Author Year Country Research Design Score Total Sample Size	Methods	Outcome
Çinar et al. 2021 Turkey RCT PEDro = 6 Level 1 N = 37	Population: 37 patients with complete (AIS A) paraplegic SCI and with a maximum of 6 months after the injury; 15 males and 22 females; mean age 34.9 years; injury level thoracic (n = 20), and lumbar (n = 17); and mean duration of injury 3.7 months. Treatment: Patients were divided into two groups: • Group 1 (n = 17): Received both RAGT with Lokomat and conventional therapy. • Group 2 (n = 20): Received only conventional therapy. Conventional treatment included training in the ROM, stretching, strengthening, coordination, and walking once a day, 5 days a week for 8 weeks. Outcome Measures: WISCI II was evaluated at the beginning and at the end of the treatment.	 No significant difference was noted in WISCI II admission—discharge change scores between the two groups (P > 0.05). However, intra-group evaluations revealed significant increase in the discharge WISCI II scores in groups I and II compared with admission scores (P < 0.05). At the time of discharge, 5 of the 17 patients in group 1 improved to ASIA B and 4 patients improved to ASIA B and 6 patients improved to ASIA B and 6 patients improved to ASIA C level.
Yildirim et al. 2019 Turkey RCT PEDro = 6 Level 1 N = 88	Population: 88 participants with SCI; 55 males and 33 females; mean age 34.25 years; injury level cervical (n = 18), thoracic (n = 53), and lumbar (n = 19); tetraplegia (n = 16) and paraplegia (n = 72); ASIA complete (n = 39) and ASIA incomplete (n = 49); and mean time since injury 3 months. Treatment: All participants received conventional therapy (joint ROM, stretching, strengthening and gait training) for 5 days a week (twice a day). Also, they were randomized into 2 groups: • The RAGT group (n = 44) underwent 30-min sessions of robotic therapy training using Lokomat for 8 weeks	 Between groups comparisons: a. The improvement in functional ambulation (as measured by the WISCI II score) was significantly higher in the robotic group (median WISCI II score went from 5.0 to 9.0) than in the control group (median WISCI II score went from 5.0 to 6.5; P = 0.011). b. The improvement in functional independence (as measured by the FIM score) was significantly higher in the robotic group (median FIM score went from 69.0 to 85.0) than in the control group (median

- twice a week. BWS was progressively increased to full body weight at the end of treatment.
- The control group (n = 44) underwent only conventional treatment.

Outcome Measures: WISCI II was assessed at baseline and at the end of training.

- FIM score went from 67.0 to 77.0; P = 0.022).
- 2. Within groups improvements were observed in both groups according to the WISCI II scores (P < 0.001).

Population: 30 participants with complete (ASIA A) and dorsolumbar SCI

- Conventional group (n = 15): Mean (SD) age: 34.60 (10.22) years 12M, 3F Mean (SD) time since injury: 7 (3) days
- Intervention group (n = 15):
 Mean (SD) age: 30.93 (7.90)
 years
 12M, 3F
 Mean (SD) time since injury: 4
 (2) days

Treatment: Joint ROM & muscle strengthening physiotherapy/ exercises was given to both groups for initial 2–3 weeks. After 3 weeks, participants were stood erect (90°) gradually on inclination table and as the participants achieved 90° of inclination with stable vitals, they were taken on Robotic machine or movement started by using KAFO, depending upon the rehabilitation group, for 12 weeks:

• In robotic assisted rehabilitation group, BWSTT with Lokomat was performed. During treatments, initial velocity of the treadmill was kept at 1.5 km/h and 0.3 km/h gain was achieved in further walking sessions depending upon the muscle power in lower limbs and step length was kept fixed (40 cm). At the

