Evidence Table

The purpose for this evidence table was to provide the learner with a detailed, summarized, central source to review the evidence addressing the use of FES when working with patients with incomplete spinal cord injury. Below, is a table of contents to help the learner locate each article more efficiently:

Table of Contents

<table>
<tr><td>Author/Title/ Year</td><td>Zhou R, Alvarado L, Ogilvie R, Chong SL, Shaw O, Mushahwar VK. Non-gait-specific intervention for the rehabilitation of walking after SCI: role of the arms. 2018.[1]</td></tr>
<tr><td>Study Design, Level of Evidence</td><td>Longitudinal Comparison of study design with pre-intervention and post-intervention comparison, Level 3</td></tr>
<tr><td>Subjects (#, Inclusion/exclusion criteria)</td><td>Subjects
12 patients with chronic incomplete spinal cord injury
iSCI over 2 years old
Levels C4 to T12
ASIA score C or D
Inclusion Criteria
Subjects had to be able to ambulate short distances. Assistance levels were variable.
Innervation had to be present to major muscles of arms and legs
Exclusion Criteria
Damage to other nervous system structures outside of spinal cord
Prescribed antidepressants
History of seizures/epilepsy
SCI injury below T12</td></tr>
<tr><td>Outcome Measures and Measurement Timeframe(s)</td><td>Conducted every 3 weeks throughout the training period:
10m walking test (maximum walking speed)
6-min walking test (endurance)
Conducted every 6 weeks throughout the training period:
AISA (assessed myotomes and dermatomes for sensory/motor function)
Berg Balance Scale (Balance)
EMG Data was gathered throughout activity and analyzed.

A variety of other biomechanical measurements were taken as well for research purposes</td></tr>
<tr><td>Description of Intervention(s)</td><td>Study was performed over 12 weeks. 1 hour per day, 5 days per week.

2 training groups
One group with Arm & Leg FES-assisted cycling
Arms and Legs were used simultaneously during movements that mimicked the coordination needed for walking</td></tr>
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	• One group with only Leg FES-assisted cycling ○ Legs only used while arms stayed static FES was only applied to muscles needed for cycling the legs and/or arms, as long as their AISA motor score was below a 4. Muscles stimulated varied depending on patient presentation. Rectangular biphasic waveform at 150-450 us Frequency of 30-40 Hz Individual intensity customized to each patient's tolerable level that produced strong muscle contraction. (10-30 mA at minimum, 60-140 mA at maximum)
Results	Overground walking distance, sensory and motor function, balance, leg muscle activation, and joint motion all saw increases after 12 weeks of receiving this intervention. Both groups saw significant increases in walking speed ($P < .001$) after training A&L group saw a significant increase in average walking speed (.27±.072 m/s) that was greater than that of the L group (.092±.022 m/s). However, one participant in the A&L group was deemed an outlier, so their data was removed. Both groups saw significant increases in walking distance relative to pretraining levels. A&L group saw greater increase (91.85±36.24m) when compared to L group (32.12±8.74m), but it was not found to be significant ($p=.67$) When compared to 9 other studies that used FES and leg-only training (gait training), this A&L cycling group saw greater improvements in walking distance and gait speed than those in the other studies. Participants, on average, saw significant increases in AISA motor scores, regardless of group. BBS scores, on average, significantly increased across both groups. (9±3 in A&L; 8±2 in L). Only one participant reduced their BBS, which was a loss of 2.
Conclusions	This study shows that training patients with incomplete spinal cord injuries while using FES and a cycle ergometer can generate significant improvements in gait-speed, when compared to the lower extremity only group. When comparing balance-related and muscle strength outcome measures, both groups saw significant increases. The gait-related measures are especially important because the use of this treatment modality can improve a patient's ability to walk further, over time, due to their quicker pace. The improved BBS scores also demonstrate that a patient is also safe while they ambulate at this pace.

	The other thing that it shows is that it is beneficial to use a training technique that combines FES, cycling, and coordinated movements of arms and legs in a pattern similar to walking. The comparison that the authors made with other studies that explored FES with training legs-only further promotes the fact that using reciprocal arm swing in coordination with leg movements generates a better outcome than training legs alone. *Although the results are exciting, we should keep in mind the limited number of participants in this study.

