CHAPTER II

LITERATURE REVIEWS

1. Characteristics of normal gait

Human gait is defined as a manner of walking or moving on foot (22). Normal gait requires the proper functioning of the musculoskeletal system and the nervous system (23). The nervous system is responsible for both motor output and sensory input (23). It is a complex synergy of muscle coordination, timing, and balance (22).

1.1 Phases of gait

Gait is composed of two primary phases (i.e. a stance phase and a swing phase) (22). The entire period during which the foot is on the ground is the stance phase. The swing phase begins when the foot is lifted from the floor until the heel is placed down (23). It is clinically divided into 8 separate sub-phases which are: (1) initial contact, 0–2% of GC (2) loading response, 0–10% GC (3) midstance, 10-30% GC (4) terminal stance, 30-50% GC (5) pre-swing, 50-60% GC (6) initial swing, 60-73% GC (7) midswing, 73-87% GC (8) and terminal swing, 87-100% GC (Figure 1) (22, 24).

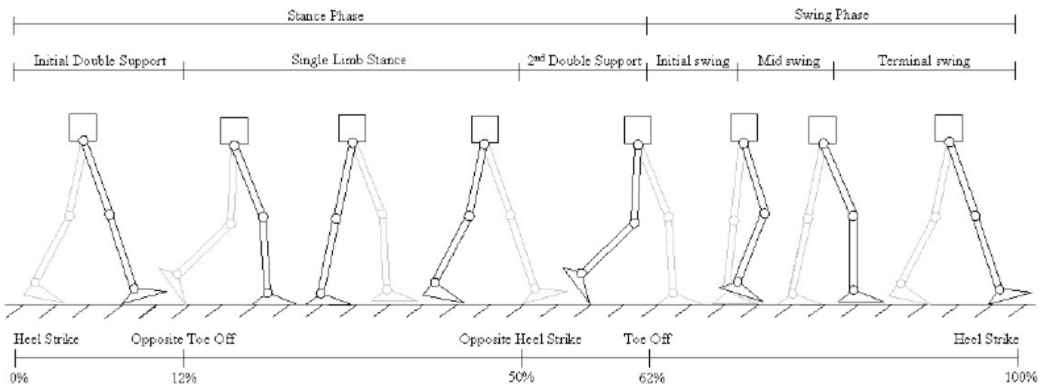


Figure 1 Human walking gait through one cycle, beginning and ending at heel strike. Percentages showing contact events are given at their approximate location in the cycle (25)

1.2 Phasic action of muscles

Many muscles are active primarily in stance phase or primarily in swing phase. This phasic contraction defines the role of that muscle in producing normal walking activity. In normal walking, muscles contract and relax in a precise, coordinated form. Level walking at a comfortable pace is a natural place to study phasic activity of muscle groups (26).

At initial foot contact, the limb begins to decelerate the body as it reaches the floor. Hip extensor contraction decelerates the thigh and aids in knee extension and foot placement. At the same time, the tibialis anterior begins a lengthening contraction to gradually ease down the foot and keep it from slapping down on the floor. Now the limb begins its loading response in which it accepts the weight of the body by contracting the knee extensors. The knee bends slightly and begins extending under the shortening contraction of the knee extensors. This knee extension is aided by plantarflexion of the ankle (eccentric contraction). The gluteus medius contracts isometrically and stabilizes the pelvis in the frontal plane. At midstance, lengthening contraction of the soleus muscle keeps the forefoot pressed against the foot, creating a force couple or linkage that allows the knee to remain extended without the need for muscle action of the quadriceps. At terminal stance, ankle plantarflexors begin a shortening contraction that accelerates the body forward.

Preswing, the hip flexors (iliopsoas and rectus femoris) begin to lift the limb and swing it forward, generally by concentric contraction. Initial swing perceives the end of iliopsoas and rectus femoris activity. The ankle dorsiflexors begin a shortening contraction to allow the foot to clear the floor. Midswing, foot clearance is continued by activity of the anterior tibialis muscle. At terminal swing, the limb begins active deceleration by contracting the hamstrings eccentrically or isometrically. This efficiently slows both hip flexion and knee extension. The knee prepares to accept weight by early quadriceps activity. The tibialis anterior continues its activity by isometric or elongating contraction as it gently floats the foot over the floor immediately before foot contact (26).

1.3 Muscle control of knee joint

Fourteen muscles contribute to knee control contract at selected intervals within the gait cycle (24). Their purposes are to provide the stability and mobility needed for walking. During stance phase, the extensors act to decelerate knee flexion. In swing phase, both the flexors and extensors contribute to limb progression. Among the multiple muscles acting on the knee, only six have no responsibility at another joint (24).

1.3.1 Knee extension

The quadriceps is the dominant muscle group at the knee. Four heads cross only the knee joint (vastus intermedius, vastus lateralis, vastus medialis oblique, vastus medialis longus). The fifth head (rectus femoris) includes both the knee and hip joint. Activity of the quadriceps muscle begins in terminal swing (90% GC). This level of effort is maintained throughout the remainder of the loading response period. The timing of rectus femoris action is much different from that of the vasti. Activity of the rectus femoris has a short period of action between late preswing (56% GC) and early initial swing (64% GC). One hip extensor muscle also contributes to knee extension in early stance. The upper gluteus maximus provides a knee extensor force through its iliotibial band insertion on the anteriorlateral rim of the tibia. Activity of this muscle begins in late terminal swing (95% GC) and terminates by the middle of mid stance (20% GC) (24).