- 1. Intervention group results (within-group): Robotic group demonstrated a significant improvement at the end of 12 weeks in terms of WISCI II score (p = 0.0001), LEMS score (p = 0.0007), and SCIM-III score (p = 0.0001).
- 2. Conventional group (withingroup): Conventional group demonstrated a significant improvement at the end of 12 weeks in terms of WISCI II score (p = 0.003), LEMS score (p = 0.003), and SCIM-III score (p = 0.0001).
- 3. Comparison of functional outcome scores and parameters between conventional and robotic group at the end of 12th week of Rehabilitation:
 In terms of the WISCI II score (p = 0.0001) and SCIM-III score (p = 0.0001), there was a statistically significant improvement in the robotic group compared to the conventional group. However, LEMS score (p = 0.052) was not statistically significant.

Khande et al. 2024

India
Prospective
controlled trial
Level 2
N = 30

beginning, 100% of each participant's body weight was supported. During the subsequent walking sessions, the BWS was reduced gradually to the minimum as tolerated without substantial knee buckling or toe drag and it was dependent upon the muscle power in lower limbs. Guidance force was maintained at 100%.

 In conventional group, participants were stood with the help of KAFO and bipedal movement was done on parallel bars. 100% body weight was on lower limbs from starting to end of conventional rehabilitation and velocity and step length varied participants to participants.

Outcome Measures: WISCI II, LEMS, and SCIM-III were assessed pre- and post-rehabilitation.

1. WISCI II:

- a. For complete injury patients, the after-treatment scores showed a significant increase compared to the scores at baseline (p = 0.008).
- In incomplete patients, after-treatment scores demonstrated a significant increase compared to the baseline scores (p = 0.002).
- c. WISCI II score improvement did not exhibit a significant difference between the incomplete and complete injury patients (p = 0.364).

Çinar et al. 2020

Turkey
Prospective
controlled trial
Level 2
N = 34

Population: 34 patients with SCI; 23 males and 11 females; mean age 32.8 years; injury level from C6 to L1, cervical (n = 6), thoracic (n = 21), and lumbar (n = 7); complete injury (AIS level A) (n = 17) and incomplete injury (AIS level B, C, or D) (n = 17); and mean duration of injury 3.5 months.

Treatment: All participants performed a robotic treatment training (Lokomat) for a total of 10 sessions for 5 weeks, twice a week; and received conventional treatment (ROM, stretching, strengthening, and walking training) for 5 days a week (twice daily). The patients were divided into two groups as complete and incomplete patients.

Outcome Measures: WISCI II was evaluated at the beginning and at the end of the treatment.

Level 2 N = 121 (47 acute)

Zieriacks et al. 2021

Germany

Prospective

controlled trial

Population: 121 patients with SCI and existing motor function of hip and knee extensor and flexor muscle groups to operate the exoskeleton; 89 males and 31 females; mean age 44.3 (16 – 74) years; AIS A with zones of partial preservation (n = 24), AIS C (n = 61) and AIS D (n = 36); injury level cervical (n = 32), thoracic (n = 55) and lumbar (n = 34); and mean (± SD) time since injury 65.3 (± 89.5). Participants were divided into two subgroups:

- Acute group (n = 47): < 12 months of SCI.
- Chronic group (n = 74): > 1 year of SCI.

Treatment: Participants performed BWSTT with the HAL robot suit exoskeleton 5 times a week for 90 – 120 min for 3 months. In addition to this, participants regularly performed a 10MWT and 6MWT without the exoskeleton with individual walking aids.

Outcome Measures: 10MWT, 6MWT and WISCI II were measured at the beginning, and after 6 and 12 weeks of training; LEMS was measured before and after the training program; and the parameters of walking time and distance were recorded each training session.

