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The Effects of Functional Electrical Stimulation on Balance, Gait and Residual Limb Atrophy in a Traumatic Transtibial Amputee: A Case Study

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THE EFFECTS OF FUNCTIONAL ELECTRICAL STIMULATION ON BALANCE,

GAIT AND RESIDUAL LIMB ATROPHY IN A TRAUMATIC TRANSTIBIAL

AMPUTEE; A CASE STUDY

BY

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Abstract

Incidence of falls in lower extremity amputees is significant, in part due to loss of proprioceptive signals from the missing foot. Loss of the stretch reflex to the residual anterior tibial (AT) muscle also results in disuse atrophy. By stimulating the residual AT muscle during swing phase of gait, this study used functional electrical stimulation (FES) to determine the effects of 12 weeks (3 hours daily) of sensory feedback on confidence, gait, balance, and residual limb girth of a female traumatic transtibial amputee, age 30. Pre-and post-testing included an Activities-Specific Confidence (ABC) scale, limb girth measurements, one- and two-leg balance trials, and gait trials with and without FES. Standard deviations (SD) of the center of pressure (COP) in the x and y directions, cadence, velocity, and symmetry of step length (SLS=shortest step length [SSL]/longest step length [LSD]), stance time (STS=involved side [IS]/non-involved side [NIS]) and knee (KFS=IS/NIS) and hip (HFS=IS/NIS) flexion were collected using a single forceplate and 3D video gait analysis system. Limb girth symmetry at the distal stump increased 1.26%. Gait pre-and post-testing with FES values (respectively) showed improvement in SLS (5.34%, 6.59%) while others improved (+) or worsened (-) when compared to 100% as perfect symmetry. These were: cadence (+1.03%, -2.0%), velocity (+3.5%, -3.33%), STS (+11.47%, -4.74%), KFS (-2.28%, +1.93%), and HFS (-8.98, +12.66). COP SDx, all stances, and SDy, single stance, were increased, indicating lower balance scores. Confidence scores increased in 7 of 16 activities. We suggest that FES sessions 3 hours/day for 12 weeks is not adequate to significantly influence stump atrophy or confidence, but there is a trend toward improvement in all variables excepting balance. Future studies should include a larger subject pool over a longer time period.

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Chapter I

Introduction

In the United States, one out of every 200 persons is estimated to have had an amputation (National Limb Loss Information Center [NLLIC] staff, 2006). Feinglass, et al. (1999) reported the lower extremity amputation rate in the United States, for the years 1995-1996, to be 24.93 per 100,000 persons. Ephraim, Dillingham, Sector, Pezzin, and MacKenzie (2003), in a review of the literature, found the incidence rate of acquired amputation rates varied among and within nations. The values ranged from 1.2 first major amputations per 10,000 women in Japan to 4.4 per 10,000 men in the Navajo Nation in the United States.

There are multiple causes for limb loss, including diabetes mellitus, peripheral vascular disease, malignancy, and trauma. The etiology leading to ninety percent of lower limb amputations is peripheral vascular disease (PVD), which is often associated with diabetes mellitus (McCollum & Raza, 2004). Pezzin, Dillingham, and MacKenzie (2000) determined that about 80% of all trauma-related amputations occurred before age 40. A significant number of these persons reported ongoing problems with the residual limb, including phantom pain, wounds and sores. Transtibial amputations were found to be more common than those at any other level.

Ability to ambulate following transtibial amputation is determined by patient and prosthetic factors. Pauley, Devlin, and Heslin (2006) concluded that one in five lower extremity amputee patients will fall at least once during inpatient rehabilitation. In a study of amputees who had used prostheses for at least 6 months, falls and the fear of falling were found to be pervasive (Miller, Speechley & Deathe, 2001). Of their

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participants, 52% reported falling in the past year, and 49% reported a fear of falling.

Fear of falling may influence balance confidence and mobility (Miller, Deathe, Speechley

and Koval, 2001). Postural control requires input from the visual, vestibular, spinal,

cortical, and somatosensory systems (Tucker, Ramirez, Krebs and Riley, 1998).

Somatosensory input derives primarily from the forces and motions exerted by the feet on

the support surface. This input is lost in transtibial amputations. The loss of this input,

also known as proprioceptive feedback, limits perception of limb orientation with respect

to the supporting surface. This perceptional loss will impair balance and gait.

With transtibial amputation, distal tendon and muscle stretch is lost. As a result,

the muscle spindles of the residual muscles have no information to convey, Golgi tendon

organ feedback distal to the amputation site is absent, no action is carried out, and

atrophy of the residual ankle extensor and flexor muscles is inevitable. Atrophy of these

muscles affects the shape of the residual limb and limits the soft-tissue weight bearing

surface. This may increase the risk of skin breakdown due to increased pressure over less

pressure-accepting structures.

Electrical stimulation is frequently incorporated into rehabilitation programs to

help regain muscle strength and function. In animal studies, results suggest that

intermittent stimulation (12 hours per day for 12 weeks) increases muscle strength and

fatigue resistance (Duan, Trumble, Scalise, & Magovern, 1999). Sabolich and Ortega

(1994) reported an 11% increase in weight distribution symmetry during gait with the use

of transcutaneous electrical neural stimulation (TENS) in their transtibial amputee

subjects. In victims of cerebral vascular accidents (CVA), electrical stimulation of the

common peroneal nerve (CP) during the swing phase of gait produces ankle dorsiflexion

in the affected limb (Liberson, Holmquest, Scott & Dow, 1961). The application of electrical stimulation for the purpose of producing muscle contractions and the accompanying movement or action is known as functional electrical stimulation (FES).

There are many studies documenting the effects of electrical stimulation to improve function in spinal cord injuries (SCI) and CVAs (Simcox, et al., 2004; Yan, Hui-Chan, & Li, 2005). Studies to evaluate the effects of electrical stimulation on amputees are limited. Research involving amputees and FES was not found. Although it is known that loss of proprioception affects gait, no studies were found that evaluate the effectiveness of FES in providing the lost sensory input as to limb orientation in relation to the supporting surface.

Statement of the Problem

The lower extremity amputation rate in the United States is significant. Within this population the incidence of falls has been found to be pervasive. One factor thought to contribute to impaired balance is loss of proprioceptive input from the foot and ankle. Although it is known that loss of proprioception affects gait, methods for providing this sensory feedback to a transtibial amputee are not well documented.

Purpose of the Study

The purpose of this study was to evaluate the effects of functional electrical stimulation on gait, balance, and residual limb atrophy in a single transtibial amputee. It has been shown that electrical stimulation of the common peroneal nerve (CP) during the swing phase of gait produces ankle dorsiflexion in the affected limb of CVA victims

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(Liberson, et al., 1961). It has also been reported (Sabolich and Ortega, 1994) that TENS, a modality normally used for pain control, increased weight distribution symmetry in the transtibial amputee gait. It is known that skeletal muscle adapts to demand. Disuse promotes atrophy while increased use promotes hypertrophy. Creating awareness of prosthetic limb position should have an impact on gait and balance, while muscle stimulation should reverse or retard atrophy. This was investigated by studying the effects of FES on the gait of a transtibial amputee.

Significance of the Study

Information from this study could have a significant impact on the life-style of transtibial amputees. The loss of sensory feedback from the amputated foot limits knowledge of limb position, which directly affects foot placement and gait confidence. The application of FES may significantly improve proprioception, improving gait and reducing the incidence of falls. Additionally, FES may reduce or reverse residual muscle atrophy. This could increase stump soft tissue weight acceptance and reduce pressure-related stump injuries. This treatment modality could be incorporated into amputee rehabilitation programs as well as influence future prosthesis development.

Research Hypotheses

As this study was designed to investigate the effects of functional electrical stimulation on balance, gait and residual limb atrophy in the transtibial amputee, there were multiple hypotheses.

1. It was hypothesized that cadence, velocity, step length symmetry, and knee and hip flexion symmetry would be increased immediately with use of FES.

2. The second hypothesis was that static balance would show reduced sway after twelve weeks of therapy.

3. The third hypothesis was that there would be increased stump girth after 12 weeks of therapy.

4. The fourth hypothesis was that after 12 weeks of therapy the Activity-Specific Balance Confidence (ABC) Scale (Powell & Myers, 1995) scores would be improved.

Limitations

1. The study was limited to only one participant; therefore it would be difficult to generalize to the population.

2. The study was conducted in a laboratory setting; outcomes may not easily extrapolate to the participant's daily activity settings.

Delimitations

1. Only one participant from a local amputee rehabilitation private practice was used due to participant criteria confines and the in-depth nature of the study.

2. The participant was a unilateral transtibial amputee who had used a prosthesis for more than 6 months and who would have FES incorporated into her ongoing rehabilitation program.

3. The participant was able to walk without assistive devices (canes, walkers, etc.)

Assumptions

1. The participant used the FES device at least 3 hours daily for the length of the study.

2. Residual muscle girth changes were the result of FES and no other rehabilitation modality.

3. Residual limb girth changes were the result of muscle changes only.

4. Residual limb fat atrophy was stable.

5. The participant exhibited her usual gait pattern when being assessed.

6. Gait changes were the result of FES and no other rehabilitation modality.

Variables

Independent Variables

1. Testing with and without FES to the residual anterior tibialis muscle during swing phase of gait.

2. Pre and post use of FES for 3 hours daily for 12 weeks

Dependent Variables

1. Girth of the residual limb in centimeters

2. Scores on the Activity-Specific Balance Confidence (ABC) Questionnaire

3. Cadence

4. Gait velocity

5. Step length

6. Stance time

7. Knee flexion

8. Hip flexion

9. Postural sway

10. Ground reaction force

Operational Definitions

Base of support (BOS) (double leg stance): The area bordered by the lateral margins of both feet, posterior margins of both feet, and the metatarsophalangeal joints of both feet.

Base of support (single leg stance): The lateral and medial margins, posterior margin, and metatarsophalangeal joints of the supporting foot.

Center of mass (COM): The point (inside or outside the body, depending on the posture) where all the mass could be considered to concentrate (Minetti, 2000).

Center of pressure (COP): The location of the vertical ground reaction force. It is the weighted average of pressures distributed over the surface of the area in contact with the ground (Gage, Winter, Frank, and Adkin, 2004).

Improved balance: A reduction of postural sway.

Motor unit: Motoneuron cell body within the spinal cord, its axon, and the muscle fibers it innervates (Whiting & Zernicke, 1998).

Postural sway: Oscillating movement about a vertical axis of the body during upright stance.

Proprioception: The perception of body and limb position and movement, usually at a subconscious level, gained from information arising from within a person's body.

Stump: The section of the extremity distal to the most distal joint remaining following amputation.

Chapter II

Literature Review

The purpose of this literature review is threefold: (a) to provide a basic understanding of normal stance and walking gait, including the mechanisms of postural control, (b) to present documentation of the effects of losing one of those mechanisms, as occurs with lower extremity amputations, and (c) to provide information on a treatment modality that may improve walking gait in lower extremity amputees. An understanding of normal gait and balance, including mechanisms of postural control, are basic to understanding the effects of loss of somatosensory feedback on amputee gait and residual limb muscles. This review presents the information in the following order: (1) static balance and postural control, (2) walking gait and postural control, (3) proprioception, (4) functional electrical stimulation, (5) skeletal muscle response to electrical stimulation, and (6) Activities-Specific Balance Confidence Scale, and (7) summary.

Static Balance and Postural Control

In quiet standing, with both feet equally supporting the body's weight, balance mechanisms function to maintain the body's COM over the base of support (BOS). As the COM passively shifts, and approaches or exceeds the margins of the BOS, reflex muscle function assists in returning the COM over the BOS. Winter, Patla, Prince, Ishac, and Gielo-Perczak (1998) concluded that the COP is controlled by ankle plantarflexor and dorsiflexor torque in the sagittal plane and hip abductor and adductor torque in the frontal plane. During quiet stance, Winter, Patla, Ishac and Gage (2003) found COM to be the passively controlled variable and COP to be the actively controlling variable.

When COP was anterior to COM, they concluded the COM was being accelerated posteriorly; when COP was to the right of COM the COM was accelerating to the left, etc. This maintained COM in a safe and fairly constant position between the two feet.

