A systematic review of the efficacy of gait rehabilitation strategies for spinal cord injury

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Abstract

OBJECTIVE—To systematically review the evidence for the efficacy of different rehabilitation strategies on functional ambulation following spinal cord injury (SCI).

METHODS—A keyword literature search of original articles was used to identify published literature evaluating the effectiveness of any treatment or therapy on functional ambulation in people with SCI. The rigor and quality of each study were scored on standardized scales by two independent reviewers.

RESULTS—The search yielded 160 articles, of which 119 were excluded for not meeting our inclusion criteria. The remaining 41 articles covered various strategies for improving gait: bodyweight supported treadmill training (BWSTT) (n=12), functional electrical stimulation (FES) (n=7), braces/orthoses (n=10), or a combination of these (n=12). There is strong evidence from randomized controlled trials that functional ambulation outcomes following body-weight supported treadmill training (BWSTT) are comparable to an equivalent intensity of overground gait training in sub-acute SCI. In chronic SCI, evidence from pre-test/post-test studies shows that BWSTT may be effective in improving functional ambulation. Pre-test/post-test or post-test only studies provide evidence that FES may augment functional ambulation in sub-acute/chronic SCI while braces may afford particular benefits to people with complete SCI to stand up and ambulate with assistive devices.

CONCLUSIONS—Rehabilitation strategies that facilitate repeated practice of gait offer the greatest benefits to functional ambulation in sub-acute or chronic SCI. Supportive devices may augment functional ambulation particularly in people with incomplete SCI.

Keywords

spinal cord injury; ambulation; gait; walking; systematic review; rehabilitation

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INTRODUCTION

Across the United States and Canada, almost 300,000 individuals live with spinal cord injury (SCI) and more than 11,000 new cases arise each year.[1] Almost half of the injuries result in incomplete SCI[2, 3] meaning that there is some preservation of function below the level of the lesion. While the recovery of walking is possible among individuals sustaining an incomplete SCI,[3] the recovery of overground functional ambulation has not been shown in people with clinically complete spinal lesions.[4] Rehabilitation strategies to improve functional ambulation therefore tend to target individuals who have incomplete SCI with spared motor function (motor-incomplete SCI).[5, 6]

Therapeutic strategies for enhancing gait have evolved from those that compensate for weakened or lost function to strategies based on fundamental concepts of the neural control of walking and motor plasticity. Strategies that employ repetitive and intensive practice of gait (e.g. treadmill training) are thought to enhance walking through the provision of task-specific sensory input associated with appropriate stepping movements.[7–9] It has been more than a decade now since it was first demonstrated that body-weight supported treadmill training (BWSTT) in animals can enhance locomotor activity after a spinal cord injury.[10] In this approach, partial body weight support is provided by an overhead harness while leg movements are assisted by therapists and a moving treadmill belt. Since then, BWSTT strategies have been introduced as a promising approach to improve gait in people with SCI.[5, 6, 11–22]

There are also other rehabilitation approaches, such as functional electrical stimulation or bracing, that enable a person to stand up and practice overground walking. The idea of compensating for paralyzed function using electrical stimulation was introduced as early as the 1960s,[23] when functional electrical stimulation (FES) of the common peroneal nerve was found to be effective in assisting foot clearance during the swing phase.[23] There are also more complex systems that involve several channels of stimulation that support proper leg extension as well as foot clearance during swing.[24, 25] These are more suitable for patients who require assistance in standing as well as gait, such as those with neurologically complete SCI. Mechanical leg braces are also useful for supporting standing and walking, particularly for people with complete SCI. These range from single-joint braces (e.g. ankle-foot orthosis, usually for individuals with low, incomplete spinal lesions), to whole-leg/long-leg braces that extend from the lower back to the ankle. These devices must be used with a walking aid (e.g. crutches or walker) for functional ambulation.

Several studies have examined the efficacy of combining these different therapies to further maximize functional ambulation. Systems that combine FES and bracing have been available for several years.[26–29] One example is the 'reciprocating gait orthosis (RGO), which is a long-leg brace with a reciprocal hip joint combined with FES to the thigh muscles. The rationale underlying these 'hybrid' systems (FES + bracing) is that while the brace provides postural stability, FES can be used to assist the leg movements required for functional ambulation. More recently, investigators have also explored whether the facilitatory effects of FES[30, 31] or pharmacological agents[32, 33] on the expression of locomotion may be further augmented by task-oriented gait training.

Whatever the strategy chosen, the key outcome from the patient's perspective is whether the therapy significantly enhances their functional ambulation. Functional ambulation is defined as "the ability to walk, with or without the aid of appropriate assistive devices (such as prostheses, orthoses, canes or walkers), safely and sufficiently to carry out mobility-related activities of daily living.[34] Measures of overground gait speed or endurance, degree of independence, the need for assistive device, or functional classification scales may therefore

be used as indicators of functional ambulation. These types of measures are essential outcomes in rehabilitation research studies so that clinicians can readily assess the efficacy of experimental interventions. Note that "functional ambulation" is distinguished here from "ambulatory capacity" which is another term that has been used in the literature to describe the degree of assistance and independence a person requires to walk in different environment contexts.[35, 36] However, the International Classification of Functioning uses the qualifier "capacity" in a different context – to describe the ability to execute a task at the highest probable level of functioning, as opposed to what one actually does in his/her environment.[37] Therefore, to avoid confusion we will use the term "functional ambulation" to describe walking outcomes.

The objective of this systematic review is to provide rehabilitation and other professionals an overview of the clinical evidence supporting the efficacy of the various strategies used to enhance functional ambulation in the SCI population. We targeted publications that assessed the effect of gait rehabilitation strategies using clinically-relevant functional measures of ambulation.

METHODS

A detailed description of the methods for this systematic review can be found in the accompanying paper.[38] Briefly, a keyword literature search[39] of original articles, previous practice guidelines and review articles was used to identify published literature evaluating the effectiveness of any treatment or therapy related to SCI ambulation. The rigor and quality of each study was scored by two independent reviewers using either the Physiotherapy Evidence Database (PEDro) Scale[40] or the Downs and Black (D&B) Tool[41] (see Eng et al[38] in this issue for more details). The PEDro Scale[40] was used to evaluate the methodological quality of randomized controlled trials (RCTs). It evaluates RCT studies using an 11-item scale yielding a maximum score of 10. Higher scores indicate better methodological quality (9–10: excellent; 6–8: good; 4–5: fair; <4: poor).[42]

The D&B Tool,[41] which is used to assess the methodological quality of non-RCT studies, uses 27 questions to assess reporting, external validity, and internal validity (bias and confounding). We used a modified version of the D&B Tool[38] to score non-RCT papers out of a maximum of 28, with higher scores indicating better methodological quality.

After each study was rated with the appropriate tool, conclusions about the level of evidence of the accumulated studies were drawn using Sackett's description of levels of evidence.[43] We collapsed Sackett's levels of evidence into 5 categories where Level 1 evidence came from "good" to "excellent" RCTs with a PEDro score 6 and Level 2 evidence corresponded to RCTs with PEDro scores 5 or non-randomized prospective controlled or cohort studies. Evidence from case control studies were assigned to Level 3. Levels 4 and 5 corresponded to evidence from pre-post/post-test/case-series and observational/case report studies, respectively.[38]

Only articles that described specific gait rehabilitation parameters, including the duration and frequency of specific training tasks, were included. Treatment intensity was defined as the minutes per week engaged in gait rehabilitation and treatment duration was defined as the number of consecutive weeks of therapy. An exception was given to studies using FES or bracing interventions, where specific treatment or usage parameters are typically not provided. In addition, articles were excluded if they did not measure functional ambulation outcomes or if they did not analyze pre- vs. post-intervention outcomes. Again, an exception was given to publications on bracing since pre-test/post-test measurements are not relevant

to this type of intervention. We did not require a minimum sample size due to the relatively limited number of publications that met these criteria.

RESULTS

The keyword literature search yielded 160 articles related to ambulation following SCI. A total of 119 articles were removed from the sample because they did not meet the inclusion/exclusion criteria, leaving 41 articles in the final analysis. The articles were divided according to specific types of gait training interventions: treadmill training (n=12), functional electrical stimulation (n=7), lower-extremity bracing (n=10), and combination strategies (n=12) (Note that some publications overlap across different categories). The results from articles that also compared functional ambulation outcomes between different interventions are presented separately in the last section.