Author/Title/ Year	A randomized trial of functional electrical stimulation for walking in incomplete spinal cord injury: Effects on walking competency. Kapadia N, Masani K, Craven BC, Giangregorio LM, Hitzig SL, Richards K, Popivic MR. 2014.[2]
Study design, level of evidence	Parallel group randomized controlled trial. Fair quality (5/10 on PEDro scale). Level 2b evidence
Subjects (#, Inclusion/ exclusion creiteria)	34 individuals with traumatic, chronic incomplete spinal cord injury (iSCI) 7 lost during the study 16 placed in intervention group completed study 11 placed in control group completed study **Inclusion criteria:** • Incomplete iSCI C2 to T12 • ASIA C or D • 18 months post-injury • Expected not to walk or to need an AD to walk • Medical clearance **Exclusion criteria:** • Contraindications for FES • Muscle denervation • Grade 2, 3, or 4 pressure sores, location depending • Cardiovascular conditions: uncontrolled hypertension, orthostatic hypotension standing for 15 min, autonomic dysreflexia

Outcome Measures and Measurement Timeframe(s)	Performed at baseline, 4 months, 6 months, and 12 months
	
	Primary outcomes:
	• Gait measures
	    ○ 6MW Test
	    ○ 10m walk test
	    ○ Assistive device score (ADS)
	    ○ Walking mobility score (WMS)
	• Balance
	    ○ TUG
	• Functional measures
	    ○ Spinal cord independence measure (SCIM)
	    ○ Functional Independence Measure (FIM)
	• Spasticity Measures
	    ○ Modified Ashworth scale (MAS)
	    ○ Pendulum test

Description of Intervention(s)	Randomization to intervention or control group (non-blinded subjects) 16 weeks, 3 days per week, 45 minutes per session **Intervention Group:** Had FES applied to them while performing gait training on a body weight supported treadmill (BWSTT) and harness system FES Parameters: • Biphasic, pulse-width modulated with constant current regulation. • Amplitudes = 8-125 mA • Pulse width = 0-300 us • Frequency = 40 Hz Muscles used = quadriceps, hamstrings, dorsiflexors, and plantarflexors as needed throughout gait cycle. PT's were responsible for controlling the sequencing of this. Gait speed and harness support were individualized to patient needs. Swing phase of gait was altered individually based on patient needs **Control Group:** Specialized exercise protocol consisting of 20-25 minutes of progressive resistance training followed by 20-25 minutes of aerobic exercise. Aerobic exercise included treadmill training for those who were appropriate for it. Both

	exercise protocols were performed at moderate levels pertaining to the Modified Borg RPE scale. All of this was supervised by a qualified physical therapist or kinesiologist.
Results	SCIM: • Significant change over time (4.75) for both groups • Differences in main effect and time-group interaction scores were not significant, indicating no difference between groups overall. FIM • No changes 6MWT • No statistical significance between the groups or times where the tests were administered 10m walk test • Wide range from 0 m/s to 1.66 m/s • No significant change over time and no significant difference between groups ADM • One participant upgraded from use of a cane to no AD • One participant upgraded to use of a walker to no AD • Both returned to using their AD by 12 months TUG 1. Significant improvement over time over 12 months o Decreased 11.4 sec on average for FES o Decreased 10.3 sec on average for control MAS (modified ashworth scale) 2. Most muscle groups showed no change over time o *Authors never reported this based on which side of the spinal cord was injured/which muscles were most/least damaged at admit. This could change perceptions
Conclusions	FES-assisted walking improved SCIM sub-score significantly when compared to control group. Overall, therapy with FES was not significantly better than a training protocol that included aerobic and resistance exercise. However, the authors cautioned that the results of this study may be influenced by heterogeneity and the small sample size that was used.

Author/Title/ Year	Effects of Locomotor Training After Incomplete Spinal Cord Injury: A Systematic Review. Morawietz C, Moffat F. 2013.[3]
Study Design, Level of Evidence	Systematic Review of RCT's only Level 1a
Subjects (#, Inclusion/ exclusion creiteria)	9 RCT's were deemed adequate initially, 8 were used in final synthesis because more information was discovered about one of them, and it was found to be below a 4 on the PEDro scale **Inclusion Criteria:** • RCT's involving locomotor training in the population of patients with iSCI • 4 or above on the PEDro scale • Dutch, German, or English • ASIA B, C, or D • Minimum age of 16 • Training parameters had to be specified **Exclusion Criteria** • Anything not meeting inclusion criteria • Any studies using invasive procedures or animal studies Total participants across all studies = 384 Participants <1 year post-SCI = 270 Participants >1 year post-SCI = 114
Outcome Measures and Measurement Timeframe(s)	Evaluation on ambulatory function and gait characteristics **Participants <1 year post-injury** • Initial walking capacity • Gait velocity • Distance • Gait parameters • FIM score **Participants > 1 year post-injury**

