Author Year Country Research Design Score Total Sample Size	Methods	Outcome
Xiang et al. 2021 China RCT (pilot) PEDro = 8 Level 1 N = 18	 Population: 18 patients with SCI; 15 males and 3 females; mean age 38.2 years; AIS A (n = 12), AIS B (n = 2), and AIS C (n = 4); level of injury T4-T10 (n = 9) and T11-below (n = 9); and median duration of injury 2 months. Treatment: The participants were divided into EAW with the AIDER (EAW) group (n = 9) or conventional group (n = 9). Intensity, duration, and frequency were similar in both groups (40–60% HR_{max}, 50–60 min/session, 4 days/week, 4 weeks): EAW group: Training session included sitting, standing, walking, climbing stairs and slope with the AIDER (AssIstive DEvice for paRalyzed patient) powered robotic exoskeleton. Conventional group: Consisted in strength training using dumbbell, aerobic exercise, such as walking training with brace. Outcome Measures: 6MWT, LEMS and ASIA scores were assessed pre and post intervention. 	 There were no AEs. Of the 10 participants who completed the final 6MWT, 2 were in the conventional group. The outcomes of distance recording as medians (IQR) were 17.3 (11.9) m and 0 (16.0) m for EAW and conventional group, respectively. Nonetheless, EAW training produced no statistical improvements in distance (p = 0.079) than conventional group. For LEMS, there was no statistical difference between two groups (p = 0.777). Additionally, neither group showed improvement in LEMS.
Gil-Agudo et al. 2023 Spain RCT PEDro = 7 Level 1 N = 21	Population: 21 participants with incomplete (AIS C or D) SCI, with enough strength in the upper limbs necessary to handle a walker or crutches and the capacity to tolerate standing. 15 males, 6 females Mean age: 46,4 years old Level of injury: C2-C8 (n = 1), T1-T6 (n = 5), T7-L1 (n = 9), and L2-L4 (n = 6) AIS C (n = 12), AIS D (n = 9) Mean time since injury: 5.2 months Treatment: Participants were randomly distributed into the two study groups:	 No major AEs were reported. Participants in the intervention group reported 1.8 cm (SD 1.0) for pain and 3.8 (SD 1.7) for fatigue using the visual analogue scale. Statistically significant differences were observed for the WISCI-II for both the "group" factor (F = 16.75, p < 0.001) and "group-time" interactions (F = 8.87; p < 0.01). A post-hoc analysis revealed a statistically significant increase of 3.54 points (SD 2.65, p < 0.0001) after intervention for

- Exoskeleton gait training (intervention group) (n = 11): The IG training protocol consisted of 15 robotic ambulatory gait training sessions (three sessions per week for 5 consecutive weeks), each session lasting 30 min. The HANK exoskeleton was used.
- Traditional gait training (control group) (n = 10): The CG rehabilitation program was comprised of 15 sessions, 30 min long, of a traditional gait training program (analytical mobilization, strengthening exercises for the lower limbs and gait re-education), distributed similarly as in the intervention group.

Outcome Measures: LEMS, 10MWT, TUG test, WISCI II, and SCIM-III were measured at baseline and end of training period (post-intervention).

- the intervention group but not in the control group (0.7 points, SD 1.49, p = 0.285).
- No statistical differences were observed between groups for the remaining variables.

Rodríguez-Fernández et al. 2022

al. 2022 Spain RCT Crossover PEDro = 7 Level 1 N = 10 **Population:** 10 participants with chronic motor-complete SCI; 9 males and one female; mean (\pm SD) age 44.10 \pm 5.93 years; level of injury T4 (n = 3), T6 (n = 1), T8 (n = 2), T10 (n = 1), T11 (n = 2), and T12 (n = 1); AIS A (n = 8) and AIS B (n = 2); and mean time since injury 10.5 years.

Treatment: Participants were randomly assigned to one of two groups, depending on the device used for the training program:

- KAFO.
- Knee-powered bilateral lower limb exoskeleton (i.e., the ABLE Exoskeleton).