Treadmill training (Tables 1 and 2)

Seven articles examined the effect of therapist-assisted[12, 14, 19–21] or robot-assisted[13, 15] BWSTT in people who had incurred an incomplete SCI < 12 months prior (acute/sub-acute phase) (aggregate N=291). Treatment intensity ranged from 60 to 300 minutes per week and treatment duration lasted between 3 and 23 weeks. Level 1 evidence from one high quality RCT[12] and two pre-test/post-test studies[13, 14] show that therapist-assisted BWSTT enhances functional ambulation in sub-acute subjects classified as ASIA (American Spinal Injury Association impairment scale)[2] C or D. Data from the RCT[12] also showed that functional ambulation outcomes did not improve in subjects who were classified as ASIA B and remained so following BWSTT.

Table 2 summarizes the results from studies that examined the effect of BWSTT on functional ambulation in people with chronic SCI (>1 year post-SCI). There were nine pre-test/post-test studies[6, 11, 13–19] and one case control study[21] that altogether studied 129 subjects with incomplete SCI with chronicity ranging from 1 to 28 years post-injury. Treatment intensity ranged from 21 to 300 minutes per week and treatment duration lasted between 3 and 48 weeks. Based on the stated primary outcome measure of each study, there is level 3 evidence that BWSTT may improve functional ambulation in chronic SCI (61% of all subjects across these studies showed improvement following treatment).

Functional Electrical Stimulation (FES) (Table 3)

Our search criteria yielded 7 pre-test/post-test studies examining the effect of FES on functional ambulation in incomplete[44–49] or complete[50] SCI subjects. Typically, participants were provided with FES systems to use at home 'as much as possible' or 'as desired' over the course of the study.[45, 47–49, 51] Only two of the studies reviewed here report specific usage parameters for FES during gait rehabilitation, whereby FES was applied for at least 30 minutes, 3 to 5 times/week for up to 3 months.[44, 50] Almost all the participants showed improvements (e.g. increased walking speed, distance, or step length) when FES was used. Aggregate data from all subjects across these studies (N=80) provided level 4 evidence that FES may improve functional ambulation. Several investigators have also reported a carryover effect after FES training such that improvements in functional ambulation (e.g. overground walking speed and distance, step length) persisted even when the stimulator was turned off.[45, 47, 49]

Orthoses/Braces (Table 4)

Our search criteria yielded 2 pre-test/post-test studies[52, 53] and 10 post-test only studies[27, 29, 54–61] that reported the effects of training with braces. Subjects in the pre-test/post-test studies (aggregate N=8) participated in 5 times/week gait training sessions with

long-leg braces for at least 2 weeks. Overall, these 12 studies provided level 4 evidence that long-leg braces may facilitate the ability of people with sub-acute or chronic complete paraplegia to stand independently and to achieve some functional ambulation skills, such as stepping up on curbs or climbing stairs, with assistive devices. The maximum walking speeds achieved with orthosis-use ranged from 0.13 to 0.63 m/s.[29, 52, 53, 55, 57, 59–61]

Combination Therapies (Table 5)

Gait Training + FES—(Table 5A) Findings from four studies (1 high quality RCT[5] and 3 pre-test/post-test[30, 31, 62] studies) demonstrated favourable outcomes in people with chronic, incomplete SCI. Thus, there was level 1 evidence of an overall enhancement of functional ambulation, as measured by overground gait speed, when BWSTT was combined with FES of the common peroneal nerve[5, 30, 62]. There is level 4 evidence from one pre-test/post-test study suggesting that BWSTT combined with FES to the quadriceps and hamstrings muscles enhances functional ambulation.[31]

Gait Training + Pharmacological Interventions —(Table 5B) We found 2 studies that used a combination of pharmacological and physical therapy gait training interventions. One high quality randomized, placebo-controlled, double-blind cross-over study[32] (N=9) provided Level 1 evidence that a combination of physical therapy (including gait training) and GM-1 ganglioside improved motor scores, walking distance and walking speed in chronic SCI subjects compared to physical therapy plus placebo. Other results from a pre-test/post-test study[33] provide Level 4 evidence that Clonidine and Cyproheptadine in conjunction with BWSTT may be effective in enabling non-ambulatory incomplete SCI patients achieve overground ambulation with assistive devices.

Bracing + FES—(Table 5C) Our search criteria yielded six post-test only studies[26–29, 60, 63] that examined the combined effect of lower extremity bracing with FES on functional ambulation in people with complete SCI (aggregate N=110). The data from these studies provide level 4 evidence that the combination of long-leg bracing and FES may enable overground ambulation of between 180 and 1400 m at one time.[27–29, 63] Further details of these studies may be found in the following section.

Comparisons between Interventions

BWSTT vs. other gait training strategies—One high quality RCT[12] and two case control[19, 21] studies have examined the issue of whether BWSTT yields better functional ambulation outcomes than 'conventional rehabilitation' approaches. There is Level 1 evidence from a single-blind RCT[12] (n=146) that there are no differences between BWSTT and an equivalent intensity of overground gait training during inpatient SCI rehabilitation for the primary outcomes of the Locomotor Score of the Functional Independence Measure or overground walking speed. These two variables in both groups improved roughly in parallel over the 12 weeks of therapy.[64] There were also no significant differences between groups for walking endurance (measured by the 6-minute walk test), Berg Balance Scale score, Walking Index for Spinal Cord Injury (WISCI), or Lower Extremity Motor Score (secondary outcome measures). In contrast, the non-randomized studies of Wernig[19, 21] showed that 87% (87/98) of their incomplete SCI subjects achieved improvements in functional ambulation with BWSTT in the acute phases of injury while only half (12/24) improved functional ambulation with conventional rehabilitation. The nature of this 'conventional rehabilitation' was not specifically defined in these studies, although it appeared to focus on wheelchair mobility in addition to gait training in parallel bars and using braces.[65]

There is one high quality RCT that compared functional ambulation outcomes between 4 different approaches to gait training: manual- or robot-assisted BWSTT, BWSTT+FES, and overground gait training.[5] Field-Fote et al[5] reported that subjects in the BWSTT+FES and those in the overground gait training group showed significant improvements in walking speed measured over 6 m following a 12-week training program. Subjects in the manual- or robot-assisted BWSTT did not show significant improvements in walking speed measured over 6 m. When walking speed measured over a longer distance (24.4 m) was compared, however, there were no significant differences between the 4 groups. Thus, there is level 1 evidence that different modes of gait training (e.g. BWSTT vs. overground) result in similar effects.

Bracing or FES Alone vs. Bracing+FES—Three pre-test/post-test studies[26, 27, 29] and one post-test study[60] directly compared the effect of bracing+FES with either FES or bracing alone. When subjects walked with braces or FES alone, maximum walking distance ranged from 3 to 400 m. When braces were combined with FES, maximum distance increased to 200 to 1400 m.[27, 29, 60] The combination of bracing+FES was also reported by three studies to enhance walking speed, although changes were not statistically significant over bracing alone.[26, 27, 29, 60] One study noted that the combination system was helpful to people who could not use bracing alone.[27] Thus there is level 4 evidence that the combination of bracing+FES may provide additional benefits to functional ambulation over either intervention alone.

DISCUSSION

An influential concept that has gained popularity over recent years is task-oriented practice of movements to enhance the recovery of function following SCI. All of the gait rehabilitation strategies reviewed here either provide direct practice of stepping movements (e.g. treadmill training) or provide secondary assistance to the production of stepping (e.g. bracing). Of all the studies included in the present review, only 3 were rated as high quality RCTs.[5, 12, 32] Note that since there were no sample size restrictions, some conclusions were based on small group sizes (N=6 to 9),[5, 32] yet these studies were rated highly according to the standardized PEDro Scale. Other conclusions were drawn from Level 3 evidence or below.

Intensive gait practice benefits both acute and chronic incomplete SCI

There is Level 1 evidence from one RCT supported by several non-RCTs that intensive locomotor training provided over the sub-acute phase in incomplete SCI significantly enhances functional ambulation.[12–15, 19–21] For individuals more than 1 year post-injury (chronic SCI), there is Level 3 evidence that additional improvements in functional ambulation may be attained with intensive BWSTT.[6, 11, 13–19, 21] However, compared to individuals at the acute/sub-acute phase of injury, outcomes during the chronic stage appear more variable across the different studies and may be dependent on initial ambulatory status. Some publications reported little or no change in functional ambulation[13, 15, 16] while others reported dramatic changes (e.g. from non-ambulatory to independent with aids).[13, 17, 19, 21] Based on results from a pre-test/post-test study, there is some evidence that the likelihood for further functional improvements following BWSTT may be greater for subjects classified as ASIA C and D rather than ASIA B.[16] Further evidence is required before we can make more specific recommendations about the best candidates for BWSTT during the chronic stage of injury.