1.3.2 Knee flexion

The single joint muscles, popliteus and the short head of the biceps femoris (BFSH), provide direct knee flexion. The BFSH is primarily active in initial and midswing (65-85% GC). The popliteus acted occurs during all phases of the gait cycle except initial and midswing. The three hamstring muscles (semimembranosis, biceps femoris long head, semitendinosis) are primary hip extensors, but these muscles are better known for their flexor role at the knee. All three hamstrings have their most intense action in late mid- and terminal swing (onset 75% GC) and continue at a lesser level into the early loading phase. The gastrocnemius relates to stance phase. While principally acting at the ankle, this muscle also is a knee flexor. The gastrocnemius progressively increases its intensity from the time of onset (15%

GC) until the middle of terminal stance (50% GC). Two hip flexor muscles also contribute to swing phase knee flexion. These are the gracilis and sartorius. Both muscles become active in initial swing and early mid swing (65% to 75% GC) (24).

1.3.3 Functional interpretation

The knee muscles have three functional responsibilities during walking. Two occur during the stance phase of gait cycle: shock absorption as the limb is loaded and extensor stability for secure weight bearing. In the swing phase of gait cycle, the knee must rapidly flex for limb advancement (24).

1.3.4 Knee function for each gait phases

Correction of the motion, muscle function and demand vectors that occur in each gait best clarifies the complexity of knee function during walking. The balance between demand and response becomes evident (Table 1) (24).

Table 1 Knee function for each gait phases (24)

Phase	Motion	Function
Terminal swing	Knee extension	Complete step length, Prepare for stance
Initial contact	Extended knee posture	Stable weight bearing
Loading response	Knee flexion (15^o)	Shock absorption
Mid stance	Knee extension	Stable weight bearing
Terminal stance	Completion of knee extension	Stable weight bearing, Further stride length
Pre-swing	Passive knee flexion	Prepare for swing
Initial swing	Knee flexion	Foot clearance for limb advancement
Mid swing	Passive knee extension	Limb advancement
Terminal swing	Knee extension	Limb advancement, Prepare for stance

2. Characteristics of gait in patients with hemiplegia

Gait in people with hemiplegia can be greatly disrupted. More than half of people with stroke in the acute phase are not able to walk, and walking impairments are still present 3 months after the onset. The degree of impairment depends on the magnitude of the neurological deficit (7). It has been found that approximately 20% of stroke survivors will be confined to a wheelchair, and approximately 60% will have limited walking capabilities (6). Motor weakness, poor motor control, and spasticity cause an altered gait pattern (7, 27, 28) and higher energy expenditure (7).

2.1 Stance phase

In the stance phase, leg instability (knee buckling) may make walking unsafe, energy inefficient, and/or painful (7). If the stability of the knee joint is inadequate during walking, patients are prone to falls. The causes of falling may be due to unstable support during standing in the stance phase and fear of falling (8).

2.2 Swing phase

During swing phase inadequate limb clearance, sensory deficits, impaired balance, and/or pain may contribute to loss of balance, fall, and increased anxiety associated with walking (7). Ineffective ankle dorsiflexion during swing phase (drop foot) and failure to achieve heel strike at initial contact lead to insufficient toe clearance during walking. These impairments, in combination with low selective control of hip and knee muscles in this patient group result in an abnormal gait. Patients may walk with hip hiking, hip circumduction, and toe catch, also called equine gait (8, 9, 29, 30). Patients usually counteract this difficulty by exaggerating the knee and hip flexion to provide foot clearance (9). Normally, the knee muscles must swing the lower leg forward and also prevent the knee from collapsing during the body's weight support (31).

2.3 Spatiotemporal components

The overall results of the compensatory movements generated by the patient with hemiplegia include a decrease in walking velocity with a shorter duration of stance phase, a decrease in weight bearing, and an increase in swing time of the affected leg. The following characterizes the unaffected leg has an increased stance time and decreased step length (7). Patients with hemiplegia usually walk with different step lengths of the left and right feet (8). Alterations of walking pattern and slow walking speed are presented (7), even if the use of a tripod cane or other assistive devices (9, 32). The range of average walking speed reported for patients with hemiplegia is 20 to 70 cm/s compared with 100 to 120 cm/s for normal subjects (33). This limitation in walking speed may be associated with advancing the affected leg efficiently in the swing phase and in shifting weight to the unaffected leg in the stance phase (33). Several researchers reported an abnormal swing/stance ratio in patients with hemiplegia. Typically the stance phase was shortened and the swing phase was lengthened in the affected leg compared with the swing and stance duration in the limb of normal subjects. To compensate for these changes in the swing/stance ratio, the unaffected leg of the patients with hemiplegia had an increased stance and decreased swing phase. Consistent with these interlimb adjustments, periods of double-limb support were longer in patients with hemiplegia than in normal subjects (33). Asymmetric steps are also characteristic of hemiplegia gait. The affected limb had a shorter stance time and step length than that of the unaffected limb. Several investigators reported that the degree of asymmetry was inversely related to the degree of motor recovery and positively related to walking speed (33).

3. Gait rehabilitation in patients with hemiplegia

Rehabilitation therapy has been clinically accepted as an effective approach to treating neurological motor dysfunctions resulting from stroke. One of the goals of rehabilitation is to retrain functional skills related to the activities of daily living (ADL) for the patient. Ambulation is considered one of the most important ADL skills to improve in order to allow the patient to have an independent lifestyle (6). There are various forms of gait rehabilitation techniques available such as traditional physiotherapy, treadmill training, FES, and orthosis (9). Depending on the severity and areas of the brain are affected, the resulting physical and cognitive disabilities can vary greatly (34).

3.1 Traditional physiotherapy

Traditional physiotherapy is the most common form of rehabilitation which involves the cooperation of a physical therapist working consistently with a patient to improve functions such as strength, range of motion, and reduction of spasticity. Early physical therapy intervention in gait training has been generally recognized as beneficial (10). One concept which is frequently used is the neurodevelopmental technique established by Bobath. This primarily focuses on the reduction in spasticity and functional changes like force development. Walking speed and endurance are considered to be of lesser importance (35). The Brunnstrom method, the proprioceptive neuromuscular facilitation concept are also widely used (36). However, no one procedure has been shown to have any greater benefit over another in term of mobility. Gait practice is only a small part of the programmed (11). Some studies indicated that repetitive task–oriented exercise programs improved functional capabilities in people with neurologic deficits. However, conventional gait training required manual support and guidance from physical therapists (10). Thus spending much time and effort on normalizing gait may be inefficient (11).

