVEMENT CONSEQUENCES OF SCI AND DETERMINANTS OF SUCCESSFUL GAIT

Barbeau et al., (1993) evaluated nine subjects with SCI before and after a six week, interactive gait training program using a BWS system. Subjects were supported optimally initially and progressed to 0% support at the completion of training. The BWS system allowed the trainer to assist and correct the locomotor patterns while the subject actively walked on the treadmill. Walking speed and endurance were increased for all subjects following training. The kinematic profiles of hip, knee and ankle angular excursions shown for one representative subject also indicate improvement in gait pattern. The investigators attribute these changes to the BWS system for allowing a progressive interaction of body weight support (prevent collapse during stance) with the other components of gait (see Figure 2.1) while retraining the locomotor patterns.

The use of drug therapy further enhances the value of interactive gait training with BWS such that a wider population of people with SCI - even those with severe spasticity - may benefit from this treatment strategy. Fung et al. (1990) used clonidine and cyproheptadine in conjunction with BWS and interactive gait training and found a positive effect on locomotor ability in two subjects with SCI. Initially, both subjects could not walk independently due to severe spasticity. In comparison to receiving placebo plus gait training, improvements were associated with periods of medication plus gait training in overground and treadmill walking speed, endurance, angular excursions at the hip, knee, ankle and trunk and activation patterns of locomotor muscles.

A treatment approach that addresses many of the aspects in Figure 2.1 involves the use of FES to assist walking. Electrical current is applied to muscle and/or nerve sites which help to support and/or move the limbs. FES has been shown to be a feasible approach in allowing people with SCI to walk overground with reduced effort and greater speed (Kralj et at., 1992). However, FES is not as yet applied widely as part of SCI rehabilitation for walking because many issues relating to the design of FES systems such as safety, reliability, functional application, energy requirements, and ease of use remain to be addressed (Kralj et at., 1992; Ragnarsson, 1992). Nevertheless, while these issues are being studied, existing FES systems can be used to achieve standing and walking in people with SCI which allows them to spend time out of the wheelchair to participate in functional, therapeutic and social activities (these applications will be discussed in detail in Section 2.2).

This discussion of new approaches to gait therapy shows that consideration of the consequences, limitations and attributes of the walking system as a result of SCI can lead to the development of devices and treatments that work to compensate and enhance the remaining function. The use of BWS, drugs and/or FES as a tool in conjunction with gait therapy shows great potential in the restoration of functional walking following SCI.

2.2 FUNCTIONAL ELECTRICAL STIMULATION

2.2.1 Neural and Biomechanic Basis of Surface FES for Gait

Voluntary motor control involves the planning and execution of a set of commands that originates as a thought and is transmitted along motor pathways that terminate on the required muscles for the desired movement. Information from the contraction of the muscles and from the environment as a result of the movement is transmitted back into the system, which can be used to guide and refine the movement. Figure 2.2 shows the normal system of motor pathways. Following a spinal cord injury the motor system is interrupted usually along the pathway connecting the higher centres to the spinal neurons. This interruption in the descending motor pathway effects both voluntary and tonic motor control resulting in certain movement consequences including the presence of spasticity, weakness, fatigue and a loss of voluntary motor control.

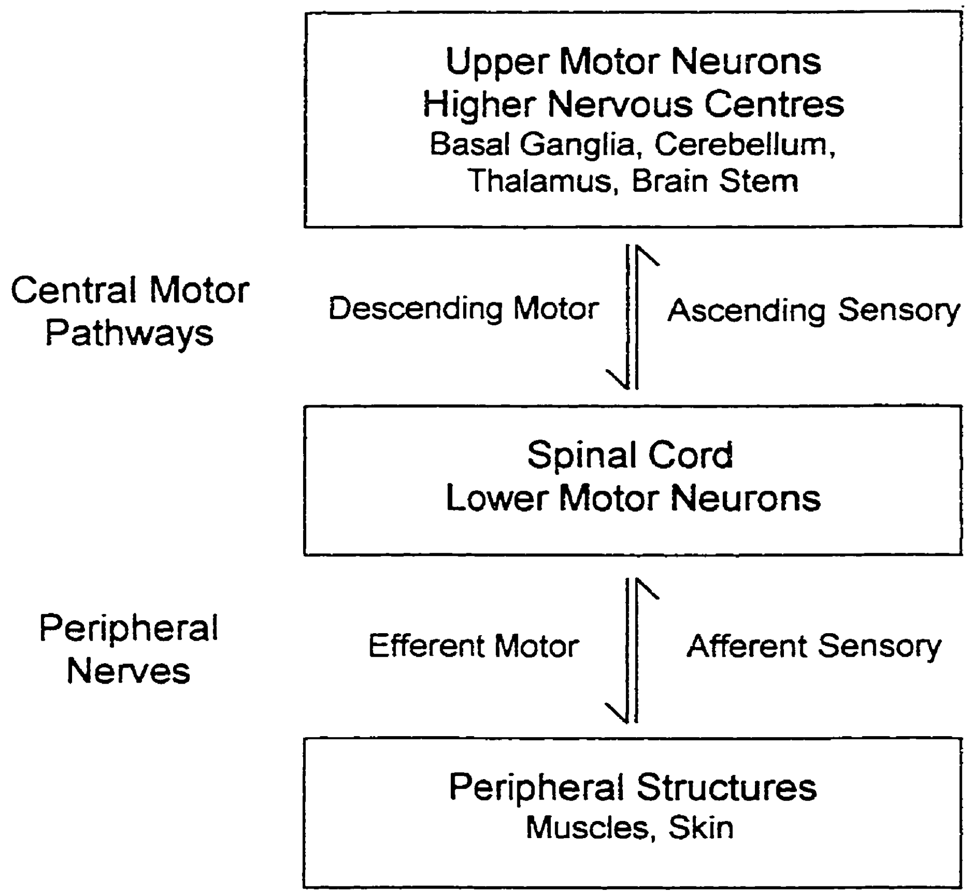


FIGURE 2.2 NORMAL MOTOR AND SENSORY PATHWAYS

Fortunately, the motor pathway system includes connections between and among groups of muscles at the spinal cord level that may be activated independent of the higher centres. These connections are referred to as *spinal reflex arcs* and serve various functions such as contracting a stretched muscle, relaxing a tense muscle or activating a set of muscles in response to a noxious stimulus. The latter reflex, the flexor reflex, is important in the application of FES to assist walking following SCI.

With the lower motor neurons and peripheral nerve pathways intact, the flexor reflex can be elicited by applying sufficient stimulation to the area of skin lying above the desired peripheral nerve (e.g., the common peroneal nerve). Because the peripheral nerve contains both motor and sensory fibres, stimulation that is *sufficient* is that which activates the sensory fibres which in turn activate the alpha motor neurons for the flexor muscles at the hip and knee and dorsiflexor muscles at the ankle. The result is a movement that when initiated in the latter stage of stance on one side can assist that leg in the swing phase by providing forward and upward momentum to the limb. Release of the stimulation allows gravity to assist in carrying the limb to the end of swing. Transfer of weight to that leg can then be carried out followed by stimulating the sensory fibres of the other leg resulting in an assisted reciprocal activation of the lower limbs.

Electrical stimulation may also be applied to the skin overlying a muscle thereby invoking the peripheral motor fibres at the point of contact with the muscle fibres. This application of FES is used to activate selected muscles for therapeutic or functional purposes. When used in gait for example, the vastus lateralis may be activated during the stance phase to provide the stability required at the knee to allow the forward rotation of the lower limb over the ankle without collapse of the lower limb.

The design specifications of the FES system may include a single, double, quadruple or more channel stimulator depending on the assistance required by each individual.

2.2.2 FES-Assisted Gait

The application of electrical stimulation as a means to obtain functional contraction of muscle following SCI has been utilized for over thirty years. The detail of FES research has progressed and diversified from a *feasibility* status indicating basic results from single subjects through to multi-centre trials addressing a variety of symptoms resulting from SCI which apply FES in the context of therapeutic and functional benefits. Advancements in technology as well as collaboration between disciplines such as electronics, neurology, biomechanics and rehabilitation has brought the use of FES systems into the lives of many people with SCI. While the application of FES for therapeutic purposes is commonly seen in rehabilitation centres for various populations, the use of FES to functionally assist gait remains mostly experimental.

One of the world leaders in FES research is the team of Kralj and Bajd and their colleagues at the University of Ljubljana. This team has approached the use of FES from many angles and has provided strong evidence as to its use in the restoration of functional walking following SCI. A paper published in 1989 (Bajd et al., 1989) identified those patients with SCI who would benefit from therapeutic as well as functional gait training protocols using FES. A group of 10 subjects with incomplete SCI participated first in a therapeutic exercise programme, eight of whom went on to the functional gait programme. The results of cyclical stimulation of the knee extensor muscles for thirty minutes daily indicated a potential for increased muscle strength as shown by torque production, reduced contractures and spasticity and increased range of motion. This study identified three groups of patients whose response to the treatment determined their eligibility for further application of FES. Groups one and two (each with 4 subjects) showed improvement in both voluntary and stimulated muscle force, and improvement in stimulated muscle force only, respectively. These groups attained joint torque improvements of at least 50 Nm and could therefore potentially benefit from the gait programme. The participants in group three did not respond to FES treatment and were, therefore, not good candidates for gait therapy.

Of those eight subjects who went on to the gait programme, further sub-groups were identified based on the pattern of injury and the stimulation parameters required for successful and efficient gait. Four subjects had symmetrical motor and sensory loss and required no external leg support to stand. These subjects were able to walk with bilateral stimulation of the peroneal nerve during the swing phase (as described above). The remaining four subjects presented an asymmetrical pattern of motor and sensory loss where one side was much weaker than the other. These subjects utilized a two or four channel FES system which provided support during stance by stimulating the knee extensor muscles in addition to peroneal nerve stimulation to engage the flexor reflex during swing.

Kralj and colleagues presented further support for the feasibility of using FES for gait restoration at the 1993 FES Conference on Mobility (Kralj et al., 1994). They reviewed the application of FES to 94 of 500 subjects with SCI referred to the University Rehabilitation Institute between 1983 and 1993. The results indicate that of all new cases of SCI annually, 11.2% of these people can become functional walkers with the aid of FES.

Another team to establish feasibility in using FES to assist gait in people with SCI hails from Glasgow, Scotland. Granat and colleagues (1992) presented the results of 6 subjects participating in a therapeutic and functional FES programme. All subjects had completed acute rehabilitation and were tested for voluntary muscle strength, spasticity and the presence of the flexion withdrawal response. The muscle conditioning programme was maintained for up to six months to enable subjects to stand with FES without any mechanical bracing. Subjects were then gait trained with stimulation designed for their individual needs. Gait parameters were measured at the onset of training and again after a minimum of two months of home training. During this period, home visits were carried out to provide further gait training. The results indicate a significant increase in quadriceps strength ($p<0.05$) and a reduction in spasticity ($p<0.005$). Walking speed was compared with and without orthoses while using FES and was not significant. The difference in walking speed over time was not reported. All subjects were able to stand and walk using FES in their home environment and three continue to use FES as their main mode of locomotion.

Further study by the same team (Granat et al., 1993) consisted of another group of six subjects with SCI who had completed their acute rehabilitation and were able to ambulate using orthoses. A more developed muscle conditioning programme (i.e., progressive resistance exercise on quadriceps plus other antigravity muscle groups) was designed for each subject based on his/her needs which was carried out for six months. Subjects were then gait trained while continuing their exercise programmes.

The variables measured at the onset and following three months of training included manual muscle testing, maximum voluntary contraction of the quadriceps, upright motor control and sway, spasticity, activities of daily living (Barthel Index), walking speed, stride length, cadence and heart rate which was used to determine the physiological cost index of gait.

The results indicate a significant increase in strength and reduction in spasticity ($p<0.05$) for all subjects. Half of the subjects showed a decrease in physiological cost index and an increase in walking speed, stride length and cadence ($p<0.05$). There was not a significant effect seen for either sway or the Barthel Index. All subjects were able to walk overground with FES and their orthoses (3 community walkers; 3 exercise walkers). One subject was even able to walk for a period of 15 minutes without FES or her knee/ankle/foot orthoses.

Based on these results, the authors suggest that further therapeutic and functional recovery may be available to persons with SCI by utilizing FES. Furthermore, no deterioration in any of the areas studied was seen and, in fact, an apparent crossover effect of training with FES was manifested as improved hip flexor strength and hip and knee range of motion. The use of FES following SCI, therefore, should be included as part of regular post injury rehabilitation.

Solomonow et al. (1993) strongly agree with the previous conclusions and have presented their own evidence of therapeutic benefits associated with FES following SCI. The intent of their research was to provide support to the claim that walking can improve the general health of persons with SCI. As discussed previously, the importance of preventing deconditioning following SCI is paramount in order to ensure a long, healthy, productive life. In this study, 26 subjects were gait trained using FES and a reciprocating gait orthosis. The variables measured prior to training and at each two month interval included bone mineral density of the femoral neck, cardiac output, stroke volume, vital capacity, expiratory force, high and low density lipoproteins and total serum cholesterol.

While no statistics were presented for the results, the results showed marked changes in all variables except bone density. All changes are in the direction which would indicate an improvement in cardiovascular, pulmonary and metabolic functioning and are consistent with the conditioning effects seen with regular exercise. The authors conclude that the conditioning effects and related psychosocial and financial benefits (improved psychological state; decreased medical expenses) of FES-assisted walking following SCI are strong evidence to warrant its acceptance as a common rehabilitation tool.

The Canadian team of Stein and colleagues (1993) quantified the gait performance of ten subjects with SCI in an effort to examine the practical benefits of simple surface (n=6) or implanted (n=4) FES systems. All subjects could stand unassisted initially and were quite diverse in their walking ability (4 unable to walk overground; 6 could walk with an AAD). Gait and oxygen analyses were conducted to compare the characteristics of the subjects while walking with and without FES.

All subjects who could walk did so at a faster speed with FES. FES enabled the four subjects who initially could not walk to do so at speeds ranging from 2.8 to 6.7 m/min. The comparison of oxygen consumption was made only on those subjects who could walk initially. While not statistically significant, a decrease in oxygen consumption was seen in five out of the six subjects while walking with FES.

This study identified those persons with incomplete SCI who could most benefit from using FES to assist gait. The gains of those subjects who could not walk at all without FES are invaluable. To these people, FES is the tool that allowed them to walk again. While the resultant walking characteristics were still far from how the *normal* population walks, this study provides evidence that simple FES systems can provide the assistance required that allows people with incomplete SCI to become upright and walk. Be it for exercise or for function, FES enabled them to spend time out of their wheelchair.

Referring again to Figure 2.1 we can see that simple FES systems may address each of the components of the consequences of SCI and determinants of gait. The use of FES in general has supported a reduction in spasticity which may contribute to a greater ease of movement. Adding stimulation to the quadriceps during stance accounts for the lack of voluntary muscle control and allows the support required to prevent collapse which in turn contributes to maintaining posture and balance. Stimulation of the flexor reflex to assist swinging the leg forward addresses the lack of voluntary control, weakness and fatigue, and contributes to the control of foot trajectory and forward propulsion.

The above review of research illustrates that FES as a means to allow people with incomplete SCI the opportunity to stand and walk is possible. While the existing FES systems are in need of further development to account for problems in the design specifications, they remain a useful tool that could be incorporated into post injury rehabilitation.

2.2.3 Combining FES with Gait Therapy

One aspect of utilizing FES as a rehabilitative tool to assist gait that is lacking in most of the above research surrounds the existence of formal Gait Therapy. Now that the feasibility and usefulness of FES to assist gait in persons with SCI has been established, it should be used in conjunction with substantial *gait training*, as opposed to just training the subjects to walk with stimulation.

Kralj and Bajd (1989) provide a detailed description of Gait Therapy when using FES in their book entitled, "Functional Electrical Stimulation: Standing and Walking after Spinal Cord Injury". The process of training with FES covers all the necessary requirements and steps before walking is attempted through each stage of gait development, including practicing the recovery from falls, encountering obstacles and changing walking aids. The progression from walker to crutches requires sufficient back and upper limb strength as well as specific training geared toward stability and safety issues. Crutch-assisted walking with FES allows for a smoother transfer of energy and is needed to attain greater walking speeds however, it also requires a certain amount of unbalancing that may present as stressful to the client. Training with crutches, therefore, includes practicing independent standing to crutches and the recovery of unbalancing to a stable state. Kralj et al. (1993) describe a system of quadrupedal crutch-assisted gait that utilizes phases of unbalancing and stabilization to achieve forward propulsion while maintaining a safe upright posture. These authors have contributed years of research in support of utilizing FES as a regular part of post injury rehabilitation following SCI and have provided great detail regarding gait training so that FES may be employed more readily worldwide.

The principles of gait training with FES as outlined by Kralj and Bajd were applied in a pilot study carried out at the School of Physical and Occupational Therapy at McGill (Ladouceur et al., 1993). Four subjects with incomplete SCI used one to four channels of stimulation and were evaluated walking with and without FES during continued gait training. Gait skills were trained for 30 minutes to one hour per day, five days per week for one month. Training then continued at home with regular supervised training sessions occurring once a week for the duration of the study. Maximal overground walking speed was measured 2 - 3 times during the first month of training and then every two months thereafter. Kinematics and electromyography (EMG) was used to quantify the gait patterns.

When comparing walking speed with FES to walking without FES, an increase in speed of 0 - 66% was seen within the same day. These figures are in line with walking speed values as reported by Stein et al. (1993) and Granat et al. (1993) in the basic application of FES. However, when looking at walking speed over time during which period the subjects participated in daily gait training, increases of 20 - 450% were observed when walking with FES. In addition, there appears to be a carry-over effect as evidenced by the 10 - 400% increase in walking speed when walking without FES. The increase in walking speed, therefore, may be attributed to the union of FES with gait therapy.

2.3 GAIT ANALYSIS

2.3.1 Describing Human Locomotion

Bipedal plantigrade locomotion is an ability that allows humans many functional opportunities over our four-legged relations. The gain in height from standing on two legs, for example, allows us to reach high into the branches of trees and see into the distance. Along with this two-legged ability however, comes certain necessary tasks that must be achieved in order to remain upright. Subsequently, humans have developed the necessary neural control that allows us to navigate virtually any surface under varying conditions, sometimes treacherous, while usually maintaining a secondary task e.g., walking through ice and snow in high winds carrying a bag of groceries. It is understandable, therefore, that the wonder of bipedal human locomotion has inspired many researchers to learn just how we accomplish this ability.

What appears to be evident from early research regarding human development and motor control is that walking, like most other motor skills, is a learned behaviour that develops into a basic pattern which carries our unique individual differences (Inman, 1966; Payne & Isaacs, 1987; Winter, 1991). In order to make inferences, therefore, about what would be considered *normal* human locomotion, the study of human walking must identify not only the underlying basic pattern but also the range of variability that accounts for these individual differences.

A great deal of research in the assessment of human walking, or gait, has been conducted by Winter and colleagues at the University of Waterloo. Many years of data collection using kinematics, kinetics and electromyography detailing normal and pathological gait under various conditions has been compiled and presented as a normative data base that may be used to describe and explain the characteristics of human walking (Winter, 1990, 1991).

Through this detailed description of the internal and external mechanisms of gait, Winter has ascertained valuable information regarding the assessment of human gait. First of all, in order to remain upright there are four basic determinants of gait that are necessary sub-tasks to walking: i) prevent the collapse of the lower limb during stance; ii) maintain posture and balance in the plane of progression and frontal plane; iii) control the forward progression of the leg and body; and, iv) control the trajectory of the foot for safe ground clearance and gentle heel contact (Winter, 1991; 1993). The smooth integration of these sub-tasks enables humans to be safely and efficiently transported from place to place.

How we achieve these sub-tasks has been found to be surprisingly consistent for some elements and extremely diverse for others. When considering the number of segments, muscle groups and possible environmental conditions that are involved in human walking such as walking speed, surface attributes (e.g., smooth, soft, level) or the presence of pain or injury, one can agree that there are a great number of possible combinations of movements involved. Thus, the ability to walk represents a complex integration of multivariate movement tasks that may be combined in various ways to ultimately achieve the goal of remaining upright (Winter 1993). This variation not only illustrates the range of movement options that may be considered normal but it also reveals the redundancy inherent in our motor control system.

The redundancy within walking sub-tasks also sheds light on the consideration of normality in pathological gait. A movement that could be mistaken as abnormal may in fact be compensatory in response to a decrease in movement options as a result of pain or injury.

Normative gait data which considers the factors effecting movement is a first step in not only determining the presence of atypical or pathological gait but also in providing the information required to correctly interpret the relative contribution of the elements in the gait pattern. An understanding, therefore, of the contributing structures and their function in the desired movement as well as the potential combinations of interlimb coordination to achieve safe, efficient walking is imperative in determining the course of action to take when presented with an atypical gait pattern.

2.3.2 Clinical Gait Analysis

There are many elements to be considered in the description of human walking under normal conditions. When the element of pathology is entered into the analysis, there are issues specific to the pathology that must be considered.

Firstly, the goal of the analysis must be clear. Craik and Oatis (1985) describe four categories of gait evaluation goals as follows:

i. To describe the degree to which a patient's performance differs from nondisabled performance;

ii. To determine whether treatment alters performance;

iii. To classify the severity of a walking disability;

iv. To identify the mechanisms responsible for producing the abnormal gait.

Once the goal of the evaluation is clear, the outcome measures must then be determined. Proper selection of gait variables to be measured depends on a firm understanding of the walking system under the effects of the pathology and any possible elements that may also contribute to the gait pattern. Familiarity with valid and reliable tools for the analysis of gait variables is also essential in obtaining a proper evaluation of the desired goal.

Once the gait information has been collected, it must be properly interpreted. Certain parameters are dependent upon others and must be normalized in order to make valid comparisons. For example, step length is dependent upon body height therefore, in order to compare this variable across subjects, the raw value of step length must be divided by the subject's height. Normalization of data must be considered even when comparing gait parameters within the same subject. For example, force data is dependent upon body weight which may also be variable. If during the course of treatment the subject lost or gained weight, this change should not be interpreted as a treatment effect and therefore must be accounted for by normalizing the force data to the subject's body weight at the time of each evaluation. There are many other factors that may effect the gait variable such as sex, age, fatigue, practice, and the type of assistance used (if any). Potentially confounding factors must also be considered when interpreting the measured outcome variables, especially when making comparisons to a standard of normal values.

The comparison of measured outcome variables to those seen in a normal population may not be appropriate in certain circumstances. What may appear to be a deviation from the normal gait pattern may in fact either fall within the range of variability of normal gait, or may be a necessary adaptation due to changes within the walking system. The goal of the treatment must be considered such that it is not necessarily to achieve a normal gait but to achieve a functional gait. Correction of an adaptive gait to bring it more toward normal may decrease the functionality of the gait and may also force the patient to walk less efficiently thereby expending more energy.

In a discussion of human locomotion, Inman (1966) illustrates the ability of the human body to effectively operate the segments and muscles of the walking system such that the energy requirement is minimal for each step. Supporting evidence by Ralston (1958) and Bard and Ralston (1959) as cited by Inman, (1966) shows that the pattern of energy expenditure (oxygen consumption vs. walking speed) falls through a minimum at a certain walking speed and increases with any change in this parameter. The walking speed at which the energy requirement is minimal correlates exactly with that which is self-selected by subjects to be the easiest, most comfortable and natural pace. This observation was repeated in subjects with an adaptive, pathological gait whose efficiency curve was found to be different from normals in terms of absolute values but nevertheless passed through a minimum. Thus, the therapist utilizing gait analysis to evaluate treatment effectiveness must understand the relationship between efficiency of walking, oxygen consumption and walking speed and know that the human body may be working at its most efficient given the conditions of the walking system. A comparison of pre-treatment to post-treatment gait performance rather than to normal may, therefore, be a more comprehensive way to judge the effectiveness of the treatment.

2.3.3 Reliability of Gait Analysis Measures

In order to accurately describe the changes in a variable, the measurement tool that defines the variable must be reliable. A measurement tool that is reliable is one that delivers a consistent, true value of the desired variable of interest (Shavelson, 1988). Each measured value of a variable contains a certain amount of measurement error surrounding the true value. The extent to which the measurement error is diminished represents the degree of reliability of the measurement tool. Testing for reliability involves taking repeated measures of the variable using the same measurement tool and circumstances.

Winter (1991) provides reliability information regarding the measurement of many gait variables using kinematic (digitized coordinates on video images) and kinetic (force platform with transducers) techniques as the measurement tools. Joint angular displacement profiles as well as ground reaction force and joint moment of force profiles are displayed for repeated measures on the same subject during the same day and over different days, and also between subjects. The coefficient of variation (CV) (see Appendix E) was calculated for all repeated measures and represents the variability-to-signal ratio which can be used as a measure of repeatability of the measurement tool.