The advent of BWSTT represents a shift in rehabilitation practice in recent years from impairment-driven strategies to task-oriented therapy for the recovery of function following

SCI. A significant question is whether functional ambulation outcomes following task-oriented BWSTT is better compared with outcomes following 'conventional rehabilitation'. The equivalent outcomes observed by Dobkin et al[12] have stirred a well-needed debate among rehabilitation scientists and clinicians about the merits of one approach over another. One issue is the type of therapy chosen as the control to compare with BWSTT. The control group in the Dobkin trial[12] underwent task-oriented overground gait retraining of equivalent intensity to the BWSTT group. The appropriateness of this 'control' has sparked intense debate as to what should be considered a realistic 'conventional' therapy.[65–67] Even so, earlier studies that promoted the superiority of BWSTT unfortunately did not define what constituted the 'conventional rehabilitation' undertaken by the control group.[19, 21] Nevertheless, it is apparent that intensive task-oriented gait retraining, whether implemented by BWSTT or overground practice, facilitates the recovery of functional ambulation especially <12-months post-injury.

Much work remains in determining optimum BWSTT parameters and progression for SCI individuals of varying severity and chronicity. From the studies reviewed here, the relationship between functional ambulation outcomes and treatment intensity, or duration could not be discerned due to the wide range of treatment parameters, the use of different outcome measures, varying injury severity and chronicity, and the inability to determine individual treatment parameters and outcomes. Although data from individual case studies can be useful for providing the specific training parameters and outcomes for each individual,[13, 15, 17, 20] there are not enough data to conduct further analysis on appropriate 'prescription' guidelines for BWSTT.

It is clear that for rehabilitation research to move forward on determining optimum parameters for gait retraining, the first step is to adopt consistent and standardized outcome measures across centers. The International Campaign for Cures of Spinal Cord Injury Paralysis (ICCP) Clinical Guidelines Panel has recently recommended that a combination of the WISCI and a quantitative timed test (e.g. 10-meter walk test) be used to assess functional ambulation in SCI subjects.[68] Several of the studies reviewed here used other scales of functional ambulation,[11, 12, 16, 18, 19, 21] many of which have not been validated in the SCI population.

FES can augment existing functional ambulation skills in incomplete SCI

FES has been used to great benefit to compensate for weak or lost muscle function due to paralysis. We found level 4 evidence from 5 pre-test/post-test studies that suggested improved functional ambulation (e.g. increased walking speed or distance) with FES-use. Only 1 pre-post study showed that FES could improve endurance and gait speed in subjects with complete SCI. Of particular interest, there is level 4 evidence from three pre-post studies that suggests carryover effects after FES training. These studies reported that persistent improvements in functional ambulation were evident even after the stimulator was turned off[45, 47, 49], suggesting the occurrence of neuroplastic changes in response to the regular use of FES during walking. Indeed, it has been shown in non-disabled human subjects that FES-use can increase corticospinal excitability.[69] Improved muscle strength and conditioning after regular use of FES could also contribute to carryover effects in functional ambulation.[44] Such training effects could also be advantageously combined with intensive task-oriented gait training and may provide additional benefits over BWSTT alone.[5] One caveat about FES systems are that their successful use will depend on factors such as technical ease of application and patient motivation.[49]

Bracing enables ambulation in complete paraplegia

We did not restrict bracing intervention studies to pre-test/post-test measurements since we recognized that such study designs would not be meaningful when braces enable standing and stepping in individuals with complete SCI who are otherwise not ambulatory. Bracing devices have typically been prescribed for people with complete paraplegia. These assistive devices may be used to facilitate sit-to-stand transfers as well as achieve some modest gains in mobility.[29, 53, 55] In some of the studies included in this review, intensive (daily) training programs were implemented to provide practice of ambulation with the assistance of long-leg braces and walking aids.[52, 53] These studies provide level 4 evidence, primarily from post-test studies, that individuals with complete paraplegia may experience gains in functional ambulation, including the ability to climb up and down stairs, with the practiced use of braces.[53]

As with FES, the successful use of braces is also dependent on other individual and pragmatic factors. It has been recommended that orthoses or braces are best for people who are well-motivated, with a complete SCI at T9 or below or an incomplete SCI at any level, with good postural control and good level of fitness.[29, 54] One recommendation is that the therapeutic health benefits of orthosis-use (e.g. health benefits from standing practice) should be stressed to patients rather than setting forth an expectation that they will enhance functional ambulation and be a replacement for wheelchair-use.[54, 59, 70, 71] The ability for a patient to don/doff the orthosis without difficulty and relatively quickly (e.g. <5 minutes) also appears to enhance the probability of their acceptance.[29, 53–55] Reports of technical problems (e.g. mechanical breakdown at the hinges, improper fitting)[29, 55] suggest that clinicians should ensure that there is appropriate technical support of these mechanical devices before prescribing them to their patients. These various issues should be considered when prescribing such assistive devices to SCI patients.

Summary

The studies reviewed here suggest that facilitating the practice of walking during rehabilitation can enhance the recovery of functional ambulation in incomplete SCI. Although specific treatment parameters that depend on the injury location, severity, and chronicity remain to be elucidated, there exists some evidence to help guide the clinical decision-making process. Task-oriented gait retraining with partial body weight support, whether provided by a treadmill and partial BWS or overground with assistive devices, appears to be more beneficial when applied sooner rather than later after the onset of injury in people with motor-incomplete lesions. Where resources permit, therapists may use a body-weight support system combined with a treadmill and manual assistance from additional personnel to implement task-oriented gait training. However, there is increasing evidence that equivalent outcomes can be obtained independent of the specific gait retraining strategy.[5, 12] For individuals with more chronic spinal lesions and who have recovered some walking, FES may provide additional gains in functional ambulation. When resources are available, more complex FES systems, with or without bracing, may be used to provide support of upright mobility in individuals with complete paraplegia. Further evidence is required to determine whether combination therapies offer significant advantages over any given approach alone. Finally, although this review has focused on functional ambulation outcomes following various rehabilitation strategies, we must also keep in mind the additional health benefits (e.g. improved cardiovascular or bone health) of performing gait exercises.

Acknowledgments

References

1. National Spinal Cord Injury Statistical Center. Facts and figures at a glance. Birmingham, AB: 2006.

2. Marino RJ, Ditunno JJF, Donovan WH, et al. Neurologic recovery after traumatic spinal cord injury: data from the model spinal cord injury systems. Arch Phys Med Rehabil. 1999; 80:1391. [PubMed: 10569432]

3. Burns SP, Golding DG, Rolle WA Jr, et al. Recovery of ambulation in motor- incomplete tetraplegia. Arch Phys Med Rehabil. 1997; 78:1169. [PubMed: 9365343]

4. Waters RL, Yakura JS, Adkins RH, et al. Recovery following complete paraplegia. Arch Phys Med Rehabil. 1992; 73:784. [PubMed: 1514883]

5. 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; 29:127. [PubMed: 16398945]

6. Wirz M, Zemon DH, Rupp R, et al. Effectiveness of automated locomotor training in patients with chronic incomplete spinal cord injury: A multicenter trial. Arch Phys Med Rehabil. 2005; 86:672. [PubMed: 15827916]

7. Barbeau H, Fung J. The role of rehabilitation in the recovery of walking in the neurological population. Curr Opin Neurol. 2001; 14:735. [PubMed: 11723381]

8. Dietz V, Muller R. Degradation of neuronal function following a spinal cord injury: mechanisms and countermeasures. Brain. 2004

9. Edgerton VR, Roy RR. Paralysis recovery in humans and model systems. Curr Opin Neurobiol. 2002; 12:658. [PubMed: 12490256]

10. Barbeau H, Rossignol S. Recovery of locomotion after chronic spinalization in the adult cat. Brain Res. 1987; 412:84. [PubMed: 3607464]

11. Effing TW, van Meeteren NL, van Asbeck FW, et al. Body weight-supported treadmill training in chronic incomplete spinal cord injury: a pilot study evaluating functional health status and quality of life. Spinal Cord. 2006; 44:287. [PubMed: 16186857]

12. Dobkin B, Apple D, Barbeau H, et al. Weight-supported treadmill vs over-ground training for walking after acute incomplete SCI. Neurology. 2006; 66:484. [PubMed: 16505299]