Walking Gait and Postural Control

As described by Ayyappa (1997), a full gait cycle is the period of time between any two identical events in the walking cycle. An example would be from heel strike of one foot to heel strike by the same foot at the next step. The stance, or support phase portion of the gait cycle, for each lower extremity, includes approximately 62% of the full cycle. This phase begins with heel strike, includes midstance, and ends with toe off. The swing phase for each lower extremity begins at toe off and ends with heel strike. There are two double limb support portions of the full gait cycle when both feet are bearing weight. The first is at heel contact while the contra-lateral foot is at toe-off. The second double limb support occurs when the contra-lateral foot is at heel contact. For the remaining portion of the full gait cycle, weight is borne by a single limb.

In the inverted-pendulum model of walking (MacKinnon & Winter, 1993; Minetti, 2000; Schmitt, 2003; Ivanenko, et al., 2004), the body vaults over the stance leg in such a way that the COM is at its lowest point at heel-strike and its highest point at midstance (Lee & Farley, 1998; Schmitt, 2003). MacKinnon and Winter (1993) demonstrated that, during the swing, or single support phase of gait, balance and posture control in the frontal plane was controlled by a precise interaction between active muscle moments, passive joint accelerational moments and destabilizing gravitational moments about the subtalar and hip joints of the supporting limb. This interaction regulated the

horizontal trajectory of the COM, maintaining it within the lateral borders of the BOS. MacKinnon and Winter's study also showed that the most important factor affecting frontal whole body balance was the mediolateral foot position relative to the COM established at initial contact.   Redfern and Schumann (1994) analyzed swing trajectories of the foot during gait with respect to the pelvis. Their results suggest that foot placements are dependent upon location of the stance foot with respect to the pelvis in order to help maintain balance during gait.

As the body falls forward in gait, COM is shifted anterior to the ankle joint, exerting a dorsiflexory force. This force is resisted by tension exerted on the calcaneus with contraction of the gastrocnemius muscles and the appropriate alternating contractions of the postural extensor and flexor muscles, shifting the COM over the supporting limb, maintaining legs and trunk equilibrium.   When the COM is shifted posteriorly, the anterior tibial muscle contacts and pulls the COM forward again. Simultaneously, muscle contractions maintain the hips and trunk in an erect position. These stabilizing activities are neuromuscular responses to signals from the muscle stretch receptors (muscle spindles), tendon contraction sensors (Golgi corpuscles), and other sensory end organs which respond to the stimulae of pressure, tension, and pain (Root, Orien & Weed, 1977).

Postural control requires input from the somatosensory, visual, vestibular, spinal and cortical systems (Tucker, Ramirez, Krebs & Riley, 1998). Somatosensory input derives primarily from the forces and motions exerted by the feet on the support surface. This gives the proprioceptive information (body position, muscle and tendon sensations, equilibrium, and pressure sensations from the bottom of the feet). This information is

integrated into the nervous system and causes appropriate motor responses. These motor

responses include subconscious involuntary reflexes and voluntary motor activity which

function to maintain a stable relationship between the COM and either a stable or

dynamic COP.   Horak, Dickstein and Peterka (2002), found that persons with

impairment of propriocepsis due to diabetic peripheral neuropathy had larger and more

variable postural sway than the control group. They concluded that disrupting postural

sway feedback from the ankle joints or total body COM motion were sensitive methods

for decreasing postural stability. Motor and sensory deficits were demonstrated in the

lower extremity amputee by asymmetric gait (Robinson, Smidt, & Arora, 1977) and

lateral weight-shifting difficulties. These changes resulted in slower cadence and

decreased forward velocity (Tibarewala & Ganguli, 1982).

Proprioception

Proprioception is primarily derived from sensory nerve terminals in joint

capsules, muscles and tendons, combined with input from the vestibular apparatus. Intact

proprioceptive sensory systems are important for maintaining balance and an upright

position by enabling muscles to vary their contraction forces in immediate response to

changes in moments of force at the joints.   Muscle spindles within the muscles and Golgi

corpuscles within the tendons are stimulated by stretching. Signals from these receptors

operate at a subconscious level. Pacinian corpuscles, found in tendons, periosteum, joint

capsules, fascia, and subcutaneous tissue, are stimulated only by very rapid movement of

the tissues. They are important in detecting tissue vibration or other extremely rapid

tension or pressure changes. Flower spray endings are found in joint capsules and muscle

spindles. They are stimulated by stretching (Guyton, 1981). The slightest movement at any joint causes tightening of the ligaments. This results in proprioceptive activation and the appropriate muscle contracts to relieve the tightness by evoking a response from the motor units. It has been suggested that following joint damage, such as anterior cruciate ligament (ACL) injuries, muscle weakness may be related to abnormal articular sensory information causing proprioceptive deficits (Hurley, 1997).

The loss of proprioceptive signals from the amputated limb may influence observed central nervous system (CNS) changes. Draganski, et al. (2006) found a decrease in gray matter of the posterolateral thalamus contralateral to the side of the amputation. These changes were positively correlated with the length of time since amputation. Kavounoudias, Tremblay, Gravel, Iancu, and Forget (2005) found, in the nonamputated limb, a reduction in movement detection at the knee and ankle levels, and diminished touch-pressure perception at the foot. They concluded that the sensory changes in the nonamputated leg suggest central sensory adaptations following amputation.

Functional Electrical Stimulation

Nerves and muscles are composed of electrically excitable cells. The fundamental neuromuscular unit is the motor unit (Whiting & Zernicke, 1998). The intact motor unit generates and propagates action potentials by the movement of positive ions (potassium and sodium) across the cell membrane (sarcolemma) which surrounds the cytoplasm (the sarcoplasma). Stimulus intensity is determined by the frequency of the action potentials transmitted. As the action potential travels into the center of the muscle cell,

depolarization of the sarcolemma activates calcium channels on the sarcoplasmic

reticulum membrane and calcium is released. Calcium binds with the muscle contractile

proteins in such a way as to cause muscle contraction. With transtibial amputation there

is loss of the stimuli that would initiate this electrical activity. As a result, there is

residual muscle atrophy and limited limb position sense.

Stimulation of the motor neuron by application of an external electrical source

will also generate action potentials. When the electrical threshold for depolarization is

met, there will be an exchange of the ions between the exterior and interior aspects of the

sarcolemma, as in the intact motor unit (Muccio, Andrews, & Marsolais, 1989).

Electrical stimulation is frequently incorporated into rehabilitation programs to

help regain muscle strength and function. This has been shown to be effective (Banerjee,

Caulfield, Crowe & Clark, 2005; Harris, LeMaitre, Mackenzie, Fox, & Denvir, 2003;

Iwasaki, et al., 2006). Muscle stimulation has been achieved by transcutaneous (Harris, et

al., 2003; Simcox, et al., 2004; Yan, et al., 2005) and surgically implanted (Davis,

MacFarland & Emmons, 1994; Dhillon, Kruger, Sandhu, & Horch, 2005; Duan, et al.

1999) devices. In animal studies, results suggested that intermittent stimulation (12 hours

per day for 12 weeks) increased muscle strength and fatigue resistance (Duan, et al.).

Following long term use of electrical stimulation to paralyzed muscle in a group of spinal

cord injury (SCI) subjects there was an increase in unloaded tissue oxygen levels (Bogie,

Phil, & Triolo, 2003). Sabolich and Ortega (1994) reported an 11% increase in weight

distribution symmetry with the use of TENS in their transtibial amputee subjects.

Electrical stimulation of the common peroneal nerve during swing phase of gait

produces anterior tibial muscle contractions. This results in dorsiflexion of the foot,

which is the in-phase function that would be expected in an intact limb. This method of

applying electrical stimulation is known as functional electrical stimulation (FES).

FES has been used to enhance motor function in persons with SCI and cerebral

vascular accidents (CVA) for more than 30 years (Liberson, et al., 1961; Nene, Hermens,

& Zilvold, 1996). In hemiplegics, FES has been shown to increase the speed of recovery.

Popovic, Popovic, Sinkjaer, Stefanovic and Schwirtlich (2003) investigated the

effectiveness of FES combined with conventional therapy for improving upper extremity

function in CVA subjects, describing this as Functional Electrical Therapy (FET). After

3 weeks of therapy they found an increase in repetitions (activities of opening, closing,

holding and releasing) from 5.8 ± 4.3 (FET group) and 4.9 ± 1.3 (controls) to 18.8 ± 10.9

(FET) and 9.6 ± 6.3 (controls) in those subjects from higher functioning groups (HFGs).

Subjects from lower functioning groups (LFGs) started with an averaged number of

repetitions of 0 for both the FET and controls, increasing to 1.9 ± 1.1 (FET) and 0.2 ± 0.1

(controls) for the same time period.   In the lower extremity FES may improve gait by

producing ankle dorsiflexion, which allows the foot to clear the supporting surface

(Liberson, et al.). Wieler, et al. (1999) included persons with incomplete SCI as well as

those with cerebral damage. They found increased walking speeds in both groups when

FES was used. A total increase of 45% was observed. There was a 55% increase in SCI

subjects compared to 19% for those with cerebral impairment. The increase in walking

speed was attributed mainly to an increase in stride length. They observed increased

stride length of over 20% ($p < .01$). Stimulating the CP nerve produces contractions and

strengthens the muscles (Stein, et al., 1992). Timing for FES has utilized a heel sensor

(Liberson, et al.) and a tilt sensor (Stein et al., 2006; Wieler, et al.). Each sensor was

programmed to activate an in-phase muscle contraction during swing phase of gait through electrodes placed over the target muscle.

Skeletal Muscle Response to Electrical Stimulation

Several studies have shown that neuromuscular electrical stimulation may improve peripheral muscle function in severely disabled patients (Bourjeily-Habr, Rochester, Palermo, Snyder, & Mohsenin, 2002; Zanotti, Felicetti, Maini, & Fracchia, 2003). Dal Corso, et al., (in press), in their analysis of baseline muscle biopsies, found a significant relationship between muscle strength and type II muscle fiber cross-sectional area (CSA). Following 6 weeks of electrical stimulation there was an increase in type II, but a decrease in type I, CSA The median change, and range, was 12.5% (-16.8% to 57.6%) vs. -9.8% (-40.8% to 36.6%), $p<.05$. They concluded that in their population of chronic obstructive pulmonary disease (COPD) patients, electrical stimulation may promote a small degree of type II muscle fiber hypertrophy, but no significant overall muscle mass increase. Scremin, et al. (1999), conducted a FES-induced cycling study involving 13 persons with neurologically complete SCI for average treatment duration of 52.8 weeks (30 minutes $2.32 \pm .26$ [SD] days weekly). This study incorporated computed tomography of the legs to assess muscle CSA and proportion of muscle and adipose tissue. They reported CSA increases > 20% in most treated muscles. Based on the analysis of a small group of these patients ($n = 4$), they concluded there was no change in adipose tissue cross-sectional area. Johnston, Smith, and Betz (2005) evaluated the effects of electrical stimulation on the knee extensors of a person with incomplete SCI. They reported a 9.8% increase in thigh mean circumferential measures following 10

months of electrical stimulation of the femoral nerve (12.3 ± 1.1 cm to 13.5 ± 1.5 cm),

$p<.001$. They also reported an increase in the quadriceps femoris isometric torque across

all angles from 7.0 ± 1.6 Nm at baseline to 14.8 ± 3.2 Nm at 10 months ($p < .001$). After

2 months with no stimulation they observed a decrease in both thigh circumference and

quadriceps femoris torque to 13.1 ± 1.3 cm and 8.5 ± 1.1 Nm ($p < .001$) respectively.

With transtibial amputation, the residual ankle dorsiflexors have contractile ability

because the peripheral nerves proximal to the amputation site are intact. Over time, these

muscles atrophy due to disuse. There are no studies found documenting the effects of

FES on the structure or function of these residual muscles.

Activities-Specific Balance Confidence Scale

Fear of falling may lead to activity restrictions and reduced independence. This

loss of confidence was reported by Tinetti, Mendes de Leon, Doucette, and Baker (1994)

in their study of persons age 72 or older. Of those that had previously fallen, 24%

acknowledged activity restrictions. The Activities-Specific Balance Confidence (ABC)

scale was developed by Powell and Myers (1995) as a measurement tool to be used in the

elderly population. The test was comprised of 16 activity descriptors (see Appendix A).

Confidence in performing each activity was assessed via the directive "How confident are

you that you will not lose balance or become unsteady?" The response was collected via

a 0-100% scale (no confidence to full confidence).