For the kinematic profiles, the variability for joint angles at the hip, knee and ankle within the same subject on the same day (n=9) and over different days (n=10) was found to be very low (CV=21, 8, and 16%; CV=12, 7, and 25%). The pattern of angular displacement profiles between subjects (N=19) walking at a slow, natural and fast cadence showed higher variability than for within the same subject however, the patterns remain consistent within the same speed of walking with only minor changes seen at the knee and ankle during weight acceptance in early stance.

The vertical and horizontal ground reaction forces measured for the same subject in the same day (n=10) and over different days (n=9) show very low values for the CV (10, 26% and 10, 21% respectively). Again, when compared to the same measures between subjects (N=19), the variability increases but a consistent pattern is evident (CV = 18 and 43%). Similar differences between intra- and inter-subject measures are seen for the moment of force profiles. While the value of the CV at individual joints is quite high at the lower walking speeds, the support moment shows a consistently low CV. This again, illustrates the redundancy within the walking system in that it has the ability to vary the action of the components while obtaining the same result. These data presented by Winter (1991) show that the processes of using kinematics to measure changes in angular displacement and kinetics to measure changes in ground reaction forces are reliable.

Kadaba et al. (1989) collected kinematic (infrared camera computer assisted motion analysis system) and kinetic (force platform transducers) data on 40 subjects to test the repeatability of these measurement tools. Three trials for each side of the body were collected at each evaluation and all subjects attended three evaluation sessions. Joint angular displacement profiles as well as the gait parameters of speed, cadence, swing/stance ratio and stride length, and joint moment of force profiles were analyzed. The repeatability of the measurements was determined using the CV. The results show very low CV values for both within the same day and over the different test days on all gait variables (in the sagittal plane) with only slightly higher CV values for between test day measures. These authors conclude by stating that these methods of measuring gait performance are reliable and suggest that they may be applied in the process of making clinical decisions related to gait.

2.4 SUMMARY OF LITERATURE REVIEW

The movement consequences of SCI include the presence of spasticity, weakness, fatigue and decreased voluntary motor control resulting in an increased need for assistance in activities of daily living, including the ability to stand and walk. Furthermore, due to the increased physical demand of standing and walking following SCI, most persons with SCI use a wheelchair as their main mode of locomotion and subsequently suffer the complications associated with inactivity including physical deconditioning. This sedentary lifestyle results in detrimental physical, psychological and physiological changes and may explain the leading causes of death among this population.

Fortunately, people with SCI do benefit from regular physical exercise by improving or maintaining physical fitness including strength, which may reduce the strain of performing the acitivies of daily living and may also facilitate the potential to stand and walk. (Hooker et al., 1992; Kralj and Bajd, 1992; Noreau and Shephard, 1992).

New, experimental treatment approaches such as the BWS system, drug therapy and FES are also enabling people with SCI the ability to walk. These treatments as a tool in conjunction with gait therapy have shown great potential in restoring functional walking following SCI (Barbeau et al., 1993; Fung et al., 1990; Kralj et al., 1992).

The feasability of using FES as a gait aid for persons with incomplete SCI has been proven by research teams around the world (Granat et al., 1992; Kralj et al., 1989, 1994; Ladouceur et al., 1993; Solomonow et al., 1993; Stein et al., 1993). The benefits as described by these studies show that the use of FES in people with SCI may help to improve or maintain physical fitness and increase strength to enable the ability to stand and walk. The most compelling evidence indicates that FES in conjunction with gait therapy may enable a person with SCI the ability to walk and, in time, may even improve their walking ability without using FES.

While there are many complex issues regarding the use of FES to assist walking that remain to be examined in an experimental environment, there may be sufficient evidence to substantiate its use in the most simple format for certain sub-populations of persons with SCI. However, certain issues that need to be addressed include identifying the long terms effect of using FES-assisted gait training and how this treatment could be applied in a clinical setting. What is needed, therefore, is a controlled clinical study that would indicate the use of FES-assisted gait therapy as a treatment approach for certain persons with incomplete SCI.

3.1 SINGLE SUBJECT RESEARCH DESIGN

3.1.1 Application in Clinical Research

Inherent in the literature review regarding persons with incomplete SCI is the heterogeneity of this population. Kralj, Bajd and colleagues considered the variance among people with SCI and thus identified certain sub-groups who would most benefit from using FES in a therapeutic as well as functional means. It is precisely because this population is so diverse in their pattern of injury, recovery and psychosocial make-up that a single subject design must be employed when conducting research that proports to establish the effectiveness of a treatment approach.

Reviewing again Badj et al. (1989) demonstrates an example of why group comparisons may not be appropriate for clinical data. In their therapeutic programme they identified three groups by the subject's response to treatment: Group A - showed improvements in voluntary and stimulated knee joint torque; Group B - showed improvement in only stimulated knee joint torque; and, Group C - showed no improvement in knee joint torque. If a group average of knee joint torque values had been presented, the improvement, or lack thereof, may have been overlooked. Subsequently, incorrect conclusions may have been drawn regarding the use of FES as a therapeutic means to increase muscle strength. By approaching the data in a single subject manner however, the treatment effectiveness was clear on an individual basis. The fact that these individual results fell into sub-groups illustrates the next step in single subject research design in that if a large group of individuals responds in the same manner to a treatment, then the potential effectiveness of that treatment becomes stronger.

The application of single subject design can take various forms and should always include systematic repeated measurements of the outcome measures and a clearly defined specific treatment. In this thesis the design employed was A-B where "A" represents the baseline period, or walking without FES and "B" represents the treatment period, or walking with FES. The repeated measurements were of gait parameters. By analyzing the subjects separately, the effectiveness of the treatment can be determined for that individual. In order to make assumptions about the potential treatment effectiveness for the entire population, an effect would have to be seen for a very large group of subjects. Therefore, the greater the number of subjects in a single subject design, the more confident one can be about the potential treatment effectiveness.

3.1.2 Statistical Analysis of Single Subject Data

The analysis of treatment effect in single subject research has traditionally been carried out by using visual inspection of the data in a graphical format (Nourbakhsh & Ottenbacher, 1994; Ottenbacher, 1986;). However, as single subject design has become more accepted as a valid means of evaluating clinical treatment approaches and is used more often in clinical research, the application of statistical analysis to these data has been considered. The controversy over whether these methods may or should be applied to single subject data has spurred an interest into detailing the characteristics of the data as well as the criteria for using such statistical methods.

Two important criteria in the application of traditional statistical methods to a set of data are the assumptions of normality and independence. Caster et al. (1994) approached the idea of the single subject as a random trial generator by testing the normality and independence of a set of biomechanical measures collected from 35 subjects. Sub-groups of subjects performed repeated trials under six different conditions of running and/or landing for a total of 35 subjects under an average of 3.3 experimental conditions. Normality of the data was determined using the Shapiro-Wilk test and independence was determined using an autocorrelation procedure. The results identified 33% of the data sets as non-normal with only 4.1% of the trials significantly correlated. The authors conclude that for within subject data, the assumptions of normality and independence are met sufficiently thereby supporting the use of traditional statistical methods.

Nourbakhsh & Ottenbacher (1994) provide a comparative examination of commonly used methods of visual and statistical analysis for single subject data. A set of 42 graphs was assembled which met strict inclusion criteria based on the design of the research (AB repeated measures) and the characteristics of the data. Half of the graphs (21) were selected from existing publications where they were originally evaluated using visual analysis and half were generated using hypothetical data. Each graph was analyzed using the following three methods: 1) Split-middle method of trend estimation (Celeration line); 2) Two-standard deviation band method; and, 3) The C Statistic. The degree of agreement between the three tests was determined and found to be quite low (38%), even when evaluating agreement between any two statistical procedures (48%: 1, 2; 71%: 2, 3; 57%: 1, 3). The discrepancies occurred mostly due to the data characteristics in the baseline phase i.e., the presence of fluctuations, or an accelerating or decelerating trend. The authors demonstrate one occurrence of disagreement by showing the graphs of two data sets each analyzed by methods 1 and 2. Visual analysis of the data shows an acceleration trend in the baseline phase which continues into the treatment phase which should not necessarily be considered a treatment effect. The celeration line method of statistical analysis shows nonsignificance where the two standard deviation band method shows a significant difference between the phases. These results support the need for further development in the application of statistical analysis methods for single subject data. The authors suggest that until the decision rules for using such methods are clearly defined, the analysis of single subject data should not be dependent upon a single method to determine treatment effect.

3.2 DEFINING THE RESEARCH PROJECT

3.2.1 Problem Formulation

The literature on incomplete spinal cord injury supports the practice of exercise such as walking as a means to obtain physical, psychological and functional benefits. Furthermore, advancements in technology have provided assistive devices that may allow persons with incomplete spinal cord injury the opportunity to regain the ability to walk. Many studies have demonstrated the feasibility of utilizing functional electrical stimulation as a means to assist gait and have tested various outcome measures which support the benefits of standing and walking.

While further development in the design and application of FES systems continues, simple surface stimulation systems may provide certain individuals with SCI the assistance they require which would allow them to participate in gait training. In order to test the treatment effectiveness of these simple systems on a specific population of persons with SCI, a clinical trial must be undertaken. This study is part of a multi-centre trial across Canada that is investigating the use of such systems. The combined results may provide evidence that would support the use of simple surface FES systems in conjunction with gait training as a means to allow persons with SCI the opportunity to reap the benefits of standing and walking. Furthermore, this study will provide kinematic and kinetic data that may explain the changes seen in the gait parameters tested.

3.2.2 Statement of Objective

The objective of this thesis is to quantify the changes in gait parameters associated with using FES in conjunction with gait training for persons with incomplete spinal cord injury. Specific questions regarding the use of FES to assist gait include the following: i) Does FES-assisted gait training have an effect on walking speed, stride length and cadence?; and, ii) What is this effect over time? A comparison of walking with and without FES over 26 weeks of training will provide the answers to these questions. Unilateral 2-D kinematic data will be used to quantify the changes in gait parameters with supplemental kinetic data presented where necessary to provide a sample of the internal biomechanics.

3.2.3 Research Design of this Study

This study is part of a multi-centre trial being carried out across Canada governed by the Network of Centres of Excellence on Neural Regeneration and Functional Recovery (see Figure 2.3). The Montréal Centre involves a collaborative effort between the laboratories of Dr. Hugues Barbeau, Dr. Ricardo Torres-Moreno (both of McGill) and Dr. Bradford MacFadyen at the Départment de Kinanthropologie at the Université du Québec à Montréal (UQAM). Included in the collaboration are two master's theses and one doctoral thesis. The overall design and experimental set up allows for a broad range of data to be collected and examined over the same group of subjects. However, the design and set up described herein will include only that pertaining to this master's thesis.

The preliminary study was quasi-experimental using repeated measures in an AB (baseline / treatment) design on a single subject. Four baseline measures were taken over five weeks with one treatment measure at week two into the FES-assisted gait training program. Analysis of this pilot data provided information as to the optimal set up for the data collection.

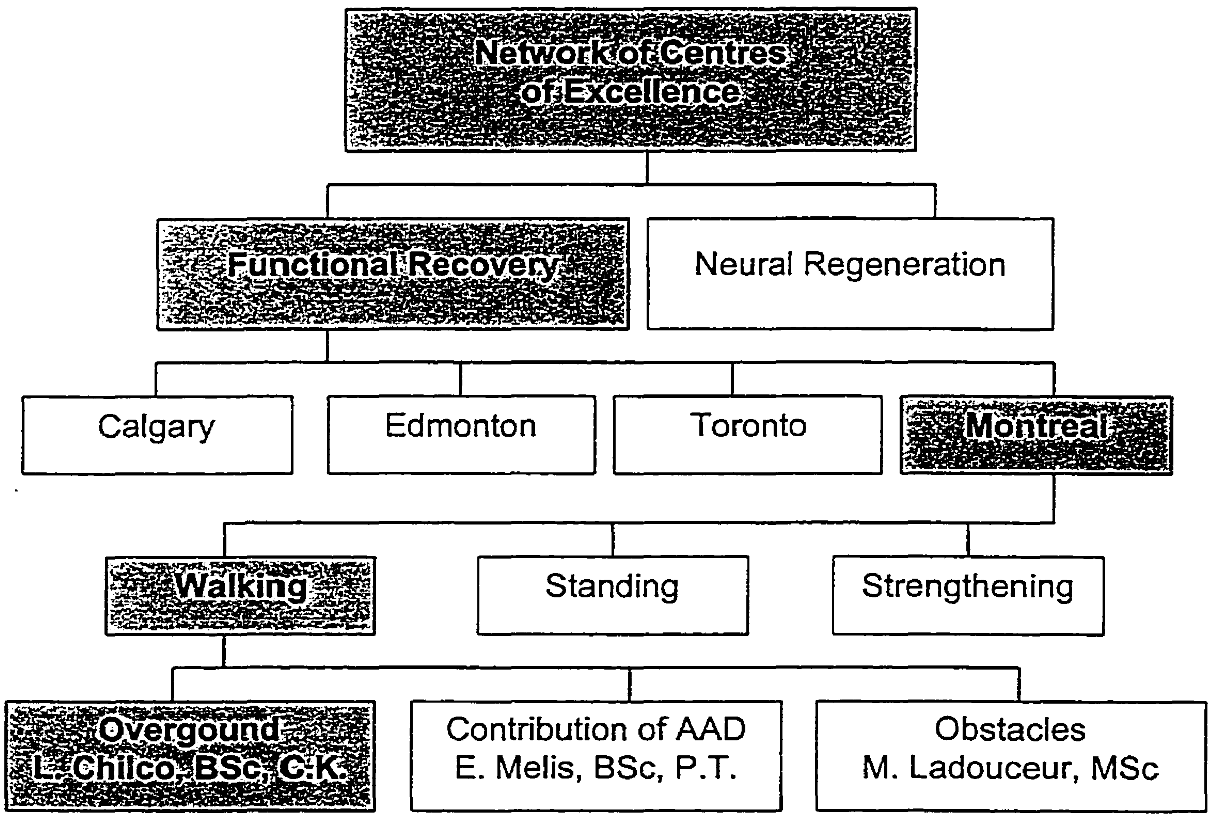


FIGURE 3.1 ORGANIZATIONAL CHART SHOWING RELATION OF THIS THESIS TO THE NCE

The main study was quasi-experimental, AB repeated measures single subject design. The experimental manipulation was the method of overground walking: walking with FES; walking without FES. The overground walking sessions included three preliminary evaluations to obtain a measure of the gait characteristics of each subject. Once the training program was begun, each subject was evaluated at two week intervals up to week 12 and then again at week 26 (after six months of training). The outcome measures are average walking speed, stride length and cadence while walking with and without FES. Kinematic and kinetic data will also be presented to describe the locomotor patterns of the subjects.

3.2.4 Hypotheses

It was hypothesized that walking speed, stride length and cadence would be greater when walking with FES than when walking without FES and that these changes in gait parameters could be explained by the kinematic and kinetic data. It was also hypothesized that there would be a carry-over effect of FES-assisted gait training such that the difference in the gait parameter values between walking with and without FES would decrease over time.

4.1 DEFINITION OF THE SUBJECTS

Two subjects with incomplete spinal cord injury participated in this study. Both subjects met the requirements of the inclusion/exclusion criteria as detailed in Appendix B. The subjects were community dwelling volunteers recruited from the Montreal Rehabilitation Institute and both were previous participants in studies in the laboratory of Dr. Hugues Barbeau at McGill University. Both subjects were screened at an introductory session whereby suitability for the study was determined. Each subject read and signed a consent form detailing the research protocol, the required time commitment, and the potential risks and benefits of participation in the study (see Appendix C). The characteristics for these two subjects are presented in Table 4.1.

TABLE 4.1 CHARACTERISTICS OF SUBJECTS IN THIS STUDY

SUBJECT	SEX	AGE (YRS)	LEVEL OF INJURY	CHRONICITY	INITIAL AAD	INITIAL WALKING VELOCITY
MA	M	36	C5-C6	6 years	Walker	0.16 m/s
DT	M	32	T11	3 years	Walker	0.05 m/s

4.2 PHYSICAL ASSESSMENT SESSION

Each subject attended a physical assessment session carried out by the trainer (this author) and a physiotherapist, Miss Ellen Melis, whereby pertinent medical information and physical measures, including muscle strength and joint range of motion, were obtained. This information was used to identify any asymmety in the subject's functional abilities and to determine his individual FES stimulation requirements.

4.3 THE FES-ASSISTED GAIT TRAINING PROGRAM

4.3.1 Protocol

The FES-assisted gait training program (FAGT) involved three stages: Stage One: Stimulation Accommodation; Stage Two: Supervised Gait Training; and, Stage Three: Gait Training at Home. The stages of the FAGT are detailed in Table 4.2. The subjects began training with their initial AAD with progression to another AAD as determined by their needs and improvement.

During Stage One subjects attended training sessions for five consecutive days. The time for each session was approximately 2½ to 3 hours including preparation time and rest periods. The amount of gait training time was dependent upon the initial walking ability of the subject and gradually increased to 30 minutes as the subject adapted to the stimulation.

In Stage Two, supervised training sessions occurred three days per week, with 1-2 hours of gait training per day. The amount of time spent on each objective was dependent on the ability of the subject to perform the new task effectively. By the end of this stage subjects were independent in using the FES system and had a good understanding of setting and realizing training goals. A schedule of home training was incorporated into the subject's existing timetable.

The subjects trained at home in Stage Three with limited supervision from the trainer. Up to week twelve, subjects attended one supervised training session each week (subject MA) or two weeks (subject DT). After week twelve, telephone contact was maintained between the subjects and the trainer regarding further training advice and/or the replenishment of supplies.

TABLE 4.2 DETAILS OF THE FES-ASSISTED GAIT TRAINING PROGRAM

Stage	Term	Training Objectives
Stimulation Accommodation	One Week	Overview of FES and relevant anatomy Explain safety, skin care, stimulator operation Learn proper application of stimulation electrodes Learn proper timing of stimulation in gait cycle Determine optimal stimulus amplitude & duration Discuss training goals and expectations
Supervised Training	Three Weeks	Increase overground walking endurance & speed Improve balance Adapt to various environmental conditions: ➢ wood, carpet, tile, cement, grass surfaces ➢ obstacles, curbs, stairways ➢ slopes, turns, doorways Gain independence in: ➢ donning/doffing FES system ➢ standing/sitting with AAD ➢ recovery from falls Discuss goals/desires for community entry Determine Home Training Schedule
Home Training	Five Months	Continued practice in walking with FES Realize Community Outing Goal Maintain Phone Contact with Trainer

4.3.2 Apparatus

The apparatus for the FAGT included the use of a multi-channel stimulator (QuadStim: Biomech Designs Ltd.) with reusable conductive self-adhesive electrodes (42002: Chattanooga Corp.), an ambulatory assistive device (walker, Canadian crutches), and training aids relevant to the specific training objectives.

<u>Stimulator</u>:

The QuadStim was chosen for this study because of its flexibility and ease of use. The QuadStim has pre-set internal parameters regarding stimulus duration, maximum current, and frequency (see Appendix D). The intensity of the stimulation can be adjusted externally and the stimulus onset is controlled by an external trigger (hand switch) which is attached to the handle of the AAD. The stimulator is powered by rechargeable batteries and can be worn either around the waist on a belt, or on a harness on the chest. The initial physical assessment and baseline gait evaluations determined the stimulation parameters for the individual subjects' needs. The application of the stimulation electrodes required the use of a razor, cotton swabs and alcohol to prepare the skin.

Ambulatory Assistive Device:

The existing laboratory inventory of walkers and crutches was used to assist the training. Other items such as ankle supports or orthotics were made available as required.

Training Aids:

The location of the training session was determined by the availability of the various overground walking surfaces desired. The regular training location included wood and carpeted surfaces whereas training over tile, cement and grass was carried out at nearby locations. A 14cm high wood riser was used as a curb and various articles were used as obstacles along a 20m carpeted walkway. The existing stairways at the regular training site were used and included those with handrails and without, both indoors and out of doors. When necessary, a BWS system available at the regular training site was used. This system was used for DT to aid in his transition to reciprocal bipedal locomotion due to the decrease in spasticity and subsequent increased instability in his ankle joints after beginning the FES-assisted training program.

4.4 EXPERIMENTAL SESSIONS

4.4.1 Protocol

A schematic representation of the experimental set up is shown in Figure 4.1. Data collection stations were set up for: a) kinematic (VCR's, video monitors and lamp switches) acquisition; and, b) kinetic (force platform) acquisition. The walkway for data acquisition was delimited lengthwise by two metal rails raised approximately 2cm above the force plate by placing rubberized wood blocks beneath them. The width between the rails was adjustable to accommodate the use of either a walker or crutches such that the gait aid did not touch the force plate as the subject walked along the walkway.

Data acquisition for kinetic data was initiated when the subject was one step away from the force plate. Verification of proper data collection was made at each station following the start of the trials. A successful overground trial was defined as one full stride making good contact onto and off of the force plate.

After preparation for collection of the data (and donning of the FES system when necessary) subjects were instructed to walk at a comfortable speed along the walkway and were allowed to practice such that their foot placement made full contact with the force platform.

The subject performed four to five trials at a time. Rest periods were mandatory and lasted approximately five to ten minutes between each set of trials. A lunch/dinner break was also taken during the evaluation sessions when necessary.

During the baseline evaluations ten successful overground walking trials were recorded. At the six month follow up evaluation five successful trials of each condition (walking with FES, walking without FES) were recorded. All trials walking with FES were recorded separately from all trials walking without FES. Randomization of the order of walking condition was used to reduce any effects of learning and fatigue during the session.

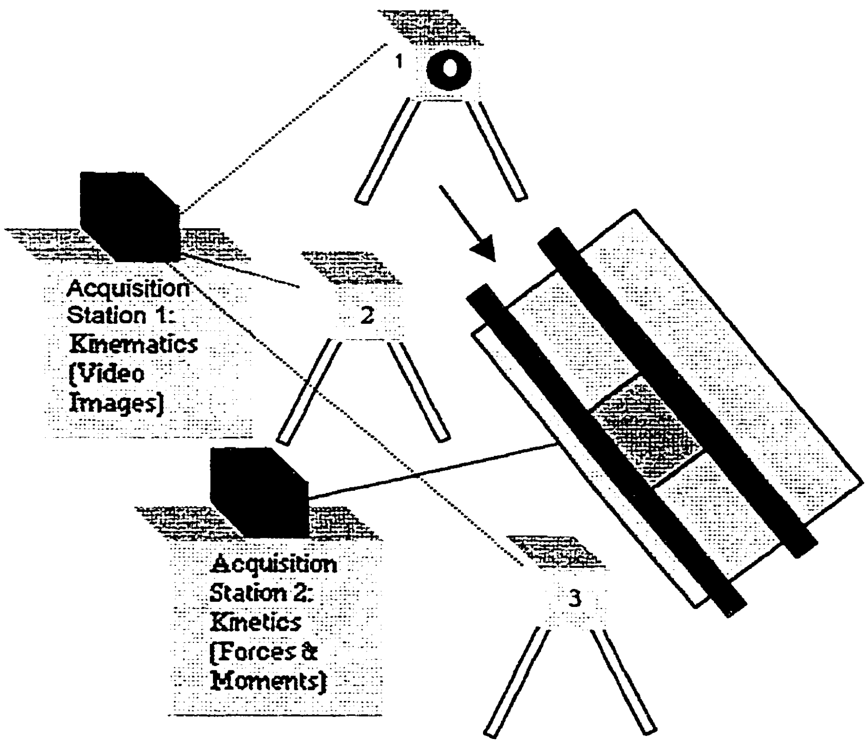


FIGURE 4.1 SCHEMATIC REPRESENTATION OF EXPERIMENTAL SET UP

4.4.2 Instrumentation

Kinematics:

Unilateral sagittal kinematic data was collected at 60Hz on ½ inch VHS video tapes (Panasonic: NV-T120ZS) using three genlocked video cameras each with its own lamp, led synchronization signal and VCR. Video monitors were used to ensure proper camera placement. Reflective markers were attached to the subject on the more affected side demarcating the foot, leg, thigh and trunk segments. Figure 4.2 shows the marker positions (acromion, the greater trochanter of the femur, joint line of the knee, lateral malleolus, calcaneus, head of the fifth metatarsal, toe) and method of segment and angle calculation.

The position of each marker and anthropometric data was measured and recorded at the first evaluation. At subsequent evaluations, the markers were placed according to the original measured placement. A calibration frame was used so that the absolute position of the markers in space could be quantified.