13. Winchester P, McColl R, Querry R, et al. Changes in Supraspinal Activation Patterns following Robotic Locomotor Therapy in Motor-Incomplete Spinal Cord Injury. Neurorehabil Neural Repair. 2005; 19:313. [PubMed: 16263963]

14. Thomas SL, Gorassini MA. Increases in Corticospinal Tract Function by Treadmill Training After Incomplete Spinal Cord Injury. J Neurophysiol. 2005; 94:2844. [PubMed: 16000519]

15. Hornby TG, Zemon DH, Campbell D. Robotic-assisted, body-weight-supported treadmill training in individuals following motor incomplete spinal cord injury. Phys Ther. 2005; 85:52. [PubMed: 15623362]

16. Hicks AL, Adams MM, Martin Ginis K, et al. Long-term body-weight-supported treadmill training and subsequent follow-up in persons with chronic SCI: effects on functional walking ability and measures of subjective well-being. Spinal Cord. 2005; 43:291. [PubMed: 15685260]

17. Behrman AL, Lawless-Dixon AR, Davis SB, et al. Locomotor training progression and outcomes after incomplete spinal cord injury. Phys Ther. 2005; 85:1356. [PubMed: 16305274]

18. Protas EJ, Holmes SA, Qureshy H, et al. Supported treadmill ambulation training after spinal cord injury: a pilot study. Arch Phys Med Rehabil. 2001; 82:825. [PubMed: 11387590]

19. Wernig A, Nanassy A, Muller S. Maintenance of locomotor abilities following Laufband (treadmill) therapy in para- and tetraplegic persons: follow-up studies. Spinal Cord. 1998; 36:744. [PubMed: 9848480]

20. Gardner MB, Holden MK, Leikauskas JM, et al. Partial body weight support with treadmill locomotion to improve gait after incomplete spinal cord injury: a single-subject experimental design. Phys Ther. 1998; 78:361. [PubMed: 9555919]

21. Wernig A, Muller S, Nanassy A, et al. Laufband therapy based on 'rules of spinal locomotion' is effective in spinal cord injured persons. Eur J Neurosci. 1995; 7:823. [PubMed: 7620630]

22. Wernig A, Muller S. Laufband locomotion with body weight support improved walking in persons with severe spinal cord injuries. Paraplegia. 1992; 30:229. [PubMed: 1625890]

23. Liberson WT, Holmquest HJ, Scot D, et al. Functional electrotherapy: stimulation of the peroneal nerve synchronized with the swing phase of the gait of hemiplegic patients. Arch Phys Med Rehabil. 1961; 42:101. [PubMed: 13761879]

24. Chaplin E. Functional neuromuscular stimulation for mobility in people with spinal cord injuries. The Parastep I System. J Spinal Cord Med. 1996; 19:99. [PubMed: 8732878]

25. Malezic M, Hesse S. Restoration of gait by functional electrical stimulation in paraplegic patients: a modified programme of treatment. Paraplegia. 1995; 33:126. [PubMed: 7784113]

26. Yang L, Granat MH, Paul JP, et al. Further development of hybrid functional electrical stimulation orthoses. Spinal Cord. 1996; 34:611. [PubMed: 8896128]

27. Marsolais EB, Kobetic R, Polando G, et al. The Case Western Reserve University hybrid gait orthosis. J Spinal Cord Med. 2000; 23:100. [PubMed: 10914350]

28. Sykes L, Ross ER, Powell ES, et al. Objective measurement of use of the reciprocating gait orthosis (RGO) and the electrically augmented RGO in adult patients with spinal cord lesions. Prosthet Orthot Int. 1996b; 20:182. [PubMed: 8985998]

29. Thoumie P, Le Claire G, Beillot J, et al. Restoration of functional gait in paraplegic patients with the RGO-II hybrid orthosis. A multicenter controlled study. II: Physiological evaluation. Paraplegia. 1995; 33:654. [PubMed: 8584300]

30. 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. Arch Phys Med Rehabil. 2001; 82:818. [PubMed: 11387589]

31. Hesse S, Werner C, Bardeleben A. Electromechanical gait training with functional electrical stimulation: case studies in spinal cord injury. Spinal Cord. 2004; 42:346. [PubMed: 14993895]

32. Walker JB, Harris M. GM-1 ganglioside administration combined with physical therapy restores ambulation in humans with chronic spinal cord injury. Neurosci Lett. 1993; 161:174. [PubMed: 8272262]

33. Fung J, Stewart JE, Barbeau H. The combined effects of clonidine and cyproheptadine with interactive training on the modulation of locomotion in spinal cord injured subjects. J Neurol Sci. 1990; 100:85. [PubMed: 2089144]

34. Stroke Engine. [accessed on March 19, 2007] Glossary of Terms. http://www.medicine.mcgill.ca/strokengine/definitions-en.html

35. Iseli E, Cavigelli A, Dietz V, et al. Prognosis and recovery in ischaemic and traumatic spinal cord injury: clinical and electrophysiological evaluation. J Neurol Neurosurg Psychiatry. 1999; 67:567. [PubMed: 10519858]

36. Kim CM, Eng JJ, Whittaker MW. Effects of a simple functional electric system and/or a hinged ankle-foot orthosis on walking in persons with incomplete spinal cord injury. Arch Phys Med Rehabil. 2004; 85:1718. [PubMed: 15468037]

37. World Health Organization. International classification of impairments, disability, and health. Geneva: World Health Organization; 2001.

38. Eng, JJ.; Teasell, R.; Miller, WC., et al. Spinal Cord Injury Rehabilitation Evidence: Methods of the SCIRE Systematic Review. In Preparation

39. Eng, JJ.; Teasell, R.; Miller, WC., et al. SCIRE: Spinal Cord Injury Rehabilitation Evidence, Chapter 2: Methods of Systematic Reviews. Vancouver: ICORD; 2007.

40. Moseley AM, Herbert RD, Sherrington C, et al. Evidence for physiotherapy practice: a survey of the Physiotherapy Evidence Database (PEDro). Aust J Physiother. 2002; 48:43. [PubMed: 11869164]

41. Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. J Epidemiol Community Health. 1998; 52:377. [PubMed: 9764259]

42. Foley NC, Teasell RW, Bhogal SK, et al. Stroke rehabilitation evidence-based review: methodology. Top Stroke Rehabil. 2003; 10:1.

43. Sackett, DL.; Straus, SE.; Richardson, WS., et al. Evidence-based medicine: how to practice and teach EBM. Toronto, ON: Churchill Livingstone; 2000.

44. Granat MH, Ferguson AC, Andrews BJ, et al. The role of functional electrical stimulation in the rehabilitation of patients with incomplete spinal cord injury--observed benefits during gait studies. Paraplegia. 1993; 31:207. [PubMed: 8493035]

45. Johnston TE, Finson RL, Smith BT, et al. Functional electrical stimulation for augmented walking in adolescents with incomplete spinal cord injury. J Spinal Cord Med. 2003; 26:390. [PubMed: 14992342]

46. Ladouceur M, Barbeau H. Functional electrical stimulation-assisted walking for persons with incomplete spinal injuries: changes in the kinematics and physiological cost of overground walking. Scand J Rehabil Med. 2000a; 32:72. [PubMed: 10853721]

47. Ladouceur M, Barbeau H. Functional electrical stimulation-assisted walking for persons with incomplete spinal injuries: longitudinal changes in maximal overground walking speed. Scand J Rehabil Med. 2000b; 32:28. [PubMed: 10782939]

48. Stein RB, Belanger M, Wheeler G, et al. Electrical systems for improving locomotion after incomplete spinal cord injury: an assessment. Arch Phys Med Rehabil. 1993; 74:954. [PubMed: 8379842]

49. Wieler M, Stein RB, Ladouceur M, et al. Multicenter evaluation of electrical stimulation systems for walking. Arch Phys Med Rehabil. 1999; 80:495. [PubMed: 10326910]

50. Klose KJ, Jacobs PL, Broton JG, et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep 1 ambulation system: part 1. Ambulation performance and anthropometric measures. Arch Phys Med Rehabil. 1997; 78:789. [PubMed: 9344294]

51. Ladouceur M, Barbeau H. Functional electrical stimulation-assisted walking for persons with incomplete spinal injuries: changes in the kinematics and physiological cost of overground walking. Scand J Rehabil Med. 2000; 32:72. [PubMed: 10853721]

52. Nakazawa K, Kakihana W, Kawashima N, et al. Induction of locomotor-like EMG activity in paraplegic persons by orthotic gait training. Exp Brain Res. 2004; 157:117. [PubMed: 14968281]

