CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

For a 28 year old male with a thoracic incomplete traumatic spinal cord injury who is non-ambulatory, is bike training with functional electrical stimulation (FES) as effective as body weight supported treadmill training with FES for locomotor recovery?

AUTHOR

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CLINICAL SCENARIO

During a clinical experience, the physical therapist had a 28-year old male patient with a mid level incomplete spinal cord injury participating in a body weight supported treadmill training intervention to improve functional mobility and to "reawaken" nerve pathways. After reading about the use of functional electrical stimulation combined with body weight supported treadmill training and cycling in the Christopher and Dana Reeve Foundation's Paralysis Resource Guide, I wondered which intervention would be able maximize functional walking ability in patients with traumatic spinal cord injury, while also utilizing equipment and resources available. Recovery of walking is considered highly important among people with spinal cord injury and paralysis.[1] Bodyweight supported treadmill training with functional electrical stimulation has been used and has been reported in the literature as a means to recover walking ability based on neuroplasticity effects of nerve stimulation of muscle contractions while allowing for a greater number of repetitions.[2,3] Investigation into which type of intervention is most effective is relevant clinically because of potential for improvement in function and independence.

SUMMARY OF SEARCH

- A total of 10 articles met the inclusion and exclusion criteria, out of which, three studies – two RCTs and one systematic review - were selected as "best evidence" based on their quality and relevance. The systematic review represents the highest level of evidence among the group of studies found and contains 2 of the articles that met the inclusion and exclusion criteria found out of the 10 articles (Postans et al 2004, Field-Fote et al. 2011) and thus encompasses more research so more weight is given to its outcomes.
- There were no articles found that investigated the effects of FES cycling on walking ability, so full attention was given to studies looking at the effects of BWSTT with FES on improving functional walking ability. This gap in the research inevitably resulted in comparing various types of locomotor training on walking ability, with BWSTT with FES as the main focus.
- Key findings of this search revealed that for individuals with incomplete spinal cord injury interventions using BWSTT with FES did improve walking ability overall, but failed to show a statistically significant difference when compared to other forms of locomotor training, which including overground walking with body weight support, conventional exercise (consisting of resistive exercise and some form of gait training), robotic assisted, or BWSTT.
- Future research is warranted comparing various types of locomotor training, as well as FES cycling on improving locomotion in individuals with incomplete spinal cord injury. It may be beneficial to compare a more homogeneous group of individuals with a larger population as the studies evaluated contained heterogeneous populations with mostly small sample sizes.

CLINICAL BOTTOM LINE

The research is inconclusive as to a superior type of locomotor training for people with incomplete spinal cord injury to improve walking function. This is significant because improvements of walking function can be made using multiple locomotor training interventions suggesting that access to potentially cost prohibitive equipment may not be crucial in the clinical setting as improvements of walking outcomes, although small, were made regardless of training method.

This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor

SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)
spinal cord injury [meSH] spinal cord injur* SCI thoracic level incomplete	bike bicycl* training cycle training rehab* exercise therapy recumbent bike recumbent bicycle stationary bike functional electrical stimulation FES FES-cycle training FES cycle training	treadmill training locomotor training body weight support* body weight supported treadmill training BWSTT body-weight supported treadmill training body weight-supported treadmill training body-weight-supported treadmill training treadmill training with partial body weight support	locomotor recovery locomotor function (gait OR walk*) walking ability ambulat*

Final search strategy:

PubMed [Filters: Human, English]
#1 (spinal cord injury OR SCI) OR "spinal cord injury" OR spinal cord injur*
#2 bike or bicycle training or cycle training or recumbent bike or recumbent bicycle or stationary bike or FES-cycle training or FES cycle training
#3 treadmill training or locomotor training or body weight support* or body weight supported treadmill training or BWSTT or body-weight supported treadmill training or body weight-supported treadmill training or body-weight-supported treadmill training or treadmill training with partial body weight support
#4 functional electrical stimulation or FES
#5 locomotor recovery or locomotor function or (gait OR walk*) or walking ability or ambulat*
#6 rehab* or exercise therapy
#7 #1 AND (#2 OR #3) AND #4 AND (#5 OR #6)

Databases and Sites Searched	**Number of results**	**Limits applied, revised number of results (if applicable)**
PubMed	**55**	**Humans, English**
CINAHL	**67**	**English, 66**
Cochrane	**68**	
Embase	**185**	**English, 182**
PEDro	**31**	**English, 30**
AMED	**13**	

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
• Published in English • Randomized control trials, controlled trials, uncontrolled trials, or systematic reviews • Published up to September 2015 • Interventions that include body weight supported treadmill training with functional electrical stimulation or biking with functional electrical stimulation or a combination of the two • Studied populations post traumatic spinal cord injury that are classified as incomplete and occur at the

thoracic level
- Subjects were not able to ambulate at baseline prior to ambulation with or without an assistive device or assistance
- Measured gait ability with or without assistive device at baseline and post intervention

Exclusion Criteria

- Participants were primarily children, adolescents, or older adults
- Levels of evidence 3-5 in the hierarchy; i.e. case studies, case series, qualitative studies, narrative review articles, expert opinion papers, dissertations.

RESULTS OF SEARCH

Summary of articles retrieved that met inclusion and exclusion criteria

Author (Year)	Study quality score	Level of Evidence	Study design
Field-Fote EC. (2001)[4]	**D&B = 13/29**	**2b**	**Quasi-Experimental (time-series design)**
Field-Fote EC, Tepavac D. (2002)[5]	**D&B = 13/29**	**2b**	**Quasi-Experimental (time-series design)**
Field-Fote EC, Roach KE. (2011)[6]	**PEDro = 6/10**	**1b**	**RCT**
Kapadia N, Masani K, Craven B, Giangregorio L, Hitzig S, Richards K, Popovic M. (2014)[7]	**PEDro = 6/10**	**1b**	**RCT**
Kuhn D, Leichtfried V, Schobersberger W. (2014)[8]	**D&B = 18/29**	**2b**	**Quasi-Experimental (time-series design)**
Mehrholz J, Kugler M, Pohl M. (2008)[9]	**AMSTAR = 9/11**	**1a**	**Systematic Review**
Morawietz C, Moffat F. (2013)[10]	**AMSTAR = 6/11**	**1a**	**Systematic Review**
Nooijen CFJ, Ter Hoeve N, Field-Fote EC. (2009)[11]	**PEDro = 4/10**	**1b**	**RCT**
Postans NJ, Hasler JP, Granat MH, Maxwell DJ. (2004)[12]	**PEDro = 5/10**	**1b**	**RCT**
Sharif H, Gammage K, Chun S, Ditor D. (2014)[13]	**D&B = 14/29**	**2b**	**Quasi-Experimental (time-series design)**