3.2 Treadmill training

Treadmill training has the advantage of allowing patients to perform repetitive functional specific tasks under the supervision of a physical therapist and/or a BWS harness. This form of treatment has shown to provided marked recovery in patients (37). In one study, a chronic patients with hemiparesis received treadmill training without BWS showed an improvement in step length symmetry, compared with traditional physical therapy (38). BWS with treadmill training was developed to support a percentage of body weight to allow safe weight shifting and stepping (10). Da Cunha-Filho et al. (39) and Visintin and Barbeau (40) showed that BWS treadmill ambulation training was a practicable and safe technique and had a hopeful role in gait training. However, a systematic review found that there were no statistically significant differences between treadmill training with or without BWS and other types of interventions for walking speed or dependence. However, the necessity of having one or more physical therapists to aid in the advancement of the affected limb and the control of trunk movement becomes one of the greatest disadvantages of treadmill training (10-12). As the therapist and patient tire, the patient' s gait may become asymmetrical and the benefit of the sustained treatment is lost (11). Hesse et al. (41) have developed a machine for more severely affected patients, which extends training beyond that of the treadmill and releases some of the therapist's time. The patients are supported in a harness and stand with their feet on motor driven footplates (11). This technique carries the disadvantages of requiring high cost machinery and lack of portability (10, 11, 37).

3.3 Functional electrical stimulation

FES is the application of electrical current to excitable tissue to supplement or replace normal control of movements and enable a repetitive exercise that is lost in neurologically impaired individuals such as stroke, multiple sclerosis or spinal cord injury (SCI) (2, 42, 43). FES is one of the reported therapeutic modalities recommended in the rehabilitation of these patients (4). FES has major therapeutic benefits in the early phase of gait rehabilitation, facilitating patients to achieve a better functional result in a shorter period of time (44).

3.3.1 Peripheral mechanisms of therapeutic benefit from FES

Possible peripheral mechanisms of therapeutic benefit from FES (43); firstly, FES might improve the fitness and strength of the remaining motor units to which the patient has voluntary access, by means of a training effect on them (45-48). Secondly, FES might improve the flexibility and range of motion of the affected limb (46-48), so that the voluntary efforts become more effective. Thirdly, FES might be reducing the amount of spasticity in the muscle (45, 47, 48), and improving function (43).

3.3.2 Central mechanisms of therapeutic benefit from FES

Possible central mechanisms of therapeutic benefits of FES are forced repetitive active movement of an affected limb. It is presumed that forced active repetitive movement facilitates cortical reorganization and the utilization of ipsilateral pathways (49). Possible central effects of FES may be enabling simulation of the sensory effects of paralyzed movements, and a correspondingly appropriate sensory context to facilitate cortical reorganization (50).

3.3.3 Clinical use of functional electrical stimulation

There are several commercially available one- and two- channel stimulators for correcting foot-drop such as, the footlifter®, the walkaide®, the Odstock dropped foot stimulator (ODFS), MicroFes®, Unistim® and COTAS® (51). The ODFS has been tested in a randomized controlled study, which demonstrated that the system increased walking speed and decreased walking effort (42). A number of FES systems is multi-channel systems for restoring standing and walking such as, ActiGait®, the Finetech Dropped Foot System®, Parastep I®, Sigmedics®, IL®, Parastim®, Complex Motion® and Quadstim® (51-53). The Finetech Dropped Foot System® is a relatively new implanted system and increased walking speed by 24% (52).

FES has also been applied to persons who have a SCI or have lost supraspinal control of ∞-motoneurons for other reasons. Kralj, Bajd, and others in Ljubljana, Slovenia (44) were the first group who introduced the technique of eliciting a flexion withdrawal reflex of the hip, knee, and ankle by stimulating the peroneal nerve. Electrical stimulation of the peroneal nerve can correct foot drop during the swing phase and the initial double limb support phase of walking. The device included a small portable stimulator, a single channel and a heel-switch trigger to start and stop the stimulation (54). A heel-switch consists of a sensor to detect when the stimulus should be delivered. A sensor is required to detect the phases of the gait cycle, so that the stimulation can be delivered during the swing phase of gait on the affected side (55). At least four channels of stimulation are required for walking after complete SCI and more channels of stimulation may be needed for greater speed and better quality of gait (56).

Stein and colleagues (56, 57) studied such FES system with 1 to 4 channels in patients with SCI. They found that participants had better gait speed with FES than without it. Improvement in walking speed more than 20% and continuing gains were seen average total improvement 45%. Parastep® uses four to six channels of bilateral surface stimulation of the quadriceps, peroneal nerves and, if necessary, the glutei to enable individuals with T4 to T12 paraplegia to walk with a walker (58). Individuals with paraplegia can stand and walk with reciprocal gait for limited distances (58). Use of the system has additional medical benefits, such as increased blood flow to the lower extremities, lowered heart rate at subpeak work intensities, increased muscle mass, reduced spasticity, and psychological benefits (42).