Activities included in the scale were collected by interviewing 15 clinicians

(physical and occupational therapist) and 12 physiotherapy outpatients over the age of 65

(7 who had fallen in the past year). The clinicians were asked to "name the 10 most

important activities essential to independent living, that while requiring some position

change or walking, would be safe and nonhazardous to most elderly persons." In

addition to the above question, the seniors were asked "Are you afraid of falling during

any normal daily activities, and if so, which ones?" The total ABC score was found to be

stable over a two-week period ($r = .92$, $p<.001$). Test-retest correlation coefficients for

individual items were found to be nonsignificant in two cases (car transfers, $r = .19$) and

walking in the home, $r = .36$). Cronbach's alpha was .96, indicating high internal

consistency of the ABC Scale. Only one of the item-total correlations was $< .60$ (reach

from eye level, $r = .49$, $p < .001$).

Miller, Deathe, and Speechley (2003) conducted their study to evaluate the

internal consistency, test-retest reliability, and construct validity of the ABC Scale in

lower limb amputee victims. In this study, Cronbach's alpha was .95, test-retest reliability

was .91 (95% confidence interval [CI], .84-.95), and individual item test-retest

coefficients ranged from .53-.87. They concluded the ABC Scale was reliable, with

strong support for validity, in measuring balance confidence in persons with lower limb

amputations.

Summary

The loss of somatosensory information from the amputated lower extremity limits

the body's perception of residual limb position in relation to the supporting surface. This

affects gait and may increase the risks of falls as well as the fear of falling. FES may

reduce these risks by providing sensory feedback which may increase limb position

sense. Additionally, FES may limit residual limb muscle atrophy. This would distribute

weightbearing forces over a greater stump soft tissue surface, reducing risk of skin

complications.

Chapter III

Methods

Participant

The participant was a 30-year-old female with a 2 year history of traumatic left transtibial amputation. She started a rehabilitation program and was fitted with a prosthesis soon after surgery. She continued with a physical therapy program of 1 – 1 ½ hour sessions 3 days weekly throughout 8 weeks of the study. These sessions included muscle strengthening by use of stretch bands and therapy applied forces, squats, bicycling, stretching exercises, balance board training, step climbing, treadmill, weight shifting control on a ski machine, and jogging short distances on predominately even terrain. She then decided to join a gym and use a personal trainer. She did not attend the gym on a regular basis.

Instrumentation

A single-channel neuromuscular stimulator (ODFS Dropped Foot Stimulator, Salisbury, Wiltshire, UK) which utilizes a foot switch, was programmed to produce anterior tibialis muscle stimulation during the swing phase of gait. The foot switch triggered continuous stimulation from heel lift to heel contact. The foot switch, or heel sensor, was connected by a single wire to the stimulator, which was worn at the waist. The stimulator was connected by wires to the two reusable 5 cm x 5 cm electrodes (Pals Electrodes, Knaresborugh, North Yorkshire, UK) provided as components of the ODFS system. The electrical stimulator parameters were as follows: alternating current; symmetrical biphasic output waveforms; pulse duration 300 µsec; pulse frequency 40 Hz;

and current amplitude approximately 65 mA, adjusted by the participant for maximal

stimulation at a level comfortable to her. The ODFS system has been found to be reliable

in stimulating the peroneal nerve during swing phase of gait (Burridge, Taylor, Hagan, &

Swain, 1997; Taylor, et al. 1999).

Prior to attaching the electrodes, the skin was cleansed with alcohol pads and

allowed to dry completely. The electrodes were positioned as follows: (1) one just

proximal and posterior to the fibula head; (2) one just distal and anterior to the fibula

head; (3) a 2mm distance separated the electrodes. Correct position was confirmed when

the participant felt the sensation of foot dorsiflexion in response to electrical stimulation.

An ABC Scale (Appendix A) was used to assess confidence levels. The ABC

Scale has been found to be reliable and with a strong support for validity among lower-

limb amputees (Miller et al. 2003).

An AMTI (Watertown, MA) force platform was used for collection of ground

reaction forces (GRF) during static balance and 3-D gait trials. The force platform has

been found to be a reliable predictor of ground reaction forces in studies such as that

completed by Centomo, Termoz, Savoie, Beliveau and Prince (2007).

For 3D gait analysis a four-camera (JVC, Wayne, NJ) video system was used,

collecting at 60 Hz, with one force platform (AMTI, Watertown, MA) imbedded in a

raised walkway. Vicon Motus software; version 8.2 (Englewood, CO) was used for

computations of GRF and gait parameters. This software has been found reliable in

studies involving video camera and force plate analysis (Lafortune & Perry, 1995).

Procedure

The participant was personally recruited from a prosthesis laboratory and rehabilitation private practice where the investigator had previously participated in an externship program. Before beginning the study, the participant signed an informed consent form approved by the institutional review board (Appendix B).

Initial training sessions in use of the ODFS were conducted by the participant's head rehabilitation specialist and continued for 1 week until she was knowledgeable and confident with placement of the electrodes and adjusting controls of the electrical stimulator. Following the training orientation and collection of baseline data, the participant used the device in her usual activity settings for a minimum of 3 hours daily. This was not continuous as the stimulator was not in use while driving from one location to another. The 3 hours was a participant-selected reduction from the planned 6 hours, as the participant found the device to be cumbersome, uncomfortable and inconvenient. The participant kept a log of the daily hours of use. She was contacted weekly by the investigator for completion of a study flow sheet (Appendix C). Additional comments were recorded in interview format (Appendix D).

The participant completed an ABC Scale pre- and post-study. Baseline and post-study girth measurements of both limbs were collected. Measurements were conducted by the same person, using the same commercial tape measuring device, at the same time of day, with the participant in a semi-recumbent position, comfortably supported at an angle of 45 degrees. Measurements were repeated until within 0.5 cm and the results were averaged. The measurement locations were as follows: (1) central patella, (2) 3",

6" and 8" proximal to central patella, (3) medial tibial plateau (MTP), and (4) 1", 2" and 3" distal to central patella.

Balance testing was conducted in the Barry University biomechanics laboratory. The participant was assessed on postural sway measures in a one test session under one-legged and two-legged stance tests on an AMTI (Watertown, MA) force platform under the following conditions: Condition 1: bilateral stance; and Condition 2: residual limb stance using a uniaxial ankle foot prosthesis. Under Condition 1 the subject performed 10 trials separated by 30 seconds of rest. The target goal for Condition 1 was 15 seconds of collection time. Under Condition 2, trials were limited to 5, separated by 30 seconds of rest, and the collection time was reduced to 5 seconds as the participant experienced hip pain during these trials. During the two-legged static balance testing the participant was asked to stand with feet maintained in a parallel position of maximal comfort. During the single-legged testing the participant was asked to stand with the non-involved leg flexed at the knee. All trials were conducted with eyes open, and with the participant instructed to look straight ahead, focusing on an area of the wall at eye level. The participant was instructed to keep her hands by her sides. The same shoes were worn for all trials. Each of these tests was repeated at 12 weeks.

Gait trials were conducted in the Barry University Biomechanics Laboratory. Reflective markers were placed on the lower extremities with strapping tape. Marker placements were as follows: (1) sacrum, (2) bilateral anterior superior iliac spine (ASIS), (3) lateral femoral epicondyle, (4) lateral malleolus, (5) heel, (6) 2nd metatarsal head, (7) mid-tibial wand, and (8) mid-femoral wand (see Appendix E). The participant walked at a self-selected comfortable pace, with the right foot contacting the force platform near the

center.   For both the initial and final data collection, three trials were conducted under

each of the following conditions: (1) gait with FES; (2) gait without FES.   Of the initial

trials, the 2nd under each condition was used for analysis. The 3rd post-test trial under

each condition was used for analysis due to technical difficulty in a 2nd trial. Vicon

Motus software; version 8.2 (Englewood, CO) was used for computations of ground

reaction forces (GRFs) and gait parameters.

Data Analysis

The standard deviations of sagittal and frontal plane COP were calculated from

the GRFs of the medial balance trial of pre- and post-treatment single and double leg

stance trials. ABC scale pre- and post- study scores were also compared. The values

from the pre- and post- treatment limb girth measurements were used to calculate limb

symmetry as follows: LGS= IS/NIS; for limb girth symmetry (LGS) measurements of the

residual, or involved side (IS), were divided by measurements of the non-involved side

(NIS). Perfect girth symmetry was indicated by a score of 100%. Gait parameters of

cadence, velocity, step length, stance time, and hip and knee flexion values with and

without FES were determined via the PEAK system. Gait symmetry was calculated as

follows: SLS = SSL/LSL; for step length symmetry (SLS) the shorter step length (SSL)

was divided by the longer step length (LSL). A score of SLS = 100% indicated perfect

step-length symmetry; STS = IS/NIS; for stance time symmetry (STS) the stance time of

the involved side (IS) was divided by the non-involved side (NIS). A score of 100 %

indicated perfect symmetry; KFS = IS/NIS and HFS = IS/NIS; for knee flexion symmetry

(KFS) and hip flexion symmetry (HFS) the degrees of flexion of the IS were divided by

the NIS. A score of 100% indicated perfect symmetry. Values for trials with and without

FES were compared.

Chapter IV

Results

Introduction

This case study was designed to assess the effects of functional electrical stimulation (FES) on selected measures of balance, gait, and residual limb atrophy in a transtibial amputee. Measurements were obtained initially, and repeated following 12 weeks of FES. Balance was measured in the static state under two conditions; (a) bilateral stance with the participant standing with feet at a self-selected position of comfort, for a trial length of 30 seconds initially, reduced to 15 seconds for the post-test due to patient discomfort, and (b) single leg stance, with the participant standing on the involved leg, wearing the same prosthesis for pre and post testing, for a trial length of 5 seconds. Gait trials were conducted with and without FES and data were collected using a 3-D system to video the participant.   Gait confidence was measured using the Activities-Specific Balance Confidence (ABC) Scale. Affects on residual limb atrophy was assessed by collecting pre- and post-trial stump measurements. Contact between the participant and the investigator was maintained by telephone or person-to-person meetings on a weekly basis. Information from these contacts was recorded in a Study Flow Sheet (Appendix C) with additional comments recorded separately, in interview format (Appendix D). The Study Flow Sheet, in addition to verifying hours of FES use, contained comfort level and foot position awareness descriptors. The participant indicated how she felt on a 0-10 point scale (0=none or not at all and 10=most or completely).

Participant

One female participant was recruited for this study. She was 30 years of age, and had a 2 year history of left traumatic transtibial amputation. The surgical procedure preserved the proximal 2/3 of the anterior tibial muscle belly while removing the tendon with amputation 4 inches distal to the fibular head. She had been active in a rehabilitation program beginning soon after surgery. She had used a prosthesis more than 6 months and did not require assistive devices. FES had never been incorporated into her rehabilitation program. She completed the study, but due to discomfort, selected to limit the daily use of FES to 3 hours following one day of attempting the 6 hours that had been planned. During the study she continued the FES but after week 8 dropped out of the rehabilitation program and joined a gym for the remaining 4 weeks of the study. She did not attend the gym on a regular basis. She had no reported injury with the use of the FES. At completion of the study she revealed she was 6 weeks pregnant and had gained 13 pounds.

Balance

The pre- and post-testing SD for COPx (anterior-posterior) and COPy (medial-lateral) were computed using Vicon software. In comparing both the bilateral and single stance testing results, the post-test SDs were increased in the anterior-posterior (80%, 33% respectively) and medial-lateral (bilateral stance 50%) direction for both stances, with one exception; medial-lateral SD in the single stance trial was smaller (14%) than in the pre-test trial. This indicated that balance sores were worse in the post-testing except in the medial-lateral direction during single stance, which was improved. For consistence

of data, the pre-testing COP SDs were re-calculated using values of only the first 15 seconds of these trials, with no change from results previously calculated for the 30 seconds.   See Table 1 for standard deviations of the balance tests.

Table 1. Balance Standard Deviations

	Bilateral Stance		Single (Amputated) Stance	
	COPx	**COPy**	**COPx**	**COPy**
Pretest	±.005	±.002	±.012	±.007
Posttest	±.009	±.003	±.016	±.006

Note. COPx=anterior-posterior postural sway. COPy=medial-lateral postural sway.
Lower SDs indicate better balance.