BEST EVIDENCE

The following 3 studies were identified as the 'best' evidence and selected for critical appraisal. Reasons for selecting these studies were:

- **Mehrholz et al. 2008**[9]**:** This Cochrane database systematic review and meta-analysis was chosen because it represents the study with the highest level of evidence among the group of studies found. It also contains 2 of the articles that met the inclusion and exclusion criteria (Postans et al 2004, Field-Fote et al. 2011), so ultimately this choice will include the most research so greater credibility will be given to its outcomes. Two RCTs were chosen over the Morawietz and Moffat[10] systematic review because they specifically evaluated BWSTT with FES compared with other forms of training rather than providing an overview of all locomotor interventions.
- **Field-Fote & Roach 2011**[6]**:** This RCT was chosen because of its relevance to the question in terms of the intervention measured (BWSTT with FES), outcomes measured (walking function), and the participant characteristics (incomplete SPI) and age was similar to the patient driving this clinical question. Also, this RCT is among the most highly rated in terms of methodological quality compared to the other RCTs. Furthermore, this RCT compares four modes of locomotor training (including BWSTT with FES), which will help guide clinical decisions when choosing interventions for this patient.
- **Kapadia et al. 2014**[7]**:** This RCT is the most recent and is ranked the highest in terms of methodological

quality compared to the other RCT's found. This RCT compared BWSTT with FES directly to a control group participating in resistive exercises exercises that was matched 1:1 for time with the experimental group. This was the only study found to use a four-channel FES system, which may be a more comprehensive form of locomotor training with FES.

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of *Locomotor training for walking after spinal cord injury* by Mehrholz J, Kugler J, Pohl M., (2008).

Aim/Objective of the Study/Systematic Review:

The authors sought to determine, through a comprehensive search of the literature, the effects of various types of locomotor training on the recovery of walking ability, specifically gait speed and gait capacity (primary outcomes), on people with incomplete spinal cord injury (ASIA B, ASIA C, ASIA D). The authors also set out to determine the effects of locomotor training on independence level, as well as, the overall safety of locomotor training measured through adverse effects and dropout rates (secondary outcomes).

Study Design

This study design was a systematic review with a sub-group meta-analysis.

Search strategy:

- The reviewers searched the following on and up until Nov 2 2011: Cochrane Injuries Group Specialised Register, Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (Ovid) (1948 to 2011); EMBASE (Ovid) (1980 to 2011); CINAHL (1982 to 2011); ISI Web of Science Citation Index Expanded (SCI-EXPANDED) (1970 to 2011); ISI Web of Science: Social Sciences Citation Index (SSCI) (1970 to 2011); ISI Web of Science: Conference Proceedings Citation Index – Science (CPcI-S) (1990 to 2011); ISI Web of Sciene: Conference Proceedings Citation Index – Social Sciences & Humanities (CPci-SSSH) (1990 to 2011); PuMed: Allied and Complimentary Medicine Database (AMED) 1985 to 2011; SPORTDiscus (1949 to 2011); the Physiotherapy Evidence database (PEDro); COMPENDEX (1972 to 2011); INSPEC (1969 to 2011).
- The reviewers also searched the reference lists of articles found to be relevant and the following conference proceedings: World Congress of Physical Medicine and Rehabilitation (2001, 2003, 2005, 2007, 2009, 2011); World Congress of Physical Therapy (2003, 2007, and 2011); Deutsch Gesellschaft fur Neurotraumatologic und Klinische Neurorehabilitation (2000 to 2011); Deutsche Gesellschaft fur Neurologic (2000 to 2011); Deutsche Gesellschaft fur Neurorehabilitation (1999 to 2011).

Selection criteria: The reviewers included randomized controlled trials– parallel group and crossover designs - only evaluating the first arm if a crossover design. RCTs included participants of all ages and genders with incomplete SCI (ASIA B,C,D), at any time following injury (acute and chronic). The reviewer included studies comparing the following forms of locomotor training: body weight supported treadmill training of any form, overground training, training modes with FES, and robotic training to control groups which included exercise, no exercise, or against other forms of locomotor training. RCT's were excluded if they contained training that was only a partial component of gait training.

Methods:

- Selection of studies: A Coordinator for the Injuries Group Trials Search and authors searched and obtained articles. Two authors reviewed abstracts and titles of potential studies independently and then obtained and reviewed the full text to determine if they met inclusion/exclusion criterion. Disagreements were settled through discussion between all three review authors.
- Data extraction/management: The two authors extracted data independently from included trials onto a data extraction form that was then checked and verified between authors, with any disagreements checked by the third author. The authors attempted to obtain missing data from the Coordinator for Injuries Group Trials Search or from the authors of included trials.
- The authors independently assessed the studies using the PEDro scale with a score of 10 points being the maximum score, with disagreements being resolved through discussion.
- The I^2 statistic was used to assess heterogeneity. If heterogeneity, between outcomes, participants, or interventions, was found to be statistically significant, then a random-effects model was used in place of the fixed-effects model.
- To measure treatment effect the authors calculated the mean difference for all outcome measures, which were scaled using intervals and a pooled estimate of the mean difference using a fixed effect or random effects model with a 95% confidence interval. Authors used a relative risk calculation for outcomes using binary scale and risk differences with a 95% CI when no between group adverse effects or dropouts were noted.
- Authors conducted three subgroup analysis: 1) BWSTT versus all other forms of training, 2) Robotic Assisted training versus all other forms of training, 3) FES and BWSTT versus all other forms of training. A separate analysis was not performed for time effect of the interventions due to the low number of studies included.

- Reviewers did not perform a sensitivity analysis because of the low number of studies, which were identified and found to have good methodological quality.

Setting

Four out of the five included studies took place in the US and one study took place in the United Kingdom. One study was a multi center study (Field-Fote 2011), however, the settings of the other four studies were not specified in this systematic review.

Participants

- A total of N=309 participants were included in this systematic review from the 5 included RCTs, ranging from 14 to 146 participants in each study
- Eligibility criteria varied from study to study with the general inclusion criteria across studies including participants that had obtained a spinal cord injury. Some studies specified a certain level, while other specified a certain classification system, such as ASIA C and ASIA D. The time since injury varied from study to study. Exclusion criteria varied as well with medical issues cited most frequently.
- The age range of participants in the included studies is 18-68, with no mean age across studies calculated. Mean age range for both experimental and control groups of all studies was 24-42 years old.
- The gender ratio for 3 out of 5 studies was 2.6 males to females - 89 male participants to 34 females.
- The range of the level of spinal cord injury of the participants is C3 to L4 with a range of ASIA A-D at baseline.
- Mean time between injury and study intervention ranged widely from 51 days to 8 years.
- Percentage of dropouts ranged from 13%-20% across studies.
- Percentage of adverse effects ranged from 0%-14% across studies.