3.3.4 Functional electrical stimulation in patients with hemiplegia

FES can be an effective tool in the rehabilitation of patients with hemiplegia after they have sustained a stroke (5). It has been shown to decrease spasticity, increase strength, increase gait speed and elicit desired movements which will improve ADL in subjects poststroke (5, 29, 46, 59). Repetitive active or passive practice of movements identical or similar to those in normal gait may enhance motor learning and recovery (43, 60). More than 45 years ago, Liberson and colleagues (54) introduced a single-channel electrical stimulation in patients with stroke to prevent foot drop or drags on the ground during the swing phase of walking because of a lack of voluntary ankle dorsiflexion. The stimulation was delivered during the swing phase of gait to allow proper foot clearance and prevented the need for hip circumduction or other unstable gait compensations (55). Many review articles have concluded that electrical stimulation can improve gait, functional ability, and motor function in patients with hemiplegia (5).

In one study, a single FES treatment applied to the affected leg muscles of patients with hemiplegia improves standing balance and gait quality (4). Studies of stroke patients have shown that the ODFS increased in walking speed of 27% and reduction in physiological cost index (PCI) of 31% (3). The ODFS providing electrical stimulation to the common peroneal nerve and motor point of the tibialis anterior muscle during the swing phase of gait cycle (3). Robbins et al. (5) conducted a meta-analysis of the effectiveness of electric stimulation in poststroke rehabilitation. They concluded that FES significantly improved in gait speed. For patients with hemiplegia adults, moderately complex FES walking systems offer as many as eight channels of stimulation, which can be combined in any configuration depending on the needs of the individual. Short-term stimulation can provide facilitation of voluntary movement in the paretic lower extremity, which has been shown to enhance walking ability, but some patients do not demonstrate long-term carry-over of improved walking ability (61).

3.3.5 Limitation of functional electrical stimulation

The use of FES is not widespread and the total number of patients being treated remains quite small. This can be attributed to several reasons, such as technical limitations and unfamiliarity with FES in therapists. Technical limitations associated with the use of surface stimulators concern the lack of selectivity over the muscles and nerves recruited the sensitivity of muscle recruitment to electrode placement, and pain and tissue irritation associated with the passage of current through the skin. Portable units are available which provide coordinated stimulation patterns to improve gait functions, however configuration and programming of the devices require a skilled technician. FES system must supply electrical stimulation continuously to the paralyzed nerves and/or muscles, which causes rapid muscle fatigue, limits standing time and walking distance, poor control of joint torques and a high energy requirement (16, 17).

3.3.6 Parameters of functional electrical stimulation

Stimulation is delivered as a waveform of electrical current pulses, which are characterized by three parameters: pulse frequency, amplitude, and duration. The strength of muscle contraction is controlled by manipulating those parameters. If the pulse frequency is too low, the muscle responds with a series of twitches. Above a certain stimulation frequency, known as the fusion frequency, the response becomes a smooth contraction. Higher stimulus frequencies produce stronger muscle contractions up to a maximum, but also increase the rate of muscle fatigue. Thus, high stimulus frequencies are generally avoided. The strength of a muscle contraction may also be increased by increasing the number of motor units activated, an effect known as spatial summation. This is achieved by increasing the stimulus pulse amplitude and/or pulse duration, which effectively increases the electric charge injected, producing a larger electric field and broader region of activation so that more axons and motor units are activated. The strength of muscle contraction is controlled by modulating the pulse amplitude or pulse duration, and the stimulus frequency is set constant and as low as possible to avoid fatiguing the muscle prematurely (42).

Stimulus waveforms are generally either monophasic or biphasic in shape. A monophasic waveform consists of a repeating unidirectional (usually cathodic) pulse. Biphasic waveforms consist of a repeating current pulse that has a cathodic (negative) phase followed by an anodic (positive) phase. The first, or primary, phase elicits an action potential in nearby axons, and the secondary positive pulse balances the charge injection of the primary pulse (42).

3.3.7 Parameters of FES for walking

The patients with stroke demonstrated a short-term carry-over effect of a single-channel stimulator. The ODFS is a single-channel stimulator providing electrical stimulation to the common peroneal nerve and motor point of the tibialis anterior muscle. The components of the movement may be varied by adjusting the electrode position and stimulation amplitude. The stimulator gives an asymmetrical biphasic output waveform of maximum amplitude 80 mA, with 300-µsec pulse duration and a frequency of 40 Hz (3). A single FES treatment applied to the affected leg muscles of patients with hemiparesis improves standing balance and gait quality. The selected muscles were repeatedly activated in the following sequence including quadriceps, hamstrings, dorsiflexors, and plantarflexors. A stimulator with four individually controllable current source channels was used to deliver electrical impulses at a frequency of 30 Hz and pulse width of 250 µs. Each muscle was activated for four seconds, generating only a slight muscle contraction, and the level of intensity was adjusted according to subject consent, but ranged between 14 and 29 mA (4).

The superiority of the multichannel functional electrical stimulation (MFES) methods as compared with conventional therapy was mainly attributed to the enhanced motor learning accomplished by application of MFES. In the study, a new method of gait rehabilitation for non-ambulatory patients with hemiplegia by means of MFES added to conventional therapy was introduced. Surface electrical stimulation was applied on the peroneal nerve for ankle dorsiflexion, the soleus muscle, the hamstring muscles, the quadriceps femoris musculature, the gluteus maximus muscle and stabilization of the pelvis during stance phase, and optionally the triceps brachii muscle for reciprocal arm swing during the swing phase of gait for the ipsilateral leg. The stimulator contained six independent, galvanically separated channels with intermittent rectangular monophasic stimulation pulses. The amplitude of stimulation pulses was set between 0 and 120 volts in each channel separately. Frequency and pulse duration were preset to 30 Hz and 200 μs for all channels and were not varied. The maximum stimulating current was limited to 50 mA (62).