The training program consisted of 10 sessions (2 sessions per week, for 5 weeks) of 90-min duration: 8 OGT sessions (sessions 1 to 4 and 6 to 9) plus 2 evaluation sessions (sessions 5 and 10). Participants spent a minimum of 30 min per training session doing sit-to-stand and stand-to-sit transitions, and standing and walking exercises using one of the two devices and the aid of a walker. There was a 2-week resting period between the final evaluation

- 1. No serious AEs were reported during the study.
- 2. The average level of assistance provided by the therapist to the participants was slightly higher for the ABLE group compared to the KAFO group (ns).
- No significant differences were found between the two groups for 6MWT and 10MWT.
- 4. Spatiotemporal parameters and gait kinematics: Walking with the ABLE Exoskeleton improved gait kinematics compared to the KAFOs, providing a more physiological gait pattern with less compensatory movements (38% reduction of circumduction, 25% increase of step length, 29% improvement in weight shifting).
- Linear regression analysis between the outcome metrics of the standardized clinical tests and the level of injury revealed significant, strong

session and the first training session with the crossed-over device.

Outcome Measures: 6MWT; 10MWT; and gait kinematics and spatiotemporal parameters (during 6MWT) were assessed at session 10.

correlations for the KAFO group. In contrast, correlations for the ABLE group were low to mild and not statistically significant.

Population: 16 participants with chronic and incomplete tetraplegia; reliant upon a wheelchair as the primary mode of mobility; and sufficient anthropometrics and ROM to achieve a normal, reciprocal gait pattern within the Ekso GTTM.

- Robotic locomotor training group (n = 8):
 Mean (SD) age: 40.5 (11.2) years 8M, 0F
 Injury level: C4-C7
 AIS C (n = 4) and AIS D (n = 4)
 Mean (SD) time since injury: 13.8 (8.2) years.
- ABT group (n = 8):
 Mean (SD) age: 38.4 (14.3) years
 7M, 1F
 Injury level: C4-C7
 AIS C (n = 5) and AIS D (n = 3)
 Mean (SD) time since injury: 7.3 (6.4)
 years.

Treatment: The exercise intervention consisted of 24 weeks of supervised robotic locomotor training and ABT. Both interventions consisted of three sessions per week, 60-min each. Participants were randomized into one of the following groups:

- Robotic locomotor training involved solely walking in an Ekso® GT Variable Assist Model exoskeleton. Intensity levels were determined by the attending therapist and ranged from standing and walking time of 10 to 50 min and between 50 and 1800 steps taken.
- ABT consisted of a combination of resistance (20-30 min), cardiovascular (20-30 min), and flexibility training in various positions. Gait retraining, without a treadmill or robotic assistance, was also performed in the ABT group.

- Participants had an average adherence of 93.9 ± 6.2% (67 out of 72 sessions) with no statistical difference between groups.
- 2. Strength capacity:
 - a. There were no significant differences between groups for LEMS (p = 0.86; ES = 0.05). Only the robotic locomotor training group showed a significant increase in LEMS from pre (16.00 ± 11.00) to post intervention (19.00 ± 11.00) (p < 0.05).
 - b. There were no significant group differences for back (p = 0.77; ES = 0.14) or abdominal muscle strength (p = 0.80; ES = 0.13). However, both groups had a significant change in abdominal strength from pre- to post intervention (p = 0.02), with a mean increase of 7.04 [0.00; 22.35] Nm and 9.84 [0.00; 22.01] Nm for the robotic locomotor training and ABT group, respectively.
- 3. Walking capacity:
 - a. There were no significant between-group differences over time for distance walked during the SCI-FAI test (p = 0.47; ES = 0.53). Only the robotic locomotor training group had a significant improvement in distance walked over time (p = 0.02), with an increase of 0.97 [0.00; 6.88] m.