Intervention Investigated

Control

- Overground walking was the most common control group used in three of the RCTs, physical therapy was used as a control group for one of the RCTs and the crossover design study. The one RCT that compared four types of locomotor training had no control group.
- Control groups matched the frequency and time per session to that of the experimental group.

Experimental

- Intervention protocol for studies included some form of either body weight supported (BWS) locomotor training or robotic assisted treadmill locomotor training. The following are the types of BWS locomotor training interventions: BWSTT (3), BWSTT with FES (2), BWSTT training with manual assist (1), BWS overground gait training (1), BWS overground training with FES (1),.
- Frequency ranged from 2-3 x's per week to 5 x's per week with the duration of the treatment varying as well, ranging from 4 weeks to 12 weeks.
- Intervention sessions ranged from 30-45 minutes/session to 60 minutes/session.
- Frequency and time were similar across locomotor training groups if there was no control group.

Outcome Measures (Primary and Secondary)

- The primary outcome measures were walking speed and walking capacity. Walking speed was most commonly measured over a 10-meter or 15-meter distance at a casual pace or a pace that was the participants fastest. Assistance was allowed during the walking speed test. Walking capacity was measured most often using the 6-minute walk test (6MWT).
- Secondary outcome measures were level of independence, safety, and dropout rate. Level of independence was measured through the use of the FIM, SCIM, or the WISCI. A participant was considered a dependent walker if a score of 5 or less on the walking portion of the FIM and a score of 3 or less on questions 12-14 of the SCIM. Safety and dropout rate was measured through the prevalence any adverse health events or reported dropouts respectively.

Main Findings

- All of the forms of locomotor training evaluated by this systematic review failed to show a significant improvement on walking capacity as measured by walking speed, walking capacity, and walking function. Safety and dropout rate was found to be similar with no significant differences across groups. Robotic training was found to have a negative effect on walking capacity, however, only involved one study (N=74).
- Due to the small number of studies a sensitivity and sub-group analysis was not performed.

The authors conducted a statistical analysis of **BWSTT** compared to all other types of training:

Walking Speed:

- 4 studies (N=274) provided data regarding walking speed at the end of the intervention period. Pooled mean difference (MD) using the fixed-effects model was 0.03m/s (95% CI -0.05 to 0.11, P=0.52, heterogeneity I^2=22%).

Walking capacity:

- 3 studies (N=234) provided data regarding walking capacity at the end of the intervention period. Pooled mean difference (MD) using the random-effects model was -1.25 meters (95% CI -41.26 to 3.77, P=0.95, heterogeneity I^2=62%).

Independence

- 1 study (N=146) provided data regarding walking independence at the end of the intervention period. Risk difference (RD) was 0.07 (95% CI -0.08 to 0.23, P=0.36).

Safety:

- 5 studies (N=309) provided data regarding adverse effects at the end of the intervention period. Risk difference (RD) using the fixed-effects model was 0.03 (95% CI -0.02 to 0.07, P=0.21, heterogeneity I^2=0%).

Dropouts:

- 5 studies (N=309) provided data regarding drop out rate at the end of the intervention period. Risk difference (RD) using the fixed-effects model was -0.05 (95% CI -0.13 to 0.04, P=0.29, heterogeneity I^2=0%).

The authors conducted a statistical analysis of **BWSTT and FES** compared to all other types of training:

Walking Speed:

- 2 studies (N=88) provided data regarding walking speed at the end of the intervention period. Pooled mean difference (MD) using the fixed-effects model was 0.03m/s (95% CI -0.11 to 0.06, P=0.53, heterogeneity I^2=50%).

Walking capacity:

- 1 study (N=14) investigating BWSTT and FES included data that was not comparable at baseline so it could not be used. 1 study (N=74) provided data regarding walking capacity at the end of the intervention period. Pooled mean difference (MD) using the fixed-effects model was 2.43 meters (95% CI -10.82 to 15.67, P=0.72).

Independence

- Not measured by studies investigating BWSTT and FES.

Safety:

- 2 studies (N=88) provided data regarding adverse effects at the end of the intervention period. Risk difference (RD) using the fixed-effects model was 0.00 (95% CI -0.09 to 0.09, P=1.0, heterogeneity I^2=0%). Range was 0%-14%.

Dropouts:

- 2 studies (N=88) provided data regarding drop out rate at the end of the intervention period. Risk difference (RD) using the fixed-effects model was 0.05 (95% CI -0.11 to 0.22, P=0.52, heterogeneity I^2=0%).

The authors conducted a statistical analysis of **Robotic Assisted** compared to all other types of training:

Walking Speed:

- 4 studies (N=274) provided data regarding walking speed at the end of the intervention period. Pooled mean difference (MD) using the fixed-effects model was 0.06m/s (95% CI -0.01 to 0.13, P=0.11).
- 1 study (N=35), data could not be pooled due to only providing median values.

Walking capacity:

- 1 study (N=74) provided data regarding walking capacity at the end of the intervention period. Pooled mean difference (MD) using the random-effects model was -10.25 meters (95% CI -41.26 to 3.77, P=0.95, heterogeneity I^2=62%).
- 1 study (N=35), data could not be pooled due to only providing median values.

Independence

- Not performed because authors were unable to pool data based on data provided in individual studies.

Safety:

- 2 studies (N=109) provided data regarding adverse effects at the end of the intervention period. Risk difference (RD) using the fixed-effects model was 0.00 (95% CI -0.07 to 0.07, P=1.0, heterogeneity

I^2=0%). Adverse events were 0%.

Dropouts:

- 2 studies (N=109) provided data regarding drop out rate at the end of the intervention period. Risk difference (RD) using the fixed-effects model was 0.05 (95% CI -0.13 to 0.15, P=0.94, heterogeneity I^2=58%). Dropout rate was between 0%-23%.

Original Authors' Conclusions

Due to the limited amount of research available, the authors concluded that there is no particular method of locomotor training, which will significantly improve walking capacity or increase adverse events in people with spinal cord injury. The authors contend that this is due to the small number of studies included in this systematic review and the heterogeneous nature of the participants across groups. Based on one study (Field-Fote 2011-also reviewed in this CAT), robotic assisted locomotor training may negatively affect walking capacity as a statistically significant decrease was detected.