Limb Girth Symmetry

Limb girth was measured at selected distances proximal and distal to the knee. To adjust for any weight gain or loss, the measures were calculated as a percentage of the residual limb girth to the non-involved limb girth. Posttest results were not consistent for all measured locations.   After 12 weeks of therapy, the symmetry percentage values at 2" and 3" distal to the mid-patella were increased 1.41% and 1.26% respectively.   See Table 2 for limb girth symmetry values. This reflects an increase in NIS girth at 2" distal to the mid-patella and an increase in IS girth at 3" distal to the mid-patella. See Table 3 for actual limb girth measurements.

Table 2. Limb Girth Symmetry

Time	MTP	Mid-Patella	P-3"	P-6"	P-8"	D-1"	D-2"	D-3"
Pretest	90.55%	90.00%	87.26%	89.36%	93.1%	93.75%	88.19%	81.95%
Posttest	90.4%	91.67%	88.83%	91.10%	92.16%	91.34%	89.6%	83.21%

Note: Location of girth measurements: medial tibial plateau (MTP), proximal to the mid-patella (P), and distal to the mid-patella (D). Higher percentages indicate greater symmetry.

Table 3. Limb Girth Measurements

	Limb	MPT	Mid Patella	P-3"	P-6"	P-8"	D-1"	D-2"	D-3"
Pre Test	**IS**	28.75 ±.25	31.5	34.25 ±.25	42.0	47.25 ±..25	30.0	28.0	27.25 ±.25
	NIS	31.75 ±.25	35.0	39.25 ±.25	47.0	50.75 ±.25	32.0	31.75 ±.25	33.25 ±.25
Post Test	**IS**	28.25 ±.25	33.0	35.75 ±.25	43.0	47.0	29.0	28.0	28.5
	NIS	31.75 ±.25	36.0	40.5	47.25 ±.25	51.0	31.75 ±.25	31.25 ±.25	34.25 ±.25
Δ	**IS**	1.74%	4.76%	4.38%	2.38%	.53%	3.33%	0	4.59%
	NIS	1.57%	2.86%	3.18%	.53%	.50%	.78%	1.57%	3.01%

Note: Location of girth measurements: medial tibial plateau (MTP), proximal to the mid-patella (P), and distal to the mid-patella (D), involved side (IS), non-involved side (NIS), change (**Δ**). Measurements are in centimeters.

Gait Symmetry

Gait parameters were computed by Vicon software. Cadence and velocity values were taken directly from the resulting gait analysis. For symmetry of the lower extremities, values for stride length, stance time, and hip and knee flexion were computed

from gait analysis values as a percentage of the involved or amputated limb to the non-involved limb. The initial gait data was inconsistent. Compared to the non-FES trial the trial with FES showed increased cadence (1.03%) and velocity (3.50%). Stance time symmetry (SLS) and step length symmetry (STS) were increased (5.34% and 11.47% respectively) while hip flexion symmetry (HFS) and knee flexion symmetry (KFS) decreased (8.98% and 2.28% respectively).

When gait trials were repeated after 12 weeks of therapy, values under FES conditions again showed increased value for SLS (6.59%) but decreased STS (4.74%), cadence (2.0%), and velocity (3.33%) values. In this trial, HFS and KFS were also increased (12.66% and 1.93% respectively). See Table 4 for gait analysis values.

Table 4. Gait Analysis Values

Initial Test	Cadence (steps/min)	Velocity (m/s)	SLS (SSL/LSL)	STS (IS/NIS)	KFS (IS/NIS)	HFS (IS/NIS)
With FES	111.340	1.273	4.86%	10.70%	8.56%	11.73%
Without FES	110.204	1.230	10.20%	22.17%	1.53%	2.78%
Post Test						
With FES	108.000	1.044	24.30%	4.74%	39.31%	39.38%
Without FES	110.204	1.080	30.89%	0%	41.24%	52.04%

Note: Step length symmetry (SLS)=shortest step length (SSL)/longest step length (LSL). Stance time symmetry (STS)=involved side (IS)/non-involved side (NIS), and knee flexion symmetry (KFS). Symmetry results are reported as the percentage of deviation from Perfect Symmetry. Lower percentages indicate greater symmetry.

With the exceptions of SLS, final gait characteristics were very dissimilar from initial gait characteristics. Final IS step length and stance time, without FES, were decreased 2.61% and 4.5% respectively. Maximal hip flexion decreased in both IS (1.50%) and NIS (3.34%). Maximal knee flexion in the IS increased 31.46% and in the NIS decreased 8.35%.   For actual gait cycle characteristic see Table 5.

Table 5. Gait Cycle Characteristics

Characteristic	Pre-test With FES		Pre-test Without FES		Post-test With FES		Post-test Without FES	
Cadence (steps/min)	111.340		110.204		108.000		110.204	
Gait Velocity (m/s)	1.273		1.230		1.044		1.080	
Extremity	IS	NIS	IS	NIS	IS	NIS	IS	NIS
Step Length (s)	0.666	0.700	0.651	0.725	0.496	0.655	0.481	0.696
Stance Time (s)	0.683	0.617	0.733	0.600	0.683	0.717	0.700	0.700
Maximal Hip Flexion (degrees)	38.126	43.193	39.944	38.864	40.740	29.230	39.344	25.877
Maximal Knee Flexion (degrees)	58.998	64.520	58.888	59.803	74.828	53.714	77.412	54.807

Note: Involved side (IS), and non-involved side (NIS).

Activity Confidence Level

To assess the participant's perceived level of confidence in her ability to perform activities without losing balance or becoming unsteady, she completed the ABC Scale questionnaire pre- and post-treatment. For 7 of the 16 activities there were increased values. These activities were: (1) up and down stairs, (2) sweep the floor, (3) walk

outside to nearby car, (4) get in/out of car, (5) walk across parking lot, (6) up and down

ramp, and (7) escalator holding rail. See Table 6 for complete ABC results.

Table 6. Activities-Specific Balance Confidence Scale Results

Activity	Level of Confidence	
	Pre-trials	Post-trials
Walk around the house	85%	85%
Up and down stairs	50%	70%
Pick up slipper from the floor	85%	85%
Reach at eye level	95%	95%
Reach on tiptoes	50%	50%
Stand on chair to reach	20%	20%
Sweep the floor	85%	95%
Walk outside to nearby car	85%	90%
Get in/out of car	80%	90%
Walk across parking lot	80%	85%
Up and down ramp	70%	75%
Walk in crowded mall	70%	70%
Walk in crowd/bumped	50%	50%
Escalator holding rail	60%	80%
Escalator not holding rail	50%	50%
Walk on icy sidewalks	10%	10%

Note: Confidence rated on a scale of 0% (no confidence) to 100% (complete confidence)
that activity will be performed without participant losing balance or becoming unsteady.

Proprioception and Comfort Levels

For assessment in user comfort and the effectiveness of FES to provide proprioception to the amputated limb, the participant rated these weekly using a 0-10 scale, with 0=none, or least, and 10=most, or always. For comfort, she maintained a level of 6. Her perception of awareness of prosthetic limb position increased from 5 to 8, as is shown in the Weekly Flow Sheet (Appendix C). The participant described her discomfort from the ODFS device as: (1) pain and pressure from the electrode wires, (2) inconvenience of wires from the heel sensor to the stimulator at her waist, and (3) annoyance with shocks to her leg when she shifted side-to-side, or attempted to cross her legs (see Appendix D).

Chapter V

Discussion

The incidence of lower extremity amputations in the United States is significant (Feinglass et al., 1999). In this population, falls and fear of falling has been found to be pervasive, and that the fear of falling may influence balance confidence and mobility (Miller, Speechley & Deathe, 2001). This is though to be due in part to loss of proprioceptive feedback. This limits perception of limb orientation with respect to the supporting surface, and may impair balance and gait. Loss of stimulation of the residual ankle extensor and flexor muscles results in loss of muscle function, and atrophy of the stump muscles is inevitable. This affects the shape of the stump and limits the soft-tissue weight bearing surface. This may increase the risk of skin breakdown due to increased pressure over less pressure-bearing structures.

FES has been incorporated into rehabilitation programs for CVA and SCI victims for more than 40 years, improving gait (Liberson et al. 1961), and muscle mass and function (Bourjeily-Habr et al., 2002; Johnston et al., 2005). Liberson et al. found that stimulating the common peroneal nerve (CP) during swing phase of gait produces ankle dorsiflexion in the affected limb of CVA victims. Studies to evaluate the effects of electrical stimulation on amputees are limited. No studies have examined the effects of FES on amputee gait or residual muscle atrophy. Thus, the purpose of this study was to evaluate the effects of FES on gait, balance, and residual limb atrophy in a single transtibial amputee. The specific aims of this study were to:

1. Investigate changes in gait as a result of FES.

2. Investigate changes in static balance as a result of 12 weeks of FES.

3. Investigate changes in stump girth as a result of 12 weeks of FES.

4. Investigate changes in activity-specific confidence levels as a result of 12 weeks of FES.

Gait data was collected using a four-camera (JVC, Wayne, NJ) video system and one force platform (AMTI, Watertown, MA). Vicon Motus software version 8.0 (Englewood, CO) was used for computation of GRF and 3D gait analysis. For these trials the participant walked at a self-selected pace, with the right foot contacting the force platform, under two conditions; (1) with and (2) without electrical stimulation to the residual anterior tibial muscle. Under the first condition, electrical stimulation was initiated by a heel sensor, with stimulation from heel lift to heel contact, using the ODFS Dropped Foot Stimulator system (Salisbury, Wiltshire, UK). Greater gait symmetry may be indicative of improved sensation of residual limb position.

Balance was measured pre- and post-treatment under both bilateral and residual limb stance conditions. For the single stance trials, the participant stood with the non-involved limb flexed at the knee, for 5 seconds. The participant stood for 30 seconds for the pre-treatment bilateral stance, but the post-treatment trial was limited to 15 seconds due to patient discomfort and difficulty in stance. The standard deviations (SD) of center of pressure (COP) in the x and y directions were used for analysis. A decrease in the SD of the COP would indicate increased balance. For consistence of data, the pre-testing COP SDs were re-calculated using values of only the first 15 seconds of these trials, with no change from results previously calculated for the 30 seconds. Balance was measured using an AMTI force platform (Watertown, MA) and analyzed with Vicon (version 8.0).

Bilateral limb girths were measured pre- and post-treatment by the same therapist, using the same commercial tape measure, at mid-morning. Measurements were repeated at each pre-selected site until within .5 cm. Each set of measurements was averaged. An increase in limb girth symmetry would indicate reduced or reversed residual muscle atrophy.

Confidence in ability to perform selected activities was measured by pre- and post-treatment completion of the ABC scale.

To attain the purpose and aims of this study, it was hypothesized that:

1. Cadence, velocity and gait symmetry would be increased immediately with the use of FES.

2. Static balance would show reduced sway after 12 weeks of FES.

3. There would be increased stump girth after 12 weeks of FES.

4. Activity-Specific Balance Confidence Questionnaire scores would be improved after 12 weeks of FES.

Summary of Results

Pre- and post-treatment measurements were taken for gait, balance, stump girth and confidence levels. For gait evaluation, increased cadence, velocity and gait symmetry may indicate improved perception of residual limb position and improved gait. Decreases in SDs of COP x and COPy would indicate reduced postural sway and increased balance ability. Greater symmetry of limb girths would indicate reduction or reversal of stump atrophy. Higher scores on the ABC scale may indicate greater balance and increased awareness of residual limb position.

The first hypothesis that cadence, velocity, and gait symmetry would increase immediately with the application of FES was not observed in all selected measures.

The second hypothesis that static balance would show reduced sway after 12 weeks of FES was not observed.

The third hypothesis that there would be increased stump girth after 12 weeks of FES was observed.

The fourth hypothesis that there would be improved ABC scores after 12 weeks of FES was observed.