Kinetics:

A strain-gauge force plate (AMTI: TM 100-5) was used to collect the kinetic data. Data from six channels was amplified at a gain of 4000 and low pass filtered at 1050Hz. The six channels represent the reaction forces in the vertical (F_z), medial-lateral (F_x), and anterior-posterior (F_y) directions and the moments about the axes (M_z, M_x, M_y). The data was acquired and stored on-line using BrainWave 3.0 software via a 12 bit 16 channel A-D converter (Data Translation DT2821) at a sampling frequency of 300Hz.

Synchronization of the Data:

The data was synchronized by placing an led signal at a frequency of 12Hz in view of each video camera and imposing a square wave signal on a separate channel entering the kinetic data at a frequency of 60Hz. The onset of the synchronization signals together with the acquisition rates set at multiples of 60 (the video cameras are the limiting frequency) enable all data to be synchronized for analysis.

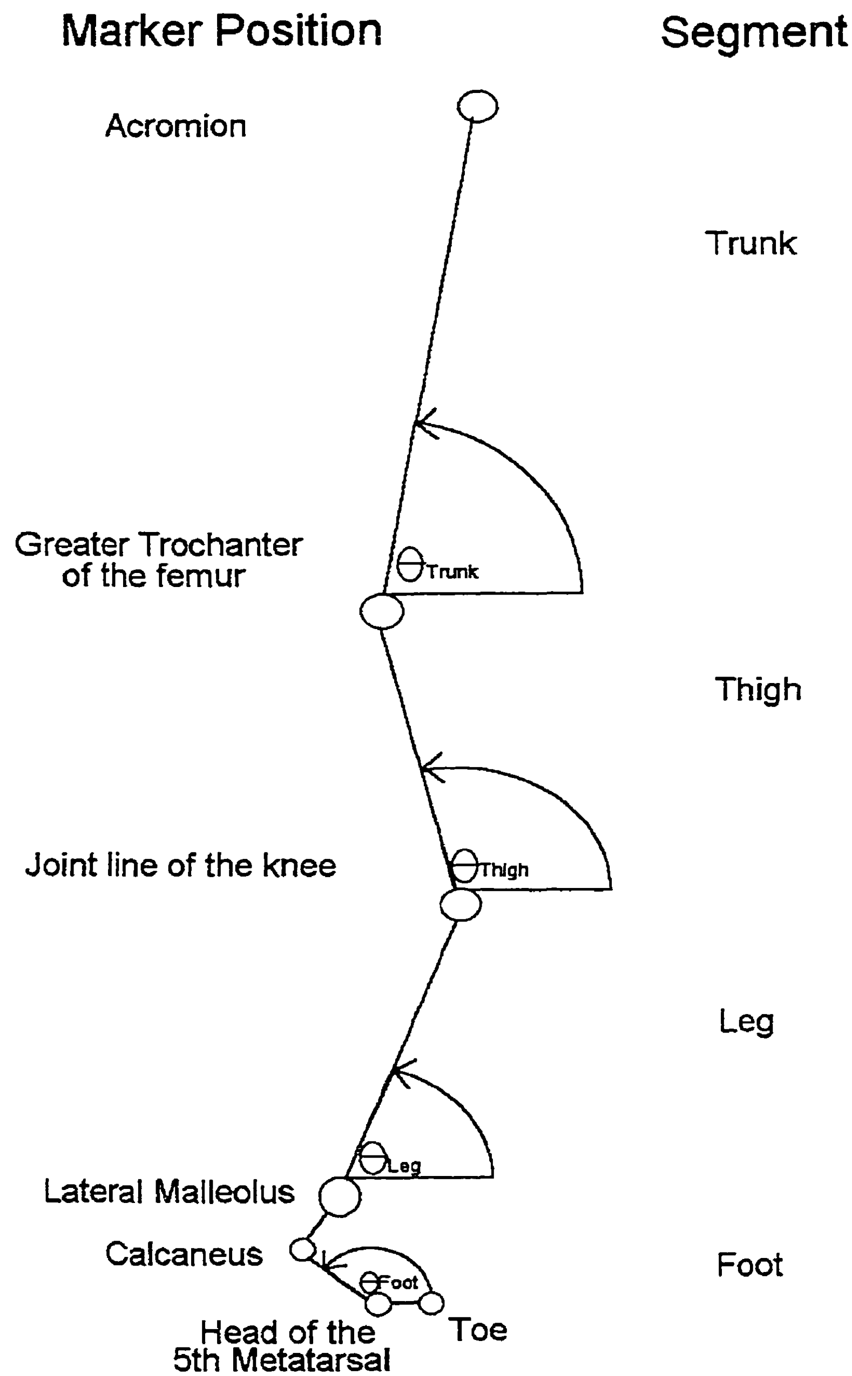


FIGURE 4.2 MARKER POSITIONS AND METHOD OF SEGMENT ANGLE CALCULATION

4.5 DATA ANALYSIS

4.5.1 Quantification of the Data

The video images from each trial were digitized using the Peak 5.0 Motion Analysis System (Peak Performance Inc.). Winter (1990) suggests that the frequencies for the majority of landmarks studied in gait analysis fall under 6Hz. Therefore, the data was filtered at 6Hz (Butterworth: 2nd order dual pass) and a direct linear transformation (DLT) process was performed providing coordinate displacement data for each marker. The kinematic coordinate data was used to calculate gait parameters including average walking velocity, cadence and stride length for the baseline and each follow-up evaluation, as well as angular excursions at the hip, knee, ankle and trunk (see Appendices E and F for calculations), angular velocity at the hip and certain marker trajectories for the baseline and week 26 evaluations. Ensemble averages of the kinematic profiles were created by first normalizing each trial to 100% over the stride period with 201 equally spaced data points (each data point representing 0.5% of the total stride time) and then taking an average of the trials digitized. The coefficient of variation was calculated for each time-series profile representing a signal to noise ratio of the data.

The kinetic data was low-pass filtered at 25Hz (Butterworth: 2nd order dual pass) and the resultant ground reaction forces and centre of pressure values were computed. These data were combined with anthropometric data based on Dempster's model (see Appendix G) and the kinematic coordinate data using an inverse dynamic link segment model formula (see Appendix H) to produce moment of force profiles in the sagittal plane for the ankle, knee and hip joints.

4.5.2 Visual and Statistical Analysis

The mean and standard deviation of the gait parameters for each set of trials at the baseline and follow up evaluations are displayed in graphical form for visual analysis.

The data for the gait parameters were examined for treatment effect by using a strip binomial method of analyzing single subject data. A least squares regression and one-way repeated measures ANOVA was performed over factors: time, trial, and FES to explain the variance in the data.

The kinematic and kinetic data are displayed in graphical form such that the angular excursion and moment of force profiles at the hip, knee, and ankle joints may be examined.

5.1 VISUAL AND STATISTICAL ANALYSIS OF GAIT PARAMETER DATA

5.1.1 Subject DT

Figure 5.1 shows the mean and standard deviation of the gait parameters (average walking velocity in m/s, cadence in steps/min and stride length in metres) for DT at baseline and weeks 2, 4, 8, 12 and 26 for overground walking with FES (WF) and without FES (NF). Visual analysis of the three graphs shows that the gait parameter is always greater when walking WF than when walking NF. The curves for average walking velocity show an increase in slope for both NF and WF with the slope for walking with FES steeper than walking without FES. The cadence curves show a similar slope for walking WF and NF and show an improvement for both over time. The curves for stride length show a slight increase over time for walking WF and a slight decrease for NF. The raw data for these variables can be seen in Appendix I.

A linear regression and one-way repeated measures ANOVA was performed separately on the velocity, cadence and stride length data. The model included the following factors: time, trial, FES, and timexFES. The results of the regression and ANOVA for each dependent variable are shown in Table 5.1. Significant effects were found in the regression for time ($p<0.01$) for velocity and cadence, FES ($p<0.01$) for velocity and timexFES ($p<0.01$) for all of the gait parameters. Trial was not significant for any parameter. A significant effect was found in the ANOVA for velocity ($F=43.62$, $p<0.01$), cadence ($F=30.51$, $p<0.01$) and stride length ($F=5.88$, $p<0.01$).

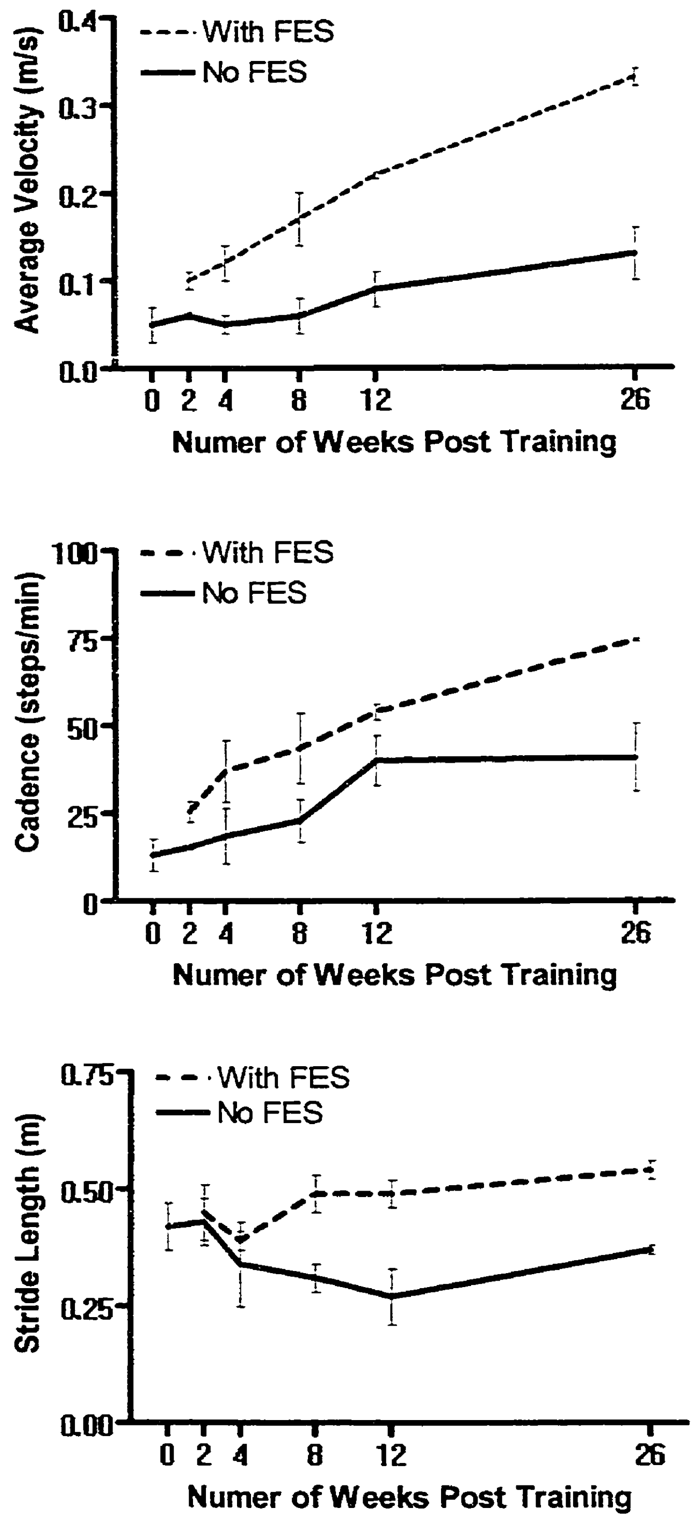


Figure 5.1: Mean ± SD of Gait Parameters for DT with and without FES

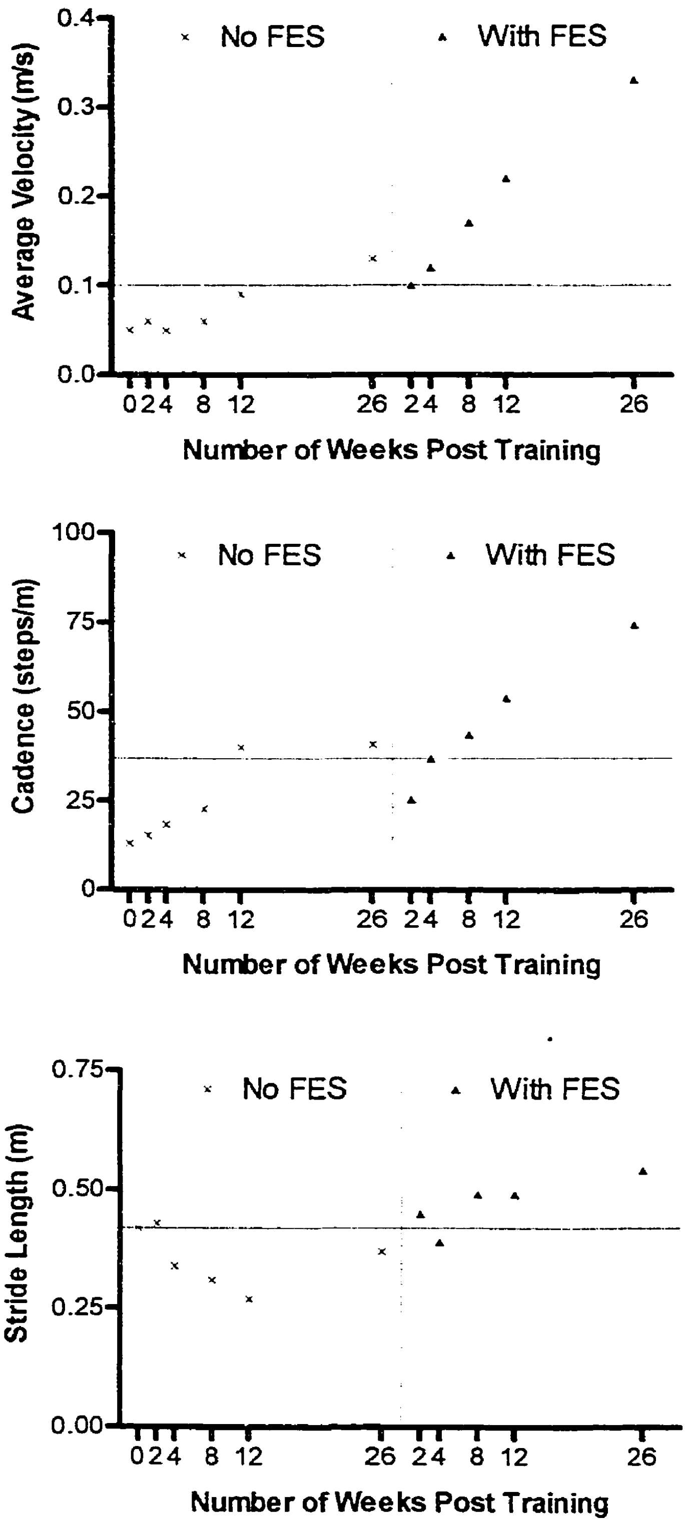


Figure 5.2: Position of Mean Gait Parameter Data relative to the Median for DT

Table 5.1: Summary of Statistical Analysis of Gait Parameter Data for DT

	Regression					
Parameter	time	trial	FES	timexFES	ANOVA	Binomial
Velocity (m/s)	S $p<0.01$	NS	S $p<0.05$	S $p<0.01$	S F=43.82 $p<0.01$	S NF=1/6 WF=4/5 $p<0.05$
Cadence (steps/min)	S $p<0.01$	NS	NS	S $p<0.01$	S F=30.51 $p<0.01$	NS
Stride Length (m)	NS	NS	NS	S $p<0.01$	S F=5.88 $p<0.01$	S NF=1/6 WF=4/5 $p<0.05$

S=Significant NS=Not Significant

Figure 5.2 shows the gait parameter data organized in a baseline / treatment manner with the median value of all data sets for each variable drawn as a dotted line through the data points. The number of data points WF and NF that fell above the median were counted and significance was determined via a strip binomial. These results are shown in Table 5.1. A significant treatment effect was found for velocity (NF=1/6: WF=4/5, $p<0.05$) and stride length (NF=1/6: WF=4/5, $p<0.05$). Cadence was not found to be significant (NF=2/6: WF=3/5).

5.1.2 Subject MA

Figure 5.3 shows the mean and standard deviation of the gait parameters (average walking velocity in m/s, cadence in steps/min and stride length in metres) for MA at baseline (walker) and weeks 2 (walker and crutches), 4, 8, 12 and 26 (all crutches) for overground walking with FES and without FES. Visual analysis shows that walking with FES is always less than walking without FES for all three variables. The curves for average walking velocity show a slight

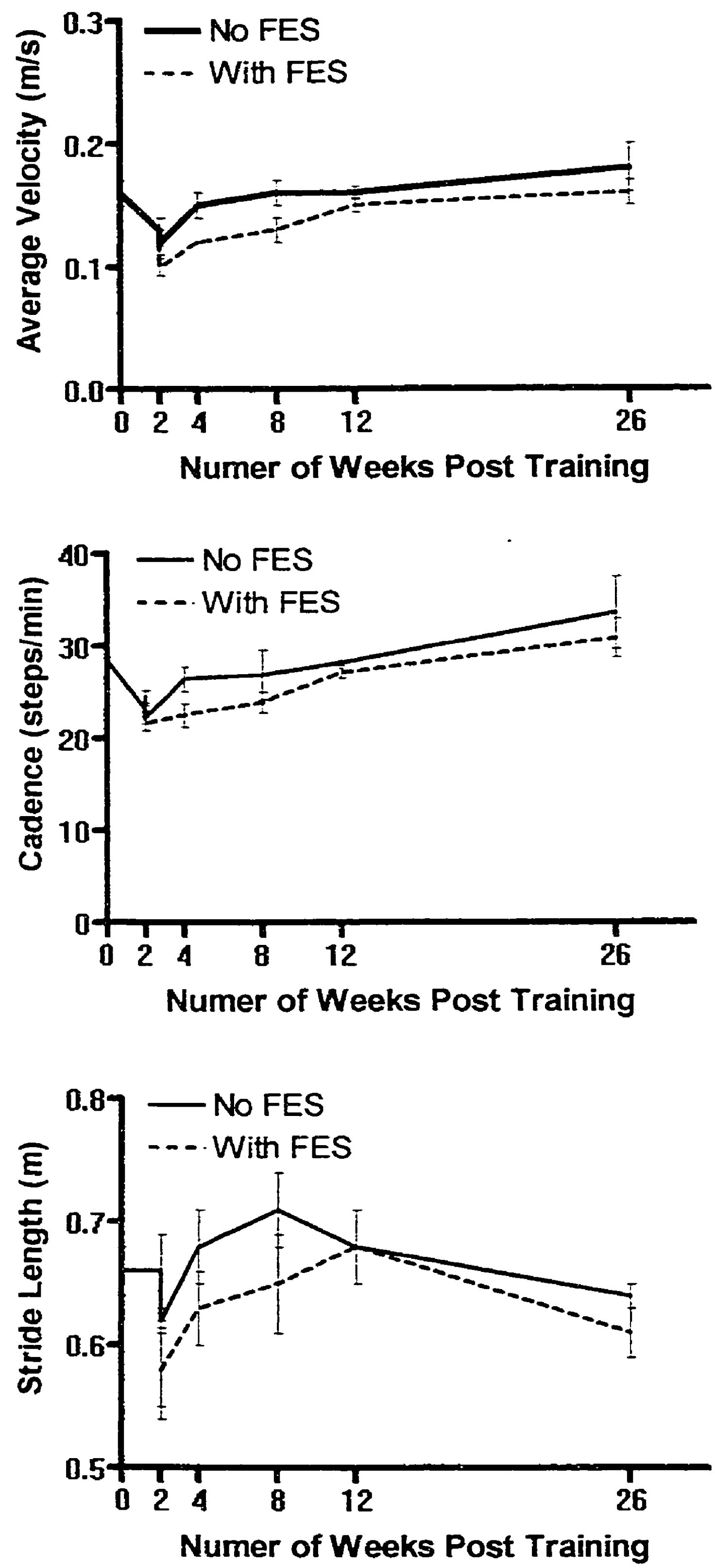


Figure 5.3: Mean ± SD of Gait Parameters for MA with and without FES

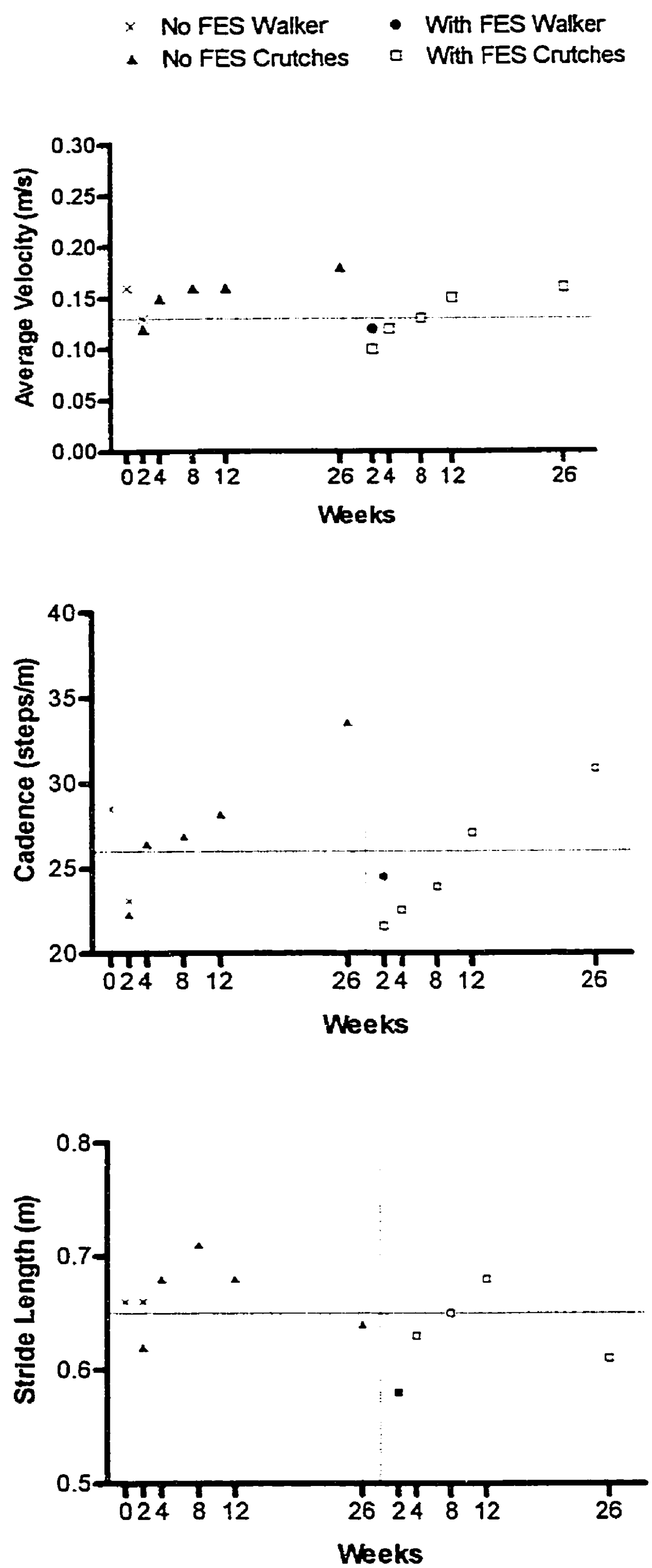


Figure 5.4: Position of Mean Gait Parameter Data relative to the Median for MA

increase in slope over time for both NF and WF at approximately the same slope. The cadence curves show a similar slope for walking WF and NF and show an improvement for both over time. The curves for stride length show a slight increase over time for walking both NF and WF to week 12 with a decrease for both to week 26. The raw data for these variables can be seen in Appendix I.

The linear regression and one-way repeated measures ANOVA performed separately on the gait parameter data over the factors time, trial, FES and timexFES are summarized in Table 5.2. A significant effect of time was seen for velocity, cadence (both $p<0.01$) and stride length ($p<0.05$), FES for velocity ($p<0.01$) and stride length ($p<0.05$). Trial and timexFES was not found to be significant for any variable. The ANOVA was significant for velocity ($F=9.53$, $p<0.01$) and cadence ($F=5.83$, $p<0.01$) but not for stride length ($F=2.31$, 0.0515).

Table 5.2: Summary of Statistical Analysis of Gait Parameter Data for MA

	Regression					
Parameter	time	trial	FES	timexFES	ANOVA	Binomial
Velocity (m/s)	S $p<0.01$	NS	S $p<0.01$	NS	S $F=9.53$ $p<0.01$	NS
Cadence (#steps/min)	S $p<0.01$	NS	NS	NS	S $F=5.83$ $p<0.01$	NS
Stride Length (m)	S $p<0.05$	NS	S $p<0.05$	NS	NS	NS

S=Significant NS=Not Significant

Figure 5.4 shows the baseline/treatment data for the gait parameters with the median value of all data sets for each variable drawn through all data points. Significance was not found for average walking velocity (NF=5/7; WF=2/6), cadence (NF=5/7; WF=2/6) nor stride length (NF=5/7; WF=1/6).