Critical Appraisal

Validity

This review is considered to be of high quality considering it is a Cochrane review, which is held to some of the highest methodological rigor in terms of systematic reviews. Also, a meta-analysis, using pooled data, was conducted when data from individual studies was available. The investigators did limit the review to only high quality studies, namely RCTs, and provided an adequate amount of details regarding their search and selection of studies. There was an attempt to reduce publication bias through the search of both published and unpublished sources, although there is always the risk of missing studies. Bias was reduced through the use of two independent reviewers with disagreements being resolved through discussion with a third reviewer. This review did address the potential for bias in each individual study in terms of selection bias (random sequence generation and allocation concealment) and detection bias (blinding of outcome assessors). Two individual studies included in this review were found to be at a high risk for bias in terms of detection bias due to assessors not being blinded. Also, there was an overall lack of evidence due to the small number of studies included and the interventions across studies lacked heterogeneity. The inclusion of studies with a possibility of bias may reduce the overall validity of the findings of this systematic review, although being that the results were not statistically significant, it may not have a large impact.

Interpretation of Results

Based on the evidence presented in this systematic review there does not seem to be a superior locomotor intervention at improving gait ability in people with incomplete spinal cord injury. However, one must be cautious when interpreting these results due to the apparent lack of support as evidenced by the inclusion of only 5 studies (4 of which were relatively small). It is possible that there is a potential benefit, which a small sample was unable to detect. Furthermore, there may be a certain population among people with incomplete spinal cord injury that would benefit significantly from locomotor training, but has yet to be identified. Another limitation of this systematic review is that it was not possible to compare all 5 studies at once because of the heterogeneity of the interventions. This was true for walking speed and distance, which was the main outcome of interest. One exception is that the meta analysis compared BWSTT to all other interventions for all 5 studies for safety and dropout rate - no statistical difference was found in terms of safety or dropout rate – suggesting that all of the interventions are generally safe and that adverse events are unlikely.

This systematic review also revealed small effect sizes, which were all very near zero, indicating little or no effect of the three interventions (BWSTT, BWSTT with FES, and robotic-assisted) when compared to other interventions. For example, the effect sizes for walking capacity ranged from -1.25 meters for BWSTT to 2.43 meters for BWSTT with FES. BWSTT with FES does show a greater effect size, a gain of 2.43 meters compared to -1.25 meters, however these results are neither statistically nor clinically significant, especially when realized during the 6MWT. According to a systematic review by Lam et al., a person with an incomplete spinal cord injury needs to walk 45.8 meters to detect a minimal change.[14]

The effect sizes were also small in terms of walking speed as well, 0.03m/s [95% CI -0.05,0.11], 0.03m/s [95% CI -0.11,0.06] for BWSTT and BWSTT with FES, respectively. According to Lam et al. 0.13m/s is clinically significant when measuring walking speed during a 10MWT.[14] Based on the confidence intervals, there were some participants in the studies that came close to that minimally clinical difference.

The largest effect size was noted for robotic assistive locomotor training showing a negative correlation and an effect of -10.25 meters, which was statistically significant, although not according to the systematic review by Lam et al, which determined 45.8 meters was needed to detect a minimal change.[14] These results give some indication at the ineffectiveness of robotic assisted gait training at improving walking capacity when compared with other training methods. Although, these results must also be interpreted with caution, as these results were based on 1 study (Field-Fote 2011 - which is reviewed in detail in this CAT).

(2) Description and appraisal of *Influence of a locomotor training approach on walking speed and distance in people with chronic spinal cord injury: A randomized clinical trial* by Field-Fote, E. C. and Roach, K. E. (2011).*

***Some information obtained from published early findings of the same study: Field-Fote EC, Lindley SD, Sherman AL. Locomotor training approaches for individuals with spinal cord injury: a preliminary report of walking-related outcomes. *J Neurol Phys Ther.* 2005;29(3):127-137.**[15]

Aim/Objective of the Study/Systematic Review:

The main objective was to determine which type of four locomotor training approaches had the greatest impact on walking speed and distance in people with chronic incomplete spinal cord injury. The four locomotor training approaches all provided body weight support:

1. Treadmill training with manual assistance (TM)
2. Treadmill training with electrical stimulation (TS)
3. Overground walking with electrical stimulation (OG)
4. Treadmill training with robotic assistance (LR)

The secondary objective was to see which if there were any significant improvements in leg strength.

Study Design

- Single blinded randomised controlled trial.
- Subjects were randomly stratified into 4 groups based on pre-training Lower Extremity Motor Scores (LEMS).
- Sample of convenience.
- Recruitment began in May 2002, final training session completed on December 2008.
- Of the 3,396 registrants, 802 were identified as eligible and contacted.
- Primary outcome measures were taken before and after training on different days to avoid fatigue - subjects were allowed to use orthotics and assistive device as needed.
- Baseline measurement compared using ANOVA and chi-squared tests, intervention effects, both time X group interaction and time effect, were compared using repeated measures ANOVA; upon finding a time effect, paired t tests were used to compare pre and post changes between group, and upon finding a time effect a paired *t* test was used.

Assessors who performed the assessment and analysis of walking speed and distance data were blinded.

Setting

All training and recruitment took place at The Miami Project to Cure Paralysis at the University of Miami's, Miller School of Medicine.

Participants

- 74 total subjects were enrolled. TM: N=19, TS: N=22, OG: N=18, LR: N=15.
- Method of recruitment: eligible subjects contacted through a single research subject volunteer registry
- Inclusion criteria for subjects: injury occurring at T10 or above, classified as (American Spinal Injury Association) ASIA C or ASIA D according to the international Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI), > 1 year post SCI, able to take a minimum of 1 step with 1 leg, and able to stand with up to moderate assistance from 1 person.
- Exclusion criteria for subjects: current orthopaedic condition, history of cardiac condition, a hip pathology, which has been detected through imaging that may be exacerbated through training.
- Gender: 51 male, 13 female (N=64).
- Mean age by group: TM: 39.3 years (SD=14.6), TS: 38.5 years (SD=12.7), OG: 42.2 years (SD=15.7), LR: 45 years (SD=8).
- 10 participants in total withdrew (TM group= 2, TS group= 4, OG group= 3, LR group= 1).
- At baseline, where N=64, groups were not statistically different in the following: age, height, weight, gender, LEMS score for R leg, LEMS score for L leg, walking speed, walking distance.

Follow-up: A convenience sample of 10 participants who showed improvement in walking speed.

Intervention Investigated

All four experimental groups (TM, TS, OG, LR)

- Subjects trained 5 days per week for 12 weeks; sessions lasted 1 hour (set up and takedown accounting from approximately 10-15 minutes).
- Subjects were encouraged to walk as fast as possible, encouraged to aim for 13 (moderate) on the Borg exertion scale, and were allowed to rest as needed.
- Body weight support provided was no more than 30% of body weight.