- 1. There were no AEs (e.g., falls).
- 2. HAL associated outcomes: Participants could significantly extend walking time with the exoskeleton on the treadmill and the ambulated distance after 12 weeks (p ≤ 0.0001); with no significant difference time observed between the subgroups (p = 0.16).
- 3. Functional outcomes:
 - a. All participants significantly improved in the functional assessments performed without the exoskeleton.
 - b. Participants significantly improved in 10MWT from baseline to after 12 weeks (p ≤ 0.0001); with no significant differences between groups (p = 0.72).
 - c. The distance ambulated (6MWT), WISCI II, and LEMS increased significantly in all participants from baseline to after 12 weeks (p ≤ 0.0001); however, acute participants improved significantly more than chronic participants (p ≤ 0.0001).

Alcobendas-Maestro et al. 2012

Spain RCT PEDro = 8 Level 1 N = 75 **Population:** 75 participants with SCI in total; all <6 months postinjury. For the Lokomat group (N=37), mean (SD) age = 45.2 (15.5); 62%M, 38%F; 68% AIS C, 32% AIS D. For the conventional treatment group (N=38); mean (SD) age= 49.5 (12.8); 63%M, 37%F; 71% AIS C, 29% AIS D.

Treatment: Randomized to 2 groups: Lokomat and conventional treatment.

- The Lokomat treatment group showed statistically significant differences in favor of Lokomat treatment over conventional treatment in the following outcome measures:
 - a. WISCI II: Lokomat [16 (8.5-19)], Conventional [9 (8-16)];p < 0.05.
 - b. 6MWT (m): Lokomat [169.4 (69.8-228.1)], Conventional [91.3 (51.4-178.7)]; p < 0.05.

	Outcome Measures: 10MWT; WISCI II; 6MWT; walking and stairs tasks of the FIM-L section; LEMS subscale; Ashworth Scale and visual analogue scale for pain.	 c. LEMS lower limb strength: Lokomat [40 (35-45.5)], Conventional [35 (29.7-40)]; p < 0.05. d. FIM-L: Lokomat [10 (6-12)], Conventional [7 (5-10)]; p < 0.05. 2. There were no differences between the Lokomat and conventional treatment group in the variables: speed (10MWT), spasticity (Ashworth scale), and pain (visual analogue scale).
Dobkin et al. 2006 USA RCT PEDro = 7 Level 1 N = 292 (enrolled) N = 117 (analyzed)	Population: 117 males and females; age 16-69 yrs; AIS B-D; <8 weeks post-injury. * These data showed that 15% of patients classified as ASIA B, 40% as ASIA C, and 75% as ASIA D at the time of admission were able to walk 150 feet at a supervised or better level of function at discharge. **Participants were subgrouped into: • Upper motor neuron, participants with a cervical to TI0/TI1 lesion. • Lower motor neuron, participants with a TI12 to L3 lesion and no upper motor neuron signs. Treatment: BWSTT vs. overground mobility training: 5x/wk, 9-12 wks, 30-45 min/session. Each participant engaged in equal amounts of either BWSTT or overground walking training. Outcome Measures: BBS, FIM-L, walking speed, 6MWT, WISCI at 3 and 6 months. Primary outcomes	 There were no significant statistical difference in FIM-L score between ASIA B and C participants. 33% (7/21) of ASIA B participants in the BWSTT group were ambulatory at 6 months and 58% (14/24) in the control group. The majority of ASIA C participants recovered independent walking; 92% of BWSTT and control participants (24/26 in each group) had a FIM-L score ≥6 at 6 months. ASIA C participants were significantly more likely than ASIA B participants to walk independently and both ASIA B and C participants who were randomized earlier (<4 weeks after SCI) had a greater probability of recovery to a FIM-L score >5. ASIA C and D – Walking speed: Primary outcome measures showed no

were FIM-L for ASIA B and C

participants and walking speed

months and 6 months after SCI.