5.2 Descriptive Profiles of Kinematic and Kinetic Data

5.2.1 Subject DT

The ensemble average profiles of the angular excursion and standard deviation for the hip, knee and ankle over one stride period at baseline without FES, at week 26 without FES and at week 26 with FES can be seen in Figures 5.5, 5.6 and 5.7.

Figure 5.8 shows the ensemble average of the trunk angular excursion and standard deviation over the stride period for baseline and week 26. The ensemble average of the angular velocity and standard deviation for the hip over 90-100% of the stride cycle (to include the swing phase) at baseline and week 26 is shown in Figure 5.9.

Figures 5.10 and 5.11 show the ensemble average profiles of the moment of force and standard deviation for the hip, knee and ankle over one stride period at baseline without FES and at week 26 with FES.

For the above-mentioned figures, the joint angle / angular velocity / joint moment is shown on the y axis with the percentage of the stance phase, swing phase or entire stride cycle on the x axis. The change from stance and swing periods is demarcated by a dotted vertical line. The coefficient of variation (CV) is shown on each graph (see Appendix E for calculation).

The maximum, minimum and range of the angular excursions for Figures 5.5, 5.6, 5.7 and 5.8 is shown in Table 5.3. The maximum, minimum and percent change over time of the moments is shown in Table 5.4. Table 5.5 shows the stride parameters over time as calculated from the kinematic data.

Table 5.3 Maximum, Minimum and Range for Angular Excursions for DT

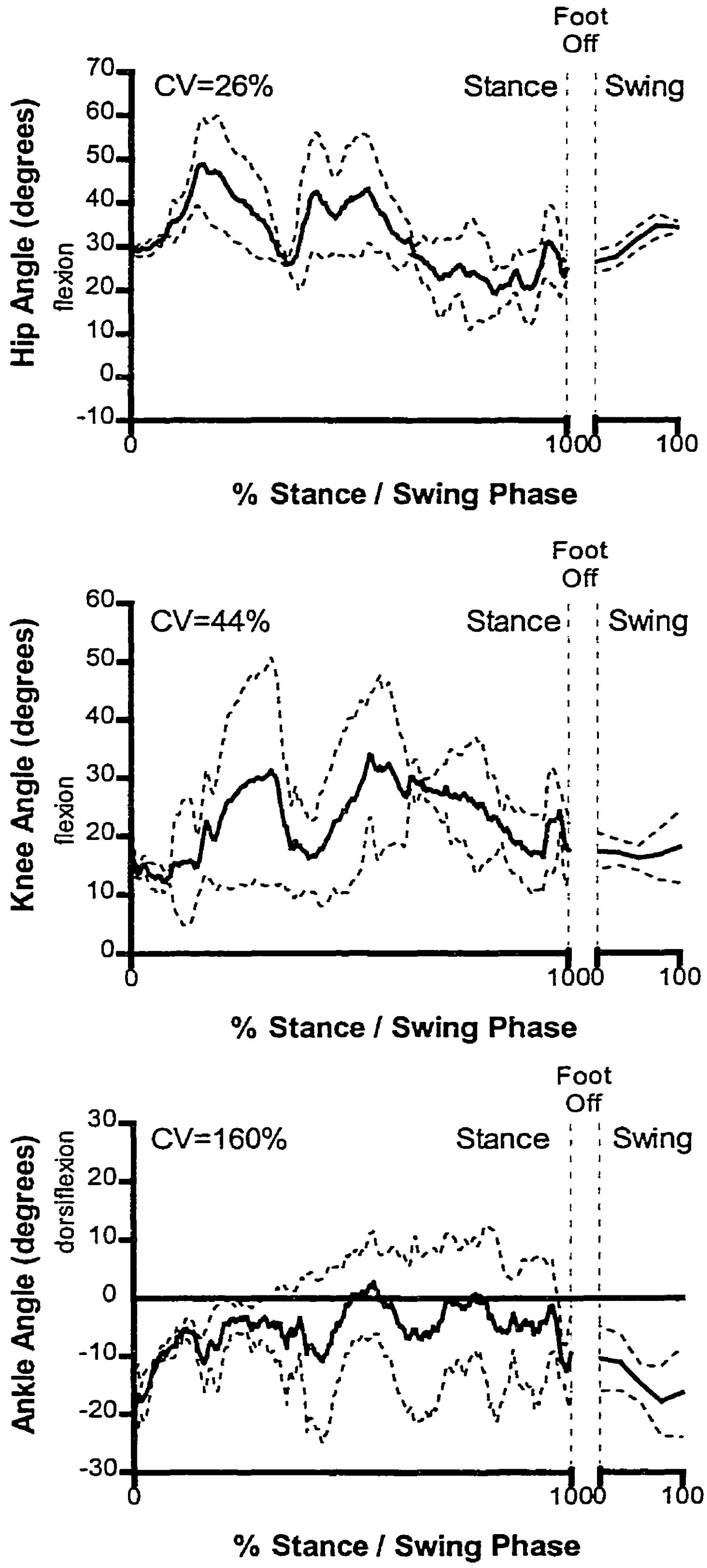
		Baseline	Week 26 NF	Week 26 WF
Hip (deg)	max	46.2	49.6	43.6
	min	18.7	18.4	19.7
	range	27.5	31.2	23.8
Knee (deg)	max	34.7	35.4	27.2
	min	12.4	16.5	17.3
	range	22.3	18.9	9.9
Ankle (deg)	max	0.4	-2.7	-4.1
	min	-18.3	-23.5	-21.5
	range	18.6	20.6	17.5
Trunk (deg)	max	65.2	73.4	70.3
	min	50.1	53.1	54.3
	range	15.0	20.3	16.1

Table 5.4: Maximum and Minimum Moments with % Change over time for DT

	Ankle		Knee		Hip	
	Maximum	Minimum	Maximum	Minimum	Maximum	Minimum
Baseline NF (N•m/kg)	0.08	-0.006	0.17	0.02	0.48	-0.07
Week 26 WF (N•m/kg)	4.80	-14.56	0.29	-30.70	0.53	-31.44
% Change / Direction	98 ⇧	100 ⇧	41 ⇧	100 ⇧	9 ⇧	100 ⇧

Table 5.5: Stride Parameters for DT at Baseline and Week 26

Evaluation	Velocity (m/s)	Cadence (steps/min)	Side	Stride Length (m)	Step Length (m)	Stride Period (s)	Stance / Swing Ratio
Baseline	0.05	13	R	0.42	0.13	13.00	98:02
			L	0.43	0.31	11.36	97:03
Week 26 NF	0.13	41	R	0.37	0.17	4.22	94:06
			L	0.41	0.24	4.71	92:08
Week 26 WF	0.33	74	R	0.33	0.28	2.32	91:09
			L	0.61	0.33	2.88	87:13



Ensemble Average of the Hip, Knee and Ankle Angular Excursion plus standard deviation at Baseline - No FES

Figure 5.5: Angular Excursion of the Hip, Knee and Ankle for DT at Baseline

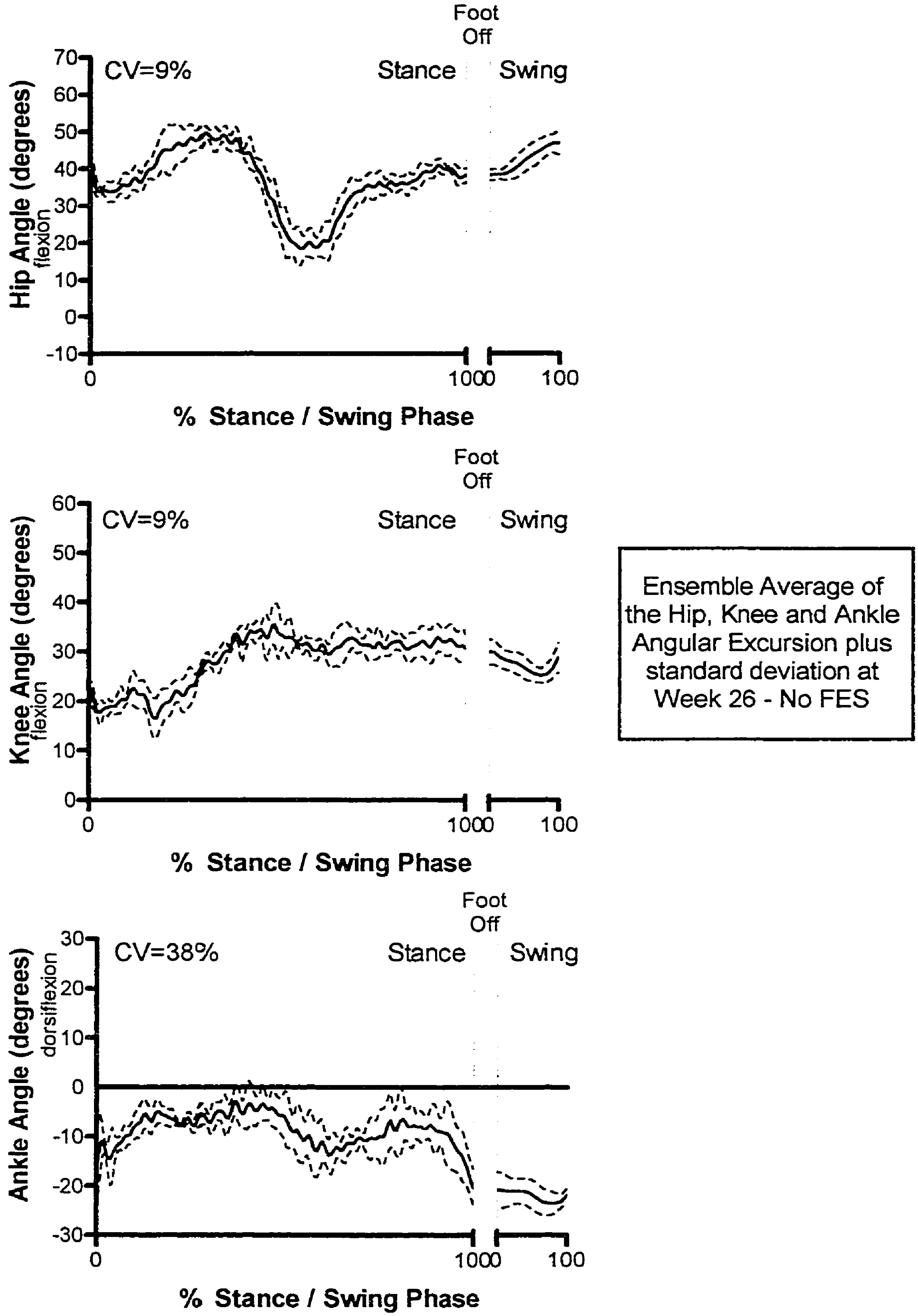


Figure 5.6: Angular Excursion of the Hip, Knee and Ankle for DT at Week 26 No FES

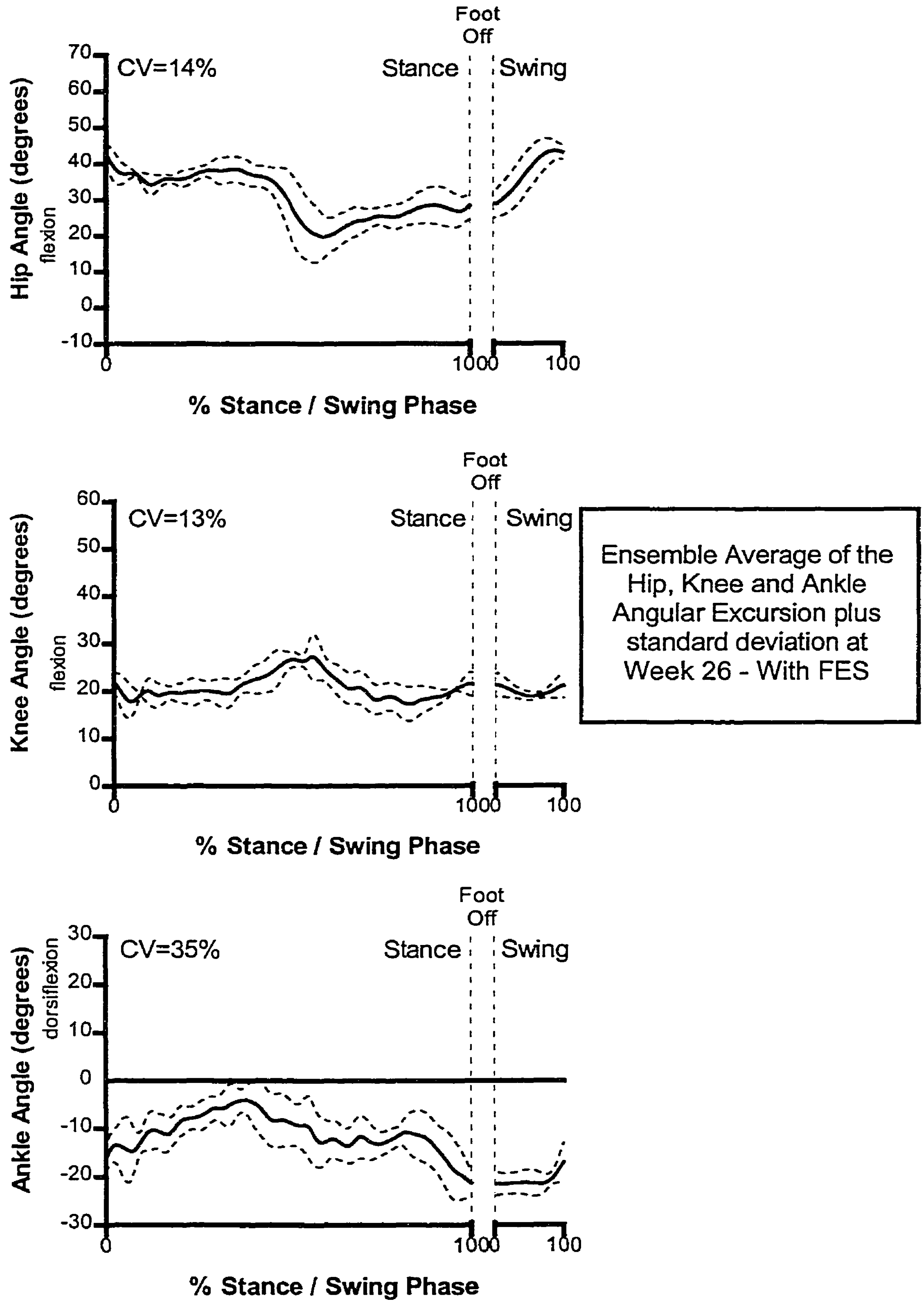
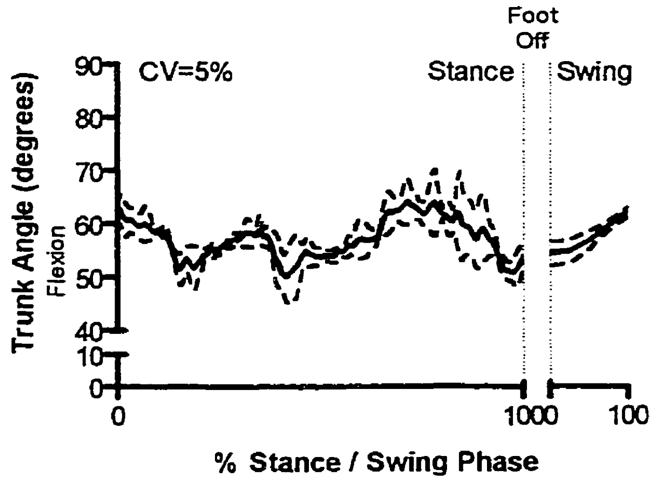
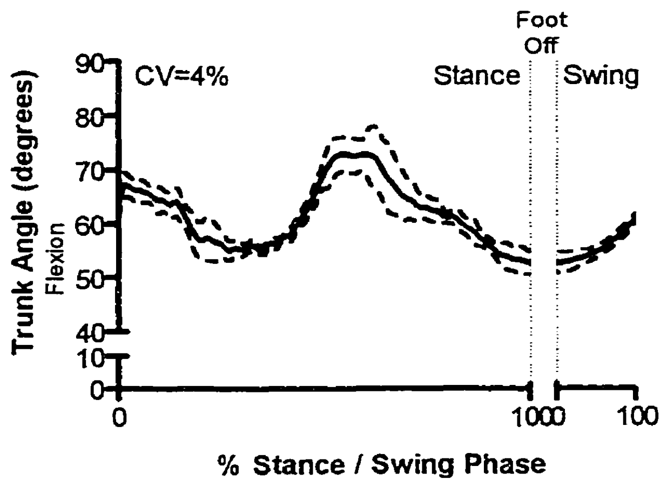


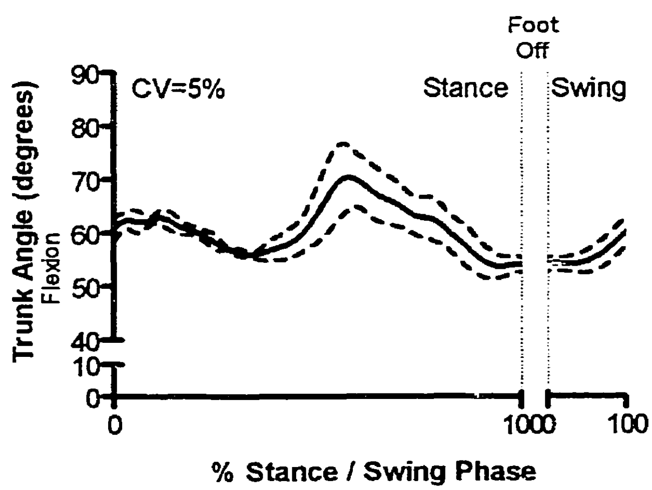
Figure 5.7: Angular Excursion of the Hip, Knee and Ankle for DT at Week 26 With FES



Ensemble Average of Trunk Angle plus standard deviation at Baseline - No FES



Ensemble Average of Trunk Angle plus standard deviation at Week 26 - No FES



Ensemble Average of Trunk Angle plus standard deviation at Week 26 - With FES

Figure 5.8: Angular Excursion of the Trunk at Baseline and Week 26 for DT

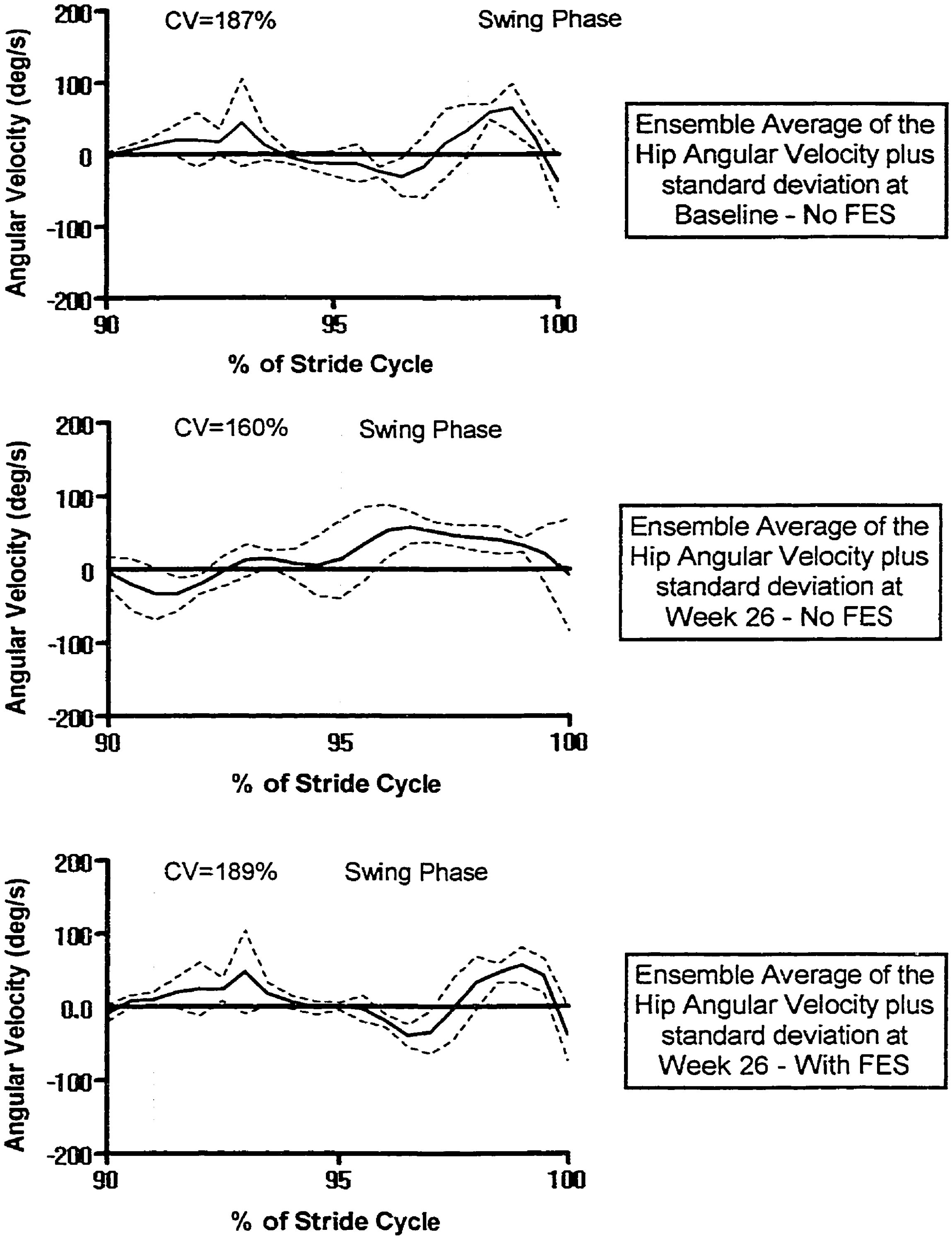
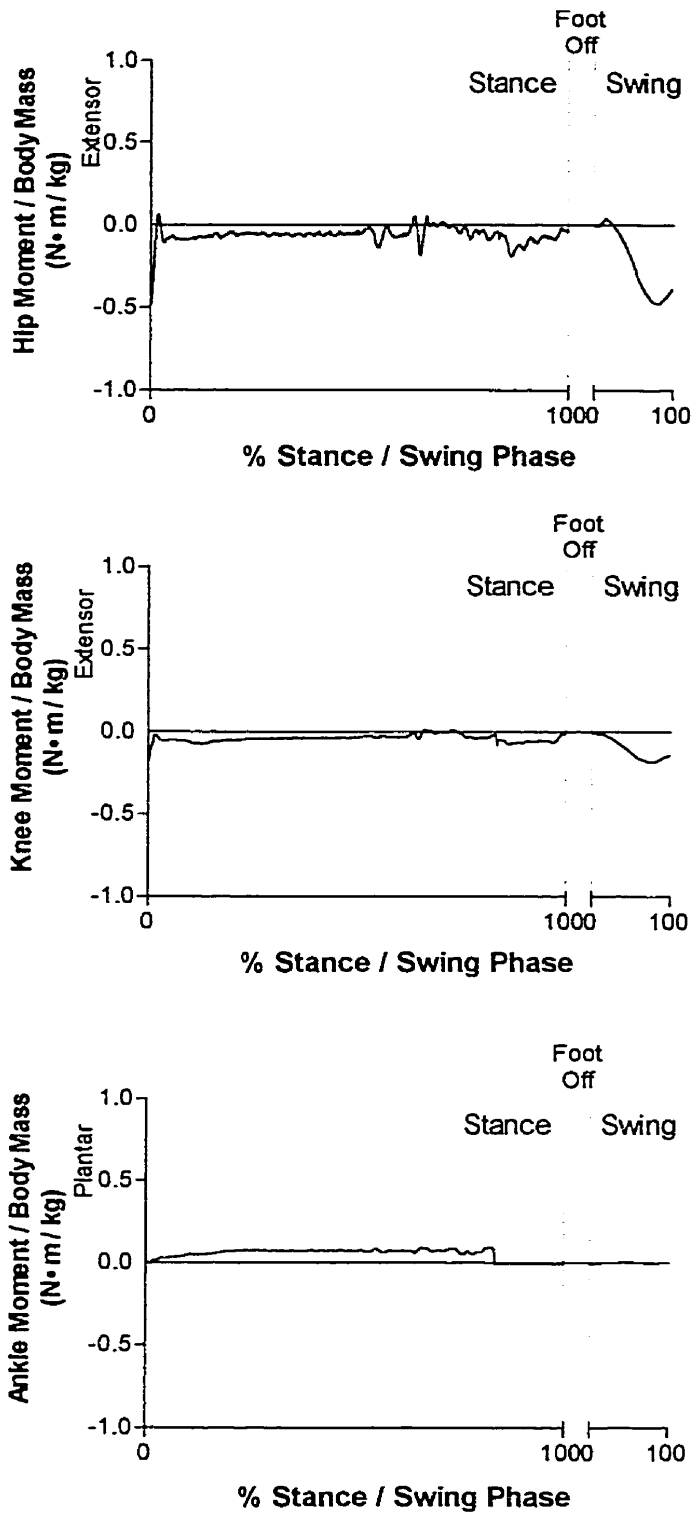
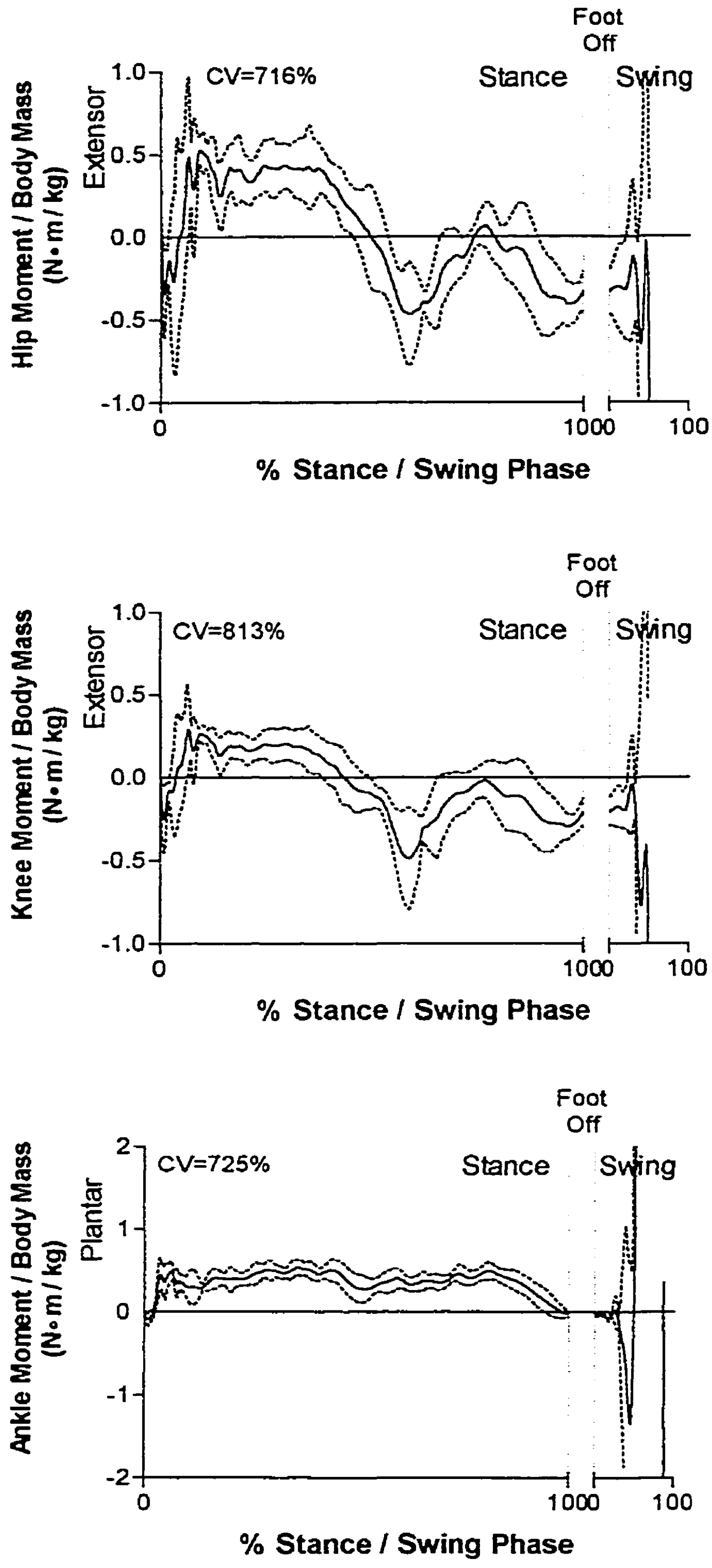