- Subjects were allowed to use upper extremities for support as needed.
- All training took place at the Miami Project location mentioned above.
- There was no specific mention who was providing the training during the interventions. However, it did say that Field-Fote, one of the authors, made clinical judgements in regard to safety and use of orthotics.

Experimental by group

Treadmill training with manual assistance (TM), Treadmill training with electrical stimulation (TS)

- Treadmill speed was increased progressively until gait quality degraded and then reduced slightly to a level where step quality was acceptable.
- After 1-2 minutes, speed was increased by 0.2miles/hour and then reduced to previous speed after subject completed 10 steps.
- Once subject recovered from increased walking speed, speed was again increased as described above until the subject was able to complete 20 steps.
- Subjects were encouraged to swing arms during training session.

Overground walking with electrical stimulation (OG) – WalkAide Stimulator

- Subjects walked around an 80 foot track.
- Subjects were allowed to use assistive device and orthotics as needed.

Treadmill training with robotic assistance (LR) – Lokomat robotic gait orthoses

- Beginning treadmill speed was 1.6mile/hour, increased each week by 0.1miles/hour.

Outcome Measures (Primary and Secondary)

- Primary outcome measures: Walking speed and distance:10 Meter walk test to detect walking speed (average of 5 trials), 2 minute walk test overground to measure functional exercise capacity (use assistive device and orthotics as needed).
- No indication was given in regards to who administered the testing, however, video recording and video analysis were performed by blinded party.
- Testing occurred pre and post 5 week training session on different days to avoid fatigue.
- Secondary outcome measure: LEMS score - part of the ASIA ISNCSCI classification tool - to measure changes in lower extremity strength (Authors did not provide information regarding scoring/administration of LEMS assessment).
- Follow-up testing of 10 subjects (sample of convenience) who met or exceeded MCID of 0.05m/s.

Other outcomes are reported in a separate paper presented by Nooijen et al. (2009) titled Gait quality is improved by locomotor training in individuals with SCI regardless of training approach.

Main Findings

Primary outcomes:

- Walking speed (minimally important difference = 0.05m/s): between group differences were not statistically significant (P=0.0930).
- Walking speed showed statistically significant improvements for TM (mean difference = 0.04m/s, SD = 0.07), TS (mean difference = 0.05m/s, SD = 0.09), and OG (mean difference = 0.09m/s, SD = 0.11) groups. The effect sizes were TM = 0.28, TS = 0.28, and OG = 0.43.
- Walking distance (minimally important difference = 4 meters): between group differences were statistically significant (P=0.004).
- Walking distance improvement was statistically significant for TS (mean difference = 3.8m, SD = 6.3) and OG (mean difference = 14.2m, SD = 15.2) groups. The effect size for TS = 0.16, and OG = 0.40.

Secondary outcomes:

- LEMS between group differences were not significant for either the right leg (P=0.9360) or the left leg (P=0.8718).
- LEMS improvement was statistically significant for left leg: TM (1.7points, SD = 1.8), TS (1.5points, SD = 2.7), OG (1.1points, SD = 1.5) and right leg TM (1.5points, SD = 2.1), TS (1.6points, SD = 2.0), OG (1.7points, SD = 2.3), LR (1.3points, SD = 1.5).

Follow up (tested an average of 20.3 months after training (SD=14.3 months):

10 participants declined in walking speed an average of 0.06m/s, SD=0.07, no significant time effect was found (P-55, r = -21).

Original Authors' Conclusions

The author concluded that overground training provides the greatest improvements in functional capacity as measured by walking distance. The author found that walking distance is a better measure for functional capacity than walking speed based on the results of this and other studies, as well as, their own clinical

observations while working with people with spinal cord injuries. The author reasoned that because overground walking requires more effort for forward progression, this might indicate that the practice of "initiating the step" is more important than greater repetition realized during treadmill training.

Limitations noted by the author: 1) training duration, number of sessions and length of session, was based on clinical judgement and may not have been optimal 2) focus was on walking speed and not on form 3) subjects used a wheelchair as primary mobility device which may have shown a smaller change compared with community ambulatory subjects 4) robotic device used assisted with gait regardless of subject effort 5) small sample size (N-10) obtained for long term follow up.

Critical Appraisal

Validity

- PEDro Scale score: 6/10 based on Eligibility Criteria: Yes; Random Allocation: Yes; Concealed Allocation: No; Baseline Comparison: Yes; Blind Subjects: No; Blind Therapist: No; Blind Assessors: Yes; >85% participant outcomes: Yes; Intention to treat analysis: No; Between group comparison: Yes; Point estimates and variability: Yes.
- The internal validity of this study is strengthened by the power to show a large enough sample size (n=16 in each group), yet weakened by lack of blinding of assessors (although not specifically mentioned); however the people recording and analysing the video of the pre and post test were blinded, the participants and therapists administering and providing instructions for the pre and post tests and walking interventions were not blinded and therefore could have biased the outcomes. Blinding of the subjects would not be possible in this type of study.
- The external validity of this study is strengthened because it is a reasonable representation of a fairly diverse population of participants, as evidenced by the percentage (~23%) of eligible participants out of the entire registry (3,396) at the Miami Project to Cure Paralysis. However, external validity is weakened because 1) this type of training requires specialized equipment (treadmills, harnesses, etc.) and may not be accessible for people outside of this study, and 2) the time commitment may be high (5 days a week for 12 weeks).
- Intention to treat analysis was not used to account for missing data: it was reported that the 10 subjects that dropped out has similar baseline characteristics but had significantly lower average walking speeds (0.06m/s vs. 0.18m/s P<.0001) and average walking distances (5.16m vs. 21.0m P<.0001) compared with the other participants at baseline. This reduces validity of this study because without these more impaired participants accounted for, the results may appear more significant (type I error).
- Walking distance, one of the primary outcomes, and LEMS were not measured during follow up.

No questionnaires were used in this study; which could be helpful in terms of clinical significance – questions regarding quality of life, increased ambulation as a result of the interventions, and depression.

Interpretation of Results

Results favoured body weight supported overground walking training with electrical stimulation (OG) compared with the three other body weight supported treadmill training groups (TS, TM, LR) for improved walking distance in a non-ambulatory population with chronic spinal cord injury classified as ASIA D or ASIA C at or above T10. It appears based on the results of this study that OG training led to a significantly greater improvement in walking distance covered. The absolute improvement for distance covered in the OG group was statistically and clinically significant and was found to be an average of 14.2 meters (SD=15.2), which is equivalent to about 46.5 feet. The results appear to support greater improvements for patients who are less impaired in regards to strength.