	• Initial walking capacity • Velocity • Distance • Gait parameters • FIM score
Description of Intervention(s)	**Participants <1 year post-injury (acute)** • BWSTT w/ overground training and stretching[11] ○ 3-5 sessions per week for 12 weeks. 60 min per session • BWSTT + FES (Initially set at 40%, changed based on patient needs)[7] ○ 5 sessions/week for 8 weeks, no greater than 60 min per session • Lokomat training with passive mobilization, stretching, and self-care (60% initially, reduced based on need)[12] ○ 5 sessions per week for 8 weeks • BWSTT w/ manual assistance, stretching and passive mobilization (40% initially, reduced 10% every 10 sessions)[13] ○ 2 sessions per week for 4 months **Participants >1 year post-injury** • BWSTT with manual assistance; BWSTT with FES; overground gait training with BWS and FES; robotic treadmill training (2005, Field-Fote, et al.[6] article listed later in this table) ○ 5 sessions/week for 12 weeks • BWSTT with manual assistance; BWSTT with FES; overground gait training with BWS and FES; robotic treadmill training[14] ○ 5 sessions/week for 12 weeks • BWSTT; overground gait training with BES; conventional PT[15] ○ 3 sessions/week for 13 weeks
Results	**Participants <1 year post injury** • Initial walking capacity was non-ambulatory or significantly impaired • Participants were able to improve gait distance and velocity in the intervention groups of all 4 studies more so than the control groups, but not significantly. • Those who were able to walk at the beginning of the trial were able to achieve greater gains than those who could not. (this is different than what has been the case with chronic patients throughout this evidence table) • Due to each study's design, it was difficult to compare outcomes for gait and distance across them.

	• BWSTT + FES saw a significant increase in stride length of .31m greater than the conventional physical therapy group.
	• BWSTT alone saw increases in step lengths of .1m.
	• For patients with ASIA B or C, average FIM locomotion scores increased from 1 to 6 in experimental groups (1-6 final range) and 1 to 6 (2-6 final range) for Control Groups.
	  ○ ASIA B participants
	    ▪ 33% achieved ambulation in BWSTT group
	    ▪ 58% achieved ambulation in over ground gait training group
	  ○ ASIA C participants
	    ▪ 92% achieved independent ambulation
	• For patients with ASIA C and D, FIM improved from 1 to 6 in both groups (6-7 range)
	
	Participants > 1 year post-injury
	
	• At baseline, participants could perform 1 step and stand with assist x 1.
	• Increases were found in gait speed with all interventions with an exception of robotic training, where results were mixed.
	• Mean distances increased significantly by 3.8m in FES + BWSTT and 14.3m in FES + OG groups. The other groups were insignificant.
	• FIM score improvements were negligible for patients using robotic gait orthoses
	  ○ Some outcomes indicate that this may be a better gait training technique for individuals earlier post-injury.

Conclusions	Based on what has been found, there is no outright superior modality to use for gait training, with one exception. Patients in the acute setting significantly benefitted in stride length when FES is utilized during gait training. All other approaches to gait training appear to offer benefits in one aspect or another, with some being superior in one outcome measure, but inferior in other outcome measures. When working with patients with chronic iSCI, application of FES may produce increases in distance travelled when the patient is trained over ground. These results suggest that there is no overwhelmingly “best” gait training strategy to use. The “best” device to use is specific to each patient, depending on what they and their PT agree are the best goals are for them. However, FES does have its benefits with regards to distance travelled and increases in stride length.

Author/Title/ Year	Mehrholz J, Kugler J, Pohl M. Locomotor training for walking after spinal cord injury. Cochrane Database of Systematic Reviews. 2012[4]
Study Design, Level of Evidence	Systematic Review with Meta-Analysis of Randomized Controlled Trials Moderate quality Level 1a
Subjects (#, Inclusion/ exclusion creiteria)	This review included 5 randomized controlled trials using one of three different modalities for gait training. 309 participants with incomplete spinal cord injury of ASIA B, C, or D. In each of the trials, the number of participants ranged from 14 to 146. The age ranged from 18 to 68. **Inclusion Criteria:** Trials that were included were those that compared gait training to any other exercise or no treatment at all. The authors specifically looked for electrical stimulation, body-weight support (BWS), or overground gait training techniques. They also made a note to include any new developments for gait training assistive modalities. The authors of the review were open to any age, gender, or stage of the injury (acute vs. chronic). **Exclusion Criteria:** Studies that were excluded were those that utilized only specific components of treatment. (Ex. Passive electrical stimulation for strength would be excluded, but functional electrical stimulation in gait training would be included)
Outcome Measures and Measurement Timeframe(s)	**Primary Outcome:** • Over Ground Walking Speed or Treadmill Walking Speed ○ This outcome measure is not necessarily standardized itself, but using the data from the 10 meter walk test, it can be assumed that the faster the gait speed, the more functionally independent the patient is. It is also significantly correlated with the 6 minute walk test up to 12 months post-injury.[16] ○ MCID = .06 m/s in the SCI population[17] ○ Mean 1.37 m/s in the SCI population[18] **Secondary Outcomes:** • 6 Minute Walk Test ○ This assessment was either given on a treadmill or over ground, depending on what group the participants were in. It has an MDC of 45.8 meters and an MCID of .1 m/s in the spinal cord injury population.[19] Mean walking speed for patients 12 months post-injury or later is .88 m/s.[20] • Functional Independence Measure