Tong et al. (10) compared the therapeutic effects of conventional gait training, gait training using an electromechanical gait trainer, and gait training using an electromechanical gait trainer with FES in people with subacute stroke. Surface electrical stimulation was applied on the common peroneal nerve and quadriceps muscle. Each participant received electric stimulation modalities, including rectangular waveform and pulse width of 400 μs with fixed values. The stimulation intensity was adjusted by the supervising physical therapist according to how successful the correct limb movement was elicited and to each participant's comfort threshold, ranged between 50 and 85 mA (10). Participants had significantly greater improvement in mobility, functional ambulation, and walking speed compared with participants who underwent conventional overground gait training (10). The summary parameters of FES for walking are presented in Table 2.

Table 2 Parameters of FES for walking

Parameters	Taylor (1999)	Isakov (2002)	Bogataj (1995)	Tong (2006)
Waveform	Asymmetrical biphasic	-	Rectangular monophasic	Rectangular
Pulse width (μs)	300	250	200	400
Frequency (Hz)	40	30	30	-
Current (mA)	80	14 - 29	50	50 - 85
Selected muscles	Common peroneal nerve and tibialis anterior.	Quadriceps, hamstrings, dorsiflexors, and plantarflexors.	Common peroneal nerve, soleus, hamstring, quadriceps, gluteus maximus and triceps brachii.	Common peroneal nerve and quadriceps.

3.3.8 Parameters for hybrid system

The electrically dependent functional training with multi-segment hybrid orthosis-stimulation system can improve in gait of patients with chronic hemiparesis (63). There are three electrodes positioned over the peroneus longus and tibialis anterior and two electrodes over the two heads of gastrocnemius muscle. Each of the 3 orthosis-electrodes devices was connected to its programmable control unit, containing a constant voltage stimulator that was set to deliver alternating current at a carrier frequency of 11 KHz, time modulated to bursts at a rate of 36 Hz. The pulses were set in an interrupted mode to elicit intermittent contraction and relaxation intervals. The appropriate intensity level of contraction is determined by the therapist during the initial visit to the clinic and stored (63). Schmitt et al. (64) evaluated the feasibility to develop a new hybrid orthosis called cyberthosis using selectively closed loop electrical muscle stimulation. They used a programmable four-channel electrical stimulator with which the current waveform as well as real time amplitude modulation, pulse width and frequency can be selected. After trials on healthy individuals, rectangular biphasic pulses with amplitude within zero to 100 mA, pulse width of 300 μs and frequency of 50 Hz were chosen. Three pairs of self-adhesive electrodes were used to stimulate separately rectus femoris, vastus lateralis, and vastus medialis. In addition, an electrical knee locks system, Akita knee joint (AKJ) that can be combined with FES was designed for patients with paraplegia. Kagaya et al. (16) developed a stimulator having two hand switches for both right and left legs, and a mode switch controlling the gait and sit-down modes. The rectangular pulse trains that were used consisted of a pulse width of 0.2 msec, a pulse interval of 50 msec, and an output voltage modulated from zero to 15 volts. Walking and sitting-down motions were all restored by this hybrid system.

Besides, the hybrid gait system was evaluated and compared to conventional four channel FES-aided gait using four subjects with paraplegia (17). The controlled-brake orthosis (CBO) provided significantly better trajectory control and reduced muscle fatigue when compared to FES-only gait. Electrical stimulation was applied through surface electrodes with a pair of electrodes over each quadriceps and the peroneal nerve to elicit a flexion withdrawal reflex for stepping. The stimulator produced asymmetric, biphasic, current-controlled pulses with amplitudes that could be varied between zero and 150 mA under computer control. Pulses applied to the quadriceps were at 25 Hz and 300 μsec width, while those to the peroneal nerve were at 50 Hz and 350 μsec (17). Moreover, a knee locker with closed-loop FES system has been developed to prevent the quadriceps weakness and the drop-foot of the patients with hemiplegia during gait training. This new knee locker with closed-loop FES system is capable of providing the patients with restoration to regular walking after appropriate gait training. Basically, FES can produce pulses having an amplitude's range from zero to 100 mA by using a 9 volts battery with frequency zero to 100 Hz, and pulse duration 70 to 1000 ms (8). The summary parameters for hybrid system are presented in Table 3.

Table 3 Parameters of hybrid system

Parameters	Alon (2003)	Schmitt (2004)	Kagaya (1996)	Goldfarb (2003)	Chen (2003)
Waveform	-	Rectangular, biphasic	Rectangular	Asymmetric, biphasic	-
Pulse width (ms)	-	0.3	0.2	0.3 and 0.35	70 – 1000
Frequency (Hz)	36	50	20	25 and 50	0 - 100
Current (mA)	-	0 - 100	-	0 – 150	0 - 100
Selected muscles	Peroneus longus, tibialis anterior, and gastrocnemius.	Rectus femoris, vastus lateralis, and vastus medialis.	Common peroneal nerve, soleus, hamstring, quadriceps, gluteus maximus and triceps brachii.	Quadriceps and peroneal nerve.	Quadriceps and tibialis anterior.

3.3.9 Adverse effect of electrical stimulation

Stimulus waveforms are generally either monophasic or biphasic in shape. Biphasic waveforms are made up of a repeating current pulse consisting of a cathodic (negative) phase followed by an anodic (positive) phase. The first, or primary, phase produces an action potential in nearby axons, and the secondary positive pulse balances the charge injection of the primary pulse. The purpose of the secondary pulse is to reverse the potentially damaging electrochemical processes that can occur at the electrode-tissue interface during the primary pulse, allowing neural stimulation without causing tissue damage (42). Stimulators are designed to regulate either current or voltage. With voltage-regulated stimulation, the stimulator output is a voltage, and therefore the magnitude of current delivered to the tissue is dependent on the impedance at the electrode interface (Ohm's Law). With the use of surface electrodes, the impedance at the electrode-skin interface increases as the electrode dries or loses contact with the skin. As electrode impedance increases, the current delivered with a voltage-regulated stimulator decreases, minimizing the possibility of skin burns owing to high current densities (42). Thus, voltage-regulated stimulation is often used for surface stimulation applications. The motor response, however, is more variable with voltage-regulated stimulation because of impedance-dependent currents. With current-regulated stimulation, the current is directly controlled and is not affected by changes in the tissue load (42). Therefore, the quantity of charge delivered per stimulus pulse can be guaranteed. To ensure that the stimulus charge is maintained within safe levels, a current-regulated waveform is often used with implanted electrodes. The use of a current-regulated stimulator also increases the likelihood of obtaining repeatable muscle responses to stimulation (42).