for ASIA C and D participants at 3

statistical differences

groups in walking velocity

combined upper motor neuron/lower motor

between treatment

at 6 months for the

- neuron participants or the upper motor neuron participants alone. The median measures for velocity in the ASIA C and D participants demonstrated a remarkably high level of walking ability and fell within the range of functional community ambulation.
- Secondary analyses; ASIA C and D at 6 months: The median quartile walking velocities at 6 months for upper motor neuron ASIA C and D participants were unexpectedly high in both arms (1.1 m/s). No significant differences between the two interventions for FIM-L, walking speed, endurance, LEMS, BBS, or WISCI score. Walking speed at the end of treatment was highly correlated (r = 0.91) with the speed at 6 months, but speeds continued to increase between 3 and 6 months. Earlier time of entry (<4 weeks) into the study after onset of SCI was associated with faster walking speeds (p = 0.001) and longer walking distances (p = 0.0001) in both arms at 6 months for each ASIA group compared to velocities attained in participants in that group who were randomized >4 weeks after SCI.

Wirz et al. 2017

Switzerland, Germany, Spain and UK RCT **Population:** 18 participants with acute SCI and limited walking ability (WISCI II < 5); 16 males and 2 females; mean age 34.9 years; level of injury C4 to Π 2; AIS B (n = 9) and AIS C (n = 9); and study inclusion

1. For the SCIM mobility subscore, within-groups comparisons show that both groups improved after 8 weeks of RAGT training (intervention= from 3.0 to

<u>PEDro = 6</u> Level 1 N = 18

was set at maximum of 60 days post-trauma.

Treatment: Patients performed 3–5 days of training per week of RAGT using Lokomat for a period of 8 weeks. Patients were randomly allocated to one of two groups:

- Intervention group (n = 9):
 50 min of RAGT training
- Control group (n = 9): 25 min. of RAGT training.

Outcome Measures: SCIM subscore mobility was assessed at baseline and at 8 weeks of training.

20.0; p = 0.008; control= 4.0 to 10.0; p=0.012).

Sadegui et al. 2015

Iran
RCT
PEDro = 3
Level 2
N = 20 (enrolled)
N = 17 (analyzed)

Population: 20 males with incomplete SCI; mean (± SD) age 32.30 (± 1.50) years; paraplegia (n = 20); and time since injury > 6 months.

Treatment: Both groups participated in traditional training consisting of a 10-min warm up with passive stretch exercises; 45-min mobilization exercises of the hip, knee, and ankle joints and overground walking assisted, functional exercises, and strengthening and stretching activities; and 10-min cool down. Over a 12-week period, participants were randomly assigned to one of two groups:

- BWSTT group (n = 10):
 Participants also performed
 BWSTT 4 times per week, 60
 min each session. BWS was
 progressively decreased to
 ensure full weight bearing at
 the end of the study.
- Traditional group (n = 10):
 Traditional training only.

Outcome Measures: LEMS, WISCI II, 10MWT, and 6MWT were assessed at baseline and at post treatment.

- I. In the traditional group, 3 participants left the study because of bedsores (n = 2) and operation (n = 1).
- LEMS tended to increase to a greater extent following BWSTT compared to other intervention training (P = 0.000).
- There were significant differences between two groups with respect to improvements of WISCI II (43.85% vs. 0%, P = 0.002).
- 4. A comparison of the changes in scores suggested that there was greater improvement in 10MWT (40.12% vs. 7.40%, P = 0.001) and 6MWT (88.23% vs. 18.74%, P = 0.001) after BWSTT compared to conventional training.

*It should be noted that baseline scores in WISCI II, 10MWT and 6MWT seem to be different (no statistical analysis was done) and better for the traditional group.

Shin et al. 2014 Seoul RCT PEDro = 5 Level 2 N = 53	
Esclarín-Ruz et a 2014 Spain RCT PEDro = 7 Level 1 N = 88	<u>a</u>

Population: 53 participants- 34 males and 19 females with incomplete SCI; 31 with cervical injuries and 22 with thoracic & lumbar injuries; 36 with traumatic SCI and 16 with non-traumatic SCI; mean age= 48.15 ± 11.14y; months post injury= 3.33 ± 2.02 months.

Treatment: Patients were included in a prospective, randomized clinical trial by comparing RAGT to regular physiotherapy.