53. Saitoh E, Suzuki T, Sonoda S, et al. Clinical experience with a new hip-knee-ankle-foot orthotic system using a medial single hip joint for paraplegic standing and walking. Am J Phys Med Rehabil. 1996; 75:198. [PubMed: 8663927]

54. Franceschini M, Baratta S, Zampolini M, et al. Reciprocating gait orthoses: a multicenter study of their use by spinal cord injured patients. Arch Phys Med Rehabil. 1997; 78:582. [PubMed: 9196464]

55. Harvey LA, Smith MB, Davis GM, et al. Functional outcomes attained by T9-12 paraplegic patients with the walkabout and the isocentric reciprocal gait orthoses. Arch Phys Med Rehabil. 1997; 78:706. [PubMed: 9228872]

56. Scivoletto G, Petrelli A, Lucente LD, et al. One year follow up of spinal cord injury patients using a reciprocating gait orthosis: preliminary report. Spinal Cord. 2000; 38:555. [PubMed: 11035478]

57. Whittle MW, Cochrane GM, Chase AP, et al. A comparative trial of two walking systems for paralysed people. Paraplegia. 1991; 29:97. [PubMed: 2023783]

58. Bonaroti D, Akers JM, Smith BT, et al. Comparison of functional electrical stimulation to long leg braces for upright mobility for children with complete thoracic level spinal injuries. Arch Phys Med Rehabil. 1999; 80:1047. [PubMed: 10489007]

59. Massucci M, Brunetti G, Piperno R, et al. Walking with the advanced reciprocating gait orthosis (ARGO) in thoracic paraplegic patients: energy expenditure and cardiorespiratory performance. Spinal Cord. 1998; 36:223. [PubMed: 9589520]

60. Sykes L, Campbell IG, Powell ES, et al. Energy expenditure of walking for adult patients with spinal cord lesions using the reciprocating gait orthosis and functional electrical stimulation. Spinal Cord. 1996a; 34:659. [PubMed: 8918962]

61. Winchester PK, Carollo JJ, Parekh RN, et al. A comparison of paraplegic gait performance using two types of reciprocating gait orthoses. Prosthet Orthot Int. 1993; 17:101. [PubMed: 8233765]

62. Field-Fote EC, Tepavac D. Improved intralimb coordination in people with incomplete spinal cord injury following training with body weight support and electrical stimulation. Phys Ther. 2002; 82:707. [PubMed: 12088467]

63. Solomonow M, Aguilar E, Reisin E, et al. Reciprocating gait orthosis powered with electrical muscle stimulation (RGO II). Part I: Performance evaluation of 70 paraplegic patients. Orthopedics. 1997a; 20:315. [PubMed: 9127865]

64. Dobkin B, Barbeau H, Deforge D, et al. The evolution of walking-related outcomes over the first 12 weeks of rehabilitation for incomplete traumatic spinal cord injury: the multicenter randomized spinal cord injury locomotor trial. Neurorehabil Neural Repair. 2007; 21:25. [PubMed: 17172551]

65. Wernig A. Treadmill training after spinal cord injury: good but not better. Neurology. 2006a; 67:1901. author reply 1901. [PubMed: 17139789]

66. Wernig A. Weight-supported treadmill vs over-ground training for walking after acute incomplete SCI. Neurology. 2006b; 67:1900. author reply 1900. [PubMed: 17130441]

67. Dietz V. Good clinical practice in neurorehabilitation. The Lancet Neurology. 2006; 5:377.

68. Steeves JD, Lammertse D, Curt A, et al. Guidelines for the conduct of clinical trials for spinal cord injury (SCI) as developed by the ICCP panel: clinical trial outcome measures. Spinal Cord. 2006

69. Kido Thompson A, Stein RB. Short-term effects of functional electrical stimulation on motor-evoked potentials in ankle flexor and extensor muscles. Exp Brain Res. 2004; 159:491. [PubMed: 15243732]

70. Jaspers P, Peeraer L, Van Petegem W, et al. The use of an advanced reciprocating gait orthosis by paraplegic individuals: a follow-up study. Spinal Cord. 1997; 35:585. [PubMed: 9300963]

71. Lotta S, Fiocchi A, Giovannini R, et al. Restoration of gait with orthoses in thoracic paraplegia: a multicentric investigation. Paraplegia. 1994; 32:608. [PubMed: 7997340]

Table 1

Studies using BWSTT in acute/sub-acute SCI (<12 months post-injury)

Articles	Methods	Results
Dobkin et al. 2006 USA PEDro *=7 N=146 RCT	146 males and females, age 16–69 yrs, ASIA† B-D; < 8 wks post-injury. BWSTT‡ vs. overground mobility training: 5X/wk, 9–12 wks, 30–45 min/session. Outcome measures: FIM-L§, walking speed, 6MWT**, WISCI†† @ 3 & 6 months	No difference in FIM-L (ASIA B & C) or walking speed (ASIA C & D) between groups. ASIA C & D subjects in both groups improved functional ambulation. No improvement in functional ambulation in the ASIA B subjects with either intervention.
Winchester et al 2005 USA D&B‡‡=14 N=2 pre-post	2 males, age 20–45 yrs, ASIA C and D, C5-C6, 14 wks to 6 months post-injury. BWSTT (Lokomat): 60 minutes, 3X/wk, 12 wks. Progressed to minimum of 20 min BWSTT (Lokomat) + overground gait training. Outcome measures: WISCI II, gait speed, combined LEMS	Both subjects ↑ WISCI-II score (0→ 16 and 6→15), ↑ gait speed (0→80.6 cm/s and 23.8→62 cm/s), ↑ LEMS (23→36 and 32→42).
Wernig et al. 1998 Germany D&B=12 N=41 Level 4 pre-post	41 males & females, incomplete, 3–16 wks post-injury. BWSTT: 30–60 min, 5X/wk, 3–22 wks. Outcome measures: Wernig Scale of Ambulatory Capacity	29/37 initially non-ambulatory subjects improved to walking with aids. Follow-up (6 months to 6 yrs post-training): 15 subjects showed continued improvement, 26 had no change.
Hornby et al. 2005 USA D&B=12 N=2 pre-post	1 female & 1 male, age 13–40 yrs, ASIA B (reclassified as ASIA D following training), C6-T2, 5–6 wks post-injury. BWSTT (Lokomat and manual): 3X/wk, 19–20 wks + 3–5 hours/day of PT and OT per day. Outcome measures: LEMS§§, FIM, WISCI II, 10MWT***, 6MWT, TUG†††, Functional Reach Test (sit or stand)	improved from non-ambulatory to distances of 144 → 190 m (6MWT) and speeds of 0.55 → 0.58 m/s (10MWT). Final FIM score = 6. ↑ WISCI II scores: 0 → 13 and 0 → 16.
Thomas & Gorassini 2005 Canada D&B=12 N=2 pre-post	2 males, age 71 and 41 yrs, ASIA D & C, T5/9 and C3/5, 0.8 and 0.6 yrs post-injury. BWSTT: <60 min, 3–5X/wk, 10–23 wks. Outcome measures: 10MWT, 6MWT, WISCI II.	Significant improvement in WISCI II score, 6MWT, and 10MWT; improvements correlated with the increase in corticospinal connectivity.
Gardner et al 1998 USA D&B=10 N=1 case report	1 male, age 28 yrs, C5/6, 7 months post-injury. BWSTT: 20 min, 3X/wk, 6 wks. Outcome measures: gait speed	↑ comfortable walking speed (1.22 → 1.37 m/s). ↑ fast walking speed (1.63 → 1.8 m/s). ↑ running speed (2.64 → 3.24 m/s).
Wernig et al. 1995 Germany D&B=9 N=97 case control	Study 1: 12 males & females, 0–4.5 months post injury. BWSTT: 30–60 min, 5X/wk, 3–20 wks (median 10.5 wks). Study 2: 85 males & females, 2–30 wks post-injury 45 subjects underwent 2–22 wks of BWSTT vs. 40 subjects (historical controls) underwent conventional rehabilitation. Outcome measures: Wernig Scale of Ambulatory Capacity	Study 1: All subjects improved (including 7 initially non-ambulatory Study 2: 33/36 non-ambulatory subjects could walk after BWSTT vs. 12/24 improved to functional ambulation with conventional rehab.