Strengths of this study include a fairly large trial (N=64) spanning many years with a sample size of 16 per group calculated by the authors to show a large effect (0.80). Also, a long-term follow up study of participants was performed. While there are strengths to this study, they may be overshadowed by the weakness, which reduce the credibility and validity of the results. A few of the major weaknesses include the possibility of bias from the lack of blinding of the people providing treatment *and* instructing the subjects during pre and post testing - although not explicitly stated, it can be assumed that this was the case. Also, dropouts included significantly more impaired subjects as evidenced by their low baseline scores, no intention to treat was performed, so there is a greater possibility for a type I error to occur.

The results that were found to be statistically significant, other than the significant improvements in the OG groups walking speed and walking distance, had relatively small effect sizes and were not clinical significant. In terms of training, the LR group showed the least amount of improvement, which may be clinically relevant in terms of avoiding this treatment option in order to improve the outcomes measured in this study. Clinically, the results of the study are significant and encouraging as they offer a lower cost, less cumbersome intervention with positive results.

(3) Description and appraisal of *A randomized trial of functional electrical stimulation for walking in incomplete spinal cord injury: Effects on walking competency* by (Kapadia, N. Giangregorio, L. Craven, C. Richards, K. Hitzig, S. L. Masani, K. Popovic, M.R., 2014)*

***Some information obtained from published findings on different outcomes from the same study**

- **Hitzig SL, Craven BC, Panjwani A, et al. Randomized trial of functional electrical stimulation therapy for walking in incomplete spinal cord injury: effects on quality of life and community participation. Top Spinal Cord Inj Rehabil. 2013;19(4):245-258. doi:10.1310/sci1904-245.**[16]
- **Giangregorio L, Craven C, Richards K, et al. A randomized trial of functional electrical stimulation for walking in incomplete spinal cord injury: Effects on body composition. J Spinal Cord Med. 2012;35(5):351-360. doi:10.1179/2045772312Y.0000000041.** [17]

Aim/Objective of the Study/Systematic Review:

The aim of this study was to investigate the effects of 16 weeks of locomotor training using a multichannel functional electrical stimulation unit to improve voluntary overground walking ability in people with a chronic incomplete spinal cord injury.

Study Design

- Single center randomized controlled trial
- 1:1 randomization occurred by having participants choose a sealed envelope, which contained a number that corresponded to either the control or experimental group.
- Assessors of outcome measures were blinded and were assessed at baseline, 4 months, 6 months, and 12 months.
- A 2 way repeated measure analysis of variance was used to compare groups across time at baseline, 4 months, 6 months, and 12 months to determine if a difference exists. Alpha set to 0.05.
- Bonferroni post hoc test to determine which groups are different.
- 34 participants was the target number for recruitment based on the original aim of the study, which was to investigate the effects of the interventions on tibial cortical bone mineral density, which was determined would demonstrate the smallest effect size. This sample size did take into account a 20% attrition rate.

Setting

Lyndhurst Centre, Toronto Rehabilitation Institute, University Health Network, Canada

Participants

- 47 were recruited and assessed for eligibility as a sample of convenience from the Lyndhurst Centre - 13 were excluded (12 failed to meet inclusion criteria and 1 was injured).
- 34 provided conformed consent and were included in the study and randomized, 17 in each group. 6 in the control group and 1 in the experimental group were lost to follow up.
- Inclusion criteria: Patients with a SPI classified as ASIA C or ASIA D, >18months post injury, not able to walk at baseline, require an assistive device to walk, or walk ≤ 0.5 m/s.
- Exclusion criteria: Any contraindication for FES (pacemaker, rash or skin lesion at site of electrodes, denervation of muscle targeted, grade 4 pressure ulcer on the lower extremities, Grade 2 or 3 pressure ulcer or above that comes in contact with the harness, uncontrolled hypertension, orthostatic hypotension within 15 minutes of standing, or at risk for autonomic dysreflexia.
- Mean age – Experimental group: 56.6 (14), Control group: 54 (16.5).
- Gender – M% – Experimental group: 82% (14), Control group: 71% (12).
- Duration of injury (years) - Experimental group: 8.75 (9.75), Control group: 10.32 (11.13).
- No significant differences between groups at baseline.

Intervention Investigated

- Sessions lasted 45 minutes, 3 days per week for 16 weeks (48 total sessions) for both groups.

Control

- Protocol: 20-25 minutes of aerobic training (arm cycle, leg cycle, ambulating using parallel bars or treadmill) at a moderate pace (target of 3-5 on modified Borg), 20-25 minutes of resistance exercise (hand weights, cables, Uppertone training system) consisting of 2-3 sets of 12-15 repetitions at a maximum resistance for all capable muscle groups.
- Kinesiologists supervised exercise for the control group.

Experimental

- Protocol: Body weight supported treadmill training (BWSTT) with FES to the quadriceps, hamstrings,

dorsiflexors, and plantiflexors was conducted for 4-5 minutes with rest breaks in between for a total of 45 minutes. The authors of the study did not specify walking speed or percentage of body weight support.
- During the first 3-5 sessions, 2-3 therapists were required for training to control the sequence of the FES system, two therapist timing the push of a button with the push off phase of gait for one leg and, if needed, one to advance lower extremities or control hips, in order to produce a fluid and natural gait pattern. After 3-5 sessions, participants were able to press the buttons during training.

Outcome Measures (Primary and Secondary)

- Gait: 1) gait speed as measured by the 10-meter walk test, 2) gait distance as measured by the 6 minute walk test (6MWT) and distances were recorded at 2 minutes, 4 minutes, and 6 minutes. Participants were allowed to use an assistive device, however, no manual assistance was given during testing. 3) Assistive device score (ADS), and 4) walking mobility scale (WMS).
- Balance and mobility: Measured using the timed up and go (TUG).
- Function: 1) Functional independence measure locomotor score (FIM-L) – score 0-7, 7 complete independence with activity, 2) the Spinal cord independence measure (SCIM), SCIM assessed at baseline and 12 months only – self-care 0-20, respiration/sphincter management 0-40, mobility 0-40, a higher score indicates a higher level of independence with each activity.
- Spasticity: 1) Modified Ashworth Scale for the following muscle groups: hip adductors, knee flexors, knee extensors, dorsiflexors, and plantarflexors, and 2) Pendulum test – measured using an electrogoniometer.

A research assistant who was blinded to the allocation obtained all outcome measures and all interventions and measurements took place at the Lyndhurst Centre in Toronto.

Main Findings

Overall, there were no significant group x time interactions or differences between groups or a time reaction on any of the outcome measures, except SCIM mobility subscale for interaction. Statistical findings below:

Significant findings:

- SCIM mobility subcale was statistically significant for interaction, F=10.716, (P=0.003).