Figure 5.9: Angular Velocity of the Hip at Baseline and Week 26 for DT



Sample Trial of the Hip, Knee and Ankle Moment at Baseline - No FES

Figure 5.10: Joint Moment of the Hip, Knee and Ankle at Baseline without FES for DT



Ensemble Average of the Hip, Knee and Ankle Moment plus standard deviation at Week 26 - With FES

Figure 5.11: Joint Moment of the Hip, Knee and Ankle at Week 26 with FES for DT

In general, the variability of the angular excursion patterns seen in Figures 5.5 to 5.8 decreased at all three joints from baseline to week 26. The pattern at each joint is more smooth at week 26 and flows through a pattern of flexion / extension relative to the exchange of weight / support between the left and right lower limbs and the walker, and to the forward progression of the body during the stride cycle.

The ankle is plantarflexed at foot contact and remains in plantar flexion throughout the stride cycle indicating that the subject is walking mostly on the ball of his foot. However, the pattern of angular excursion follows a trend toward dorsiflexion that nearly reaches neutral during stance and is most plantar flexed at foot off, which coincides with the stability required during the weight transfer / single stance phase and the forward progression of the body in space.

The knee excursion changes little during the stride cycle at each evaluation and remains flexed between approximately 20-35 degrees at week 26. The pattern without FES at week 26 for the knee shows the greatest range of motion with the least variability. The characteristic rise to a peak of nearly full flexion following foot off is absent indicating a very stiff legged walking pattern.

The hip angle remains flexed during the stride cycle at each evaluation with large double peaks at baseline during the stance phase. This pattern relates to the very slow walking speed of the subject at this time and to the forward flexed posture maintained by the subject (please see the trunk angle). At week 26 with FES, the pattern of hip angular excursion follows a more smooth transfer toward extension during late stance however a forward flexed posture is still maintained.

The trunk angle remains consistent in terms of variability over each of the evaluations however, the pattern is more smooth at week 26 with the greatest range of motion at week 26 without FES. The subject carries himself in a forward flexed posture which relates to his use of the walker in that he maintains his balance by assuming a tripod-like position between his two legs and the walker. After thrusting the walker forward, he brings his legs to meet the posterior edge of the walker therefore never becoming completely upright.

The angular velocity at the hip is highly variable at baseline and at week 26. The pattern at foot off to foot contact for baseline and week 26 without FES shows an increase in angular velocity to a peak about halfway during swing then a decrease toward zero at foot contact. The pattern at week 26 with FES is different in that there is an increase and decrease to zero from toe off to mid-swing followed by a dip below zero and another increase to a peak slightly higher than the first peak which then decreases to below zero at foot contact.

The joint moment profile at baseline for each joint is essentially flat with very little activity over the stride period. At week 26 there is a recognizable pattern of extensor / flexor moment activity through the stride period at each joint however, the moments are extremely variable. The ankle moment shows no rise toward foot off indicating that there is no power being generated to contribute to the forward propulsion of the body. In compensation for this lack of power generation at the ankle, the hip flexor moment during late stance indicates that a "pull-off" technique is used to assist in swinging the leg forward. This pattern is often seen in pathological gait as a compensation for a weak or non-existent push-off (Winter, 1991).

The stride parameters calculated from the kinematic data averaged over three trials each at baseline and week 26 with and without FES are shown in Table 5.5. These parameters include those analyzed statistically and the left limb stride length, the right and left step length, the stride period and the stance / swing ratio.

The changes in velocity and cadence as previously discussed illustrate a more dramatic impact when comparing the baseline directly to the follow-up data. The largest difference is seen when comparing baseline without FES to week 26 with FES, however, an important cross-over effect can be seen when comparing baseline without FES to week 26 without FES. This subject showed an improvement in his ability to ambulate overground without using FES.

There was an increasing difference between the left and right sides from baseline to week 26 with FES for stride length with the right side decreasing and the left side increasing. The overall minimal changes in stride length indicate that the changes seen in velocity can be attributed to the change in cadence.

Step length became more similar between the left and right sides with the right side increasing from baseline to week 26 with FES and the left side remaining relatively constant.

The stride period was about the same on each side with a substantial decrease from baseline to week 26, which coincides with the dramatic increase in cadence. The stride period for walking with FES was less than when walking without FES.

The stance / swing ratio showed a decrease in stance time with an increase in swing time from baseline to week 26. Both sides decreased equally in stance over time however, the right side always has a slightly higher stance time to swing when compared to the left side.

5.2.2 Subject MA

The ensemble average profiles of the angular excursion and standard deviation for the hip, knee and ankle over one stride period at baseline without FES, at week 26 without FES and at week 26 with FES can be seen in Figures 5.12, 5.13 and 5.14. Figure 5.15 shows the ensemble average of the trunk angular excursion and standard deviation over the stride period for baseline and week 26. The maximum, minimum and range of the angular excursions for these figures is shown in Table 5.6.

The ensemble average of the vertical displacement and standard deviation of the heel marker over one stride period at baseline and week 26 is shown in Figure 5.16. Figure 5.17 shows the angular velocity and standard deviation for the hip over 80-100% of the stride cycle (which includes the swing phase) at baseline and week 26.

The joint moment profiles for the hip, knee and ankle at baseline and week 26 without FES are shown in Figures 5.18 and 5.19. The maximum, minimum and percentage change for these profiles is shown in Table 5.7.

The stride parameters for three trials each at baseline and week 26 with and without FES are shown in Table 5.8.

Table 5.6 Maximum, Minimum and Range for Angular Excursions for MA

		Baseline	Week 26 NF	Week 26 WF
Hip	max	37.8	27.8	28.9
min		5.8	-4.7	-5.4
range		32.0	32.5	34.3
KNEE	max	57.8	55.5	53.8
min		3.9	-1.1	-0.1
range		53.9	56.5	53.9
ANKLE	max	6.8	5.2	7.7
min		-9.8	-13.9	-6.8
range		16.6	19.1	14.5
TRUNK	max	81.9	85.8	84.9
min		66.5	75.2	72.9
range		15.5	10.6	12.0

Table 5.7: Maximum and Minimum Moments with % Change over time for MA

	Ankle		Knee		Hip	
	Maximum	Minimum	Maximum	Minimum	Maximum	Minimum
Baseline NF (N•m/kg)	0.87	-0.02	0.45	-0.22	0.82	-0.39
Week 26 NF (N•m/kg)	1.32	-0.03	0.92	-0.19	0.73	-0.35
% Change / Direction	34 ⇧	33 ⇧	51 ⇧	16 ⇩	12 ⇩	11 ⇩

Table 5.8 Stride Parameters for MA at Baseline and Week 26

Evaluation	Velocity (m/s)	Cadence (steps/min)	Side	Stride Length (m)	Step Length (m)	Stride Period (s)	Stance / Swing Ratio
Baseline	0.16	28	R	0.66	0.36	6.03	88:12
			L	0.62	0.30	5.96	91:09
Week 26 NF	0.18	34	R	0.64	0.32	5.41	84:16
			L	0.64	0.32	5.33	84:16
Week 26 WF	0.16	31	R	0.61	0.30	5.74	84:16
			L	0.63	0.33	5.82	85:15

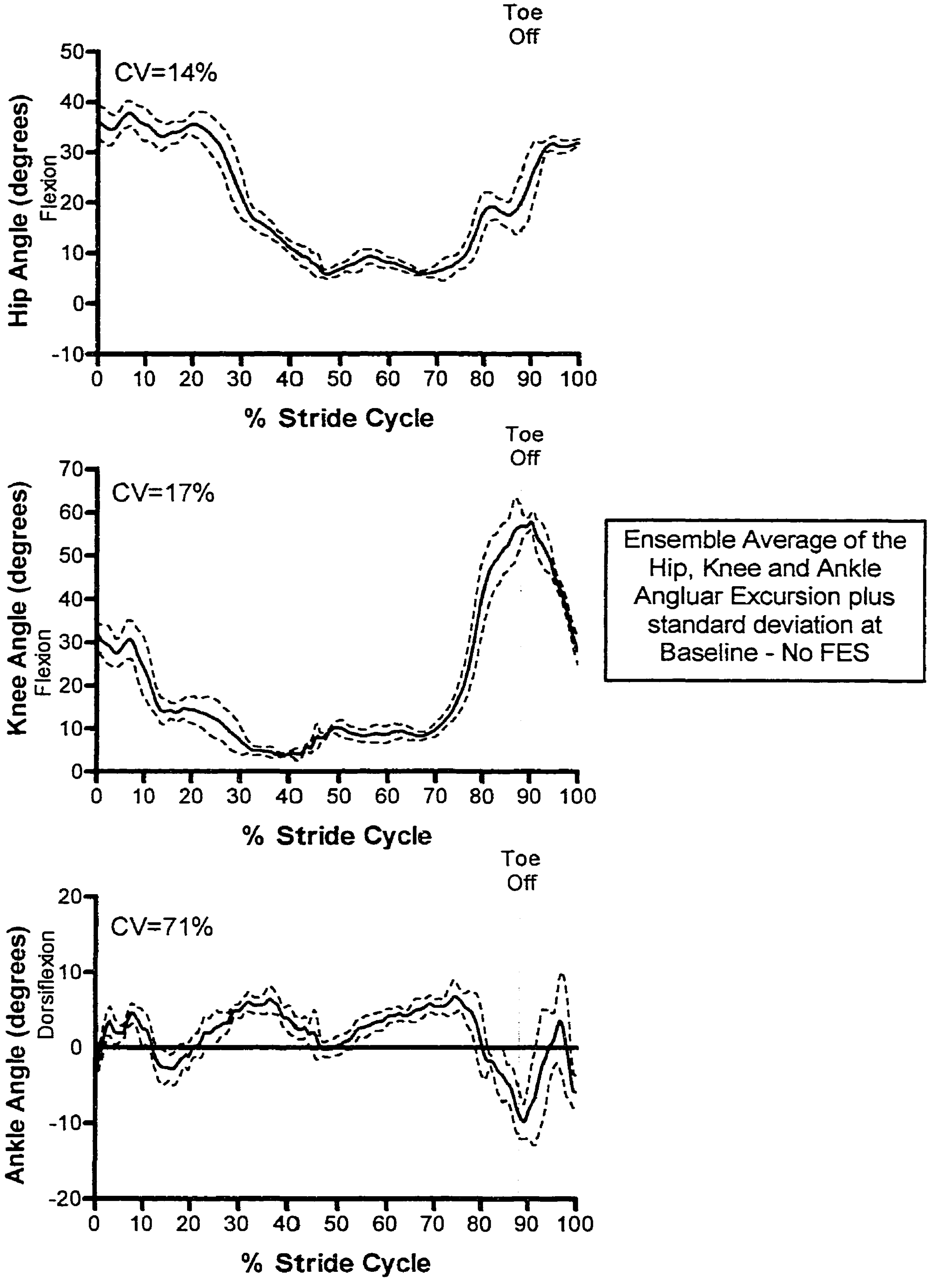


Figure 5.12: Angular Excursion of the Hip, Knee and Ankle for MA at Baseline

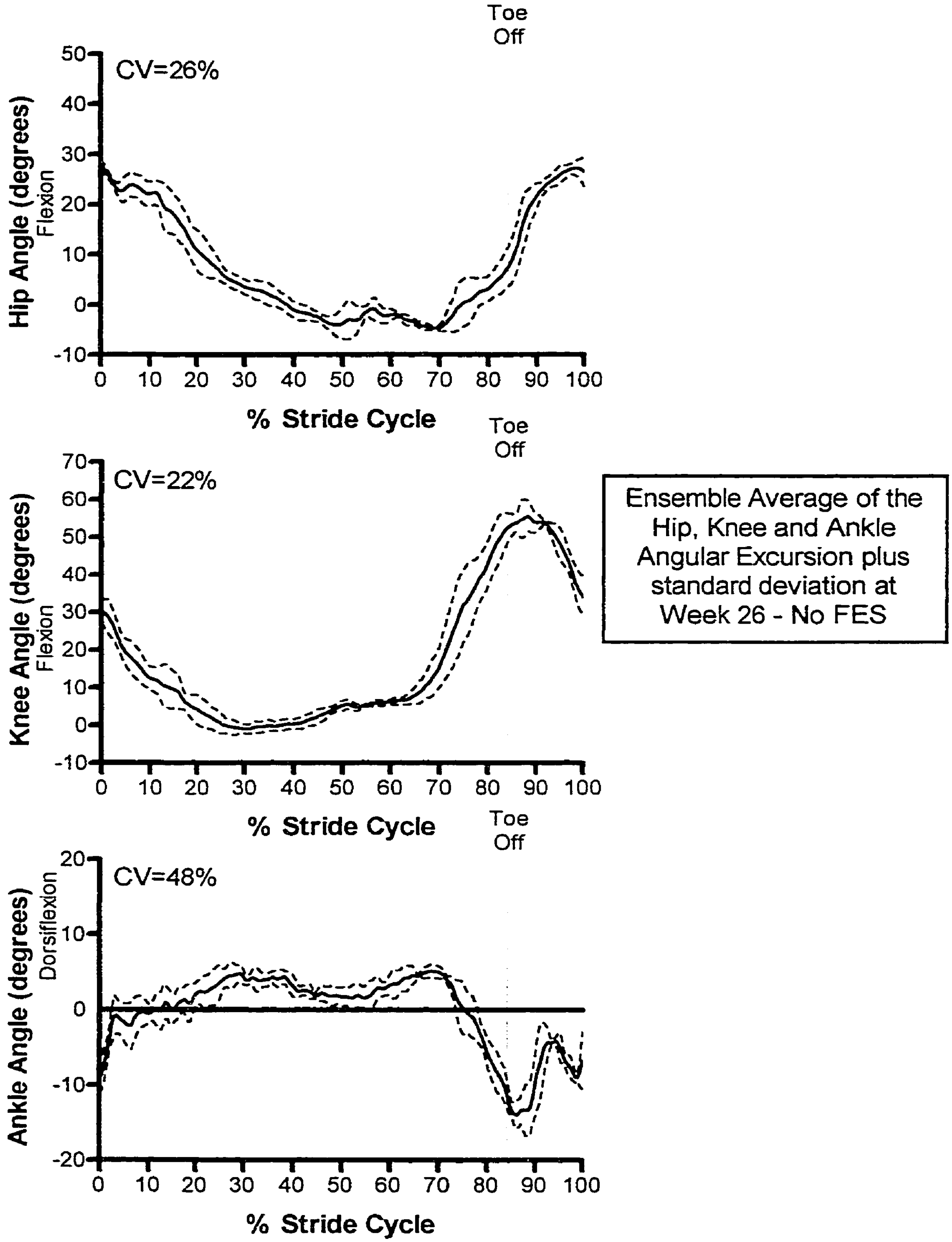


Figure 5.13: Angular Excursion of the Hip, Knee and Ankle for MA at Week 26 No FES

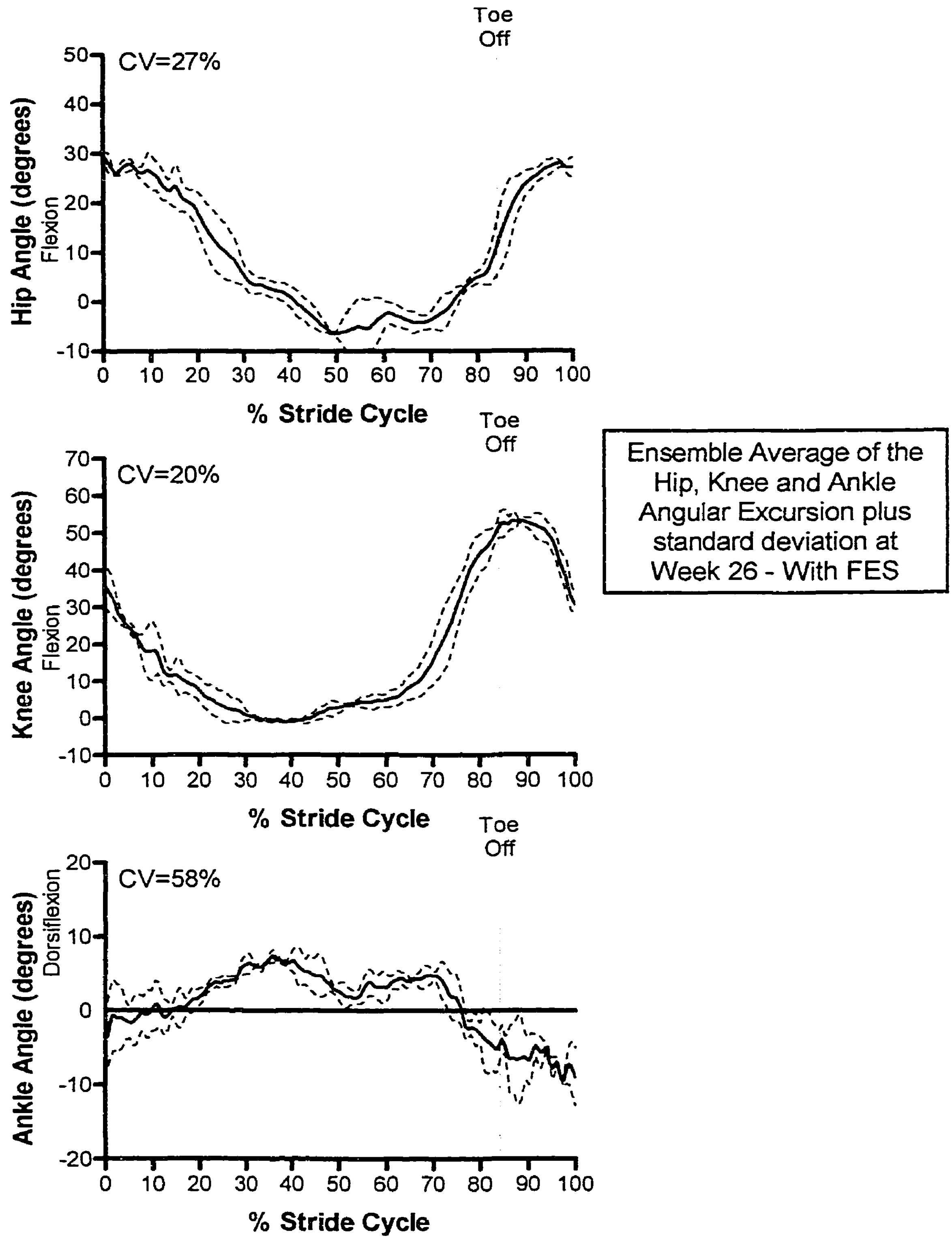


Figure 5.14: Angular Excursion of the Hip, Knee and Ankle for MA at Week 26 With FES