Acceptance of the FES systems was good and improved systems have been developed using feedback from the subjects. Wieler et al. (56) tested the long-term benefits of several noninvasive systems for FES during walking. No stimulation induced complications requiring medical attention, such as burns, falls, or fractures. A few subjects showed minor skin irritation transiently.

Electrical stimulation causes a tingling sensation on the skin. Very occasionally, patients find the electrodes irritate their skin. Before each participant's first training session, intermittent stimulation was tested continuously on the participant for at least 10 minutes to rule out skin allergy (10). Using hypoallergenic electrodes or changing the type of stimulation used can often solve that problem. It has found very rarely that stimulation increases spasticity of muscle and in these cases treatment will be stopped (65). Assess the effects of daily neuroprosthetic FES in sub-acute stroke the stimulation patterns are a Russian waveform of 11 kHz, with stimulation frequencies of 18 or 36 Hz depending on the stimulation mode selected. The pulse amplitude is adjustable and set by the therapist. The pulse duration varies from 0.01 to 0.5 msec, and may be adjusted by the patient in a step-wise manner. There were no adverse effects from treatment in either group. Self-report by patients indicated a high level of compliance with the neuroprosthetic treatment protocol. All patients completed the study, with no treatment dropouts (66). Two patients with chronic stroke who utilized an ankle foot orthosis (AFO) prior to study entry were evaluated at baseline and after 4 weeks of daily use of a surface peroneal nerve stimulator. Two medically stable stroke patients with dorsiflexion and eversion weakness of greater than 3 months were invited to participate in this case study. The first participant during week 1 utilized the ODFS for an average of 2 hours per day; throughout weeks 3 and 4, the participant self reported stimulator usage of 5 hours daily. The participant reported no adverse side effects associated with device usage. The second participant self-reported use of the ODFS of 6 to 8 hours daily during week 1 and an average of 8 hours daily through weeks 3 and 4. The participant reported no adverse side effects associated with device usage (67).

3.4 Orthosis

Orthosis is a more inclusive term than brace, and its use reflects the development of devices and materials for dynamic control in addition to stabilization of the body (68). The commonly stated goals of orthosis is to protect, stabilize, and improve function (69). In the case of lower extremity orthosis for ambulation, the goals can be more specifically defined (70).

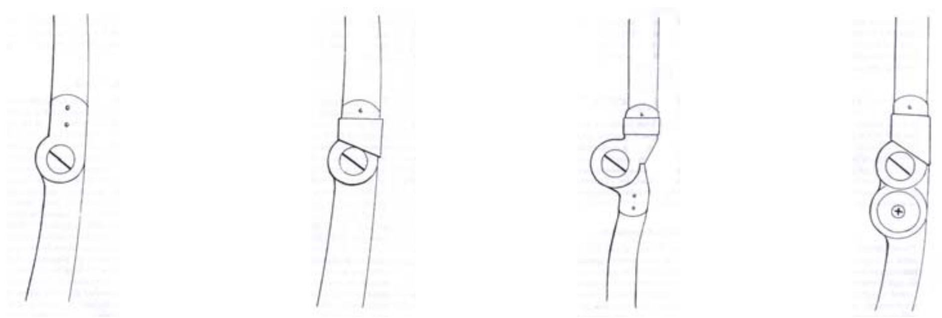
In the rehabilitation of stroke, the most commonly seen problem during the training of standing and walking movements is inadequate knee joint support strength as well as drop-foot (8). Mild CVA, rarely require orthotics intervention. More severe cases exhibit impairment to body awareness, balance, muscle strength, and coordination and include both the upper and lower extremities. Rehabilitation of these patients often requires varying degrees of orthotics intervention (34).

3.4.1 Knee-Orthosis

A KO only provides support or control of the knee but not of the foot and ankle (21). If the patient does not have adequate gastrocnemius delineation so that there is a shelf for the distal end of the orthosis to rest on, the brace may slide down the leg with wear. In that case, the brace needs to extend to the sole of the foot (21). A wide variety of orthotics knee joints is available for use in KAFO in current clinical practice. When a patient has a special need, the orthotist uses knowledge of mechanics and product availability to tailor a joint to the specific needs of that patient (69).

3.4.2 Characteristics of knee-orthosis

The mechanical knee joint can be polycentric or single axis. Polycentric is used for significant knee motion. A single axis is designed to pivot around a single point or axis, like a simple hinge (69), which is used for knee stabilization (21). Although many type of rehabilitation KO are on the market, an effective orthosis has several important characteristics (Figure 2). It must remain in the desired position on the limb during upright and sitting activities (71).



A **B** **C** **D**

Figure 2 Orthosis knee joint often used in KAFO. (A) Single-axis knee joints (B) Single-axis locking knee (C) Offset knee joint (D) Variable position orthosis knee joint (69)

A. Single-axis knee joint

The single-axis knee, also known as a straight knee joint without drop lock or a free knee, permits unrestricted flexion and extension to neutral in the sagittal plane. The most designs prevent hyperextension while providing medio-lateral stability (69).

B. Single-axis locking knee

The single-axis locking knee with the addition of a locking mechanism, such as a ring or drop lock provides rigid stability to the knee in all planes. This type of orthosis knee joint is appropriate for patients who are unable to control the knee effectively during stance phase and unlocked to permit knee flexion in sitting (69).