Balance and Gait

Standing and walking are both influenced by balance. In quiet standing, mechanisms function to maintain the body's COM over the BOS. This is thought to be controlled by a feedback system. When the COM shifts toward the margins of the BOS, the bones of the feet move and reflexive muscular contractions of the lower extremities and the trunk shift the COM back over the BOS. The muscles then relax and the process is repeated, resulting in oscillating movement about a vertical axis. This is visualized as postural sway and can be measured as the means and standard deviations of the shifting GRFs in the anterior-posterior and medial-lateral directions. It is thought that anterior-posterior control is by the ankle flexion and extension muscles, and that medial-lateral control is by the hip muscles (Winter et al., 1998). With amputation there is loss of proprioception and reflexive muscle function. Persons with impairment of proprioception have been found to have larger and more variable postural sway than control groups (Horak et al., 2002). FES can be used to stimulate muscle contractions,

and when timed to stimulate the anterior tibial muscle during swing phase of gait, may

promote the amputee's awareness of limb position. The current study does not support

the hypothesis that using FES over a 12 week period improves static balance in a

transtibial amputee. In this study, post-treatment SDs were greater than pre-treatment,

indicating greater sway. This might have been due to the increased weight associated

with pregnancy; however a study by Butler, Colon, Druzin, and Rose (2006) does not

support the participant's first trimester pregnancy as a contributing factor to increased

postural sway.   Their data suggested that postural stability declined during the second

and third trimesters of pregnancy and remained diminished 6-8 weeks after delivery, but

was relatively stable during the first trimester, when trials were conducted with eyes

open. They found no significant association between the amount of weight gained or lost

and postural sway measures. However, there was no mention of amputee participants in

the Butler, et al. study. The discontinuation of physical therapy which included balance

and proprioception training using a balance board, 4 weeks prior to the post-treatment

trials, may have been a factor in larger SDs.

The participant experienced hip and stump pain during the single-leg stance.

Though not activated during static stance, the stimulator, including the surface electrodes

were in place during the trials. Discomfort in the stump due to wire placement during

single leg stance may have increased due to weight gain, and this may have influenced

the outcome. Additionally, when discussing the results with the participant, she felt she

may have been distracted as she had been preoccupied with personal matters during the

post-test session. These findings do suggest that the effect of FES used during the gait

cycle does not carry over into static balance.

In walking the COM shifts anterior to the BOS, and a step is taken. The COM oscillates over a shifting BOS with each step. Somatosensory input derived primarily from the forces and motions exerted by the feet on the support surface are required for maintaining postural control and a stable gait. In the lower extremity amputee the sensory and motor deficits are demonstrated by asymmetric gait (Robinson et al., 1977) and lateral shifting difficulties. These changes result in slower cadence and decreased forward velocity (Tibarewala & Ganguli, 1982). In this study FES was applied during swing phase of gait to increase the participant's sense of position of the residual limb in relation to the supporting surface. The initial trial showed increased cadence and velocity when FES was applied, which was the expected outcome in agreement with Tibarewala and Ganguli's findings. SLS and STS were also increased due to an increase in step length and decrease in stance time of the residual limb which were factors in the increased velocity and cadence. It is difficult to relate this to Robinson's findings of longer step length on the involved side (IS) in amputee gait. The initial gait of this participant demonstrated shorter step length and longer stance time on the IS, both of which were reversed with application of FES. Increased HKS and KFS did not occur. Initial maximal hip flexion was greater on the IS, and may have reflected loss of proprioception, with the participant flexing the hip more to assure the foot's clearing the supporting surface, as is seen in stroke victims. With the application of FES there may have been over-compensation that would account for change in symmetry from 2.78% from perfect symmetry (0%) in the positive direction, indicating greater flexion in the IS, to 11.73% in the negative direction, indicating less IS flexion and, in this case, also an increase in NIS flexion.

FES post-test trials supported the expected findings of increased HFS, KFS, and SLS, but cadence, velocity and STS were less than in the initial trials. In these trials there was greater hip and knee flexion bilaterally than in the initial trials and IS flexion was much greater than NIS. This occurred with less velocity (shorter steps) and unchanged cadence compared to the initial trials. Stance time on the IS was reduced from initial trials and had reached perfect symmetry without FES. This may indicate that with 12 weeks treatment time, FES has carry-over effect. The participant's perception of prosthetic foot position increased after 10 weeks of treatment, which coincides more closely with the increased joint flexion symmetry and shorter step length than to initial testing (Appendix C). Additionally, the participant's continued stump discomfort due to electrode wires may have resulted in less time spent on the IS. Discontinuation of the rehabilitation modalities to improve balance and side-to-side weight shifting (ski machine, balance board) may have contributed to increased hip and knee flexion. Again, the participant's state of mind (her distraction and preoccupation with other matters during the trials) may have contributed to the final testing results. These findings do support the theory that providing somatosensory input may improve gait symmetry, and that continued use may increase FES effectiveness.

Limb Girth Symmetry

With transtibial amputation there is loss of somatosensory input normally derived from the forces and motions exerted by the foot on the supporting surface. There is loss of the stretch reflexes as well. This results in residual muscle atrophy of disuse. There is loss of soft tissue, the stump shrinks, and there is less pressure-accepting tissue over

which to distribute weight bearing pressure. This increases risk for tissue breakdown and stump discomfort. In animal studies Duan et al. (1999) found that intermittent electrical stimulation of muscles 12 hours daily for 12 weeks, increased muscle strength. Incorporation of FES into the rehabilitation programs of SCI victims has been shown to promote improved muscle strength and function. Scremin et al. (1999) found greater than 20% increase in CSA in most treated muscles after average treatment duration of 52.8 weeks (30 minutes for 2.32± .26 days per week). Johnston, Smith and Betz (2005) reported 9.8% increase in thigh mean circumferential measures following 10 months of electrical stimulation of the femoral nerve (12.3±1.1 cm to 13.5±1.5cm), $p<.001$. They reported an increase in the quadriceps femoris isometric torque across all angles from 7.0±1.6 Nm at baseline to 14.8±3.2 Nm at 10 months ($p<.001$). After 2 months of no stimulation they observed a decrease in both thigh circumference (13.1±1.3cm) and quadriceps femoris torque (8.5±1.1 Nm), $p<.001$. In this study, at 3" inches distal to the mid-patella there was increased stump girth of 1.25 cm. with increased limb girth symmetry of 1.26%. While this increase is small it shows a trend toward increased stump girth. This does agree with results reported by Johnston et al., of 9.8% increase in thigh girth following 10 months (1 hour/day, 6 days/week) of treatment.

The increase in girth of the thighs, 3" proximal to the mid-patella, is similar to the increases at 3" distal to the mid-patella. The IS increased by 1.5 cm, and the NIS increased by 1.25 cm. There was less increase at 6" with the increase greater on the IS. The increase at 8" proximal to the mid-patella was .25 cm. for both limbs. These increases may be related to increased knee flexion.

Activity Confidence Level

Lower extremity amputees have an increased risk of falling. Miller, Speechley and Deathe (2001) found that 52% of their participants reported falling in the past year, and 49% reported a fear of falling. Fear of falling may influence balance confidence and mobility (Miller, Deathe, Speechley, & Koval, 2001). A contributing factor of increased risk of falls and fear of falling may be the loss of proprioceptive information. Horak, Dickstein and Peterka (2002), found that persons with impairment of propriocepsis due to diabetic peripheral neuropathy had larger and more variable postural sway than the control group. Hurley (1997) study suggests that following joint damage, muscle weakness may be related to proprioceptive deficits. In this study, following 12 weeks of FES as the instrument to enhance proprioceptive function, the participant indicated increased confidence in her ability to perform 7 of the 16 selected activities included in the ABC scale. The increased values ranged from 5% increased confidence in walking up and down a ramp to 20% in walking up and down stairs and using an escalator while holding the rail. In no activity did she feel less confident. She did express her difficulty in rating any activity on any numerical scale (0-10 or 0%-100%). These findings suggest that FES improves confidence, but it cannot be completely excluded that she responded with values she believed the investigator expected to hear. While her 13 pounds weight gain of pregnancy may have changed her COM, it did not decrease her level of confidence. This study does support the hypothesis that ABC scores will be improved with 12 weeks of FES, but it cannot be concluded that the improved scores were due to FES only.

Proprioception and Comfort Levels

By applying electrical stimulation to the anterior tibial muscle during swing phase of gait, the amputee was provided with somatosensory feedback, promoting an increased sense of limb position. She rated her perceived sense of limb position on a scale of 0-10, and did have an increase from 5 to 8. These results are supportive of the increased confidence scores. The participant had been using a prosthesis and receiving physical therapy for more than 18 months prior to this study. The improved confidence and proprioceptive levels over the 3 months of the study suggest they are the results of the FES. There may be a training effect component in these results, as the participant became more accustomed to using the electrical stimulation device, but this cannot explain initial gait changes. Therefore, training effect may not be a major component in the final data.

The ODFS dropped foot stimulator was designed to be used in CVA victims, promoting ankle dorsiflexion and allowing the foot to clear the ground in swing phase of gait. In this situation, the wires from the stimulator to the surface electrodes would be worn under comfortable clothing only. Additionally, the electrodes and wires would be over an intact lower extremity. In contrast, when the electrodes are on a residual limb which has lost soft tissue, and also under a socket liner and inside the vacuum socket, there is greater pressure, less soft tissue to absorb these forces, and compliance may be directly related to comfort. In this study the participant rated her comfort level at 6 on a 0-10 scale and reduced the daily use to 3 hours instead of the proposed 6. This was not continuous use as she could not use it when driving. She does plan to continue to use the

ODFS, but less than the 3 hours used during this study. Her perceived primary advantage in using the ODFS was that it made her more aware of leg position (see Appendix D).

The participant described her discomfort from the ODFS device as: (1) pain and pressure from the electrode wires, (2) inconvenience with wires from the heel sensor to the stimulator at her waist, and (3) annoyance with shocks to her leg when she shifted side-to-side, or attempted to cross her legs. For greater compliance, these factors will need to be addressed.

Conclusions

The incidence of lower extremity amputations in the United States is significant. In this population, falling and the fear of falling may further limit mobility and independence. Atrophy of the residual limb muscles, due to disuse, reduces pressure bearing soft tissue. This results in less surface area for the distribution of weight bearing forces and may increase discomfort and the risk for skin breakdown.

Application of FES may improve amputee gait and reduce the fear of falling by providing somatosensory feedback, giving the amputee a greater sense of limb position. Additionally, by stimulating the residual muscles, stump atrophy may be reduced or reversed. In this study an increase in stump girth was observed, as were aspects of gait symmetry and increased confidence level in ability to perform selected activities of daily living. While it cannot be concluded from this study that these changes were due only to FES, there is an observed trend toward improved gait, confidence, and reversal of stump atrophy. Though small, these changes warrant further study in the application of FES in amputee gait.

Further studies could impact the prosthesis industry, as incorporation of electrical stimulation devices into the prosthesis may promote greater comfort and amputee compliance as discussed in the prosthetist interview (Appendix F).

Recommendations

No studies have examined the effects of FES on lower extremity amputee gait, balance, stump atrophy, or confidence levels. This case study demonstrates a trend toward improvement of these factors, excepting balance, which demonstrated a decrease. The participant's weight gain of pregnancy may have affected the results in all areas. In this study, comfort level was a major factor in FES use. Future studies investigating FES should include:

1. Longer treatment time. This study was of 12 weeks duration, and this may not be adequate to demonstrate residual limb responses.

2. Larger sample size. This was a case study. A larger trial may provide statistically significant results.

3. Both male and female participants.

4. Incorporate a tilt sensor for FES. This study incorporated a heel sensor which limited the ability to comfortably shift weight side-to-side.

5. Reposition electrode wires through the socket liner to promote comfort, and use a pin socket. This study used a vacuum socket that may have increased pressure to the electrodes and wiring, contributing to the discomfort.

6. Incorporate MRI or CT to assess muscle mass changes.

7. Interval data collection to determine when changes are occurring.

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8. Include a measurement of proprioception.

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Appendix A

Activities-Specific Balance Confidence (ABC) Scale

Activities-Specific Balance Confidence Scale

Activity	Level of Confidence
Walk around the house	
Up and down stairs	
Pick up slipper from floor	
Reach at eye level	
Reach on tiptoes	
Stand on chair to reach	
Sweep the floor	
Walk outside to nearby car	
Get in/out of car	
Walk across parking lot	
Up and down ramp	
Walk in crowded mall	
Walk in crowd/bumped	
Escalator holding rail	
Escalator not holding rail	
Walk on icy sidewalks	

How confident are you that you will not lose your balance or become unsteady when performing the above activities? Rate your confidence on a scale of 0% (no confidence) to 100% (complete confidence).