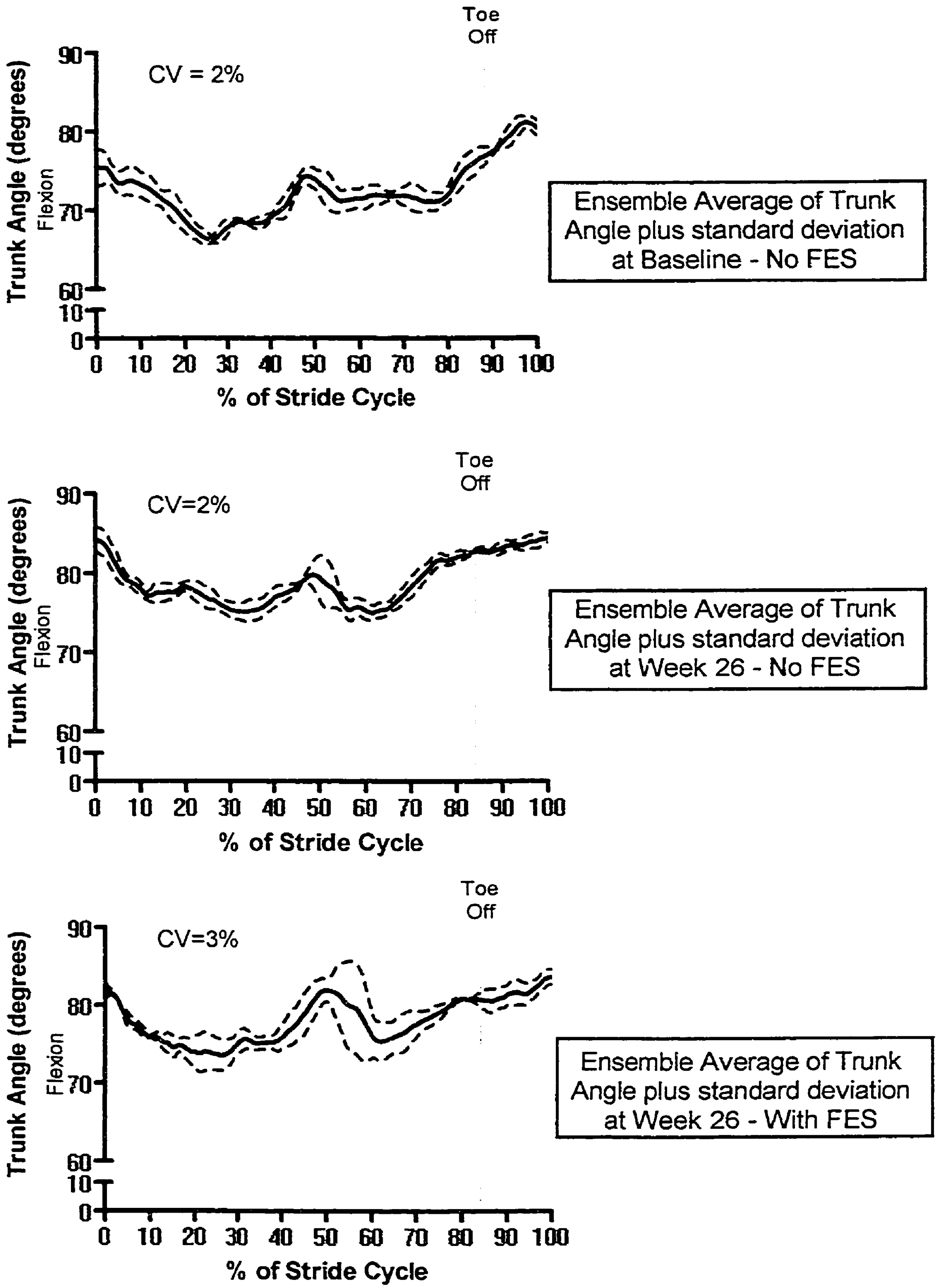


Figure 5.15: Angular Excursion of the Trunk at Baseline and Week 26 for MA

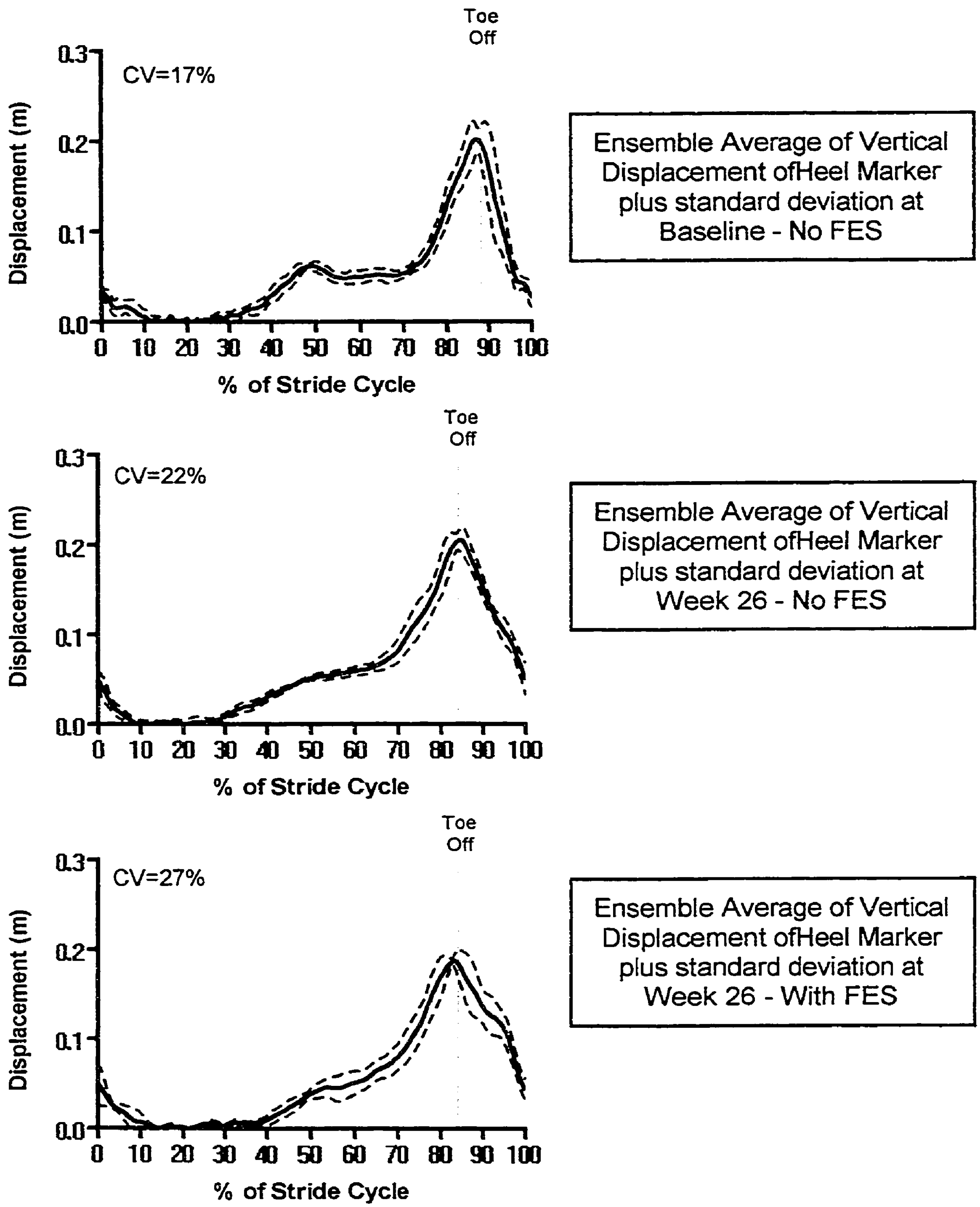
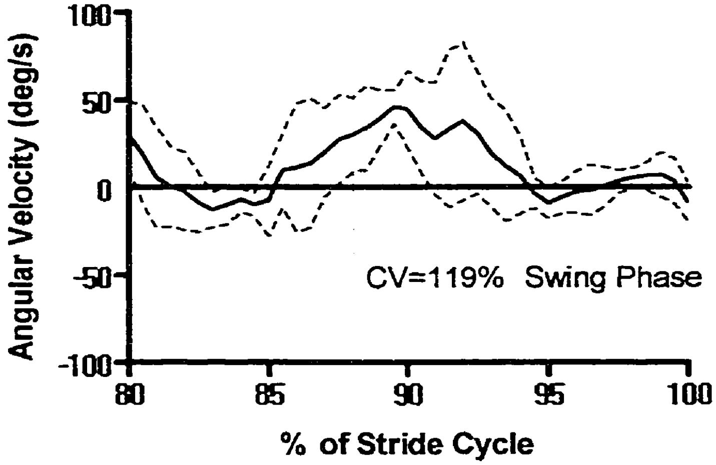
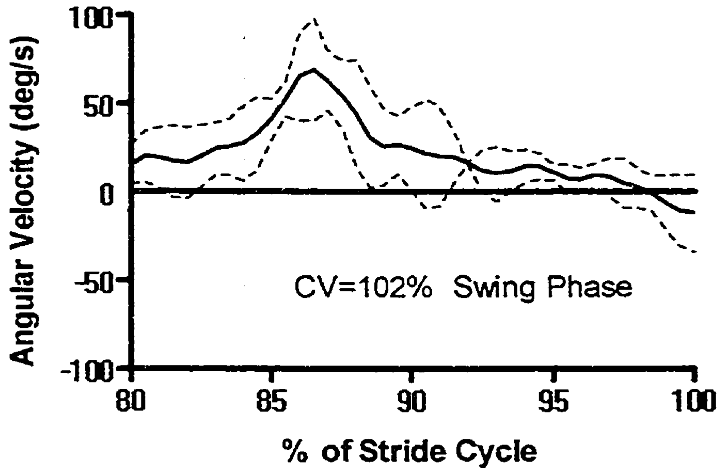


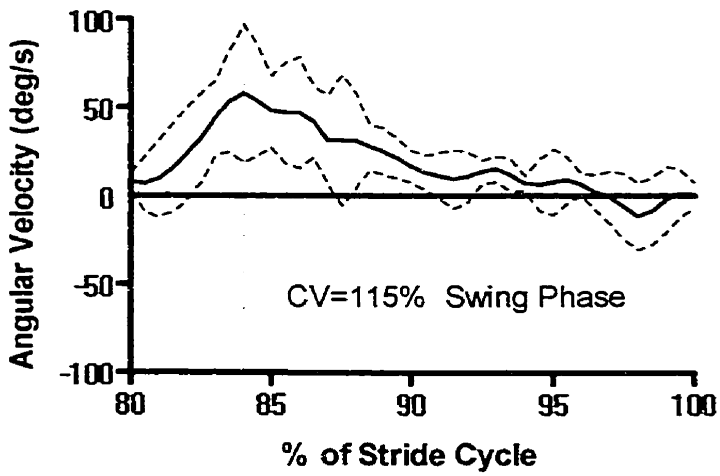
Figure 5.16: Vertical Displacement of the Heel Marker at Baseline and Week 26 for MA



Ensemble Average of Hip Angular Velocity plus standard deviation at Baseline - No FES



Ensemble Average of Hip Angular Velocity plus standard deviation at Week 26 - No FES



Ensemble Average of Hip Angular Velocity plus standard deviation at Week 26 - With FES

Figure 5.17: Angular Velocity of the Hip at Baseline and Week 26 for MA

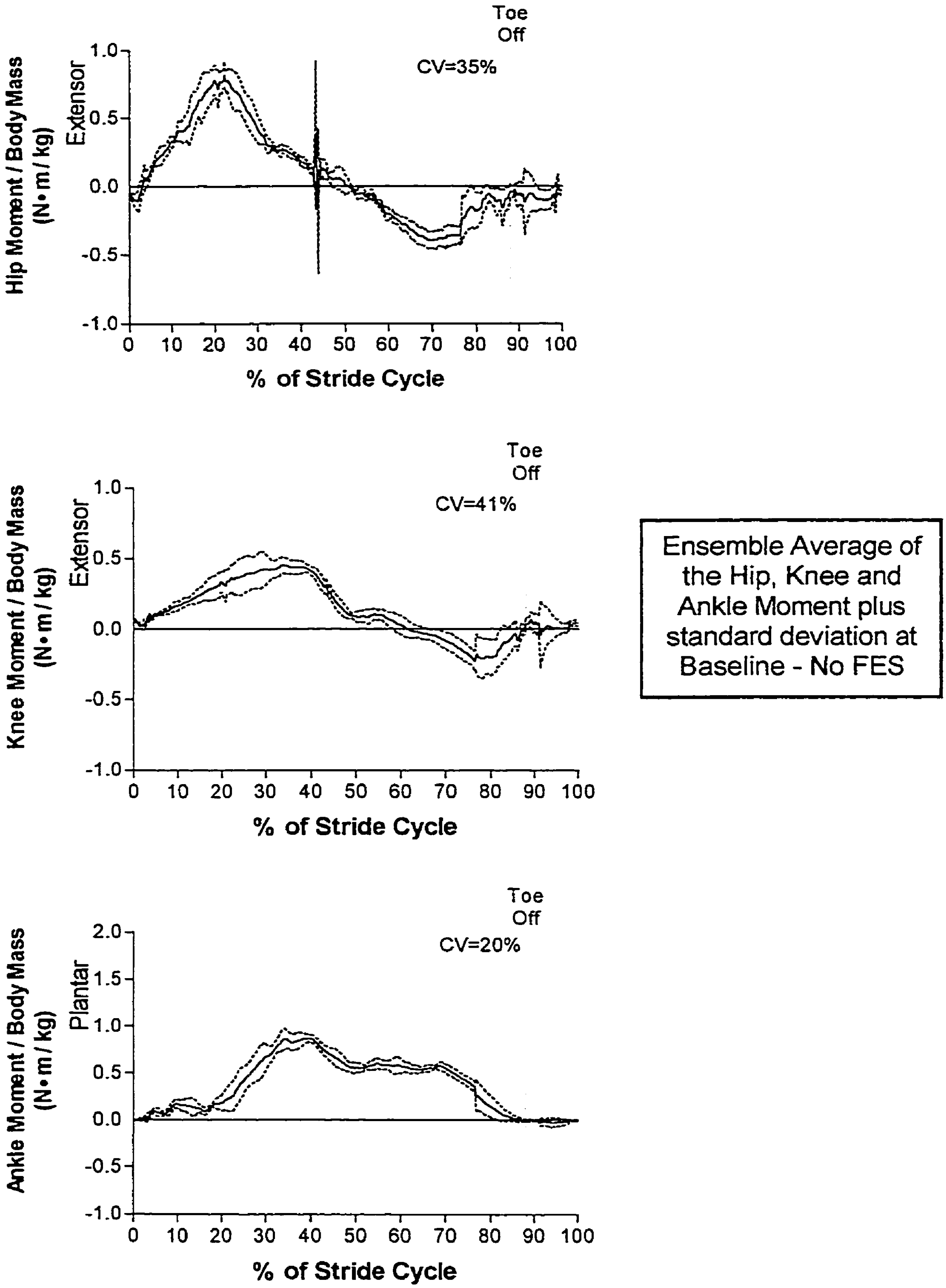


Figure 5.18: Joint Moment of the Hip, Knee and Ankle at Baseline without FES for MA

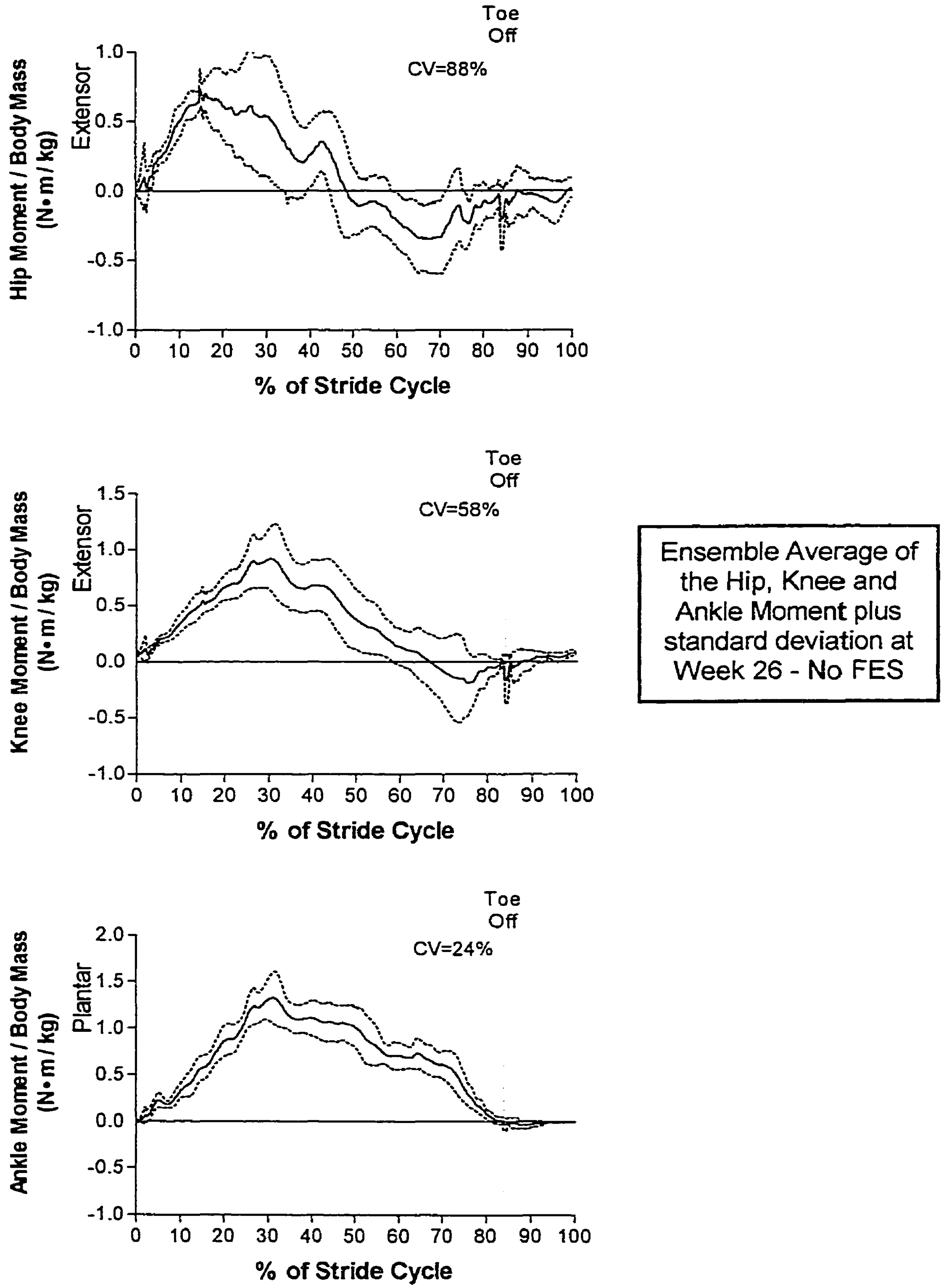


Figure 5.19: Joint Moment of the Hip, Knee and Ankle at Week 26 without FES for MA

The variability in the pattern of angular excursion from baseline to week 26 as seen in Figures 5.12 to 5.14 shows an increase at the hip, little change at the knee and a decrease at the ankle. Generally a nearly normal pattern is seen for the hip, knee and ankle over the stride period in each evaluation.

The pattern at the ankle becomes more smooth from baseline to week 26 with the least variable pattern occurring at week 26 without FES. Peak plantar flexion occurs at toe off for baseline and week 26 without FES and was greatest at week 26 without FES. This pattern is consistent with the use of FES in that when the stimulation is applied just before toe off, the foot is forced into dorsiflexion as part of the flexor reflex.

The knee pattern shows a flexed knee at foot contact followed by a period of extension during stance with an increased flexion occurring toward a peak at toe off. There is little change in the maximum, minimum and range of motion at the knee from baseline to week 26.

The hip pattern is relatively the same over the evaluations. However, there is a phase shift from baseline to week 26 in that the overall pattern is decreased in hip flexion. This pattern coincides with the changes seen in the trunk angle in that the subject is walking more upright. The hip is flexed at foot contact and is extended during stance with a slight peak in flexion at mid-stance followed by an increase in flexion toward toe off that further increases in flexion during swing. The mid-stance peak can be explained in conjunction with the patterns seen at the trunk (Figure 5.15) and vertical displacement of the heel (Figure 5.16).

The trunk angle and vertical heel displacement patterns remain relatively equal in variability from baseline to week 26. The trunk pattern shows an initial decrease during stance (forward flexion) followed by a slight peak at mid-stance then an increase in flexion toward toe off with further flexion during swing. This mid-stance peak relates to a peak seen in the hip angle and in the vertical displacement of the heel on the supporting foot. As the subject swings through the contralateral leg, he thrusts his hips forward and rises on the ball of the supporting foot, displacing his trunk backward. This event is aligned with the point of maximum hip extension indicating the subject's use of hip thrust to assist in swinging his leg through.

The range of trunk motion decreased from baseline to week 26 with the least amount of flexion / extension occurring at week 26 without FES. The trunk angle also experienced a phase shift more toward upright from baseline to week 26. The mid-stance "hip thrust" peak decreased for the vertical heel displacement and for the hip over time however, remains present in the trunk pattern.

The angular velocity at the hip shown over the swing period follows approximately the same pattern from baseline to week 26 and is highly variable. The peak angular velocity is greatest at week 26 without FES.

The pattern of the joint moment profiles remains relatively consistent at each joint over time when walking without FES. There is a recognizable pattern of flexor / extensor activity at each joint during the stride cycle. There is an increase in extensor / plantar moment at the knee and ankle joints from baseline to week 26. The patterns are more variable over time with the greatest change in variability seen at the hip. The peak plantar flexor moment at the ankle occurs at mid-stance rather than at toe off indicating that the ankle is not contributing to the forward progression of the body. This mid-stance peak relates to the same peak seen in the angular displacement graphs where the subject uses a hip thrust technique and rise to the ball of his foot to lift the limb forward. Evidence of the use of this technique is also seen in the hip moment profile where there is a slight extensor peak at mid-stance. The unusually large peak of extensor moment in the hip and knee at early stance relates to the increased need to control the collapse of the leg due to the increase in plantar muscle force as the subject begins to rise onto the ball of his foot.

The stride parameters not analyzed statistically include a comparison of right and left sides in stride and step length, stance period and stance / swing ration. The right and left sides are relatively the same for each of these stride parameters with little change from baseline to week 26. There is a slight decrease in stride and step length on the right side with a slight increase in these variables for the left side from baseline to week 26. The difference between the left and right sides is most notable in the stance / swing ratio at baseline however, the stance time for each side decreased over time and became virtually identical at week 26 indicating a more symmetrical walking pattern.

6.1 LOCOMOTOR CHANGES QUANTIFIED

In addressing the objectives and hypotheses of this study, it was found that the use of FES-assisted gait training had a significant treatment effect on walking speed, stride length and cadence. This effect was seen both when comparing walking without FES to walking with FES at one point in time and when comparing these conditions at the baseline measures over time to follow-up measures 26 weeks following the onset of the FES-assisted gait training program.

The first hypothesis that walking speed, stride length and cadence would be greater when walking with FES than when walking without FES was found to be true for one subject (DT) but not for the other subject (MA). Furthermore, the second hypothesis that there would be a carry-over effect of FES-assisted gait training such that the difference in gait parameter values between walking with and without FES would decrease over time was found to be true for some of the gait parameter variables but not in the same respect for each subject. The details of these changes will be discussed separately for each subject by examining the statistical differences found in the gait parameters and by relating these changes to the locomotor patterns as described by the kinematic and kinetic profiles.

6.1.1 Subject DT

The initial reciprocal walking status of this subject was effectively nil. The presence of extensor and adductor spasticity made it very difficult for DT to walk reciprocally however, because the level of injury (T11) left the upper limbs intact, DT was able to develop the upper limb strength required to adopt a *swing to* gait by using a walker for support. This walking pattern, however, was not analyzed. The comparisons discussed are made on the subject's *reciprocal* walking pattern, which was very slow and difficult but achievable during the baseline evaluations and dramatically improved over time with FES-assisted gait training.

Visual analysis of the data shows that the use of FES allowed DT to walk with a greater velocity, stride length and cadence as compared to walking without FES (see Figure 5.1; Table 5.1). This effect was seen at each evaluation over time with the difference between walking with and without FES for velocity, cadence and stride length increasing over time such that walking with FES increased at a steeper slope. Therefore, walking with FES allowed DT to increase his velocity, cadence and stride length at a faster rate than when walking without FES. The increase in velocity and cadence over time when walking without FES indicates that there was an effect independent of the use of FES. This effect of *time* could be attributed, for example, to gait training in general, to an increase in lower limb strength, to a decrease in lower limb spasticity of the extensor and adductor muscles or to an adaptation of the motor system relating to an in increase in voluntary motor control due to the plasticity of the central nervous system. The FES-assisted gait training allowed the expression of a reciprocal locomotor pattern, which, over time, may have stimulated the development of physiological changes within the central nervous system that allowed new or adaptive motor pathways to be entrained. This may explain the improvement in gait parameters over time when walking without FES. In addition, FES as an orthosis showed improvement in these parameters in the early stages of training similar to those results seen by Granat, 1993 and Stein, 1993 however, the long term benefits of the combination of FES with gait training are evidenced by the steeper slope seen when walking with FES as compared to walking without FES. The lack of a plateau in the data also indicate that further improvements may be seen over time.

When looking at the regression results (Table 5.1), we see a significant effect for velocity under the factors of time, FES and time *x* FES, for cadence under time and time *x* FES and for stride length under only time *x* FES. The factor of FES alone had an effect only on velocity whereas the factor of time had an effect on velocity and cadence and time *x* FES had an effect on all three parameters. These results indicate that it is the use of FES in conjunction with gait training over time that provides the best result for this subject on these gait parameters. The increase in velocity can be explained by the increase in cadence and stride length. The use of FES together with gait training allowed DT to overcome the lower limb spasticity enough to increase the speed and distance at which he moved his lower limbs, therefore increasing the cadence and velocity.

When looking at the treatment effect of these data (Figure 5.2; Table 5.1), we see that a significant effect was found for velocity and stride length. By plotting the individual data points in relation to the median of all the points, the number of points lying above the median as compared to those lying below the median determines the significance of the treatment effect. For velocity, 4 out of 5 data points when using FES fell above the median as compared to only 1 out of 6 when not using FES. This indicates that there is a significant treatment effect of FES on velocity. The same effect was found for stride length (NF=1/6; WF=4/5). For the variable of cadence, 2 out of 6 data points without FES fell above the median and 3 out of 5 data point with FES fell above rendering these data as insignificant. The two data points without FES above the median, however, are those at weeks 12 and 26 which substantiate the improvement of cadence over time as evidenced by the regression analysis and demonstrate the long term benefits of FES-assisted gait training.