	○ Scored from 18 to 126, with the highest values being indicative of the greatest amount of function.[21] ○ 5 cognitive tasks and 13 motor tasks.[21] However, for the purposes of this systematic review, the scores that were taken were those from the 'locomotion' category.
Description of Intervention(s)	**Control** The trials used in this systematic review and meta-analysis had control groups whom either had no treatment or had other exercise modalities besides gait training. One trial included individual physiotherapy as a control, and others were comparison trials that utilized multiple groups, with different groups receiving either body weight support treadmill training, overground walking, robotic-assisted treadmill walking, treadmill training with peroneal nerve stimulation. In these studies, there was not a "control", but rather different groups being compared on different gait training techniques. **Experimental** All trials that were included had experimental groups that received body weight supported treadmill training, hybrid strategies including BWSTT and functional electrical stimulation, and/or robot-assisted gait training. Specifically, two trials utilized the 'Lokomat' assistive device. All studies included used bodyweight supported treadmill training, and one study used a combination of manual assistance and functional electrical stimulation. The amount of sessions for treatment was reported to have ranged from 2-3x per week to 5x per week, with duration lasting either 4 weeks, 8 weeks, or 12 weeks, depending on the trial. However, this information is only shared in the first section of the review, and not in the individual tables of each study. Therefore, we don't know which specific study utilized which frequency or duration.
Results	When comparing the bodyweight supported treadmill training (BWSTT) with robotic-assisted locomotor training (RALT) as well as functional electrical stimulation combined with bodyweight supported treadmill training (BWSTT + FES), the results showed that the body weight supported treadmill training did not increase walking velocity, the 6MWT distance, safety of exercise, or risk of participants dropping out. In all four of these analyses, the confidence interval included 0, indicating that even if there had been a change, it would not have been significant. When comparing the RALT with BWSTT and BWSTT + FES, there was a change in walking speed of .06 m/s, however, it was not statistically significant ($p = .11$). The distance achieved in the 6-minute walk test was actually reduced by 10.29m, and was statistically significant ($p = .05$). This finding indicates that individuals who participate in RALT may see a decrease in their distance on the 6MWT over time. When comparing BWSTT + FES with BWSTT and RALT, there were no statistically significant changes in any of the outcomes measured. Additionally, all mean differences included 0 in the confidence interval, consistent with lack of statistical significance at alpha=0.05.

Conclusions	The results of both the systematic review and the accompanying meta-analysis showed that the trials didn't have very large sample sizes and that the number of quality trials was very limited. The effect sizes were all approaching null values, indicating small or negligible treatment effects. Many confidence intervals included zero, indicating that the null hypothesis could not be rejected. Additionally, it was difficult to gather a good association of the FES when compared to other treatments, because a few of the comparisons were only able to gather mean differences and confidence intervals from one study, thereby reducing the strength of the comparative analysis. The one study that did show a significant change was the RALT, indicating that patients who use RALT will actually see a decrease in 6MWT distance over time when compared with the other two interventions. However, the decrease they found was 10.29 meters. The MDC of the 6MWT is 45.8 meters, so is this change found in the meta-analysis actually significant?[19] We should also consider fatigue, considering walking for 6 minutes with the added weight of a robotic limb can be very tiresome. There is not enough evidence to determine which form of locomotor training is most effective in treating patients with spinal cord injuries. I also agree that more research needs to be performed in this area to allow us gather a larger set of trials with a greater number of patients. Therefore, we should choose whatever modality the physical therapist deems most appropriate and effective for progressing the individual patient.

Author/Title/ Year	A systematic review of the efficacy of gait rehabilitation strategies for spinal cord injury. Lam T, Eng JJ, Wolfe DL, Hsieh JT, Whittaker M. 2007.[5]
Study Design, Level of Evidence	Systematic Review Level 1
Subjects (#, Inclusion/ exclusion creiteria)	41 articles (RCTs and non-RCTs) covering different ways to improve gait in the iSCI population. 7 were specific to FES. **Inclusion Criteria:** • Included frequency and duration of training tasks (unless FES involved) • Involved gait training with this patient population **Exclusion Criteria:** • Did not measure functional or ambulation-based outcomes • Did not measure and compare pre/post outcomes (Unless bracing was used)

Outcome Measures and Measurement Timeframe(s)	FIM Locomotor score Walking endurance BBS WISCI LEMS

Description of Intervention(s)	**Treadmill Training:**
	• Robot or therapist assisted Body weight supported treadmill training (BWSTT)
	• Intensity ranging from 60 to 300 minutes per week
	• 3 to 23 weeks
	Functional Electrical Stimulation ONLY:
	• FES applied for home use in some studies
	• Other studies had FES applied in therapeutic setting for 30 min, 3 to 5 times/week, up to 3 months.
	Orthoses/Braces
	• 2 Pre-/post-test studies used orthoses/braces 5 times/week for 2 weeks
	• Other 10 studies were post-test only
	Combination Therapies
	• FES + gait training (4 studies total, 1 being high quality (discussed next table))
	• Gait training + Pharmacological interventions (2 studies)
	    o GM-1 ganglioside plus gait training and physical therapy
	    o Clonidine and cyproheptadine + BWSTT → overground ambulation
	• Bracing + FES
	    o 6 post-test only studies with complete SCI (will not be discussed in this table)