Appendix B

Informed Consent

Barry University
Informed Consent Form

     Your participation in a research project is requested. The title of the study is The Effects of Functional Electrical Stimulation (FES) on Balance, Gait, and Residual Limb Atrophy in a Traumatic Transtibial Amputee. The research is being conducted by Jeanette Johnson, a student in the Sports and Exercise Sciences department at Barry University, and is seeking information that will be useful in the field of biomechanics. The aims of the research are to investigate the effects of electrical stimulation of a residual limb muscle on: (1) walking gait and, (2) residual limb atrophy. In accordance with these aims, the following procedures will be used: (1) walking across a platform while being videotaped, with and then without electrical stimulation, and (2) standing on a flat metal surface (a forceplate) while movements are recorded. Standing will be on both feet for 30 seconds, and then on the prosthetic limb for 5 seconds. We anticipate the number of participants to be 1.

     If you decide to participate in this research, you will be asked to do the following: (1) allow measurements of the lower extremity to be taken and recorded, (2) walk across a platform 3 times while being videotaped, first with, and then without electrical stimulation, and (3) stand on both feet on a flat metal surface (a forceplate) for 10 trials of 30 seconds, and then on your prosthetic limb for 10 trials of 5 seconds, while movements are recorded. The preparation and conduction of this will require approximately 2 hours. Your will also be asked to: (4) wear the electrical stimulation device at least 6 hours daily for 12 weeks, and (5) maintain a daily log of the hours. At 12 weeks all testing will be repeated, requiring another 2 hours.

     Instrumentation: ODFS is a functional electrical stimulation and has been used successfully in victims of incomplete spinal injuries and cerebral vascular accidents (strokes). The device is used in persons with partial paralysis of the ankle dorsiflexory muscles (anterior lower leg) to stimulate the anterior tibial muscle during swing phase of gait (pulling the foot up). This produces dorsiflexion of the foot, allowing the foot to clear the supporting surface, which is the natural function of the muscles. By stimulating the anterior tibial muscle during swing phase of gait, the ODFS provides sensory feedback informing the subject of the position of her foot in relation to the supporting surface.

     Your consent to be a research participant is strictly voluntary and should you decline to participate or should you choose to drop out at any time during the study, there will be no adverse effects on your health and rehabilitation care. The risks of involvement in this study are minimal and include losing balance while standing on the prosthesis for 5 seconds. The following procedure will be used to minimize this risk: a chair or walker will be placed at your side. If you prefer a personal assistant, this will be provided. A second risk could be the receiving of a mild shock that could be temporarily uncomfortable. To minimize this risk you will have time to become familiar with the device, and will be able to adjust the controls.   The benefits to you for participating in this study may include an improvement in your walking and balance abilities and confidence. An alternative treatment would be to decline to participate in the study.

     As a research participant, information you provide will be held in confidence to the

extent permitted by law. Any published results of the research will refer to study averages only and no names will be used in the study. Data will be kept in a locked file in the Biomechanics Laboratory. Videotapes will be kept in the Barry University biomechanics laboratory. Your signed consent form will be kept separate from the data. All data will be destroyed after 5 years.

If you have any questions or concerns regarding the study or your participation in the study, you may contact me, Jeanette Johnson, at (954) 254. 0624, my faculty advisor, Dr. K. Ludwig at (305) 899.4077, or the Institutional Review Board point of contact, Mrs. Nildy Polanco, at (305)899-3020. If you are satisfied with the information provided and are willing to participate in this research, please signify your consent by signing this consent form.

Voluntary Consent

I acknowledge that I have been informed of the nature and purposes of this experiment by Jeanette Johnson and that I have read and understand the information presented above, and that I have received a copy of this form for my records. I give my voluntary consent to participate in this experiment.

_____   _____

Signature of Participant   *Date*

_____   _____   _____
  _____

Researcher   *Date*   *Witness*   *Date*

Appendix C

Weekly Flow Sheet

Weekly Flow Sheet

Week	1	2	3	4	5	6	7	8	9	10	11	12
How many hours daily are you wearing the device?	3	3	3	3	3	3	3	3	3	3	3	3
Rate the comfort level when wearing the device, 1-10.	5	6	6	6	6	6	6	6	6	6	6	6
Rate your perception of prosthetic foot position, 1-10.	5	6	6	6	6	6	6	6	6	6	8	8
Rate your sense of loss (how much you miss the stimulation) when not using it	1	1	1	1	1	1	1	1	1	1	1	1
Additional comments are on a separate page, yes/no.	no	yes	yes	yes	no	no	yes	yes	yes	yes	no	yes

When using the scale to answer, 1= least, or none and 10 = most, or complete.

Appendix D

Participant Interview

Participant Interview

Week 2

Investigator: You have been using the ODFS about 1 ½ weeks. What differences, if any, do you see in how you are changing your sock liners?

Participant: I don't use sock liners with this new prosthesis. The vacuum in the socket makes it fit. The one I use when I wear the ODFS is manual vacuum, and I really can't determine any difference.

Investigator: What other differences have you noticed, or felt, when using the ODFS?

Participant: When I feel the shock I usually feel like I need to contract my muscle. The electrode wires bother me. They don't usually hurt, but are uncomfortable.

Week 3

Investigator: What, if any, differences have you noticed when walking with the ODFS as opposed to the times you are not wearing it?

Participant: I guess I feel more confident in knowing where the foot is, but I can only wear it 3 hours a day, as the wires are uncomfortable, especially when sitting.

Week 4

Investigator: You continue to wear the stimulator 3 hours daily. What could be done differently to promote comfort so you could wear the device for longer periods?

Participant: I don't like the addition of wires to my leg and all the other things I have to do. If there were no wires from the leg up to the waist this would help. It's inconvenient and requires more time just for things like going to the restroom. Maybe if the stimulator were part of the leg that would be better.

Week 7

Investigator: What changes, if any, have occurred this week?

Participant: Everything is pretty much the same. We are out of town, but I am still wearing the stimulator. The problem is still that the wires are inconvenient.

Week 8

Investigator: What part of the day do you wear the ODFS? What activities are you usually doing at that time? Have you tried wearing it while walking in the mall?

Participant: I usually wear it in the mornings, in the house. I turn it off when driving, until I get to the supermarket, or wherever I'm going. No, I have not tried walking in the mall with this. And there have been no real changes in comfort. The wires to the electrodes rub against the skin, and this can be uncomfortable. The inconveniences include not being able to lift the heel during usual activities. I can't sit and cross my legs, because I get a shock. I can't shift my weight from side-to-side when holding or rocking my son without a shock. I feel I can't completely relax, even when sitting for a meal. All this is annoying. The big plus is in knowing when my leg is lifted. This gives me greater confidence in using the prosthesis.

Week 9

Investigator: What changes, if any, have you had in the amount of vacuum you apply during the day, at any specific times, to maintain a good fit?

Participant: I still can't judge that in any way. I don't know if there have been any changes.

Week 10

Investigator: When you are not wearing the stimulator, how does this affect your walking, or what effects does turning off the stimulator have on you?

Participant: Sometimes I can still feel the shocks to the leg when I pick up my foot, but it doesn't last long, maybe 30-45 minutes, but less than an hour. I can't think of anything else to say about it.

Week 12

Investigator: Do you plan to continue to wear the ODFS now that this trial is finished? Have you talked to your doctor about using this while you are pregnant? It is usually recommended not to use it, as it could cause early labor. It would be best not to use it any more until after you talk to your doctor.

Participant: I will talk to my doctor, and I won't use it any more until then. Yes, I do plan to use the ODFS, but probably not as long as I have been wearing it.

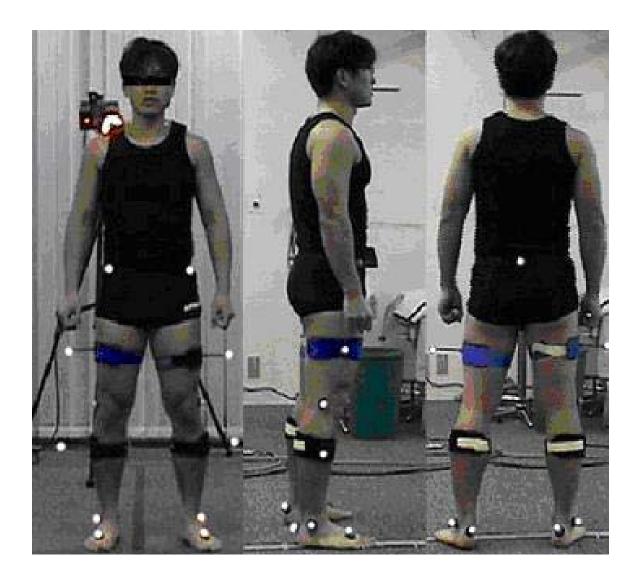**Investigator**: Do you have any recommendations for improving the use of ODFS for other amputees? Do you feel this would be beneficial to other amputees?

Participant: Yes, I think this would help others in walking. The only thing I recommend is like (the prosthetist) mentioned. The wires could go through the stump liner.

Appendix E

Gait Marker Placement

Gait Marker Placement

Appendix F

Prosthetist Interview

Prosthetist Interview

Investigator: The participant has stated that the wires running from the electrodes are uncomfortable, and at times painful, especially when she stands for a long time, or has increased weight on the stump, as in the single leg balance trials. What do you think could reduce that discomfort in future trials?

Prosthetist: The wires could be run through an opening in the stump liner, placing them away from direct contact with the skin, but the liners are too expensive for her to do this. That is something that could be considered in future liner designs. Another possibility would be to use this system in sockets incorporating pins instead of vacuum. With a vacuum socket there is the negative pressure pulling the stump into the socket, and this maintains a pressure against the skin, which could increase the discomfort over the electrodes and wires.

Investigator: Another problem has been that the stimulator is activated whenever the participant lifts her foot, making it impossible for her to cross her legs when sitting, or shift her weight from side to side. How do you think this could be corrected?

Prosthetist: Using a tilt sensor instead of a heel sensor would correct some of this. The tilt sensor can be programmed for activation related to the position of the lower leg. Shifting weight from side to side should not cause stimulator activation. Sitting would not be a problem even though there may be loss of contact of the heel with the floor. Crossing of the legs would change the angle of the lower leg. This may require more research into device programming. A problem with using the tilt sensor is that it is like wearing a box on the leg. Some people may not want this. A solution would be to have

the sensor modified so it could be laminated into the prosthesis. This would not be difficult to do.

Investigator: Are the electrical stimulators covered by insurances for this use?

Prosthetist: Not at this time. This is an out-of-pocket expense. Nobody has worked with this use for FES enough for it to be part of the accepted treatment for amputees. All the studies have been in spinal cord injuries and stroke victims. When enough studies have been done to show that this really improves the life of the amputees, then there may be a change in insurance coverage.

Appendix G

Article

The Effects of Functional Electrical Stimulation on Balance, Gait, and Residual Limb Atrophy in a Traumatic Transtibial Amputee; a Case Study

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Abstract

The purpose of this study was to measure the effects of 12 weeks (3 hours daily) of functional electrical stimulation (FES) on confidence, gait, balance, and residual limb girth of a female traumatic transtibial amputee, age 30. Pre-and post-testing included an Activity-Specific Confidence (ABC) scale, limb girth measurements, one- and two-leg balance trials, and gait trials with and without FES. SD of the center of COP in the x and y directions, cadence, velocity, and symmetry of step length (SLS), stance time (STS) and knee (KFS) and hip (HFS) flexion were collected using a single forceplate and 3D video gait analysis system. Limb girth symmetry (LGS) at the most distal stump increased 1.26%. Gait pre-and post-testing with FES values (respectively) showed improvement in SLS (5.34%, 6.59%) and inconsistency in other parameters, with some values improving (+) and other worsening(-) when compared to 100% as perfect symmetry of IS/NIS. These values were: cadence (+1.03%, -2.0%), velocity (+3.5%, -3.33%), STS (+11.47%, -4.74%), KFS (2.28%, 1.93%), and HFS (-8.98, +12.66). COP SDx, all stances, and SDy, single stance, were increased, indicating lower balance scores. Confidence scores increased in 7 of 16 activities. We suggest that FES sessions 3 hours/day for 12 weeks is not adequate to significantly influence stump atrophy or confidence, but there is a trend toward improvement in all variables excepting balance. Future studies should include a larger subject pool over a longer time period.