*Physiotherapy Evidence Database (PEDro) Scale (maximum possible score = 10)

†American Spinal Injury Association (classification scale)

‡Body-Weight Supported Treadmill Training (therapist-assisted)

§Functional Independence Measure - Locomotor

**6-Minute Walk Test

††Walking Index for Spinal Cord Injury (I or II)

‡‡Downs and Black Tool (maximum possible score from modified version = 28)

§§Lower Extremity Motor Score

Table 2

Studies using BWSTT in chronic SCI (>1 year post-injury)

Articles	Methods	Results
Field-Fote et al. 2005‡‡‡ USA PEDro=6 N= 27 RCT	27 males & females, age 21–64 yrs, incomplete, C3-T10, >1 year post-injury. Randomized to 4 gait training strategies, 45–50 min, 5X/wk, 12 wks: **1) manual BWSTT (n=7);** 2) BWSTT + FES (common peroneal nerve) (n=7); 3) BWS overground+FES (n=7); **4) BWS Lokomat (robotic gait device) (n=6).** Outcome measures: walking speed over 6 m (short-bout) and 24.4 m (long-bout)	No significant differences between pre- and post-intervention walking speed in the manual BWSTT or BWS Lokomat groups. However, there was a tendency for subjects with initially slower walking speeds (<0.1 m/s) to have a greater percent increase in walking speed (57 to 80%) compared to those with initially faster walking speeds (– 19 to 5%).
Hicks et al. 2005 Canada D&B=18 N=14 pre-post	14 males & females, age 20–53 yrs, ASIA B (n=2) & C (n=12), C4-L1, 1.2 to 24 yrs post-injury. BWSTT: <45 min, 3X/wk, 144 sessions (12 months). Outcome measures: Walking Capacity Scale (Wernig)	6/14 subjects improved, but only 3 maintained improvements at 8 months post- training. 3/10 initially non-ambulatory subjects could walk (with assistance) post- training.
Wirz et al. 2005 Switzerland D&B=17 N=20 pre-post	20 males & females, age 16–64 yrs (mean 40, SD 14), ASIA C (n=9) & D (n=11), C3-L1, 2 to 17 yrs post-injury. BWSTT: <45 min, 3–5X/wk, 8 wks. Outcome measures: WISCI II, 10MWT, 6MWT	2/20 subjects improved WISCI II scores. Overall ↑ in 10MWT of 0.11 +/– 0.10 m/s (56% improvement). 15/16 subjects improved in 6MWT.
Winchester et al 2005 USA D&B=14 N=2 pre-post	2 males, age 44–49 yrs, ASIA C, C5-C6, 1–4 yrs post- injury. BWSTT: 60 min, 3X/wk, 12 wks. Progressed to minimum of 20 min BWSTT + overground gait training. Outcome measures: WISCI II, gait speed (over 3.66 m walkway), LEMS	Both subjects initially non-ambulatory. 1 subject improved (WISCI-II =6, gait speed=10.5 cm/s, ↑ LEMS 22→27), other showed no change.
Protas et al 2001 USA D&B=13 N=3 pre-post	3 males, age 34–48 yrs, ASIA C & D, T8-T12, 2–13 yrs post-injury. BWSTT: 20 min, 5X/wk, 12 wks. Outcome measures: Garrett Scale of Walking, Assistive Device Usage Scale, Orthotic Device Usage Scale, gait speed (5 m), gait endurance (5 minutes).	All subjects showed ↑ gait speed and endurance. All subjects showed improvement, indicated by the Garrett Scale of Walking or the type of assistive or orthotic devices used.
Wernig et al. 1998 Germany D&B=12 N=35 pre-post	35 males & females, age 19–70, C4-T12, 1 to 15 yrs post- injury. BWSTT: 30–60 min, 5X/wk, 8–20 wks. Outcome measures: Walking Capacity Scale (Wernig).	20/25 initially non-ambulatory improved to walking with aids. 2/10 ambulatory patients improved functional class, but all improved speed and endurance. At follow-up (0.5–6.5 yrs later) all ambulatory patients remained ambulatory, with changes only in functional class.
Thomas & Gorassini 2005 Canada D&B=12 N=6 pre-post	6 males & females, age 29–78 (mean 54.4, SD 14.8) yrs, ASIA C (n=4) & D (n=2), C5-L1, 2 to 28 yrs post-injury. BWSTT: <60 min, 3–5X/wk, 10–23 wks. Outcome measures: 10MWT, 6MWT, WISCI II.	5/6 subjects improved WISCI II score. Overall significant improvements in 6MWT, and 10MWT and improvements correlated with the increase in corticospinal connectivity.
Hornby et al. 2005 USA D&B=12 N=1 case report	1 male, age 43 yrs, ASIA C, C6, 18 months post-injury. BWSTT: 1–3X/wk, 16 wks + 3 sessions of PT and OT/wk, which included gait and mobility training. Outcome measures: LEMS, FIM, WISCI II, 10MWT, 6MWT, TUG, Functional Reach Test (postural stability in sit or stand)	No change in LEMS (remained at 31/50). ↑gait speed (0.11 → 0.21 m/s) and endurance (30 → 61 m) No change in WISCI II (13).
Effing et al 2006 Netherlands D&B=11	3 males, age 45–51 yrs, ASIA C & D, C5-C7, 29–198 months post-injury. BWSTT: 30 minutes, 5X/wk, 12 wks. Outcome measures: Walking Capability Scale (Wernig), gait speed over 7 m	Gait improvements in all subjects, indicated either by faster gait speed or higher score in Walking Capability Scale.

Articles	Methods	Results
N=3 pre-post		
Behrman et al 2005 USA D&B=11 N=1 case report	1 male, age 55 yrs, ASIA D, C5/6 BWSTT for 30 min + overground gait training for 20 min, 5X/wk, 9 wks. Outcome measures: gait speed, WISCI II, # of steps/day	↑ self-selected gait speed: 0.19 → 1.01 m/s ↑ maximum gait speed: 0.36 → 1.2 m/s ↑ WISCI II: 6 → 20 ↑ steps/day: 1054 → 3924 steps/day
Wernig et al. 1995 Germany D&B=9 N=68 case control	Study 1: 44 males & females, chronic para- or tetraplegia. BWSTT: 30–60 min, 5X/wk, 3–20 wks (median 10.5 wks). Study 2: 53 males & females, chronic para- or tetraplegia. 29 subjects underwent BWSTT (as in Study 1) versus 24 historical controls who underwent conventional rehabilitation. Outcome measures: Wernig Walking Capacity Scale	Study 1: 25/33 initially non-ambulatory could walk after BWSTT. At 6 months post- training, 18/21 ambulatory patients maintained abilities. Study 2: 14/18 initially non-ambulatory subjects could walk after BWSTT, compared with only 1/14 in the conventional rehab group.

*** 10-Metre Walk Test

††† Timed Up and Go test

‡‡‡ Only the results from subjects who were in the manual- or Lokomat-assisted BWSTT groups are included in this table.