Results	**BWSTT vs. other gait training strategies** • No significant differences in outcome measures between BWSTT and an equivalent intensity of overground gait training during inpatient SCI rehabilitation during randomized controlled studies • Non-randomized controlled trial saw significant improvements in functional ambulation measures in 87% of subjects using BWSTT vs. 50% using "conventional therapy" (over ground walking and exercises) • BWSTT + FES showed significant improvements in walking speed over 12 weeks. • Overall, level 1 evidence that different modes of gait training end up showing similar effects in outcome measures related to ambulation or function. **Bracing or FES Alone vs. Bracing + FES** • Level 4 evidence that the combination of bracing + FES may be more beneficial for improving functional ambulation than Bracing or FES alone

	There is level 1 evidence that intensive gait training is beneficial for patients with iSCI in acute, sub-acute and chronic settings. However, outcome measures for patients in the chronic setting are more variable, whereas outcome measures in the acute and sub-acute settings show more consistency towards improvement in outcomes. Also, prior to training, patients with chronic iSCI who have lower baseline ambulation outcome scores tend to see greater improvements in gait outcomes after training than those with higher baseline scores. There is level 4 evidence that the use of FES (with or without any form of gait training) can improve functional ambulation in patients with iSCI. There is also level 4 evidence that the gains made with FES have carryover effects after completing training with it. This means there is a possibility that training with FES can produce neuroplastic changes in the spinal cord and/or peripheral nerves.
Conclusions	The results of this systematic review tell us that FES-assisted gait training is just as effective as BWSTT or other forms of gait training. However, FES potentially has a carryover effect that other forms of gait training have not been able to show. This systematic review also tells us that gait training is a critical component of patient care with patients who have iSCI, regardless of stage. It also tells us that patients in the acute stage of recovery tend to see greater and more consistent improvement in gait-related outcomes when compared to patients in the chronic stage of recovery.

Author/Title/ Year	Locomotor training approaches for individuals with spinal cord injury: A preliminary report of walking-related outcomes. Field-Fote EC, Lindley SD, Sherman AL. 2005.[6]
Study design, Level of Evidence	Randomized Controlled Trial with 4 groups High quality (6/10 on PEDro scale) Level 2 evidence
Subjects (#, Inclusion/ exclusion creiteria)	27 subjects with iSCI aged 21-64. Greater than 1 year post injury. Levels C3-T10. Subjects recruited **Inclusion criteria:** • iSCI > 1 year prior to study • T10 or above • Able to take 1 step with one leg • Able to perform sit to/from stand transfer with mod A or less **Exclusion criteria:**

	• Current orthopaedic problems • History of cardiac issues • Hip pathology • Physological instability
Outcome Measures and Measurement Timeframe(s)	LEMS 6m walk test 24.4m walk test
Description of Intervention(s)	Patients randomized to 1 of 4 groups: • Manual BWSTT (BWSTT) • BWSTT + FES • BWS over ground + FES (OG + FES) • BWS Lokomat (Robotic) (BWS L) Participants partook in gait training for 45-50 min, 5x/week for 12 weeks.
Results	Short bout and long bout walking speed increased by .03 m/s, on average, across all groups. Training was associated with a 55% increase in short bout walking speed and a 37% increase in long bout walking speed across all groups In the BWSTT + FES group and OG + FES groups, there was a significant increase in short bout walking speed, but not in the other two groups. Walking speed for individuals with baseline walking speeds less than .10 m/s increased greater (.04 -> .08 m/s) than the gait speed for those with baseline speeds greater than .10 m/s (.20 -> .22 m/s) The BWSTT + FES group saw more even increases in step length than the BWSTT group (20% stronger leg and 22% weaker compared to 11% and 24%) OG + FES saw increases of 30% and 27% LR group saw decreases of 1% and 22%

Conclusions	The findings from this study show that all training modalities can increase gait speed and walking performance, with a few exceptions in the LR group. It also tells us that the OG and BWSTT + FES groups saw greater improvements in some statistical data than groups that did not use FES. The greatest of these was step length. It also supports claims in other articles in this evidence table that state that patients with chronic iSCI and low gait speeds at baseline tend to see greater improvements with gait training than those with higher gait speeds. Finally, it shares important information about training on a treadmill vs. testing outcomes over ground. "Training speed [in this study] is not really associated with training outcomes, because those who trained in the OG + FES group walked at slower training speeds, but they had the greatest improvements in tests that tested real-world overground walking ability" (Field-Fote EC, personal communication. February 27th, 2019). Therefore, over ground training tends to translate better to improved outcome measures, whereas training on a treadmill just trains the patient to work with the treadmill.