Significant overall improvements:

- All groups SCIM scores improved over time, regardless of which group the participant was in F=4.75 (P=0.039).
- TUG scores were significant over time for all groups, F=5.55 (P=0.016).
- MAS - Right quadriceps showed statistically significant worsening of spasticity in both groups at baseline and 4 months F=5.272, (P=0.015).Control group F=0.58 (SD=1.17) at baseline and F=0.92 (SD=1.24) at 4 months; experimental group F=0.13 (SD=0.34) at baseline and F=0.44 (SD=0.81) at 4 months.

Non significant findings:

- Walking speed measured by the 10-meter walk test was not statistically significant between groups F=0.048, (P=0.829), over time (P=0.084), nor when measured for interaction (P=0.195).
- Walking distance covered in 2 minutes during the 6MWT did improve for most participants; F=7.09m (P<0,001) at 2 minutes, F=6.33m (P=0,001) at 4 minutes, F=5.80m (P=0,002) at 6 minutes. However, the distances improved were not statistically significant between groups at 2 minutes F=1.79, (P=0.199), 4 minutes F=2.40, (P=0.141), or at 6 minutes F=3.18, (P=0.096). There were also no significant differences over time or when measured for interaction at 2 minutes, 4 minutes, or 6 minutes. (It should be noted that out of the 34 participants, 18 were able to perform the 2 minute walk test and 4 minute walk test and 16 were able to perform the 6 minute walk test)
- Functional measures: SCIM did not improve significantly between groups (P=0.619) or over time (P=0.115). No statistical analysis was performed for the FIM as there were no differences in scores for any of the participants. SCIM-subscale was not significant over time or by group.
- TUG scores were not significant between group (P=0.138) or for interaction (P=0.528).
- No statistical analysis was performed for measures of ADS or WMS because no changes were seen in the type of assistive device used except in 2 participants that did not need their assistive device at 4 months, but did require it at 12 months.
- In terms of spasticity – MAS - there was no significant difference for time group interaction (P=0.942), no group effect (P=0.115). No statistical difference for the pendulum test over time, between groups, or time x group interaction.

Absolute Effect Sizes (calculated from mean scores for walking outcomes and TUG scores only from data presented in chart):

- 6MWT @ 2 minutes: Experimental group: Baseline-4 months=11.1m, Baseline–6 months=9.5m, Baseline-12 months=10.1m. Control group: Baseline-4 months=16.1m, Baseline–6 months=18.4m, Baseline-12 months=15.5m.
- 6MWT @ 4 minutes: Experimental group: Baseline-4 months=18.8m, Baseline–6 months=19.9m, Baseline-12 months=22.8m. Control group: Baseline-4 months=30.2m, Baseline–6 months=36.4m, Baseline-12

months=33.7m.
- 6MWT @ 6 minutes: Experimental group: Baseline-4 months=29.2m, Baseline–6 months=31.4m, Baseline-12 months=44.6m. Control group: Baseline-4 months=51.5m, Baseline–6 months=52.9m, Baseline-12 months=47m.
- 10 Meter Walk Test: Experimental group: Baseline-4 months=0.05m/s, Baseline–6 months=0.062m/s, Baseline-12 months=0.003m/s. Control group: Baseline-4 months=0.144m/s, Baseline–6 months=0.119m/s, Baseline-12 months=0.081m/s.
- TUG Score: Experimental group: Baseline-4 months=10.6s, Baseline–6 months=10.4s, Baseline-12 months=11.3s. Control group: Baseline-4 months=12.1s, Baseline–6 months=18.4s, Baseline-12 months=10.3s.

Original Authors' Conclusions

The authors concluded that BWSTT using a multichannel FES system was not superior to a conventional exercise regimen at improving walking ability in terms of speed or capacity. However, it was noted that both groups made significant improvements in walking ability. Also, the authors did feel that BWSTT with FES was better at improving SCIM mobility subscale scores. The authors were encouraged by the results of the study, which suggest that regardless of training, people with chronic incomplete spinal cord injury (>18 months) were able to make clinically and statistically significant improvements in walking function over time despite time from injury being >18months for most participants, indicating improvement is still possible beyond the time traditionally expected improvement are made. The authors felt that some of the limitations, which may have affected their results, were the heterogeneous nature of walking ability between the groups, missing data, and that the study may have been underpowered.

Critical Appraisal

Validity

- PEDro Scale score: 6/10 based on Eligibility Criteria: Yes; Random Allocation: Yes; Concealed Allocation: Yes; Baseline Comparison: Yes; Blind Subjects: No; Blind Therapist: No; Blind Assessors: Yes; >85% participant outcomes: No; Intention to treat analysis: No; Between group comparison: Yes; Point estimates and variability: Yes.
- The internal validity of this study is strengthened by the blinding of assessors, yet weakened by 1) lack of blinding of participants - although not possible in this type of study, may have contributed to a higher rate of dropout in the control groups (reported 1 dropped because the participants was assigned to the control group and 3 dropped out for unknown reasons), 2) the study may have been underpowered to show a large effect because the calculation was based on a tibial bone mineral density outcome, which was not calculated in this study and was only able to show a small effect, and 3) key outcomes were obtained from less than 85% of the subjects initially allocated and there was no intention to treat analysis.
- The external validity of this study is strengthened because 1) it is a reasonable representation of a fairly heterogeneous population with a wide range of abilities, and 2) the time commitment seems reasonable (3 days a week, 45 minutes/session, for 16 weeks). However, external validity is weakened because 1) this type of training requires specialized equipment (treadmills, harnesses, multi channel FES unit etc.) and may not be accessible for people outside of this study, and 2) independent set up may be difficult if attempting to use FES system.
- One of the strengths of this study was that the control group did perform a more intensive exercise regimen that was matched for time with the experimental group, which may have helped to reduce dropout and counter any demoralization.
- Based on the graphical data, there was a participant with significantly greater walking abilities when compared to the rest of the participants, which may have affected the internal validity of this study, skewing the results.
- Intention to treat analysis was not used to account for missing data: it was reported that the 7 subjects dropped out, but no mention was made regarding reconciliation of missing data. The effect sizes were not presented in numerical form, making it more difficult and time consuming to interpret results.