C. Offset knee joint

The offset knee joint is positioned behind the anatomic knee axis, increasing the biomechanical stability of the orthosis. It is available with and without a locking mechanism (69).

D. Variable position orthosis knee joint

The variable position locking orthosis knee joint is also known as a dial lock or as an adjustable locking knee joint. This design is intended for patients who are unable to achieve full extension due to knee flexion contracture (69).

3.4.3 Indication of knee-orthosis

In 1984, the American Academy of Orthopaedic Surgeons (71) developed a classification system that groups knee orthosis by their intended function including 2 type;

A. Prophylactic knee-orthosis

The prophylactic knee orthosis is designed to reduce the risk of knee injury for those individuals who are engaged in high risk activities, especially those individuals who have a history of previous knee dysfunction.

B. Rehabilitative knee-orthosis

The rehabilitative knee orthosis is used to protect a knee that has been injured or surgically required until adequate tissue healing has occurred. Functional KO is attempted to provide biomechanical stability when ligaments are unable to do so during daily activities.

3.5 Electro-orthosis system

Electro-orthosis system like a hybrid systems, which use both electrical stimulation and conventional external bracing (42). Hybrid FES has been developed to prevent muscle fatigue, reduce energy consumption, and enable better stability in the lower extremities, although it is more cumbersome than pure FES.

3.5.1 Characteristics of electro-orthosis system

3.5.1.1 Patients with paraplegia

Electro-orthosis in patients with paraplegia have been explored widely (72). Kim et al. (73) investigated effect of FES with that of a hinged AFO on walking in persons with incomplete SCI. The FES was the walkaide® systems, a simple 1-channel stimulator that stimulates the common peroneal nerve and assists with foot clearance during swing, thus improving walking. A hybrid FES system, consisting of Walkabout® and a four-channel surface FES system developed by Saito et al. (74), was applied to a T10 complete paraplegic. In addition, the Akita group also recently utilized the Walkabout® with percutaneous FES to restore locomotion in a patient with paraplegia (Figure 3)(75).

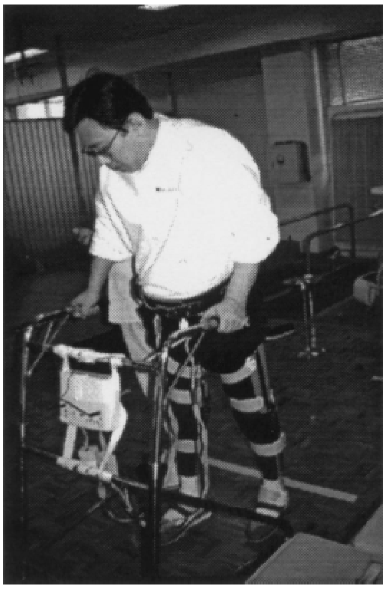


Figure 3 A hybrid FES with Walkabout® and percutaneous FES (75)

Another Akita hybrid FES system with a knee unlocking mechanism using a solenoid was applied to a T8 patient with paraplegia (16). This knee system unlocks the knee electrically and allows knee flexion during the swing phase of the gait. When the knee is extended by electrical stimulation of the knee extensors, the knee is automatically locked by the weight of the locking bar, and the stimulation of the knee extensors is stopped. Therefore, stimulation of knee extensors was unnecessary and fatigue in the patient was reduced (Figure 4) (16).

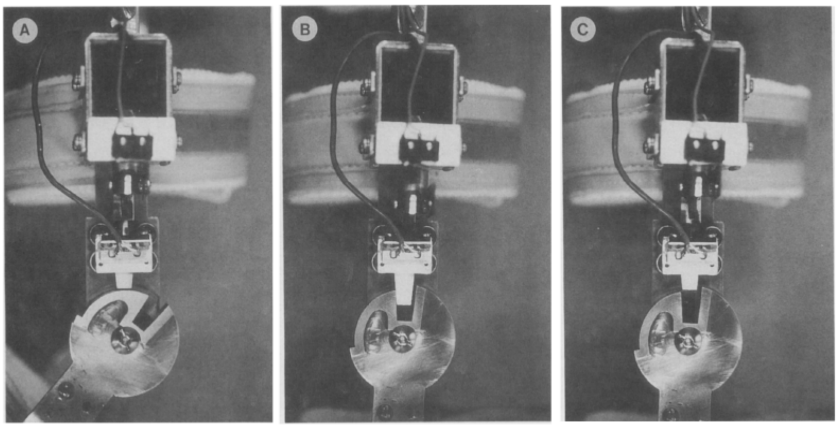


Figure 4 Akita knee joint. (A) Knee flexion. The knee is always unlocked. (B) Knee extension. The knee is automatically locked by gravity. (C) Knee extension. Current to the solenoid is given and the knee is unlocked (16).

The most widely tested hybrid system is the reciprocal gait orthosis (RGO) (20, 76, 77), which uses surface stimulation of hip extension on one side to cause the RGO mechanism to move the contralateral limb forward. Thus, walking is achieved by alternating stimulation of the hip extensors. Hybrid RGO are often successful in allowing users to stand and walk with less energy consumption (42).

The CBO is utilizing FES in combination with a controllable passive orthosis using for patients with paraplegia (78). The brakes can be in the free state, the locked state, or any state in between (17). By locking the brakes during stance phase and turning off stimulation to the quadriceps, muscle fatigue is reduced. Smooth, repeatable leg motions are achieved during swing phase using the stimulated muscle as a source of power and regulating limb motion through continuous computer control of the brakes (17).

3.5.1.2 Patients with hemiplegia

A knee locker with closed-loop FES system has been developed to prevent the quadriceps weakness and the drop-foot of the patient with hemiplegia during gait training (Figure 5) (8). This system includes a waveform generator, a current amplifier, a voltage amplifier and a power isolation circuit (8).