Introduction

In the United States, one out of every 200 persons is estimated to have had an amputation (National Limb Loss Information Center [NLLIC] staff, 2006). Feinglass, et al. (1999) reported the lower extremity amputation rate in the United States, for the years 1995-1996, to be 24.93 per 100,000 persons. Ephraim, Dillingham, Sector, Pezzin, and MacKenzie (2003), in a review of the literature, found the incidence rate of acquired amputation rates varied among and within nations. The values ranged from 1.2 first major amputations per 10,000 women in Japan to 4.4 per 10,000 men in the Navajo Nation in the United States. Pezzin, Dillingham, and MacKenzie (2000) determined that about 80% of all trauma-related amputations occurred before age 40. Transtibial amputations were found to be more common than those at any other level.

Ability to ambulate following transtibial amputation is impaired. Pauley, Devlin, and Heslin (2006) conclude that one in five lower extremity amputee patients will fall at least once during inpatient rehabilitation. In a study of amputees who had used prostheses for at least 6 months, falls and the fear of falling were found to be pervasive (Miller, Speechley & Deathe, 2001). Of their participants, 52% reported falling in the past year, and 49% reported a fear of falling. Fear of falling may influence balance confidence and mobility (Miller, Deathe, Speechley and Koval, 2001). Proprioceptive input derives primarily from the forces and motions exerted by the feet on the support surface. In the transtibial amputee this perceptional loss will impair balance and gait. Additionally, disuse of the residual muscles results in stump shrinkage. This may increase the risk of skin breakdown due to increased pressure over less pressure-accepting structures.

Electrical stimulation is frequently incorporated into rehabilitation programs to help regain muscle strength and function. In animal studies, results suggest that intermittent stimulation (12 hours per day for 12 weeks) increases muscle strength and fatigue resistance (Duan, Trumble, Scalise, & Magovern, 1999). Sabolich and Ortega (1994) reported an 11% increase in weight distribution symmetry during gait with the use of transcutaneous electrical neural stimulation (TENS) in their transtibial amputee subjects. Functional electrical stimulation (FES) is used in victims of cerebral vascular accidents (CVA) during the swing phase of gait to produce ankle dorsiflexion in the affected limb (Liberson, Holmquest, Scott & Dow, 1961). There are many studies documenting the effects of electrical stimulation to improve function in spinal cord injuries (SCI) and CVAs (Simcox, et al., 2004; Yan, Hui-Chan, & Li, 2005). Studies to evaluate the effects of electrical stimulation on amputees are limited. Research involving amputees and FES was not found. Although it is known that loss of proprioception affects gait, no studies were found that evaluate the effectiveness of FES in providing the lost sensory input as to limb orientation in relation to the supporting surface.

Methods

Participant

The participant was a 30-year-old female with a 2 year history of traumatic left transtibial amputation. She started a rehabilitation program and was fitted with a prosthesis soon after surgery. She continued with a physical therapy program of 1 – 1 ½ hour sessions 3 days weekly throughout 8 weeks of the study. These sessions included muscle strengthening by use of stretch bands and therapy applied forces, squats, bicycling, stretching exercises, balance board training, step climbing, treadmill, weight

shifting control on a ski machine, and jogging short distances on predominately even terrain. She then decided to join a gym and use a personal trainer. She did not attend the gym on a regular basis.

Instrumentation

A single-channel neuromuscular stimulator (ODFS Dropped Foot Stimulator, Salisbury, Wiltshire, UK) which utilizes a foot switch, was programmed to produce anterior tibialis muscle stimulation during the swing phase of gait. The foot switch triggered continuous stimulation from heel lift to heel contact. The foot switch, or heel sensor, was connected by a single wire to the stimulator, which was worn at the waist. The stimulator was connected by wires to the two reusable 5 cm x 5 cm electrodes (Pals Electrodes, Knaresborugh, North Yorkshire, UK) provided as components of the ODFS system. The electrical stimulator parameters were as follows: alternating current; symmetrical biphasic output waveforms; pulse duration 300 μsec; pulse frequency 40 Hz; and current amplitude approximately 65 mA, adjusted by the participant for maximal stimulation at a level comfortable to her. The ODFS system has been found to be reliable in stimulating the peroneal nerve during swing phase of gait (Burridge, Taylor, Hagan, & Swain, 1997; Taylor, et al. 1999).

Prior to attaching the electrodes, the skin was cleansed with alcohol pads and allowed to dry completely. The electrodes were positioned as follows: (1) one just proximal and posterior to the fibula head; (2) one just distal and anterior to the fibula head; (3) a 2mm distance separated the electrodes. Correct position was confirmed when the participant felt the sensation of foot dorsiflexion in response to electrical stimulation.

An ABC scale was used to assess confidence levels. The ABC scale has been found to be reliable and with a strong support for validity among lower-limb amputees (Miller, Deathe, & Speechley, 2003).

An AMTI (Watertown, MA) force platform was used for collection of ground reaction forces (GRF) during static balance and 3-D gait trials. For 3D gait analysis a four-camera (JVC, Wayne, NJ) video system was used, collecting at 60 Hz, with one force platform (AMTI, Watertown, MA) imbedded in a raised walkway. Vicon Motus software; version 8.2 (Englewood, CO) was used for computations of GRF and gait parameters.

Procedure

The participant was personally recruited from a prosthesis laboratory and rehabilitation private practice where the investigator had previously participated in an externship program. Before beginning the study, the participant signed an informed consent form approved by the institutional review board.

Initial training sessions in use of the ODFS were conducted by the participant's head rehabilitation specialist and continued until she was knowledgeable and confident with placement of the electrodes and adjusting controls of the electrical stimulator. Following the training and collection of baseline data, the participant used the device in her usual activity settings for a minimum of 3 hours daily. This was a participant-selected reduction from the planned 6 hours, as the participant found the cumbersomeness of the device to be uncomfortable and inconvenient. The participant kept a log of the daily hours of use. She was contacted weekly by the investigator.

The participant completed an ABC scale pre- and post-study. Baseline and post-study girth measurements of both limbs were collected. Measurements were conducted by the same person, using the same commercial tape measuring device, at the same time of day, with the participant in a semi-recumbent position, comfortably supported at an angle of 45 degrees. Measurements were repeated until within 0.5 cm and the results were averaged. The measurement locations were as follows: (1) central patella, (2) 3", 6" and 8" proximal to central patella, (3) medial tibial plateau (MTP), and (4) 1", 2" and 3" distal to central patella.

Balance testing was conducted in the Barry University biomechanics laboratory. The participant was assessed on postural sway measures in a one test session under one-legged and two-legged stance tests on an AMTI (Watertown, MA) force platform under the following conditions: Condition 1: bilateral stance; and Condition 2: residual limb stance using a uniaxial ankle foot prosthesis. Under Condition 1 the subject performed 10 trials separated by 30 seconds of rest. The target goal for Condition 1 was 15 seconds. Under Condition 2, trials were limited to 5, separated by 30 seconds of rest, and the target goal was reduced to 5 seconds as the participant experienced hip pain during these trials. During the two-legged static balance testing the participant was asked to stand with feet maintained in a parallel position of maximal comfort. During the single-legged testing the participant was asked to stand with the non-involved leg flexed at the knee. All trials were conducted with eyes open, and with the participant instructed to look straight ahead, focusing on an area of the wall at eye level. The participant was instructed to keep her hands by her sides. The same shoes were worn for all trials. Each of these tests was repeated at 12 weeks.

Gait trials were conducted in the Barry University Biomechanics Laboratory. Reflective markers were placed on the lower extremities with strapping tape. Marker placements were as follows: (1) sacrum, (2) bilateral anterior superior iliac spine (ASIS), (3) lateral femoral epicondyle, (4) lateral malleolus, (5) heel, (6) 2nd metatarsal head, (7) mid-tibial wand, and (8) mid-femoral wand. The participant walked at a self-selected comfortable pace, with the right foot contacting the force platform near the center. For both the initial and final data collection, three trials were conducted under each of the following conditions: (1) Gait with FES; (2) gait without FES. The 3rd trial under each condition was used for analysis. Vicon Motus software; version 8.2 (Englewood, CO) was used for computations of ground reaction forces (GRFs) and gait parameters.

Data Analysis

The means and standard deviations of sagittal and frontal plane COP were calculated from the GRFs of the medial balance trial under each pre- and post-treatment condition. ABC scale pre- and post- study scores were also compared. The values from the pre- and post- treatment limb girth measurements were used to calculate limb symmetry as follows: LGS= IS/NIS. For limb girth symmetry (LGS) measurements of the residual, or involved side (IS), was divided by measurements of the non-involved side (NIS). A score of 100% indicated perfect girth symmetry. Gait parameters of cadence, velocity, step length, stance time, and hip and knee flexion values with and without FES were determined via the Vicon system. Gait symmetry (S) was calculated as follows: SLS = SSL/LSL. For step length symmetry (SLS) the shorter step length (SSL) was divided by the longer step length (LSL). A score of SLS = 100% indicated perfect step-length symmetry; STS = IS/NIS. For stance time symmetry (STS) the stance time of the

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IS was divided by the NIS. A score of 100 % indicated perfect symmetry; KFS = IS/NIS.

For knee flexion symmetry (KFS) the degrees of flexion of the IS was divided by the

NIS. A score of 100% indicated perfect symmetry;

HFS = IS/NIS. For hip flexion symmetry (HFS) the degrees of flexion of the IS was

divided by the NIS. A score of 100% indicated perfect symmetry. Values for trials with

and without FES were compared.

Results

Participant

One female participant was recruited for this study. She was 30 years of age, and

had a 2 year history of left traumatic transtibial amputation. The surgical procedure

preserved the proximal 2/3 of the anterior tibial muscle belly while removing the tendon

with amputation 4 inches distal to the fibular head. She had been active in a

rehabilitation program beginning soon after surgery. She had used a prosthesis more than

6 months and did not require assistive devices. FES had never been incorporated into her

rehabilitation program. She completed the study, but due to discomfort, selected to limit

the daily use of FES to 3 hours following one day of attempting the 6 hours that had been

planned. During the study she continued the FES but dropped out of the rehabilitation

program and joined a gym for the remaining 4 weeks of the study. She did not attend the

gym on a regular basis. She had no reported injury with the use of the FES. At

completion of the study she revealed she was 6 weeks pregnant and had gained 13

pounds.

Balance

The pre- and post-testing means and SD for COPx (anterior-posterior) and COPy (medial-lateral) were computed using Vicon software. In comparing both the bilateral and single stance testing results, the post test SDs were increased in the anterior-posterior (80%, 50% respectively) and medial-lateral (bilateral stance 33%)direction for both stances, indicating lower balance scores with one exception; medial-lateral SD in the single stance trial was smaller (14%) than in the pre test trial. See Table 1 for standard deviations of the balance tests.

Table 1. Balance Means and Standard Deviations

Time	Bilateral Stance		Single (Amputated) Stance	
	COPx	**COPy**	**COPx**	**COPy**
Pretest	±. 005	±.002	±.012	±.007
Posttest	±.009	±.003	±.016	±.006

Note: Higher SDs indicate more sway variation and less balance.

Limb Girth Symmetry

Limb girth was measured at selected distances proximal and distal to the knee. To adjust for any weight gain or loss, the measures were calculated as a percentage of the residual limb girth to the non-involved limb girth. Posttest results were not consistent for all measured locations. After 12 weeks of therapy, the symmetry percentage values at 2" and 3" distal to the mid-patella were increase by 1.41% and 1.26% respectively. These results reflect an increased NIS girth at 2" and an increased IS girth at 3".   See Table 2 for limb girth symmetry values. See Table 3 for actual girth measurements.

Table 2. Limb Girth Symmetry

Time	MTP	Mid-Patella	P-3"	P-6"	P-8"	D-1"	D-2"	D-3"
Pretest	90.55%	90%	87.26%	89.36%	93.1%	93.75%	88.19%	81.95%
Posttest	90.4%	91.67%	88.83%	91.10%	92.16%	91.34%	89.6%	83.21%

Note: Location of girth measurements: Medial Tibial Plateau (MTP), proximal to the mid-patella (P), and distal to the mid-patella (D). Higher percentages indicate greater symmetry.