Table 3

Studies using FES to Improve Locomotor Function

Articles	Methods	Results
Ladouceur & Barbeau 2000a Canada D&B=16 N=14 pre-post	14 males & females, age 25–49 yrs, C3-L1, incomplete, 1.8–19.1 yrs post-injury. Surface FES: bilateral or unilateral common peroneal nerve, home use as much as possible ~1 yr (26 and 56 wks), 2 subjects also had bilateral quadriceps. Outcome measures: temporal gait measures.	Mean ↑ of 0.10 m/s in walking speed and ↑ of 0.12 m in stride length (both with and without FES) over the first year of FES-use.
Wieler et al. 1999 Canada D&B= 15 N=31 pre-post	31 males & females, mean age 36 (SD 2) yrs, injury level above lumbar levels, incomplete, mean 6 (SD 1) yrs post- injury Surface FES: common peroneal nerve; some subjects also received FES to hamstrings, quadriceps, gluteus medius, duration of FES ranged from 3 months to over 3 yrs. Outcome measures: walking speed, stride length, cycle time.	Overall ↑ in gait speed which persisted even when FES off. Greatest % improvements for the initially slower walkers.
Klose et al. 1997 USA D&B=15 N=16 pre-post	16 males & females, mean age 28.4 (SD 6.6) yrs, T4-T11, complete, 0.7–9.0 yrs post-injury. Surface FES: Parastep®: 6 channels (bilateral common peroneal nerve, quadriceps, glutei). 3X/wk, 32 sessions (once subjects had sufficient strength to stand) Outcome measures: walking distance and speed (with FES)	Most subjects improved endurance and gait speed. Longest distance walked with FES was between 12 to 1707 m (mean: 334 m; SD 402 m).
Granat et al. 1993 Scotland D&B=14 N=6 pre-post	6 males & females, age 20–40 yrs, C3-L1, Frankel C & D, 2 to 18 yrs post-injury. Surface FES: quadriceps, hip abductors, hamstrings, erector spinae, common peroneal nerve, home program >30 min, 5X/wk, 3 months. Outcome measures: walking speed, stride length, cadence.	Significant mean ↑ in stride length, but not speed or cadence. 3 to 4 subjects had significant individual ↑ in gait speed, stride length and cadence.
Johnston et al. 2003 USA D&B=14 N=3 pre-post	2 females, 1 male, age 12–17 yrs, C6-L2, ASIA C, 3 yrs post- injury. Percutaneous intramuscular FES: pelvis, hip, and knee muscles. Subjects used system at home, as desired, for 1 yr. Outcome measures: temporal gait measures.	↑ voluntary strength. Significantly ↑ maximum walking distance and speed. Gains evident even when FES was off.
Ladouceur & Barbeau 2000b Canada D&B= 13 N=14 pre-post	14 males & females, age 25–49 yrs, C3-L1, incomplete, 1.8–19.1 yrs post-injury. Surface FES: bilateral or unilateral common peroneal nerve, 2 subjects also had bilateral quadriceps, home use as much as possible ~1 yr. Outcome measures: temporal gait measures.	7/14 subjects showed improvement based on type of ambulatory device. 13/14 subjects ↑ gait speed with FES. Training/carryover effect after long– term use: ↑ evident even when FES off in 12/14 subjects
Stein et al. 1993 Canada D&B=6 N=10 pre-post	10 males & females, age 20–44 yrs, C2-T10, incomplete, 2.5–10 yrs post-injury. Surface, percutaneous, or implanted FES of common peroneal nerve, and sometimes quadriceps, glutei, and psoas. Outcome measures: speed, gait parameters	All subjects ↑ gait speed when FES was on (mean change was 4 m/min), particularly significant for more disabled subjects.

Table 4

Studies of bracing interventions in SCI

Articles	Methods	Results
Thoumie et al. 1995 France D&B=19 N=26 post-test	26 males & females, age 20–53 yrs, C8-T11, complete, 9–144 months post-injury. RGO-II§§§ orthosis: long-leg brace with reciprocal hip joint combined with FES to the quadriceps and hamstrings. 4–6 wks of gait training with orthosis alone followed by RGO– II+FES (hybrid) program (total program time: 2–5 months inpatients, 3–14 months outpatients). Outcome measures: walking distance and speed with RGO and with RGO+FES	When subjects with RGO-II alone, they achieved distances of 150 to 400 m. Average walking speed was 0.29 m/s (SD 0.03; range 0.22–0.41 m/s).
Bonaroti et al. 1999 USA D&B=18 N=5 post test	5 males and females, age 9–18 yrs, motor-complete, C8-T8, 1–9 yrs post-injury. Mobility training alternating between FES (<16 channels) and orthosis (long-leg brace or knee-ankle-foot); 4 weeks upright mobility training (e.g. stand-and-reach, 6-m walking, stairs). Outcome measures: Functional Independence Measure	Subjects achieved FIM score of at least 4 ("minimal assist") for 6-m walking, at least 3 ("moderate assistance") for stair ascent and descent.
Harvey et al. 1997 Australia D&B=17 N=10 post test	10 males and females, mean age 37 years (SD 8.4), T9-T12, motor complete, 4–19 years post-injury. Walkabout Orthosis (WO) vs. Isocentric Reciprocal Gait Orthosis (IRGO): training with first orthosis 2–3 hours, 2- 3X/week for 6–8 weeks, followed by 3-month home trial period. 2-month wash-out period (no orthosis) followed by other orthosis. Outcome measures: functional skills (e.g., curbs, stairs, donning/doffing, sit-stand), Functional Independence Measure, gait speed over flat and inclined surfaces	Both orthoses resulted in "stand-by" or "minimal" assist for stairs and curbs and "independent" or "stand-by" for level gait. IRGO tended to enable faster gait (mean IRGO=0.34 m/s ± 0.18, mean WO=0.14 m/s ± 0.12; p=.002) and allowed more independent gait compared to WO. Neither orthosis enabled subjects to be fully independent in the key skills necessary for functional ambulation after 8-week training.
Franceschini et al. 1997 Itlay D&B=14 N=74 post test	74 males and females, mean age 27 years, T1-T12, complete (Frankel A & B), mean 37 years post-injury. Orthoses: RGO (n=53), Advanced RGO (RGO with links between mechanical hip joints and hip and knee joints) (n=17), and Hip Guidance Orthosis (HGO) (n=4): practice to don/doff device and functional mobility. Follow-up at hospital discharge and 6 months later. Outcome measures: Garrett Score, ability to climb up and down 12 steps	At discharge, 28 patients could climb stairs (13 with crutches, 15 with a walker). The ability to climb stairs or Garrett score at discharge was associated with continued orthosis-use. 31 patients achieved functional gait (Garrett = 2–5) and 9 achieved community ambulation (Garrett=4–5). 19 used orthosis only for exercise (Garrett=1).
Scivoletto et al. 2000 Itlay D&B=14 N=24 post test	24 males and females, mean age 33.6 years (SD 3.2), T1-T12, complete (ASIA A), mean 5.3 years (SD 2.1) post-injury. RGO: training, then home-use for 1 year. Outcome measures: gait speed, going up and down stairs, use of walker or crutches, Garrett Score (out of 6; 6 = community ambulation with no limitations; 1=hospital ambulation).	No difference between RGO-users and RGO- non-users for gait speed, stair climbing, or ambulatory aid. However, RGO-users achieved home ambulation with limitations or home ambulation (Level 2–3) while non- users achieved hospital ambulation or home ambulation with limitations (Level 1–2). No one reached community ambulation levels.
Nakazawa et al 2004 Japan D&B=14 N=3 pre-post	3 males, age 22–28 yrs, T8–12, ASIA A, 8–12 months post- injury. Weight Bearing Control Orthosis (WBCO): 1 hour, 5X/wk, 12 wks. Outcome measures: gait velocity	All subjects showed ↑ in gait velocity: 7.7→13.2; 11.8→21.2, 22.4→25 m/min.
Whittle et al. 1991 UK D&B=12 N=22 post test	22 males and females, age 21 to 44 years, T3-T12. Hip Guidance Orthosis (HGO) (aka Parawalker) + crutches vs. Reciprocating Gait Orthosis (RGO) + rollator walker; practice period + 4 months of home use, followed by switch to second orthosis. Outcome measures: walking speed, cadence, stride length	No significant differences between orthoses for gait speed, cadence, and stride length. Mean walking speed with either orthosis was 0.24 m/s. RGO enabled faster sit-to-stand and stepping up on curbs.
Marsolais et al. 2000 USA D&B=11 N=6	6 males & females, age 22–50 yrs, C7-T12, severity not reported, 2.5–20.6 yrs post-injury. Case-Western Reserve University Hybrid Gait Orthosis (modification of IRGO****) combined with FES to various muscles (combination of 8–16 muscles). Outcome measures: walking speed and distance	2 subjects who used the IRGO alone achieved distances of 3 to 90 m during overground walking with either standard walker or crutches.

Articles	Methods	Results
post-test		
Winchester et al. 1993 USA D&B=11 N=4 post test	4 males, age 24–36 yrs, 2 complete and 2 motor-incomplete, T5-T10, 25 to 58 months post-injury. Gait training with RGO or IRGO: 2 hours, 2–3 times/week (average total time = 35±7.5 hours) Outcome measures: gait velocity, cadence	Overall, subjects achieved overground velocity of 12.7±1.9 m/min with RGO and 13.5±2.1 m/min with IRGO; cadence of 30.3±6.2 steps/min with RGO and 31.3±7.9 steps/min with IRGO.
Massucci et al. 1998 Italy D&B=10 N=6 post test	6 males, age 16–31 yrs, complete (Frankel A), T3-T12, 12–51 months post-injury. Rehabilitation training with advanced reciprocating gait orthosis for 6–8 weeks (including muscle strengthening, standing balance, gait training, stair climbing). Outcome Measures: walking speed over 5 m	Subjects achieved walking speeds of between 7.8 and 16 m/min with the orthosis.
Saitoh et al. 1996 Japan D&B=10 N=5 pre-post	5 males, age 26–36 yrs, T5-L1, 4 complete (Frankel A) and 1 incomplete (Frankel C), 8.4–70 months post-injury. MSH-KAFO[††††]: long-leg hip-knee-ankle-foot brace with medially-placed single-axis hip joint. Patients were trained to stand and walk using device daily for 2 wks, followed by an exercise program 1–2X/wk. Outcome measures: walking speed and distance	4/5 could stand without crutches with MSH- KAFO. 3/5 could climb stairs with crutches and rail. After 3–10 months of therapy, gait speed ↑ from 0.05–0.2 m/s to 0.17–0.63 m/s) and walking distance ranged from 300 to 4000 m.
Sykes et al. 1996a UK D&B=10 N=5 post-test	5 males and females, age 24–37 years, C2 -T6, 3 ASIA A, 1 ASIA B, 1 ASIA C. Following conditioning program, RGO+FES bilaterally to quadriceps and hamstrings for home use. Outcome measures: walking speed over 40 m	When subjects walked with RGO alone, they achieved walking speeds ranging from 0.13 to 0.40 m/s.