Interpretation of Results

It appears based on the results of this study that both methods of training leads to an improvement in walking function in a population with chronic incomplete spinal cord injury. Results did not favour BWSTT with FES compared with the exercise control group for all of the outcome measures, except for the statistically significant improvement seen in SCIM mobility sub scale scores. This improvement using functional measures was not seen in the FIM, most likely because the SCIM has been found to be more sensitive at detecting changes, especially in regards to the mobility subscale as evidenced by a Catz et al study.[18]

The effect sizes showed clinically meaningful changes in walking speed, walking distance, and TUG scores. According to a systematic review by Lam et al. a person with an incomplete spinal cord injury needs to walk 45.8 meters to detect a minimal change during a 6MWT.[14] The control group did improve by that much collectively as evidenced by the absolute effect sizes in the control group: Baseline-4 months=51.5m, Baseline–6 months=52.9m, Baseline-12 months=47m. The effect sizes in the intervention group were also clinically significant, reaching a minimal detectable change at 6 months: Baseline-4 months=29.2m, Baseline–6

months=31.4m, Baseline-12 months=44.6m. These results indicate better results in the control group, however, these results may have been skewed because 2/7 participants in the control group were not able to walk at baseline during the 6MWT, but were able to complete the 6MWT at 4,6, and 12 month follow up. The authors did not comment on this, leaving the reader to wonder why these 2 participants' test scores were not obtained at baseline as they clearly affect the results. If they attributed this change to the control intervention, then it would have most likely been mentioned.

The effect sizes were also clinically significant in terms of walking speed based on the absolute effect sizes for the control group, but not for the intervention group, however the difference may not equate to a noticeable difference functionally. According to Lam et al. 0.13m/s is clinically significant when measuring walking speed during a 10MWT.[14] However, despite the significant increase in effect size, when analysing the graph showing each participant's test results, while the effect sizes calculate the mean change, the individual results varied greatly, indicating that no everyone made a positive change. While the TUG scores did change for both groups significantly, both groups were still significantly above the 12-15-second cutoff for most other populations tested, which indicates a high risk for falls.[19] However, both groups were able to decrease their TUG times shown by their effect sizes, indicating a better score, and did meet and exceed the minimum clinical difference of 10.8 seconds according the Lam et al. study.[14]

While both groups did make improvements, the lack of true control group included in the study, one not performing any exercise, would have helped to distinguish between any differences in improvements made by chance - reduced the overall chance of making a type I error (false positive). On the other hand, if one were to reject the null hypothesis and consider another scenario, it could be that the improvements made in the control group (strength training) may have had a greater effect on upper extremity strength, which may have allowed for a greater change in that group, as participants were allowed to use an assistive device, relying more on their upper extremities, resulting in improved scores, but not an actual improvement in walking ability. If this is the case, perhaps clinically, it may be effective to combine both types of training for the greatest clinical effect. The control group also participated in walking exercises, on the treadmill or parallel bars, which could have also had an effect.

Strengths of this study include a good internal validity and a long-term follow up study of participants was performed, which showed that improvements were for the most part sustained over time, only dropping slightly. While there are strengths to this study, including blinding of assessor, there are weaknesses, which slightly reduce validity of the results: no intention to treat was performed, so there is a greater possibility for a type I error to occur. Also, the mean age of the population in this study was older (54-56 years) than that of the person in question (28 years).

EVIDENCE SYNTHESIS AND IMPLICATIONS

After analysing the "best" evidence, synthesis of the data suggests that body weight supported treadmill training (BWSTT) with FES is no better than the other locomotor training interventions at improving walking ability in people with incomplete spinal cord injury. Based on the results of the Field-Fote 2011 study, it appeared that overground walking was more effective at improving walking ability in people with chronic incomplete spinal cord injury when compared with BWSTT with or without FES. However, this study was included in the Mehrholz et al. systematic review and meta analysis and when the results of the Field-Fote study were pooled and compared with results from 4 other RCTs, the results did not favour any one locomotor training method. The results from the Kapadia et al. study did show clinically significant improvements in walking speed and walking distance in both the experimental (BWSTT with FES) and the control group (strength training plus gait) but were not found to be statistically significant over time. Also, significant improvements of one or two participants in each group (intervention and control) may have skewed the overall results in the Kapadia et al study.

Taken together, these results suggest that improvements can be made with BWSTT with FES, but that other interventions, such as overground walking and even strength training, can also help to improve walking ability. The results from the Kapadia et al. study show that the improvements were retained at 12 months; however, they did drop slightly, suggesting that an exercise regimen of choice needs to be maintained. There are other benefits of BWSTT with FES including bone mineral density, psychological outlook, and aerobic fitness, which are not discussed here, which a clinician may also want to consider before ruling out BWSTT with FES.[20]

While the results of this systematic review do not indicate any silver bullet for improving walking ability in people with incomplete spinal cord injury, it may still be a clinically important intervention. One must still assess each individual patient independently as the results of individual participants varied widely as seen with walking speed. One might almost be better off analysing the individual studies evaluated in this systematic review to see details on which participants improved most significantly to possibly match characteristics in order to help make a clinical decision, while weighing the patient's preferences and utilizing available resources.

These studies revealed other factors to consider when using body weight supported treadmill training in the clinic. One aspect to consider is the amount of time the intervention needs to be done both per week and per session in order to make a clinically meaningful improvement in walking ability. To date there is really no consensus on the amount of time or repetitions needed to make the greatest impact, with the interventions ranging from 3 days per week for 45 minutes to 5 days a week for 1 hour. Another aspect to consider is length of time from injury of the patient. The length of time since injury in the patient in question was not revealed but typically most significant improvements are seen within 6 months.[7] It is worth noting that the participants

of the 2 RCTs (Field-Fote 2011, Kapadia 2014) were considered chronic, >1 post injury, while the systematic review (Mehrholz 2008) included studies with participants both chronic >1 year and acute <6 months. This demonstrates the overall heterogeneous nature of the subject groups across all of the studies, which makes it more difficult when applying to this particular patient.

A large factor to consider clinically is whether the body weight supported treadmill training with functional electrical stimulation is a cost-effective intervention. As described in the Field-Fote (2011) article, this type of training involves quite a lot of set up and staff, with at times needing up to three people in the early stages.[7] The use of extra staff to conduct BWSTT with FES may or may not be feasible depending on the human resources of the particular clinic. Judging from the small improvements made this intervention may not be worth the extra cost. Also, the decision of whether a clinic will invest in treadmill, harness, and FES units would be based on the amount of patients served which would benefit from the use of this specialized equipment.

There is an apparent gap in the research showing the effects of FES cycling on gait ability. Future studies of high quality are needed with large sample sizes to increase statistical power comparing BWSTT with FES to other forms of locomotor training using more homogeneous populations in terms of following characteristics: ASIA classification, level of injury, and time from injury. These quality studies should compare people with similar characteristics to help understand which populations would benefit the most, as research to date has not found an ideal population yet. Future research is warranted because there is a limited amount of high quality research as evidenced by the limited amount of relevant articles found and evaluated in the Mehrholz et al. systematic review. There was a list of current ongoing studies regarding the effects of BWSTT with FES in the Mehrholz et al. systematic review and it will be interesting to see the future results. When enough data is available, future meta analysis may be warranted comparing the effects of locomotor training methods while grouping participants by their characteristics.

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