A B

Figure 5 (A) The knee locker in stance phase (B) The knee locker in swing phase (8)

3.5.2 Indication of electro-orthosis system

This system is suitable for CVA, cerebral palsy, complete thoracic or lumbar level SCI, and incomplete SCI at any level (61). A knee locker with closed-loop FES is capable of providing the patients with hemiplegia to restore regular walking (8).

A number of hybrid systems have been reported to restore mobility in a patient with paraplegia such as, the Walkabout® with percutaneous FES (74, 75), Akita hybrid FES system (16), hybrid RGO (20, 76, 77) and the CBO (17).

3.5.3 Advantages of electro-orthosis system

The electro-orthosis systems take advantage of the added stability provided by bracing and reduce the energy expenditure required for walking (42). The bracing supports the user's body weight, and the stimulation provides propulsion (42). The major advantage of this system compared with bracing alone is improved efficiency as measured by decreased energy cost, increased velocity, and increased walking endurance (61). Advantages of this system compared with walking systems using stimulation alone include increased safety in the event of a stimulation system failure and prevention of undesirable motions (61).

The Walkabout® with FES to restore locomotion in patients with paraplegia could improve walking parameters and energy cost better than in orthotics walking (74). Adding FES to RGO improved walking distance from 100 to 800 m, reduced energy expenditure by 15% to 30%, and improved balance (79). There was a significant reduction in heart rate and in PCI when walking by adding FES, but no change in cadence, step length or velocity was noted (79). Energy consumption is high with FES alone and subjects tire easily. Bracing can reduce the energy cost somewhat and can improve endurance (20, 56). The CBO provided significantly better trajectory control and reduced muscle fatigue when compared to FES-only gait (17).

A knee locker with closed-loop FES in patients with hemiplegia could significantly improve the mean velocity, cadence, stride length, active ankle motion range, and functional ambulation category (FAC) (8).

3.5.4 Disadvantages of electro-orthosis system

A major foible of this system is the extent of bracing required. It takes time to don and remove, may not be cosmetically appealing to some individuals, and does not approximate a normal walking pattern (79). Whereas the energy cost of using this system may be superior to that of bracing alone (61) but is often bulky and inconvenient to use for long periods (56). Therefore, this system have low long-term usage rates (42).

3.5.5 Muscles stimulation of electro-orthosis system

FES of key muscle groups in proper sequence for walking has now been used in patients with paraplegia. Common muscles stimulated are gluteus medius, gluteus minimus, gluteus maximus, iliacus, rectus femoris, vastus lateralis, vastus intermedius, and vastus medialis. The quadriceps is necessary to maintain upright posture and support of the stance leg during gait (80). The CBO, pulses applied to the quadriceps were at 25 Hz and 300 μsec width, while those to the peroneal nerve were at 50 Hz and 350 μsec (17). The addition of FES to the gluteals during stance phase when using the long leg braces resulted in a 36% reduction in the crutch force, a 30% reduction in PCI and provided forward propulsion by driving the stance leg into extension (79). AKJ, the electrodes implanted near the femoral nerve and at motor points of both the vastus lateralis and the vastus medialis provided stimulation for knee extension. The electrodes implanted at the motor point of the iliopsoas muscle provided stimulation for hip flexion. Besides, the electrodes implanted near the common peroneal nerve provided stimulation for hip flexion by eliciting the preserved flexion withdrawal reflex (16). Moorong Medial Linkage Orthosis (MMLO), a free-knee hybrid MMLO, however, does show promise as the kinematic data demonstrates an adequate foot clearance of the swing leg can be achieved. The buttons are used by the subject to initiate a step by stimulating the quadriceps of the swing leg while simultaneously stimulating the contralateral gluteal (81).

3.5.6 The cost of electro-orthosis

Available in a thermoplastic AFO model or in carbon composite AFO and KAFO models, this custom-made, custom-fit brace improves walking function, balance, and stability for people with leg weakness, drop foot or other gait problems. It is easy to put on and take off and comfortable to wear. The starting retail price is 87,500 bath per leg for the thermoplastic model or 175,000 bath per leg for the carbon model (82). A number of foot-drop stimulators have been designed and built over the years (Mikrofes, VeriDFS and I-GO). In addition, large manufacturers such as Medtronics and Empi had developed protocols for adapting their neuromuscular stimulators to be used for foot-drop. The Walkaide treats foot-drop, a condition in which individuals are unable to engage the muscles needed to lift their foot off the ground. As a result, the foot is dragged when walking. The Walkaide is a fully self-contained unit equipped with a number of novel features; a tilt sensor which allows adjustment of the threshold angles for turning the stimulation on and off, electronics and stimulating electrodes, and a stretchable, breathable garment. The averaging price is 26,250 bath (83).

Knee orthoses are similar to high-support knee braces, but are custom made. They are used for knee instability, post surgical weakness, or ligament instability/weakness and to correct abnormal knee bending. One type of knee orthosis was priced. It allows for supported knee movement with a double hinge at the knee connected to girdle like supports surrounding the upper and lower leg. The average price of knee orthosis is 38,767 bath (84). The KAFO is a support that stretches from the upper leg and provides support to the knee, ankle, and foot. The KAFO is typically used when there is weakness in the entire leg. The KAFO is tubular, plastic above and below the knee, with a double hinge at the knee and enclosing three-quarters of the limb with thigh and calf straps. The average price of KAFO is 61,885 bath (84).

Despite, there are a number of reports related to electro-orthosis in many countries. There is no evidence of gait training using a KEO in Thailand. The AKJ and Northeastern university knee orthosis have been used in Japan and America (16, 25). However, the cost of these electro-orthoses is very high for Thai people. The present study is planned to develop a simple knee electro-orthosis which is affordable and can improve walking performance in patients with hemiplegia.