§§§Reciprocating Gait Orthosis (predecessor to the IRGO)

****Isocentric Reciprocating Gait Orthosis

Table 5A

Combination Therapies – Gait Training + FES

Articles	Methods	Results
Field-Fote et al. 2005[††††,‡‡‡‡] USA PEDro=6 N=27 RCT	27 males & females, age 21–64 yrs, incomplete, C3-T10, >1 year post-injury. Randomized to 4 gait training strategies, 45–50 min, 5X/wk, 12 wks: 1) manual BWSTT (n=7); **2) BWSTT + FES (common peroneal nerve) (n=7)**; 3) BWS overground+FES (n=7); 4) BWS Lokomat (robotic gait device) (n=6). Outcome measures: walking speed over 6 m (short-bout) and 24.4 m (long-bout).	Significant ↑ in short-bout walking speed across subjects who received BWSTT + FES. Tendency for initially slower walkers (<0.1 m/s) to show greater improvement (106%) compared to initially faster walkers (17%).
Field-Fote 2001 USA D&B=15 N=19 pre-post	19 males & females, mean age 31.7 (SD 9.4) yrs, ASIA C, para- and quadriplegia. BWSTT + common peroneal nerve FES: <90 min, 3X/wk, 12 wks. Outcome measures: gait speed.	Significant ↑ in walking speed (median: 77%).
Field-Fote & Tepavac 2002 USA D&B=13 N=14 pre-post	14 males & females, age 18–50 yrs, ASIA C, C4-T7. BWSTT + common peroneal nerve FES: <90 min, 3X/wk, 12 wks. Outcome measures: overground gait speed.	All subjects showed ↑ in walking speed. Subjects with slower walking speeds showed greater improvement.
Hesse et al 2004 Germany D&B=11 N=4 pre-post	3 males, age 45–62 yrs, ASIA C & D, C5-T8, 8–18 months post-injury. Electromechanical gait trainer + FES to quadriceps and hamstrings: 20–25 min, 5X/wk, 5 wks. Outcome measures: gait velocity and endurance	Gait ability ↑ in all patients; 3 could walk independently overground with aids. Overall gait speed and endurance more than doubled.

[††††]Medial-placed, Single-axis Hip joint-Knee-Ankle-Foot Orthosis

[‡‡‡‡]Only the results from subjects who were in the BWSTT + FES group are included in this table.

Table 5B

Combination Therapies – Gait Training + Pharmacological Agents

Articles	Methods	Results
Fung et al 1990 Canada D&B=10 pre–post	2 males, age 23–26 yrs, incomplete SCI, C7-T4, 8–11 months post-injury. combined cyproheptadine and clonidine + BWSTT (manual): 1–2 hours, 3–5 times/wk, 3–8 wks. Outcome measures: gait speed	Both subjects wheelchair-bound pre- treatment. Following medication and training, both subjects could walk overground with ambulatory aids (crutches or walker) at 0.1–0.2 m/s.
Walker & Harris 1993 USA PEDro=8 N=9 RCT	9 males & females, age 21–44 yrs, incomplete SCI, C5-L1, 1–13 yrs post-injury. Treatment: Double-blind, placebo-controlled crossover study design: Intravenous GM-1 ganglioside (Sygen®) or placebo + 2 hours PT (gait training) 6X/wk for 2 months, followed by switch of drug administration (total 4 months). All subjects given 6 months of PT before trial. Outcome measures: motor score, walking distance and velocity.	GM-1 + PT resulted in ↑ motor scores, walking distance, and walking velocity. Effects of GM-1 persisted in subjects who were given GM-1 before placebo.

Table 5C

Combination Therapies –FES + bracing

Articles	Methods	Results
Thoumie et al. 1995 France D&B=19 N=26 post-test	26 males & females, age 20–53 yrs, C8-T11, complete, 9–144 months post-injury. RGO-II§§§§ orthosis: long-leg brace with reciprocal hip joint combined with FES to the quadriceps and hamstrings. 4–6 wks of gait training with orthosis alone followed by RGO-II+FES (hybrid) program (total program time: 2–5 months inpatients, 3–14 months outpatients). Outcome measures: walking distance and speed with RGO and with RGO+FES	21/26 completed the training program, 19 could stand up alone. Following program, walking distance ranged from 200–1400 m with hybrid orthosis, 150–400 m with RGO II. Maximal walking speed with the hybrid orthosis (mean 0.32 m/s; SD 0.02; range 0.21–0.45 m/s) was not significantly different from that with orthosis alone (mean 0.29 m/s; SD 0.03; range 0.22–0.41 m/s).
Sykes et al. 1996b UK D&B=13 N=5 post-test	5 males and females, age 24–37 years, C2 -T6 (2 tetraplegics ASIA A & C, 3 paraplegics ASIA A & B), 8–14 years post-injury. RGO and FES: 20–40 weeks of RGO use at home followed by RGO+FES bilaterally to quadriceps and hamstrings. Outcome measures: RGO pedometer measured number of steps over 18 months	Number of steps taken per week varied between 306 and 1879 steps (99 to 845 m/week). Use of the RGO was low and no increase in use or function after hybrid system supplied. 1 subject (ASIA C) was already a community ambulator and showed most frequent use of RGO but across all subjects, RGO-use was variable, intermittent and generally poor.
Solomonow et al. 1997 USA D&B=12 N=70 post-test	70 males and females, age 16 to 50, C6-T12, 1–10 years post-injury, severity not reported. RGO-use and gait training 1–3 hours, 3 times/week, 6 weeks followed by RGO+FES (bilateral quadriceps and hamstrings) for another 6 weeks. Outcome measures: walking ability, 180 m walk	After training, 57 patients could walk at least 180 m (19 could walk >450 m). 77% of patients could walk independently on different surfaces (grass, ramps, curbs).
Marsolais et al. 2000 USA D&B=11 N=6 post-test	6 males & females, age 22–50 yrs, C7-T12, severity not reported, 2.5–20.6 yrs post-injury. Case-Western Reserve University Hybrid Gait Orthosis (modification of IRGO*****) combined with FES to various muscles (combination of 8–16 muscles). Outcome measures: walking speed and distance	Subjects who were unable to use RGO alone could ambulate with hybrid system. 3 subjects who were previously ambulatory with either RGO or FES alone showed improvement in walking distance with the hybrid system (from 3–90 m to 200–350 m). 2 subjects could climb stairs with hybrid system.
Yang et al. 1996 UK D&B=11 N=3 pre-post	3 subjects, age 28–42 yrs, C6 -T8 (tetraplegic incomplete, paraplegics complete), 3–15 yrs post-injury. RGO +/– FES: RGO with and without FES to common peroneal nerve stimulation. Outcome measures: walking speed, stride length	RGO+FES: modest (non-significant) ↑ in walking speed and stride length compared with RGO without FES. When subjects walked with the RGO+FES, average walking speed was 13% faster and stride length was 5% longer.
Sykes et al. 1996a UK D&B=10 N=5 post-test	5 males and females, age 24–37 years, C2 -T6, 3 ASIA A, 1 ASIA B, 1 ASIA C. Following conditioning program, RGO+FES bilaterally to quadriceps and hamstrings for home use. Outcome measures: walking speed over 40 m	Without FES, subjects' walking speeds ranged from 0.13 to 0.40 m/s. With RGO+FES, speeds ranged from 0.14 to 0.45 m/s, corresponding to changes ranging from –1 to 14%.

§§§§ Reciprocating Gait Orthosis (predecessor to the IRGO)

***** Isocentric Reciprocating Gait Orthosis (IRGO)