This comparison of the variability among the results of the analysis methods amplifies the discussion presented in Chapter 2 whereby Nourbakhsh & Ottenbacher (1994) conclude that no single method of analysis should be used to interpret the data collected in single subject research. The combined scrutiny of the data by visual and several statistical methods leads to the conclusion that, for this subject, this simple FES system used in conjunction with gait therapy was beneficial in increasing his walking velocity, cadence and stride length both when comparing walking with FES and without FES at one point in time and over a time period of 26 weeks.

Kinematic and Kinetic Interpretation of Changes

The major achievements seen in the locomotor pattern as a result of the FES-assisted gait training include a vast improvement in the ability to walk reciprocally, a more symmetrical gait pattern, improved posture, a decrease in variability, a smoother pattern of angular excursion and an increase in joint moment.

The increase in walking velocity can be attributed to the increases in stride length and cadence. From baseline to week 26 (see Figure 5.1), the change in velocity is relatively constant as seen by the steadily increasing slope. The relative contribution of cadence and stride length to this increase in velocity fluctuates over time. Up to week 12 we see a decrease in stride length with an increase in cadence which results in an overall increase in velocity. The strategy for walking faster was to take shorter steps but more of them. The cadence then levels off from week 12 to week 26 but there is an increase in stride length during this time therefore the velocity is seen as increasing. The first stage of FES-assisted gait training therefore, allowed DT to move his lower limbs more quickly but not necessarily further. The latter stage shows a trend that indicates an increase in stride length that can be related to the increase in hip angular excursion and moment (see Table 5.3 and 5.4).

The interpretation of the change in hip angle must be made with consideration of the trunk angle. While the maximum excursion of the hip angle appears to decrease over time from 46.2° at baseline to 43.6° at week 26 with FES, the absolute trunk angle becomes closer to vertical therefore the actual excursion of the thigh relative to the trunk is greater. The following calculations should illustrate this point. The change in the maximum angular excursion of the trunk from baseline to week 26 without FES is 8.2° toward vertical (65.2°-73.4°). The change in maximum angular excursion of the hip is -3.6° which results in an absolute difference in the hip angle relative to the trunk of +4.6°. The same comparison between walking without FES to with FES at week 26 nets an increase in hip angle relative to the trunk of 2.9° (trunk: 73.4-70.3=3.1; hip: 49.6-43.6=6.0). Therefore the hip excursion actually increased relative to vertical in addition to the trunk moving toward a more vertical posture thereby resulting in an increased stride length.

The increase in hip angular excursion and stride length over time can also be related to the increase in joint moment at the hip. The hip moment at baseline is effectively flat-line hovering just below zero (see Figure 5.10). The moment is calculated using certain kinematic variables with the reaction forces obtained from the force plate. As mentioned above, DT's walking pattern at baseline was very slow (0.05m/s) where he used a lot of upper limb strength to support his body weight on the walker (up to 65% as cited with permission by Melis, 1995). In addition, because of the spasticity, his legs acted more like pegs with little action at the hip, knee and ankle joints (see Figure 5.5). Therefore, there was more force acting through the walker than though the lower limbs resulting in the very low joint moments at baseline. A dramatic increase in the flexor hip moment (100%) can be seen in Figure 5.11, especially during the swing phase where the moment is contributing to the increased hip angular excursion and therefore increased stride length. This increase in moment, however, cannot be distinguished as to the relative contribution of muscular vs. gravitational moment.

This increase in hip flexor moment may also be contributing to the increase in cadence. While there is no visible increase in angular velocity during swing (see Figure 5.9), the increase in cadence may be attributable to DT's ability to control his lower limbs more during stance and in the initiation of swing. The relative contribution to the total stride time spent in stance and swing (stance / swing ratio) changes from 98:02 at baseline to 94:06 at week 26 without FES and 91:09 at week 26 with FES (see Table 5.5). A large portion of time was spent during stance which was attributable to the time it took to overcome the spasticity to initiate swing (baseline stride period: 13.00 s; stance: 12.74s; swing: 0.26s). Following training, the change in stride period (week 26 NF stride period: 4.22 s; stance: 3.97 s; swing: 0.25 s / week 26 WF stride period: 2.32 s; stance: 2.11 s; swing: 0.21 s) shows that the majority of the decrease is attributable to a decrease in stance time. This indicates an increased ability to control the lower limb during stance and initiate the limb movement into swing i.e., an increased capacity to generate the moment at the hip. Spasticity per se was not measured in this study however, observations reported by DT during training sessions indicate a reduction in spasticity which may be attributable to the FES itself, to the FES-assisted gait training or to the stretching and standing protocols that were also in place as part of the overall training.

The percentage change and direction of the change in the maximum and minimum moments for the hip, knee and ankle over the stride period from baseline to week 26 can be seen in Table 5.4. There was an increase in maximum (extensor / plantar-flexor) and minimum (flexor / dorsi-flexor) moments at each joint most notably in the flexor moments at the knee and hip and for both the plantar- and dorsi-flexor moments at the ankle.

Table 5.5 shows the stride parameters for the left and right sides for stride length, step length, stride period and stance / swing ratio. Only the right side variables were used in the statistical analyses however, the data for both sides are shown to demonstrate the changes in the degree of symmetry of the locomotor pattern. The difference in left and right stride length increased over time with the right side remaining relatively the same and the left side increasing. However, the step length between sides shows the opposite pattern. The left step length is initially almost three times that of the right and becomes approximately the same at week 26 with FES. Initially, DT would take the same size stride on the right and left sides but the placement of one foot relative to the contralateral foot would be offset. Over training, DT was able to even out the placement of his feet relative to each other (symmetrical step length) but the stride length became larger on the left side.

The relationship between sides regarding temporal parameters shows that the left side has a slightly better stance / swing ratio at each evaluation and there was an increase in symmetry for stride period from baseline to week 26 with the left side being shorter initially.

The kinematic and kinetic profiles illustrate the contributing factors to the increases seen in walking velocity, cadence and stride length. There was an overall improvement in the locomotor patterns with less variability, smoother reciprocal activation among and between the joints over the stride period as well as an increase in symmetry between the timing and placement of the feet. These changes in locomotor pattern indicate an improved ability to control the movement of the lower limbs.

The improvement in motor control as evidenced by the locomotor pattern changes is a result of the components of the FES-assisted gait training program. Initially, it was the stimulation that moved DT's lower limbs reciprocally. Continued movement of the limbs through the training sessions increased DT's ability to control the movement of his limbs when using FES and when not using FES. FES was the tool that helped to generate the motion. Over time, the control of the movement increased due to the reduction in spasticity and the increase in voluntary motor control. The combination of FES with the gait training over time was instrumental in bringing about these changes.

Secondary benefits observed as a result of the FES-assisted gait training program include a reduction in spasticity which allowed freer movement at the joints of the lower limb and an increase in strength which led to an increase in endurance (see Appendix J). DT was able to nearly double his maximum training time for overground walking from approximately 11 minutes to 20 minutes of walking during a single session over four weeks of supervised training. DT was also able to attempt tasks such as maneuvering around obstacles while walking with the walker. He also gained the strength and confidence to attempt walking with Canadian Crutches during a supervised training session and visit a local mall using the walker during his home training.

6.1.2 Subject MA

The initial walking status of MA was good. The level of injury was C5-C6 and MA had sufficient strength and hand function to walk at a velocity of 0.16m/s with a walker. MA's walking pattern was smooth and steady in which he adopted a *pull through* method at the hip of swinging the lower limb forward rather than a *push off* from the ankle. Even though MA could walk reciprocally with a walker, he choose to use the wheelchair as his main mode of locomotion in the six years since sustaining his injury.

Figure 5.3 shows the relationship of the gait parameters at baseline and follow-up evaluations walking with and without FES. In each evaluation and for each gait parameter, visual analysis shows walking with FES to be less than walking without FES. Generally the difference between conditions is small except during the first 8 weeks of training for stride length. Week 12 shows nearly identical measures for velocity, cadence and stride length with a slight difference opening up to week 26. Velocity and cadence increase over time for both walking with FES and without FES. Stride length shows a peak at week 8 for walking without FES and a peak at week 12 for walking with FES. These increases over time show that there is an effect of training that carries over between the conditions of waking with and without FES.

An important factor in interpreting these data is that this subject changed walking aid from a walker to two Canadian Crutches at week 2 into the FES-assisted gait training program. Evaluations with both walking aids are shown for week 2 where MA walked at slower pace thereby decreasing his velocity. The change in walking aid may explain the initial drop in each gait parameter value from baseline to week 2.

Following week 2, there is a steady increase over time in velocity, which can be attributed to an increase in both cadence and stride length up to week 12 after which velocity and cadence continue to increase and stride length decreases. Examination in Figure 5.4 of the relationship between stride length and cadence shows that there was an increase in cadence from week 8 to 12 as well as from week 12 to 26 associated with a decrease in stride length at the same intervals. MA was, therefore, taking quicker, shorter steps. The net change in these parameters caused only a slight increase in velocity.

The trade off between stride length and cadence is related to many factors including balance, strength and even confidence. As MA grew more confident and comfortable with the new walking aid, he was able to increase the pace at which he was walking. The stride length measures attained in the early weeks of training indicate that MA is capable of achieving a greater velocity as he could potentially maintain the cadence adopted at week 26 as he recovered his stride length to his previous maximum. Further long term evaluation of these parameters would reveal if this were possible.

Table 5.2 shows a summary of the statistical analyses. The regression shows a significant effect for velocity, cadence and stride length over the factor of *time*. Velocity and stride length were found to be significant over the factor FES and no variables were significant over time *x* FES. The most important information from this analysis is the effect of *time* on the variables. Even though walking with FES was always less than walking without FES, there was an effect seen over time that was greater than the baseline measures. The slopes of each variable did approach one another up to week 12 therefore decreasing the difference between walking with and without FES.

The treatment effect where the number of data points falling above and below the median value are counted and tested for significance showed no variable to be significant (see Figure 5.4). The one way repeated measures ANOVA showed significance for velocity and cadence but not for stride length. Once again, the importance for duplicate analyses is shown for this type of data in that one measure shows very different results than another. In this case, the visual analysis is best at interpreting these data as Figure 5.3 shows clearly that the velocity and cadence show an increasing trend over time with relatively equal slopes between walking with and without FES for each variable.

Kinematic and Kinetic Interpretation of Changes

The locomotor patterns seen in the kinematic profiles (Figures 5.12, 5.13 and 5.14) show a nearly normal pattern of activity at the hip and knee joints with a decreased angular excursion at the ankle joint. There is minimal change over time at the hip and knee joint with a somewhat smoother pattern of ankle activity from baseline to week 26, especially when walking without FES. The variability of these profiles also remains relatively constant. Because the initial walking status of MA was relatively good, the lack of change in locomotor pattern is understandable.

The trunk angular excursion shows a trend toward the vertical indicating a better upright posture with low variability and less movement from baseline to week 26. Initially, MA would use a flexion / extension pattern of trunk movement to aid in thrusting the lower limb forward during swing. This action is reduced with training as seen in the more flat excursion of the trunk angle during swing.

Another gait deviation that was present initially as a compensatory movement is illustrated in Figure 5.16 by the vertical displacement of the heel marker. During stance, MA would rise onto the ball of his foot and thrust his hips forward and trunk backward to aid in clearing the lower limb during swing of the contralateral limb. This pattern can be seen at baseline as a peak in heel vertical displacement at approximately 50% of the stride cycle. This mid-stance peak aligns with a similar peak in the trunk and hip angular excursions. The peak is diminished at week 26 without FES and even more so at week 26 with FES for the hip and the vertical displacement of the heel however, it remains for the trunk angular excursion at week 26 with FES.

The change in hip and heel mid-stance peak when walking without FES may be related to MA's increased ability to control his lower limb during swing. The change as seen when walking with FES is related to the stimulation of the flexor reflex which actively allowed MA the impulse needed to assist the initiation of swing as well as the power to lift the swinging leg through. Therefore, he needed less thrust at the hip to move his lower limb forward. These changes are also related to the increase in cadence seen at week 26 which may be explained by the increase in angular velocity at the hip as shown in Figure 5.17 as a result of the stimulation. The peak angular velocity reaches between 50 - 75 deg/s at week 26 for both with and without FES whereas at baseline, the peak angular velocity is approximately 45 deg/s. Again, the FES is providing the motion which allows MA to move his limb faster through swing. The fact that MA is able to attain the same angular velocity at the hip during swing when walking with and without FES indicates a cross-over effect of training whereby he has more voluntary control over his lower limb.

The trunk motion into extension at mid-stance as the leg is swinging through is diminished at week 26 without FES as compared to baseline and is greatest at week 26 with FES. This movement may therefore be a stabilizing strategy. MA may be using this motion as a means to temper the forward momentum created by the flexor reflex in response to the stimulation in the lower limb in an effort to maintain his balance.

The increase in MA's ability to swing the lower limb through faster and without hiking his hip and lurching the trunk may also be related to the increase in joint moment (see Figures 5.18 and 5.19). The peak hip flexor moment is increased at toe off from baseline to week 26 without FES. There is a large increase in plantar flexor moment during stance that is related to the heel rise as noted above. There is also an increase in the knee moment during stance from baseline to week 26 without FES that allows a more stable and secure base on which to transfer weight. This may be attributable to an increase in knee extensor strength. The variability within the joint moment profiles is relatively small and consistent at the ankle and is moderate to large at the hip and knee with more change at the hip especially at week 26 without FES.

When examining the side to side variables, MA walked very symmetrically initially and continued this pattern through to week 26 with FES and without FES. There was no difference in the stride length and step length measures nor in stride period and stance / swing ratio between right and left sides. However, the stance / swing ratio did improve over time from 91:09 to 85:15 on the left side and from 88:12 to 84:16 on the right side indicating a more symmetrical locomotor pattern.

It is important to note that this subject did not consider walking faster to carry a lot of weight as a training goal therefore, the FES-assisted gait training program concentrated on other functional aspects including increasing endurance, learning alternate propulsion methods, maneuvering around and over obstacles, climbing and descending stairs and increasing his daily use of the crutches as compared to using the wheelchair.

The greatest improvement for this subject was his ability to adapt to walking with Canadian Crutches and his self-generated confidence in using the crutches as part of his daily routine. At the peak of the supervised training session, MA achieved a maximum training time of 50 minutes of continuous walking (see Appendix J). He averaged approximately 25 minutes of walking per session over the training period up to week 9. He reported that when using the FES system he was able to walk for longer periods of time because it decreased the level of effort required to move his limbs. Functional use of the FES system was important to this subject so excursions to public places such as restaurants and to his workplace were included in the training protocol.

The improvements in locomotor pattern as described by the kinematic and kinetic profiles help to explain the changes seen in the gait parameter variables. The adaptation of compensatory movements by this subject as a result of decreased motor control were allowed to be diminished by using FES-assisted gait training. The changes in velocity, cadence and stride length may seem small however, consideration of the initial walking status of this subject and his adoption of a comfortable walking speed that served his purposes demonstrates that they are nonetheless functionally significant. There is also an indication in the gait parameter data that the strategy of increasing velocity was by increasing cadence up to week 26. The potential, therefore, to further increase velocity was within the determination of MA in that he demonstrated the ability to attain a greater stride length than he performed at week 12 and 26.

6.2 FES-ASSISTED GAIT TRAINING AS A REHABILITATIVE TOOL

The above discussion of the changes in locomotor pattern and gait parameters when using FES as an aid in conjunction with gait training shows that this simple FES system used can be of benefit to these two subjects. While their outcome measures were very different, they each made improvements in certain areas as a result of using FES-assisted gait training. It is imperative to have a good understanding of the initial functional status of each subject as well as to clearly define the training goals in order to correctly interpret the results.

From this study the use of FES-assisted gait training has shown to be of benefit in overcoming the consequences of SCI to a certain degree. Referring back to Figure 2.1 regarding the movement consequences of SCI and the determinants of successful gait, this tool was successful in addressing each of the areas of concern. Under movement consequences of SCI, spasticity was seen to be reduced in DT, weakness and fatigue were each decreased as shown by increased strength and endurance in both DT and MA, and the loss of voluntary control was shown to be reduced both by training effects and by using FES as a tool in providing the impulse needed to initiate and control swinging the lower limb forward.

Regarding the determinants of gait, training effects were seen that improved posture and balance by obtaining a more upright trunk angle, increased moment at the knee and hip to prevent collapse during stance, improved control of the foot trajectory by training to maneuver around and over obstacles and improving the control of forward propulsion by increasing the hip and ankle flexor moments leading into swing.

These results indicate that for these two subject, the use of FES-assisted gait training is beneficial in compensating for and enhancing the remaining function following incomplete spinal cord injury and that a simple two channel FES system can be considered a rehabilitative tool.

The feasibility of using a 2-channel FES system to restore walking in persons with incomplete SCI has been proven (Bajd et al., 1989; Granat, 1993; Kralj et al., 1992). Dramatic results such as enabling a person with SCI the ability to walk overground while using FES, when he / she could not otherwise, have been documented (Bajd et al., 1989; Stein, 1993). However, the clinical acceptance of using FES as a rehabilitative tool in the treatment of persons with incomplete SCI remains to be attained.

The hesitation to widespread clinical use of FES could be due to the lack of an optimal tool that would restore a fully *functional* gait. However, while researchers continue to develop the ultimate FES tool, it is believed that simple 2-channel FES systems can be of use in the treatment of certain individuals with incomplete SCI (Granat, 1993; Bajd et al., 1989; Stein, 1993). Within the total population of persons with incomplete SCI, approximately 11.2% may successfully be trained to walk using FES (Kralj et al., 1994). Furthermore, there is evidence to support that FES be used as a tool in conjunction with long term gait training to warrant the best results in gait restoration (Granat, 1992; Ladouceur, 1993).

The results of this study support the use of FES-assisted gait training for these two subjects. The training protocol allowed one subject to progress from a "*swing-to*" locomotor pattern to a reciprocal pattern that allowed him to walk overground for exercise and within the community. This subject showed improvements in voluntary motor control, posture and cadence and attained an increase in walking velocity of 660% (0.05m/s to 0.33m/s). This subject also improved his endurance for remaining upright, which may result in the prevention of secondary complications due to immobility such as the development of pressure sores or contractures, muscle atrophy and changes in bone density (Kavanaugh, 1984; Ragnarsson, 1992).

The other subject was able to progress from walking with a walker to walking with two Canadian Crutches. This change in gait aid provided him with greater flexibility in maneuvering in and around various environments, including climbing stairs and over obstacles. This subject showed improvements velocity, cadence and stride length, attained a more upright, symmetrical gait and increased joint moment of force production. This subject also reported increased confidence in his ability to walk over various surfaces, including snow, as well as in using his crutches to walk while at work rather than using his wheelchair.

After 12 weeks of supervised training and an additional 14 weeks of home training, both subjects continued to use the simple 2-channel FES system to assist walking. They were able to move their limbs faster through either a reduction in spasticity and / or an increase in moment at the hip joint or an improvement in voluntary motor control. Both subjects also reported using less effort in movement when using FES, which enabled them to greatly increase their walking endurance.

As part of a National-wide clinical trial, the objective of this study was to quantify the changes in gait parameters associated with using FES in conjunction with gait training for persons with incomplete SCI. The results indicate that FES-assisted gait training does have an effect on walking velocity, stride length and cadence, that shows improvement over time. In addition, there is a significant cross-over effect of training such that improvements in gait were seen for both subjects while walking without FES. This result supports the importance of combining structured gait therapy with FES in order to allow the repeated expression of the locomotor patterns and subsequent re-training of voluntary motor control. Future research into studying this relationship should investigate the use of FES-assisted gait training at an early stage in the rehabilitation of persons with incomplete SCI.

As single subject design warrants in a large-scale clinical trial, the more individuals who show a treatment effect with this tool, the more generalizable the results become. For these two individuals with incomplete spinal cord injury, the use of FES-assisted gait training proved to be a useful rehabilitative tool.

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Ambulatory Assistive Device:	A walking aid that provides support for balance, stability and propulsion.
Anthropometrics:	Measures of the human body such as segment lengths and masses.
Calibration frame:	A measured reference system used to calibrate the space in which the video images are recorded so that the data may be converted to real space values.
Clonus:	A clinical sign associated with spasticity whereby oscillations occur at the joint that the stretched muscle crosses in response to a ballistic stretch.
Cut-off Frequency:	The theoretical value at which frequencies of a signal are blocked from passing through a filter.
Direct Linear Transformation:	A process of calibrating kinematic data obtained through video images.
Ensemble Average:	The process of averaging two or more normalized trials of data.
Flexion Reflex:	A spinal reflex that results in flexion at the joints so as to pull away from a noxious stimulus.
Gain:	The amount of amplification of a signal.
Gait Analysis:	The process of quantifying the gait parameters and locomotor pattern of an individual.
Gait Parameters:	Descriptors of gait such as walking speed and stride length.
Inverse Dynamics:	A process of calculating joint moments of force based on ground reaction and inertial forces and anthropometric measurements.

Kinematics:	A description of the relative or absolute spatial movements of the body independent of the forces that cause the movement.
Kinetics:	A description of the forces that cause movement.
Led:	A light emitting diode used in view of the camera lens to synchronize the video images.
Locomotor Pattern:	A description of the gait events for an individual.
Low Pass Filter:	A process of obtaining only the lower frequencies of a signal by allowing those frequencies below the set cut-off frequency to pass.
Moment of Force:	The product of a force acting at a perpendicular distance about an axis of rotation that causes rotation at that joint.
Normalize Data:	A process applied to data which relates the data to a standard value e.g. force can be normalized to body mass.
Physical Fitness:	A measure of certain physical constructs that relate to good health e.g. strength.
Reaction Force:	The resultant force as measured by a force transducer acting on or at any point on the body.
Spasticity:	A symptom associated with an interruption to inhibitory influences on spinal motor neurons manifested by increased muscle tone and exaggerated reflexes.
Square Wave:	A form of a periodic signal that is on / off at a particular value.
Stance Phase:	The period of time when the foot is in contact with the walking surface.
Stride Period:	The period of time for two steps measured

	from an event on one foot to the same event on the same foot.
Successful Overground Walking Trial:	A trial where each foot contacts the force plate and all stations report good collection of data.
Surface Functional Electrical Stimulation:	The application of electrical stimulation to the skin overlying nerves and/or muscles so that a functional muscle contraction may be produced.
Swing Phase:	The period of time during the stride cycle when the foot is not in contact with the walking surface.
Traumatic Spinal Cord Injury:	Damage to the spinal cord as a result of trauma.

These criteria were determined by the team of researchers headed by Dr. Richard Stein at the University of Alberta in Edmonton, which is the head office for the multi-centre trial that this study was a part of.

Inclusion Criteria:

- incomplete spinal cord injury between C4 and T12
- at least one year post injury to ensure stable baseline
- no peripheral nerve damage (upper motor neuron lesion)
- able to tolerate stimulation without pain, at a level that produces a functional muscle contraction (e.g., flexion reflex)
- able to obtain standing position from sitting
- walking speed < 0.3m/s
- ability and willingness to attend frequent sessions for training, assessment and evaluation sessions
- realistic and reasonable expectations of both the time commitment involved and the benefits derived from intervention with FES

Exclusion Criteria:

- severe muscle weakness of the lower limb
- unstable medical condition (e.g., high blood pressure, urinary tract infection)
- severe spasms not decreased by drug intervention
- severe joint contractures not amenable to stretching
- severe cognitive impairment
- bone density measurements < 50% of age and sex matched normals
- fracture identified on bone scan

FORMULE DE CONSENTEMENT

"Les effets de la stimulation électrique fonctionnelle lors de la marche chez des blessés médullaires: Etude Multicentre"

Par la présente, je soussigné(e) ______________________________ (nom du/de la bénéficiaire) accepte de participer au projet de recherche ci-haut mentionné.

Je reconnais avoir été informé(e) de façon satisfaisante sur la nature de ma participation au projet qui est brièvement décrit (page suivante). Il est entendu que le responsable du projet a fourni toutes les explications et a répondu a mes questions de façon satisfaisante.

La présente recherche porte sur l'évaluation des effets de la stimulation électrique fonctionnelle appliquée au(x) membre(s) inférieur(s) en vue d'améliorer le patron de marche chez des sujets ayant subi une lésion partielle de la moelle épinière. Dans le cadre de mon séjour à l'Institut de Réadaptation de Montréal (IRM), je serai entrainé(e) à utiliser un stimulateur électrique lors de la marche et poursuivra l'entraînement à la maison. En début et fin d'entraînement, mes capacités locomotrices seront évalués(es) sur le tapis roulant ainsi qu'au sol. Ces évaluations se feront à l'université McGill de même qu'à l'IRM.