Author/Title/ Year	Functional Electrical Stimulation to Augment Partial Weight-Bearing Supported Treadmill Training for Patients with Acute Incomplete Spinal Cord Injury: A Pilot Study. Postans NJ, Hasler JP, Granat MH, Maxwell DJ. 2004.[7]
Study design type/level of evidence	Before/after crossover trial with control and intervention group Level 3
Subjects (#, Inclusion/ exclusion creiteria)	14 participants (12 men, 2 women) Mean time post-injury was 12.2 weeks 2 dropouts 1 non-complaint **Inclusion Criteria:** • ASIA Class C or D iSCI with some motor function • Acute iSCI • Non-ambulatory or had severe gait impairments
Outcome Measures and Measurement Timeframe(s)	Walking endurance (via 6MW test) 5x over 3 days during each assessment window Temporal spatial gait variables (6m walk test) x 10 in each assessment period Observational gait analysis (via Rancho Los Amigos Observational Gait Assessment) Clinical examination (MMT) x 2 during each assessment period

Description of Intervention(s)	Treadmill walking with PWB harness-support augmented by FES 25 min/day, 5 days/week, 4 weeks 2 2-channel stimulation units were used that were triggered by patient's shoe strike or by the researchers. Typical FES-stimulation pattern was to stimulate the quadriceps during stance and stimulate the flexion withdrawal response during stepping. Typical BWS percentages were 40%. This was increased or decreased depending on patient's need. Over the course of the study, BWS percentages were slowly reduced depending on patient need. Intervention groups received standard PT for 4 weeks

Results	Treadmill walking
	• All subjects increased walking speed on treadmill (mean increase .175 m/s) in control -> trial group and in trial -> control group (.145 m/s)
	• Distance
	  ○ Control -> trial group (327.3m increase)
	  ○ Trial -> control group (261.2m trial over control)
	• 9 subjects were able ambulate with use of FES but without BWS or assist from researchers by end of trial
	Overground walking
	• CT group saw an increase in endurance (72.2 m)
	• TC group saw an increase of 63.8m (via walking distance)
	• Walking speed improved by .17 m/s in TC group and .23 m/s in CT group

Conclusions	When compared to standard PT, the use of FES and PWB on a treadmill can generate greater increases in walking distance and gait speed in the population of patients with acute iSCI. We still need to transition these patients to over ground walking, and we should still use assistive devices without FES in the chance that the patient cannot use FES after leaving acute care.

Author/Title/ Year	Kim, et al. Effects of a simple functional electrical system and/or a hinged AFO on walking in individuals with incomplete spinal cord injury. 2004.[8]
Study design, level of evidence	Within-subject comparison of walking under 4 conditions Level 3

Subjects (#, Inclusion/ exclusion creiteria)	19 subjects with incomplete spinal cord (iSCI) injury 5 with ASIA C, 14 with ASIA D All subjects volunteered **Inclusion Criteria:** • Present with foot drop • Able to walk independently or with supervision for 6 minutes regardless of AD/orthosis **Exclusion Criteria:** • Orthopedic or other neurological condition
Outcome Measures and Measurement Timeframe(s)	**Primary Outcome:** • 8m walk test (gait speed) • 6 minute walk test (6MW) (endurance) • Foot clearance **Secondary Outcome:** • Manual muscle test
Description of Intervention(s)	FES system used was the WalkAide. Electrodes were located over the common peroneal nerve (just posterior to the head of the fibula). Electrodes fired during swing phase of gait. Participants walked with their usual AD along 8-m distance. 3 trials of each of the following were done by each participant in randomized order: • With AFO (hinged with plantarflexion stop and free dorsiflexion) • With FES • With AFO (same as above) and FES • With no orthosis They then each performed a 6MW test without feedback under each of the situations (split over 2-4 days to reduce fatigue)

Results	One patient was unable to walk without the use of FES. Two participants did not complete all 4 6MW tests Greatest increase in gait speed was found to be FES + AFO (+.07 m/s) compared with "no orthosis" Significant increase in gait speed between FES and "no orthosis" (+.04 m/s) Non-significant increase in gait speed between AFO and "no orthosis" (+.03 m/s) FES + AFO was greatest change from "no orthosis" group for 6MW test distance (32.02 m; significant), followed by AFO (22.35; significant), then FES (13.85 m; not significant). Authors used the Mann-Whitney U tests to address hip flexor/extensor, knee flexor, and ankle dorsiflexor strength. They found that those with reduced strength benefitted more on the outcome measures when using FES than those with greater strength.
Conclusions	This study explored the immediate effects of AFO vs. FES vs. both with regards to gait on patients post-iSCI. They found that using an AFO in conjunction with FES can provide the greatest immediate effect on endurance and gait speed with patients in this population. They also found that the benefit of FES was greater for individuals with weaker leg muscles than those with stronger leg muscles, indicating that these patients may be more appropriate for the use of FES because they will see a greater change in function.