- The RAGT group received RAGT with Lokomat three sessions per week at duration of 40 min with regular physiotherapy in 4 weeks.
- The conventional group underwent regular physiotherapy twice a day, 5 times a week.

Outcome Measures: LEMS, ambulatory motor index, SCIM-III mobility section (SCIM-III-M), WISCI II.

Population: 88 participants; 44

(group A) and 44 with lower motor

with upper motor neuron SCI

- 1. At the end of rehabilitation. both groups showed significant improvement in LEMS, Ambulatory Motor Index, SCIM-III-M, and WISCI II.
- 2. Patients in the RAGT group showed significant greater gain (from 3 [IQR, 0-14] to 11 [IQR, 0-19]) compared to controls in the WISCI-II (from 4 [IQR, 0-16] to 9 [IQR, 0-20]). P=0.01.

neuron SCI (group B); 59 AIS C and 25 AIS D; mean age= 43.6 ± 12; days post injury= 125.6 ± 65.2.

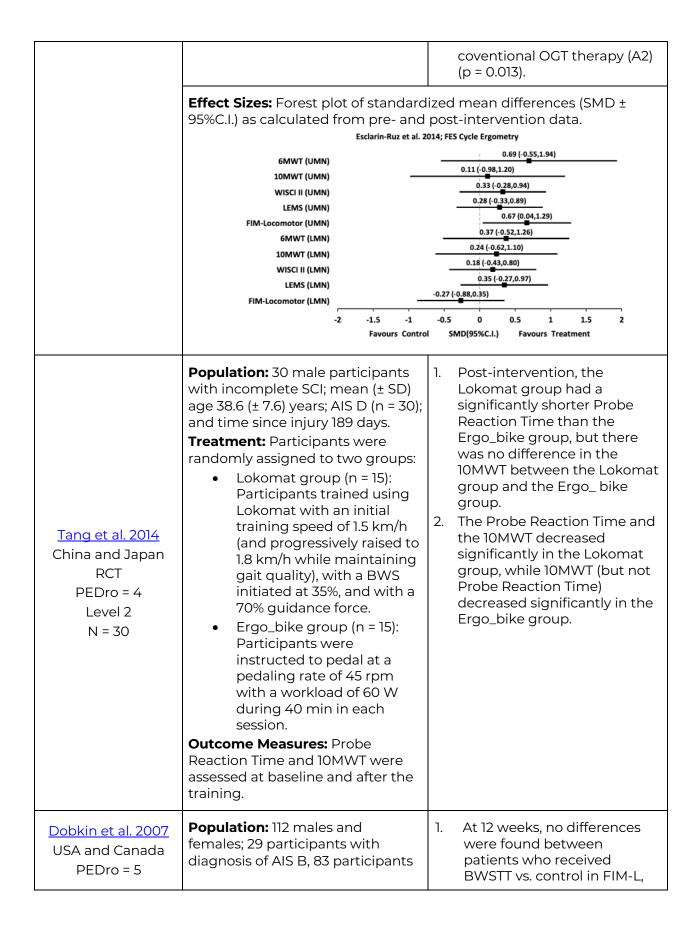
Treatment: Participants with UMN and LMN were randomized into 2 training groups:

- Condition 1: Subgroups A1 and B1 were treated with robotic LT plus overground therapy for 60 min.
- Condition 2: Subgroups A2 and B2 received 60 min of conventional OGT 5 days per week for 8 weeks.

Outcome Measures: 10MWT, 6MWT, WISCI II, LEMS, and the FIM-L were assessed.