J'accepte que l'information recueillie puisse être utilisée pour fins de communication scientifique et professionnelle.

Il est entendu que l'anonymat sera respecté à mon égard.

Pour la durée du projet, je permets au responsable ou aux chercheurs associés au projet de consulter mon dossier médical.

Il est aussi entendu que je peux me retirer en tout temps du projet en avisant le responsable. Ce dernier s'engage à faire approuver par le Comité d'éthique toute modification significative du projet.

____
Date

______________________________ ______________________________
Signature du/de la bénéficiaire ou du parent | Signature du témoin

______________________________ ______________________________
Signature du responsable | Nom du participant

CONSENT FORM (FRENCH)
Université du Québec à Montréal, Département de Kinanthropologie

FORMULAIRE D'INFORMATIONS ET DE CONSENTEMENT

Responsables de projets:

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Coordonnateur du projet,
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Brad McFadyen, PhD
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Ellen Melis, BSc, PT
Responsable du projet sur les aides de marche

Lucy Chilco, BSC (Kin)
Responsable du projet sur la marche au sol avec SEF

En accord avec les règlements de l'université du Québec à Montréal relatifs à la déontologie et aux droits de la personne, ce formulaire d'informations et de consentement est présenté à chacune des personnes évaluées.

OBJECTIFS

L'objectif de ce projet est de mesurer l'effet de la stimulation électrique fonctionnelle appliquée au(x) membre(s) inférieur(s) de personnes ayant subies une lésion partielle de la moelle épinière, dans le but d'améliorer leurs patron de marche.

DESCRIPTION DE L'ÉVALUATION

L'expérience consiste en une série de 11 évaluations réparties sur une année. Chacune d'entres elles est d'une durée approximative de 5 heures, et se décompose en deux parties soit la préparation et une série de séquence de marche sur une distance de 5 mètres. La préparation de l'évaluation comprend la mise en place de marqueurs réfléchissants, de commutateurs aux pieds et d'électrodes de surface.

Les marqueurs réfléchissants sont mis en place à l'aide de ruban adhésif de chaque côté du corps (droit et gauche). On retrouve ces demiers sur le gros orteil, le coté du pied, le talon , la cheville, le mollet, le genou, la cuisse, la hanche, le bassin, le dos, et l'épaule. Pour leurs parts, les électrodes de surface sont placées au-dessus des muscles des jambes pour enregistrer l'activité musculaire durant la marche. L'emplacement occupé par les électrodes doit être rasé et nettoyé avec un peu d'alcool. Enfin, des semelles sont insérées dans les souliers afin de déterminer les temps pendant lesquels les pieds sont en contact avec le sol. Lors des séquences de marche, on enregistre les déplacements des marqueurs à l'aide d'une caméra vidéo, les signaux provenant des électrodes ainsi que le temps de pose des pieds au sol. On mesure également, à l'aide de plate-formes de force et d'aides à la marche instrumentées, les forces qu'applique le corps sur le sol.

Lors des trois premières évaluations, on utilise l'aide à la marche usuelle de la personne. Par la suite, l'équipe de recherche pourrait décider de changer l'aide à la marche pour un aide plus approprié. Les séquences de marche s'effectuent avec ou sans stimulation électrique fonctionnelle et avec ou sans obstacles sur la voie de marche. La hauteur des obstacles sont de 5 et 30 millimètres.

RISQUES

Les participant(e)s peuvent trébucher lors des séquences de marche. Pour éviter que ceux ci ne tombent, une personne se tient à leurs cotes lors de leurs marches. Puisque les traumatismes médullaires peuvent avoir comme conséquences l'ostéoporose, il existe un risque de fracture lorsque l'on met son poids sur ses jambes. Pour diminuer ce risque, une mesure de densité osseuse est effectuée avant le début du projet et ensuite lorsque le chercheur principal le juge pertinent. Les autres risques sont reliés à la stimulation électrique et concernent des problèmes de peau (rougeurs et dans des cas extrêmes des lésions cutanées. Bien entendu, une attention particulière sera portée au site de stimulation par les responsables de L'évaluation. A noter que les stimulateurs portatifs sont agréés par l'association canadienne des normes.

AVANTAGES

Les résultats obtenus à la suite de ces évaluations permettront de faire avancer les connaissances du contrôle moteur pendant la marche. Certaines de ces connaissances pourront permettre une amélioration des techniques de réadaption de personnes ayant subi un traumatisme de la moelle épinière.

CONFIDENTIALITE

Toutes les données recueillies sont confidentielles et ne sont utilisées que dans le cadre de publications scientifiques et professionnelles. Les données sont conservées en sécurité par les responsables des évaluations. Il est entendu que l'anonymat des participants est respecté. Pendant la durée du projet, les dossiers médicaux des particpants peuvent être consultés par les responsables des évaluations ou par les chercheurs associés au projet.

CONSENTEMENT LIBRE

Les responsables des évaluations s'engagent à considérer la personne évaluée au meilleur de son intérêt en tenant compte des éléments exprimés dans ce document, et d'exercer leurs expertises professionnelle dans le domaine de la kinanthropologie afin de mieux protéger la santé et les droits des personnes participantes.En accord avec les règlements de l'Université du Québec à Montréal relatifs à la déontologie et aux droits de la personne, ce formulaire d'informations et de consentement est présenté à chacune des personnes évaluées.

J'ai pris connaissance de l'information contenue dans ce formulaire d'informations et de consentement, je comprends les procédures et je consens librement à participer à ces évaluations. Il est entendu que je conserve le droit de formuler toute critique et de me retirer en tout temps de l'expérience, sans que cela ne me porte préjudice.

SUJET ______________________________

DATE____________________

(SIGNATURE)

______________________________ Tél:______________________

(NOM)

Responsables des évaluations

____

DATE____________________

(SIGNATURE)

______________________________ Tél:______________________

(NOM)

These features and specifications are as listed in Appendix C of the Quadstim User's Manual, page 15.

Features:

- monophasic constant current output
- isolated output on all four channels
- CSA approved battery charger
- low battery indication
- hand controlled standby mode with indication
- hand controlled function of stimulus
- prevention of both hand switches being active simultaneously
- adjustable ramp up/down time, frequency, pulse duration, maximum intensity, exercise cycle time
- chest case for mobile use

Specifications:

- Output Current: adjustable from 0 to 150 mA
- Stimulus Frequency: adjustable from 10 to 30 Hz
- Stimulus Pulse Width: adjustable from 50 to 500 us
- Battery Charger Input Voltage: 9 Volts, D.C., 300 mA
- Approximate Operation Time per Charge: Four hours

walking velocity: the average horizontal speed in meters per second over a number of stride cycles as measured by the difference between the position of the right heel marker at the onset of the synchronization signal to the position of the right heel marker at the last right foot contact (RFC) within the same trial divided by the period of time from the synchronization signal to the last RFC:

$$\underset{(m/s)}{Averagewalkingvelocity} = \frac{X_{rfc2} - X_{synch}}{time_{rfc2} - time_{synch}}$$

cadence: the number of steps per minute as measured using the velocity and stride length calculations:

$$\underset{(steps/m)}{Cadence} = \frac{velocity\frac{meters}{second}}{stridelength\frac{meters}{1stride}} x \frac{2steps}{1stride} x \frac{60seconds}{1minute}$$

stride length: the distance in meters between a point on one foot at foot contact to the same point at the next foot contact of the same leg as measured by the difference between the position of the right/left heel marker at the first foot contact to the position of the same heel marker at the second foot contact within the same trial:

$$\underset{(m)}{StrideLength} = X_{fc2} - X_{fc1}$$

step length: the distance in meters between a point on one foot at foot contact to the same point at the next foot contact of the opposite leg as measured by the difference between the heel marker of the first foot at foot contact and the heel marker of the opposite foot at the next foot contact:

$$\underset{(m)}{StepLength} = X_{heel1fc} - X_{heel2fc}$$

stride time: the time in seconds from foot contact to foot contact of the same leg as measured by the difference between the picture number at the first foot contact and the picture number at the second foot contact divided by 60:

$$\underset{(s)}{StrideTime} = \frac{picturenumber_{fc2} - picturenumber_{fc1}}{60}$$

stance/swing ratio: the ratio between the period of time in stance divided by the stride time to the period of time in swing divided by the stride time as measured by the difference between the picture number at the first foot contact and the picture number at foot off divided by 60 (stance) divided by the stride time and the difference between the picture number at foot off and the picture number at the next foot contact divided by 60 (swing) divided by the stride time:

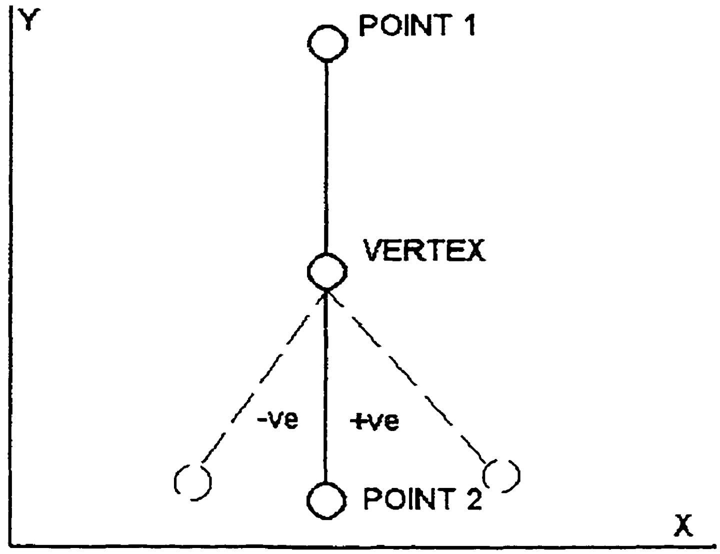
$$\underset{(\%stride)}{Stance} = \frac{\dfrac{picturenumber_{foff} - picturenumber_{fc1}}{60}}{StrideTime} * 100$$

$$\underset{(\%stride)}{Swing} = \frac{\dfrac{picturenumber_{fc2} - picturenumber_{foff}}{60}}{StrideTime} * 100$$

coefficient of variation: the mean variability over the stride period expressed as a percentage of the mean value of the signal calculated as follows:

$$\underset{(\%)}{CV} = \frac{\sqrt{\dfrac{1}{N}\sum_{i=1}^{N} \delta_i^2}}{\dfrac{1}{N}\sum_{i=1}^{N} |X_i|} * 100$$

HIP AND KNEE ANGLE CALCULATION:
The angle at the joint is defined by the points connecting above and below the vertex.

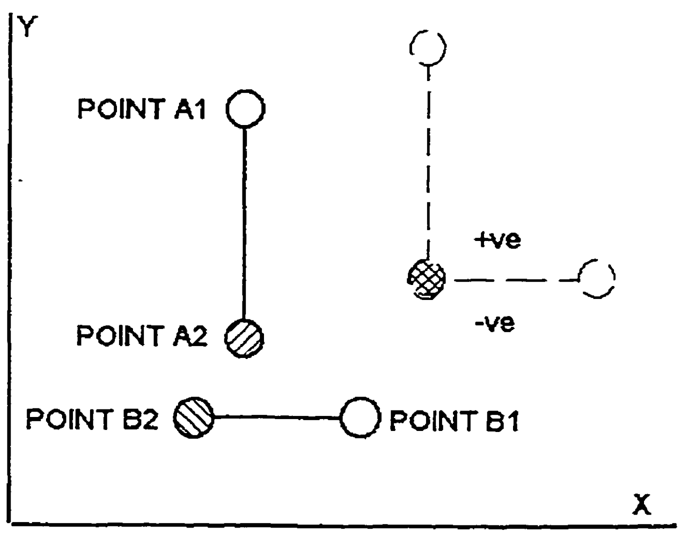


The angle is reported within the range of 0 - 180° with 0° being when all points are aligned vertically.

A change in angle toward the positive x direction results in a positive angle ➢ hip flexion; knee extension

A change in angle toward the negative x direction results in a negative angle ➢ hip extension; knee flexion

ANKLE ANGLE CALCULATION:
The angle at the joint is defined by the segment connecting Points A1 and A2 (leg) and the segment connecting Points B1 and B2 (foot)



Peak takes the unconnected segments A and B and connects them at the defined point 2

A change in angle in a counter-clockwise direction results in a positive angle ➢ dorsiflexion

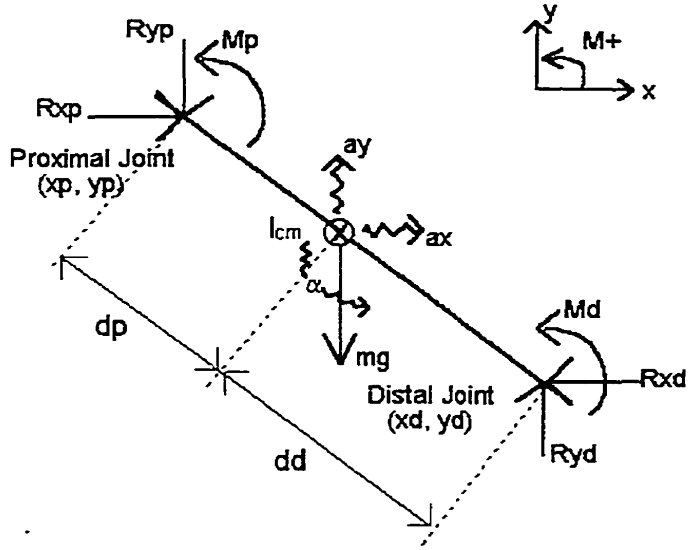
A change in angle in a clockwise direction results in a negative angle ➢ plantar flexion

These anthropometric data are based on Dempster's model as cited in Biomechanics and Motor Control of Human Movement (Winter, 1990).

Segment	Definition	A	B	C	D
Foot	Lateral malleolus/head metatarsal II	0.0145	0.5	0.5	0.475
Leg	Femoral condyles/medial malleolus	0.0465	0.433	0.567	0.302
Thigh	Greater trochanter/femoral condyles	0.100	0.433	0.567	0.323
HAT (head, arms, trunk)	Greater trochanter/mid rib	0.678	1.142	—	0.903

A Segment Weight/Total Body Weight
B Centre of Mass/Segment Length - Proximal
C Centre of Mass/Segment Length - Distal
D Radius of Gyration/Segment Length (Centre of Gravity)

Free Body Diagram:



Equations:

$$\Sigma F_x = m \bullet a_x \qquad (R_{xp}) + (R_{xd}) = m \bullet a_x$$

$$\Sigma F_y = m \bullet a_y \qquad (R_{yp}) + (R_{yd}) - mg = m \bullet a_y$$

$$\Sigma M = I_{cm} \cdot \alpha$$

$$M_p + M_d + (R_{xp} \cdot |\sin\theta| \cdot d_p) + (R_{yp} \cdot |\cos\theta| \cdot d_p) + (R_{xd} \cdot |\sin\theta| \cdot d_d) + (R_{yd} \cdot |\mathrm{co}$$

Where:

F_{xy}	force acting on the segment
m	mass of segment
a_{xy}	linear acceleration of segment centre of mass
g	linear acceleration due to gravity = 9.82m/s^2
M_{pd}	net muscle moment of force acting at the proximal/distal end of segment
R_{xpd}, R_{ypd}	joint reaction force acting at the proximal/distal end of segment
I_{cm}	moment of inertia about the centre of mass of the segment
α	angular acceleration of segment in plane of movement
θ	segment angle in plane of movement

Subject DT:

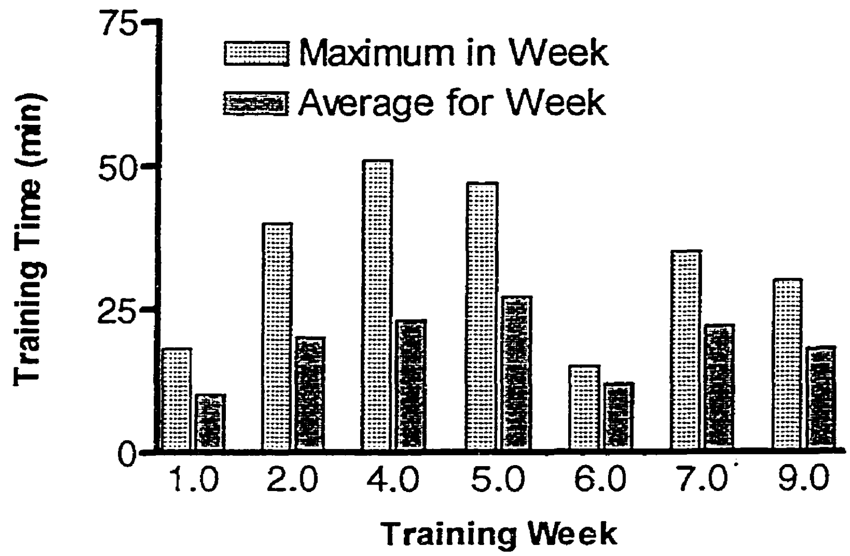
EVALUATION	Walking Speed (m/s)		Cadence (steps/min)		Stride Length (m)	
	NF	WF	NF	WF	NF	WF
Baseline	0.05 ± 0.02		13.14 ± 4.64		0.42 ± 0.05	
Week 2	0.06 ± 0.004	0.10 ± 0.01	15.31 ± 0.77	25.44 ± 2.92	0.43 ± 0.05	0.45 ± 0.06
Week 4	0.05 ± 0.01	0.12 ± 0.02	18.58 ± 7.91	37.04 ± 8.76	0.34 ± 0.09	0.39 ± 0.02
Week 8	0.06 ± 0.02	0.17 ± 0.03	22.88 ± 6.04	43.49 ± 10.01	0.31 ± 0.03	0.49 ± 0.04
Week 12	0.09 ± 0.02	0.22 ± 0.004	40.04 ± 7.07	53.86 ± 2.23	0.27 ± 0.06	0.49 ± 0.03
Week 26	0.13 ± 0.03	0.33 ± 0.01	40.87 ± 9.66	74.33 ± 0.37	0.37 ± 0.01	0.54 ± 0.02

NF No FES
WF With FES

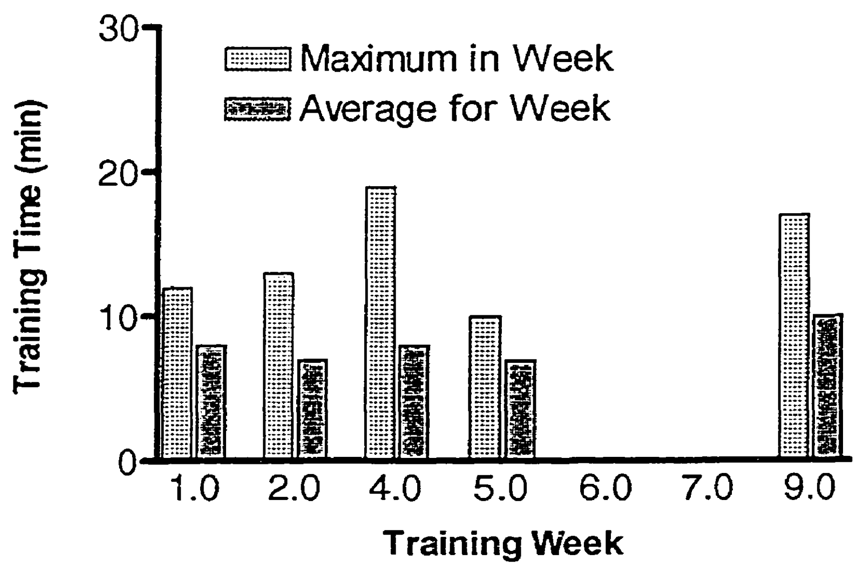
Subject MA:

EVALUATION	Walking Speed (m/s)		Cadence (steps/min)		Stride Length (m)	
	NF	WF	NF	WF	NF	WF
Baseline	0.16 ± 0.01		28.49 ± 0.29		0.66 ± 0.02	
Week 2: Walker	0.13 ± 0.01	0.12 ± 0.01	23.18 ± 0.40	24.51 ± 0.67	0.66 ± 0.03	0.58 ± 0.04
Week 2: Crutches	0.12 ± 0.003	0.10 ± 0.007	22.30 ± 0.73	21.61 ± 0.76	0.62 ± 0.006	0.58 ± 0.03
Week 4	0.15 ± 0.01	0.12 ± 0.001	26.42 ± 1.35	22.52 ± 1.26	0.68 ± 0.03	0.63 ± 0.03
Week 8	0.16 ± 0.01	0.13 ± 0.01	26.89 ± 2.68	23.91 ± 1.12	0.71 ± 0.03	0.65 ± 0.04
Week 12	0.16 ± 0.005	0.15 ± 0.006	28.16 ± 0.28	27.08 ± 0.54	0.68 ± 0.03	0.68 ± 0.03
Week 26	0.18 ± 0.02	0.16 ± 0.01	33.58 ± 3.93	30.82 ± 2.09	0.64 ± 0.01	0.61 ± 0.02

NF No FES
WF With FES

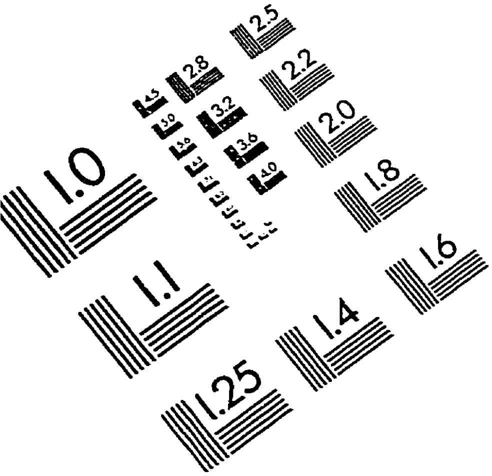


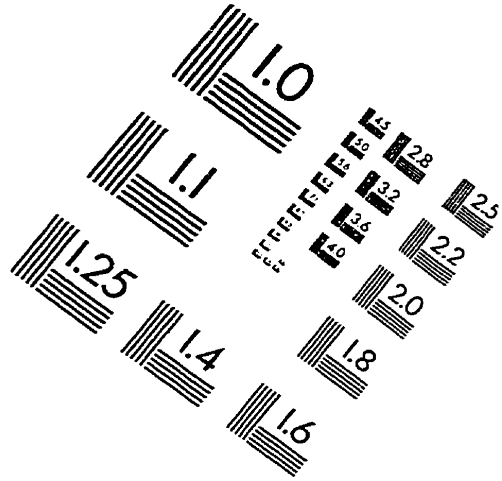
a) Maximum and Average Training Time for MA up to Week 10

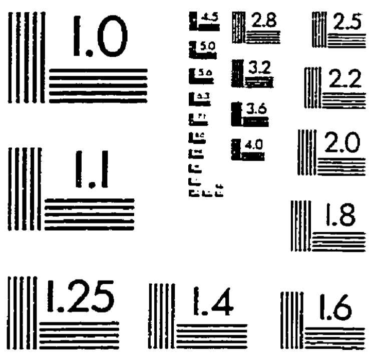


b) Maximum and Average Training Time for DT up to Week 10

IMAGE EVALUATION TEST TARGET (QA-3)

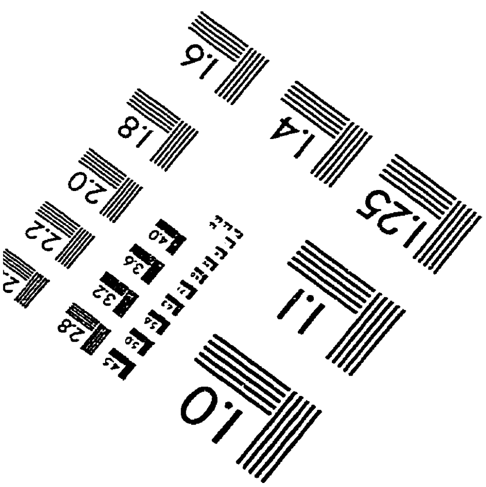


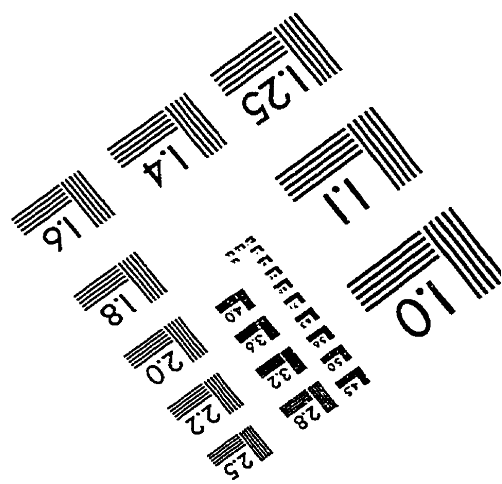




150mm

6″





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