Author/Title/ Year	Functional electrical stimulation for augmented walking in adolescents with incomplete spinal cord injury. Johnston TE, Finson RL, Smith BT, Bonaroti DM, Betz RR, Mulcahey MJ. 2003.[9]
Study Design, Level of Evidence	3-patient case series. Fair quality (16/29 on Downs and Black). Level 4 evidence.
Subjects (#, Inclusion/ exclusion criteria)	3 subjects • 1. 12 y.o. F, C6 ASIA C iSCI 3 years prior • 2. 16 y.o. F, C7 ASIA C iSCI 3 years prior • 3. 17 y.o. M, L2 ASIA C iSCI (timeframe unknown) **Inclusion Criteria:** • Age 6 to 18

	• Motor incomplete SCI demonstrating neurologic stability and functional plateau • MMT less than or equal to 2/5 in hip abduction and/or extension • Ability to attain standing with bracing/assistance if needed • Intact lower motor neurons in targeted muscles • No bony orthopaedic issues • Well managed spasticity • Flexion contractures less than 15 deg at hip and knee • Flexion contractures less than 10 deg at ankle
Outcome Measures and Measurement Timeframe(s)	Data collected at baseline, 3 months, 6 months, and 12 months MMT Energy cost (via Sensormedics Vmax29 metabolic cart) Walking distance Walking speed Step length Cadence Joint kinematics EMG
Description of Intervention(s)	Implanted, percutaneous intramuscular electrodes in more involved extremity Participant 1: Electrodes placed for: • hip abduction (gluteus medius) • hip extension (adductor magnus) • flexion (peroneal reflex) Participant 2: Electrodes placed for: • Hip extension (g. maximus AND adductor magnus) • Hip abduction (g. medius) • Knee extension (vastus lateralis) • Hip flexion (Iliopsoas) • Knee flexion (biceps femoris) Participant 3: electrodes placed for: • Hip extension (g. maximus) • Hip abduction (g. medius) Stimulation parameters: • Biphasic asymmetric waveform • Amplitude fixed at 20 mA • Frequency 20-30 Hz

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Pulse duration 0-200 Hz
Stimulation programs were set and individualized to each patient

Exercise program:

4 weeks of daily exercise
Endurance pattern = Supine exercise for 60 min with stimulation
2.5 sec on/.5 sec off
Strengthening pattern = prone or supine with stimulation
4 sec on/ 8 sec off

Gait program (started after 4 weeks of exercise program):

Timing of stimulation set by sensors in shoe or AFO
Participants 1 and 2 wore AFOs in combination with FES

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<tr><td>Results</td><td>
All participants made improvements in the following categories:

FES on AND off
MMT (greatest in hip abduction and extension)
Cadence

All participants made significant improvements in the following categories:

FES on AND off
Energy cost of walking
Walking distance
Walking speed
Step length
Pelvic stability

All 3 participants felt comfortable using the FES system at home and were pleased with the study. They reported higher functioning with FES training than prior to the study. All 3 participants were able to wean off of FES after 6 months and felt that they maintained their gains through FES-free exercise.
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Conclusions	This study found that there is a carryover effect after the prolonged performance of exercise with FES on. Once all participants reached a certain point (~6 months), they were able to switch their units off and maintain the gains that they had made for 6-months after that point. This study also found that the use of exercise and gait training with implanted electrodes over 6-12 months could potentially improve strength, gait distance, gait speed, pelvic stability, A few considerations need to be made. This study demonstrated low-level evidence considering it is a case series of 3 subjects. Also, since this study ended at 12 months, further research should assess what happens to the gains that are made after that 12-month period ended. Are gains maintained or lost?

Author/Title/ Year	Field-Fote EC. Combined use of body weight support, functional electric stimulation, and treadmill training to improve walking ability in individuals with chronic incomplete spinal cord injury. 2001.[10]
Study Design, Level of Evidence	Longitudinal study design with pre-intervention and post-intervention comparison Level 3a Good quality
Subjects (#, Inclusion/ exclusion creiteria)	19 individuals with ASIA class C incomplete spinal cord injuries. Median time post-injury was 56 months, with 12 months being the absolute minimum. 13 men, 6 women with mean age of 31.7 +/- 9.4 years. 13 of these subjects had tetraplegia while 6 had paraplegia. **Inclusion criteria:** Asymmetric LE strength Ability to perform sit to stand with no greater than moderate assistance Stand upright with no more than 30% of body weight support needed With 30% body weight support they are able to progress one leg forward independently at .1 mph Able to display a robust flexion withdrawal reflex at tolerable levels of electrical stimulation **Exclusion criteria:** This was not listed, but assumed to be an individual that did not meet the inclusion criteria.