- The distance covered in the 6MWT was statistically greater for the robotic plus overground therapy group than for the conventional OGT group (p = 0.047).
- 2. For the 10-MWT, there were no differences between conditions (p = 0.09).
- 3. For the WISCI II. there were no differences between conditions (p = 0.10).
- 4. Patients who underwent robotic LT plus overground therapy therapy obtained higher LEMS strength values than did patients in conventional OGT therapy.
- 5. In group A: upper SCI patients who underwent robotic LT plus overground therapy (A1) obtained higher FIM-Locomotor scores than did patients who underwent

n-Ruz et al. 2014



RCT Level 2 N = 112 with diagnosis of AIS C-D; age 16-70 yrs; mean 4.5 wks post-injury.

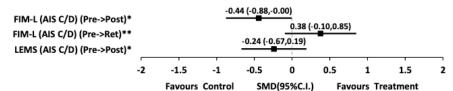
Treatment: BWSTT vs. overground mobility training (control): 5x/wk, 9-12 wks, 30-45 min/session.

Outcome Measures: FIM-L (range from 1 (total physical dependence) to 7 (independence to walk > 150 feet)), walking speed, 6MWT, LEMS.

- walking speed, LEMS, or distance walked in 6 min.
- FIM-L ≥ 4 was achieved in < 10% of AIS B patients,
 92% of AIS C patients, and all of AIS D patients; few AIS B and most AIS C and D patients achieved functional walking ability by the end of 12 weeks of BWSTT and control.
- 3. Time after injury is an important variable for planning interventions to lessen walking disability. Patients who started their rehabilitation sooner (<4 weeks after onset) had better outcomes. Thus, entry within 4 weeks allowed some patients to start at a lower level of function.
- 4. By 6 weeks after entry, most patients with SCI who will recover have improved their FIM-L to >3 and are improving in walking speed.

Effect Sizes: Forest plot of standardized mean differences (SMD \pm 95%C.I.) as calculated from pre- to post-intervention data and pre-intervention to retention/follow-up data.

Dobkin et al 2007; Weight-supported Treadmill



*SD of post-intervention measurements used for calculation

Hornby et al. 2005a

USA RCT PEDro = 5 Level 2 N = 30 **Population**: 30 patients with SCI (ASIA classification of B, C, or D) Inclusion Criteria: traumatic or ischemic SCI above the TIO spinal cord level experienced between 14 and 180 days prior to study

- Mean changes in all groups improved significantly during the training regimen, with significant changes in FIM-L subscores, WISCI scores, and LEMS.
- 2. Significant difference in

^{*}SD of follow-up/retention measurements used for calculation

enrollment, partial preservation of voluntary motor control in at least one muscle of the lower extremities.

Treatment: Randomly assigned to one of three 8-week training regimens: Robotic-assisted BWSTT, therapist-assisted BWSTT, and overground ambulation with a mobile suspension system.

Outcome Measures: LEMS, WISCI II, FIM.

- the total distance ambulated over ground: mean (SD) distance walked 1282 (606) m vs. both robotic-assisted (2859 (111) m) and therapist-assisted (2759 (215) m) BWSTT groups.
- 3. The number of therapists required to provide gait training on the treadmill or over ground was significantly greater than that required for the robotic-assisted group for the first 5 weeks of training.
- 4. There were no significant differences noted between therapist- and roboticassisted BWSTT groups for the final 3 weeks of training.

Schwartz et al. 2011

Israel Case control (single experimental group with matched historical control). Level 3

N = 56

Population: 56 participants with SCI as a result of traumatic (57%) or non-traumatic causes; 37 males and 19 females; mean age 42.5 years; level of injury cervical (n = 26), thoracic (n = 16), and lumbar (n= 14); AIS A (n = 6), AIS B (n = 7), AIS C (n = 13), and AIS D (n = 2); and mean time since injury 24 days.

Treatment: Participants in the intervention group were prospectively included and those in the control group were retrospectively matched.