Table 3. Limb Girth Measurements

	Limb	MPT	Mid Patella	P-3"	P-6"	P-8"	D-1"	D-2"	D-3"
Pre Test	**IS**	28.75 ±.25	31.5	34.25 ±.25	42.0	47.25 ±..25	30.0	28.0	27.25 ±.25
	NIS	31.75 ±.25	35.0	39.25 ±.25	47.0	50.75 ±.25	32.0	31.75 ±.25	33.25 ±.25
Post Test	**IS**	28.25 ±.25	33.0	35.75 ±.25	43.0	47.0	29.0	28.0	28.5
	NIS	31.75 ±.25	36.0	40.5	47.25 ±.25	51.0	31.75 ±.25	31.25 ±.25	34.25 ±.25
Δ	**IS**	1.74%	4.76%	4.38%	2.38%	.53%	3.33%	0	4.59%
	NIS	1.57%	2.86%	3.18%	.53%	.50%	.78%	1.57%	3.01%

Note: Location of girth measurements: medial tibial plateau (MTP), proximal to the mid-patella (P), and distal to the mid-patella (D), involved side (IS), non-involved side (NIS), change (**Δ**). Measurements are in centimeters.

Gait Symmetry

Gait parameters were computed by Vicon software. Cadence and velocity values were taken directly from the resulting gait analysis. For symmetry of the lower extremities, values for stride length, stance time, and hip and knee flexion were computed from gait analysis values as a percentage of the involved or amputated limb to the non-

involved limb. The initial gait data was inconsistent. Compared to the non-FES trial the

trial with FES showed increased cadence (1.03%) and velocity (3.50%). Stance time

symmetry (SLS) and step length symmetry (STS) were increased (5.34% and 11.47%

respectively) while hip flexion symmetry (HFS) and knee flexion symmetry (KFS)

decreased (8.98% and 2.28% respectively).

When gait trials were repeated after 12 weeks of therapy, values under FES conditions

again showed increased value for SLS (6.59%) but decreased STS (4.74%), cadence

(2.0%), and velocity (3.33%) values. In this trial, HFS and KFS were also increased

(12.66% and 1.93% respectively). See Table 4 for gait analysis values and Table 5 for

actual gait cycle characteristics.

Table 4. Gait Analysis Values

Initial Test	Cadence (steps/min)	Velocity (m/s)	SLS (SSL/LSL)	STS (IS/NIS)	KFS (IS/NIS)	HFS (IS/NIS)
With FES	111.34%	1.273	95.14%	110.70%	96.15%	88.24%
Without FES	110.204	1.230	89.80%	122.17%	98.43%	102.78%
Post Test						
With FES	108.000	1.044	75.70%	95.26%	139.31%	139.38%
Without FES	110.204	1.080	69.11%	100%	141.24%	152.04%

Note: Step length symmetry (SLS), stance time symmetry (STS), knee flexion symmetry (KFS), hip flexion symmetry (HFS), involved side (IS), non-involved side (NIS), shorter step length (SSL), longer step length (LSL), functional electrical stimulation (FES). Percentage numbers closest to 100% indicate improved symmetry.

Table 5. Gait Cycle Characteristics

Characteristic	Pre-test With FES		Pre-test Without FES		Post-test With FES		Post-test Without FES	
Cadence (steps/min)	111.340		110.204		108.000		110.204	
Gait Velocity (m/s)	1.273		1.230		1.044		1.080	
Extremity	IS	NIS	IS	NIS	IS	NIS	IS	NIS
Step Length (s)	0.666	0.700	0.651	0.725	0.496	0.655	0.481	0.696
Stance Time (s)	0.683	0.617	0.733	0.600	0.683	0.717	0.700	0.700
Maximal Hip Flexion (degrees)	38.126	43.193	39.944	38.864	40.740	29.230	39.344	25.877
Maximal Knee Flexion (degrees)	58.998	64.520	58.888	59.803	74.828	53.714	77.412	54.807

Note: Involved side (IS), and non-involved side (NIS).

Activity Confidence Level

To assess the participant's perceived level of confidence in her ability to perform activities without losing balance or becoming unsteady, she completed the ABC Scale questionnaire pre- and post-treatment. For 7 of the 16 activities there were increased values. These activities were: (1) up and down stairs, (2) sweep the floor, (3) walk outside to nearby car, (4) get in/out of car, (5) walk across parking lot, (6) up and down ramp, and (7) escalator holding rail. See Table 6 for complete ABC results.

Table 6. Activities-Specific Balance Confidence Scale Results

Activity	Level of Confidence	
	Pre-trials	Post-trials
Walk around the house	85%	85%
Up and down stairs	50%	70%
Pick up slipper from the floor	85%	85%
Reach at eye level	95%	95%
Reach on tiptoes	50%	50%
Stand on chair to reach	20%	20%
Sweep the floor	85%	95%
Walk outside to nearby car	85%	90%
Get in/out of car	80%	90%
Walk across parking lot	80%	85%
Up and down ramp	70%	75%
Walk in crowded mall	70%	70%
Walk in crowd/bumped	50%	50%
Escalator holding rail	60%	80%
Escalator not holding rail	50%	50%
Walk on icy sidewalks	10%	10%

Note: Confidence rated on a scale of 0% (no confidence) to 100% (complete confidence) that activity will be performed without loss of balance or becoming unsteady.

Proprioception and Comfort Levels

For assessment in user comfort and the effectiveness of FES to provide proprioception to the amputated limb, the participant rated these weekly using a 0-10 scale, with 0=none, or least, and 10=most, or always. For comfort, she maintained a level of 6. Her perception of awareness of prosthetic limb position increased from 5 to 8. The participant described her discomfort from the ODFS device as; (1) pain and pressure from the electrode wires, (2) inconvenience with wires from the heel sensor to the

stimulator at her waist, and (3) annoyance with shocks to her leg when she shifted side-to-side, or attempted to cross her legs.

Discussion

Somatosensory input derived primarily from the forces and motions exerted by the feet on the support surface are required for maintaining postural control and a stable gait. In the lower extremity amputee the sensory and motor deficits are demonstrated by asymmetric gait (Robinson et al., 1977) and lateral shifting difficulties. These changes result in slower cadence and decreased forward velocity (Tibarewala and Ganguli, 1982). In this study FES was applied during swing phase of gait to increase the participant's sense of position of the residual limb in relation to the supporting surface. The initial trial showed increased cadence, velocity, SLS and STS with FES use. Increased HKS and KFS did not occur. Post-test trials supported the expected findings of increased HFS, KFS, and SLS, but cadence, velocity and SLS, were less than in the initial trials. It can not be concluded that these findings are due to FES alone. Participant's weight gain of pregnancy and discontinuation of physical therapy may have been contributing factors in all final values.

There are no findings to suggest improved balance. In this study, post-treatment SDs were greater than pre-treatment, indicating greater sway. This might have been due to the increased weight associated with pregnancy; however a study by Butler, Colon, Druzin, and Rose (2006) does not support the participant's first trimester pregnancy as a contributing factor to increased postural sway. Their data suggested that postural stability declined during the second and third trimesters of pregnancy and remained diminished 6-8 weeks after delivery, but was relatively stable during the first trimester,

when trials were conducted with eyes open. They found no significant association between the amount of weight gained or lost and postural sway measures. However, there was no mention of amputee participants in the Butler, et al. study. The discontinuation of physical therapy which included balance and proprioception training using a balance board, 4 weeks prior to the post-treatment trials, may have been a factor in larger SDs.

The participant experienced hip and stump pain during the single-leg stance. Though not activated during static stance, the stimulator, including the surface electrodes were in place during the trials. Discomfort in the stump due to wire placement during single leg stance may have increased due to weight gain, and this may have influenced the outcome. Additionally, when discussing the results with the participant, she felt she may have been distracted as she had been preoccupied with personal matters during the post-test session. These findings do suggest that the effect of FES used during the gait cycle does not carry over into static balance.

With transtibial amputation there is loss of somatosensory input normally derived from the forces and motions exerted by the foot on the supporting surface. There is loss of the stretch reflexes as well. This results in residual muscle atrophy of disuse. There is loss of soft tissue, the stump shrinks, and there is less pressure-accepting tissue over which to distribute weight bearing pressure. This increases risk for tissue breakdown and stump discomfort. In animal studies Duan et al. (1999) found that intermittent electrical stimulation of muscles 12 hours daily for 12 weeks, increased muscle strength. Incorporation of FES into the rehabilitation programs of SCI victims has been shown to promote improved muscle strength and function. Scremin et al. (1999) found greater than 20% increase in CSA in most treated muscles after average treatment duration of 52.8

weeks (30 minutes for 2.32± .26 days per week). Johnston, Smith and Betz (2005)

reported 9.8% increase in thigh mean circumferential measures following 10 months of

electrical stimulation of the femoral nerve (12.3±1.1 cm to 13.5±1.5cm), $p<.001$. They

reported an increase in the quadriceps femoris isometric torque across all angles from

7.0±1.6 Nm at baseline to 14.8±3.2 Nm at 10 months ($p<.001$). After 2 months of no

stimulation they observed a decrease in both thigh circumference (13.1±1.3cm) and

quadriceps femoris torque (8.5±1.1Nm), $p<.001$. In this study there was increased limb

girth symmetry at 2" and 3" inches distal to the mid-patella (1.41% and 1.26%). The 2"

distance was due to decreased NIS girth measurements and the 3" location was due to

4.56% increase of the distal stump measurement. While this increase is small it does

show a trend toward increased stump girth and does agree with results reported by

Johnston et al., of 9.8% increase in thigh girth following 10 months of treatment.

. In this study, following 12 weeks of FES as the instrument to enhance proprioceptive

function, the participant indicated increased confidence in her ability to perform 7 of the

16 selected activities included in the ABC scale. The increased values ranged from 5%

increased confidence in walking up and down a ramp to 20% in walking up and down

stairs and using an escalator while holding the rail. In no activity did she feel less

confident. She did express her difficulty in rating any activity on any numerical scale (0-

10 or 0%-100%). These findings suggest that FES improves confidence, but it cannot be

completely excluded that she responded with values she believed the investigator

expected to hear. While her 13 pounds weight gain of pregnancy may have changed her

COM, it did not decrease her level of confidence.   This study does support the

hypothesis that ABC scores will be improved with 12 weeks of FES, but it cannot be concluded that the improved scores were due to FES only.

The ODFS dropped foot stimulator was designed to be used in CVA victims, promoting ankle dorsiflexion and allowing the foot to clear the ground in swing phase of gait. In this situation, the wires from the stimulator to the surface electrodes would be under comfortable clothing only. Additionally, the electrodes and wires would be over an intact lower extremity. In contrast, when the electrodes are on a residual limb which has lost soft tissue, and also under a socket liner and inside the vacuum socket, there is greater pressure, less soft tissue to absorb these forces, and compliance may be directly related to comfort. In this study the participant rated her comfort level at 6 on a 0-10 scale and reduced the daily use to 3 hours instead of the proposed 6. She does plan to continue to use the ODFS, but not as much as she has during this study. Her perceived primary advantage in using the ODFS was that it made her more aware of leg position.

The participant described her discomfort from the ODFS device as: (1) pain and pressure from the electrode wires, (2) inconvenience with wires from the heel sensor to the stimulator at her waist, and (3) annoyance with shocks to her leg when she shifted side-to-side, or attempted to cross her legs. For greater compliance, these factors will need to be addressed.

Conclusions

The incidence of lower extremity amputations in the United States is significant. In this population, falling and the fear of falling may further limit mobility and independence. Atrophy of the residual limb muscles, due to disuse, reduces pressure

bearing soft tissue. This results in less surface area for the distribution of weight bearing forces and may increase discomfort and the risk for skin breakdown.

Application of FES may improve amputee gait and reduce the fear of falling by providing somatosensory feedback, giving the amputee to have greater limb position sense. Additionally, by stimulating the residual muscles, stump atrophy may be reduced or reversed. In this study increase in stump girth and some of the gait parameters were observed, as was increased confidence level in ability to perform selected activities of daily living. While it cannot be concluded from this study that these changes were due only to FES, there is an observed trend toward improved gait, confidence, and reversal of stump atrophy. Though small, these changes warrant further study in the application of FES in amputee gait. For future studies, we recommend a larger study over a longer treatment time. We also recommend the incorporation of a tilt sensor for FES. This study incorporated a heel sensor which limited the ability to comfortably shift weight side-to-side.

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