<table>
<tr><td>Outcome Measures and Measurement Timeframe(s)</td><td>
Outcomes were measured at the beginning of the study, prior to implementation of the intervention, and again at the end of the end of treatment. There was no blinding or allocation as all participants were recruited.
Primary Outcome:
Overground Walking Speed or Treadmill Walking Speed
This outcome measure is not necessarily standardized itself, but using the data from the 10 meter walk test, it can be assumed that the faster the gait speed, the more functionally independent the patient is. It is also significantly correlated with the 6 minute walk test up to 12 months post-injury.[16]
MCID = .06 m/s in the SCI population[17]
Mean 1.37 m/s in the SCI population[18]
The author measured this outcome on a 2-minute timed walk along an 80-foot track with the subjects walking at a comfortable pace.
Secondary Outcome:
The Lower Extremity Motor Score (LEMS)
This was used for addressing muscle strength in the affected lower extremity vs the non-affected lower extremity. The LEMS is scored based on a 0-5 scale for each lower extremity myotome from L2-S1. This makes each leg scored out of 25 to total score out of 50 bilaterally.[22]
Both of these assessments were administered by the author in the rehabilitation hospital where the study was being performed.
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<tr><td>Description of Intervention(s)</td><td>
Control
No specific control. This study did assess utilize FES only on the less affected leg, however. There is a table of change LEMS score for the affected leg that received treatment with FES vs. the non-affected leg that did not receive treatment with FES.
Experimental
3 months of gait training at a frequency of 3 times per week, 1.5 hours per session.
The patients received this gait training on a treadmill using body weight support (BWS) and functional electrical stimulation. The participants received their BWS at up to 30% body weight because this amount of support most closely aligns with gait mechanics at 0%.[23]
The patients were allowed to select their own walk/rest bouts.
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	Parameters for the stimulation units were standardized at 500ms train, 50 pulses/s, 1 ms duration, and 60-100 volts depending on voltage needed to elicit a flexion withdrawal reflex.

Results	• Good correlation between Over Ground Walking Speed and Treadmill Walking Speed
	    ○ Initial: (r=.71)
	    ○ Final: (r=.82)
	• There was a good correlation between Over Ground Walking Speed and Walking Mobility Score (r=.74)
	• A Median increase of 3 points was shown in LEMS of each leg.
	    ○ FES assisted leg: 8 to 11 ($p < .005$)
	    ○ Non-FES assisted leg: 15 to 18 ($p < .005$)
	    ○ In 4 individuals, LEMS for 1 leg was lower than before training. In 3 individuals, 1 leg showed no change.
	• Correlations were found between OGWS and LEMS
	    ○ Pretraining: moderate (r_s=.64)
	    ○ Post-training: fair (r_s=.39)
	• Mean treadmill distance showed significant increase between initial and final readings (p = .000001)
	    ○ Initial: 93 +/- 84m
	    ○ Final: 243m +/- 139m
	    ○ This increase was reported as statistically significant (p =.000001)
	    ○ Mean difference: -150 m [-76.97, -223.03] indicating that the mean of the first time point is less than the mean of the second time point. But we must consider that the results are highly variable.
	• Mean OGWS improved
	    ○ Initial: .12 +/- .8 m/s
	    ○ Final: .21 +/- .15 m/s
	    ○ This change was reported as statistically significant (p=.0008)
	    ○ Mean difference: -.09 [-0.47, 0.28] Indicating the mean of the first time point is less than the mean of the second time point.
	• Mean TWS improved
	    ○ Initial: .23 +/- .12 m/s
	    ○ Final: .49 +/- .2 m/s
	    ○ This improvement was reported as statistically significant (p=.00003)
	    ○ Mean difference: -.26 [-0.16, -0.36] indicating that the mean for the initial time point is less than the mean for post.

	• A priori power analysis ○ Effect size for OGWS was reported as large (r=.77) and produced a power of 65% The findings from this study show that when we combine functional electrical stimulation and gait training, it can significantly improve lower extremity strength, treadmill gait speed, and treadmill gait distance during gait training. However, they also claimed that it can statistically improve over ground gait training, but the confidence interval of the mean differences calculation (which I did) of the over ground walking speed crosses over 0. This suggests that the actual confidence interval from the study is close to zero, indicating that clinical significance may be questionable. However, with the power analysis provided, the mean effect was large (r=.77), indicating that this improvement in gait speed is clinically significant.
Conclusions	The author concluded that if a patient is able to have some form of ambulatory function post-incomplete SCI, then they could see an improvement in ambulatory functioning when using a walking program that utilizes a combination of body weight support, functional electrical stimulation, and treadmill training. They mentioned that although each patient will see a different result, the findings from this study suggest that there will be improvement. They also stated, "Use of FES for assistance with limb advancement offers advantages over other forms of assistance. This training regimen employs the principles of task-oriented training and uses the purported locomotor-generating circuitry of the spinal cord." (823)[10] This study shows that functional electrical stimulation, when paired with body weight supported treadmill training can demonstrate a significant improvement in treadmill walking speed and treadmill walking distance. These improvements will not be equal in all patients, but nonetheless, will benefit them. However, I am hesitant to state that it can improve over-ground walking speed due to its very wide confidence interval. But, the effect size for OGWS was r = .77, indicating it as large, and therefore very clinically useful. I do agree with the author, in this instance, that a combined gait training intervention using FES and BWSTT can improve both gait speed and distance. It also can improve LE strength as demonstrated by the LEMS increase throughout the interventions.

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