- Intervention group (n = 28): Participants received 30-min sessions of RAGT with Lokomat with individualized progression in speed and BWS, and 30-45 min of regular physiotherapy sessions; for 2-3 times a week and 12 weeks.
- Control group (n = 28): Participants were treated by regular physiotherapy for 30-

- Though there were no significant differences between groups on walking ability after 12 weeks of RAGT or regular physiotherapy training, both groups showed a significant improvement in ambulation ability according to FAC (Wilcoxon signed ranks test Z = -5.21, P < 0.01).
- 2. During the rehabilitation period both groups achieved a significant improvement in WISCI II with no significant interaction effect between groups over time.

	45 min five times a week using Bobath principles. Outcome Measures: FAC scale and WISCI II were assessed upon admission and upon discharge from the rehabilitation department.	
Benito-Penalva et al. 2010 Spain Case control Level 3 N = 42	Population: 29 patients with motor incomplete SCI (24 males, 5 females, mean age 47; Group A < 3 months post-injury (n=16), Group B > 3 months post-injury (n = 13), and 13 healthy volunteers (10 males, 3 females, mean age 32) with pretest only. Treatment: Gait training using either the Lokomat or Gait Trainer GTI (based on availability of the system), 20-45 min per sessions (5 days a week for 8 weeks). Outcome Measures: LEMS, WISCI II, 10MWT, H reflex modulation by TMS.	 After gait training, there was a significant improvement in LEMS, WISCI and 10MWT for both group A and B, with a significantly greater improvement in 10MWT for group A vs. group B. After gait training, Group A showed significantly greater H reflex facilitation with TMS at 20 ms than Group B (170.7 + 10.2% vs. 125.3 + 5.6%), with no significant differences at 50 and 80 ms.
Benito-Penalva et al. 2012 Spain Pre-post Level 4 N = 105	Population: 105 participants with SCI. 39 randomized to Lokomat treatment and 66 to Gait Trainer GT I treatment. Mean age for both groups = 45 yrs. • For the Lokomat group, 26M 13F and 5 AIS A&B, 18 AIS C, 16 AIS D. • For the Gait Trainer GT I group, 45M 21F, and 6 AIS A&B, 26 AIS C, 34 AIS D. Majority of participants were <1 year post-injury. Treatment: Patients received LT with one of the electromechanical devices [Lokomat or Gait Trainer GT I System], 5 days/wk for 8 wks. Outcome Measures: LEMS, WISCI, 10MWT were collected at baseline, midpoint (4wks) and end of program (8 wks).	 Compared to conventional standard of care from the EM-SCI database, both ASIA grade C and D patients receiving electromechanical device system gait training had a significantly greater rate of change in motor function when compared to matched patients from EM-SCI group. Rate of clinical change across the training period was not significantly different between the two treatment groups for any of the three outcomes. For the total sample, all 3 clinical outcomes showed statistically significant improvement after the use of electromechanical systems: LEMS: pre= 22.07(1.08), post=30.56(1.15).

		b. WISCI: pre=3.97(0.49), post=9.16(0.68).c. 10MWT: pre=0.082(0.01), post=0.26(0.03).
Harkema et al. 2012 USA Pre-post (subacute and chronic) Level 4 N = 196	Population: 196 participants (148 male, 48 female) with incomplete SCI; mean age 41±15 yrs; YPI- <1 yrs (n=101), 1-3 yrs (n=43), >3 yrs (n=52). Treatment: LT with three components: (1) 1 hour of step training in the body-weight support on a treadmill environment, followed by 30 min of (2) overground assessment and (3) community integration. Outcome Measures: BBS, 6MWT, and 10MWT.	Scores on the BBS significantly improved by an average of 9.6 points. 6MWT distances and 10MWT speeds of all patients significantly improved by an average of 63m and 0.20m/s, respectively. 168 (86%) patients (66 of 66 AIS grade C, 102 of 130 AIS grade D) scored lower than 45, the reported threshold for risk for falls for the BBS: Patients with AIS grade C had significantly lower scores at enrollment than those with AIS grade D walked significantly farther than those with AIS grade C had significantly farther than those with AIS grade D walked significantly farther than those with AIS grade C.