Shackleton et al. 2024 South Africa

RCT PEDro = 6 Level 1

N = 16

Outcome Measures: LEMS, isometric dynamometry of abdominal flexion and back extension, and SCI-FAI were measured at pre, 6 weeks, 12 weeks, and post (24 weeks).

- b. Six (n = 4 ABT; n = 2 robotic)locomotor training) of the 16 participants were nonambulatory from baseline and continued to be so for the length of the intervention. Two participants in the robotic locomotor training group who were non-ambulatory at baseline, both managed to achieve an improved distance of 2.44 m and 0.82 m by week 24.
- c. SCI-FAI device score and technique score remained unchanged for both interventions over time.

Population: 28 participants with acute SCI and with enough hand function to partially manage a walking aid.

- incorporated EAW group (n = 16): 10M. 6F Mean (SD) age: 45.8 (18.3) years. Level of injury: Cervical (n = 7), thoracic (n = 5), and lumbar (n = 4). AIS A (n = 3), B (n = 4) and C (n = 9). Etiology: Traumatic (n = 13) and nontraumatic (n = 3).
- Standard acute inpatient rehabilitation group (n = 12): 9M.3F Mean (SD) age: 46.8 (18.3) years. Level of injury: Cervical (n = 5), thoracic (n = 4), and lumbar (n = 3). AIS A (n = 4), B (n = 2) and C (n = 6). Etiology: Traumatic (n = 9) and nontraumatic (n = 3).

Acute inpatient rehabilitation with

Treatment: Both groups received 15 hours of acute inpatient rehabilitation therapy per week, which included physical therapy and occupational therapy for bed mobility, seated and standing balance, strength, gait, transfers, and wheelchair mobility training to improve participants' independence in ADLs. Additionally,

Tsai et al. 2024 USA

RCT PEDro = 6 Level 1 N = 28

There was a significant main effect of time in the SCIM total score [F(1, 26) = 117.78, p < 0.01]. Participants had significantly higher SCIM total scores at discharge compared with the scores at admission. There was also a significant treatment group-by-time interaction effect in the SCIM total score [F(1, 26) = 5.59, p = 0.03]. The pattern of improvement in the SCIM total score between admission and discharge was significantly different between the acute inpatient rehabilitation with incorporated EAW and Standard acute inpatient rehabilitation groups, which was in favor of the acute inpatient rehabilitation with incorporated EAW group. Changes in the SCIM total scores between admission and discharge were approximately 13 points (95% CI [1.7, 24.1]) higher in the acute inpatient rehabilitation with incorporated EAW group

participants were randomly allocated into one of the following groups:

- The acute inpatient rehabilitation with incorporated EAW group (n = 16) received EAW training for overground walking utilizing a powered exoskeleton (EksoGT) as part of a minimum of their 15 hours per week of acute inpatient rehabilitation therapies, and aimed to provide two to three 1-hour sessions per week.
- The Standard acute inpatient rehabilitation group (n = 12) received the same amount of acute inpatient rehabilitation therapies incorporating walking with the use of parallel bars, a treadmill with an overhead lift, and ceiling track, or a body-weight support device on wheels.

Both groups also had the same discharge criteria. Participants would be discharged from acute inpatient rehabilitation when they had achieved the functional mobility and performance of ADLs goals set by the clinicians or when their progress in reaching those goals had reached a plateau.

Outcome Measures: SCIM-III and LEMS were measured at admission and at discharge from acute inpatient rehabilitation.

- compared with the Standard acute inpatient rehabilitation group.
- 2. There were significant effects of time in SCIM mobility score (F(1, 26) = 111.75, p < 0.01) and LEMS (F(1, 26) = 33.29, p < 0.01). Participants had significantly higher SCIM mobility scores and LEMS at discharge compared with the scores at admission. There were significant treatment group by time interaction effects in the LEMS [F(1, 26) = 5.82, p = 0.02]. The patterns of improvement in LEMS from admission to discharge were significantly different between the acute inpatient rehabilitation with incorporated EAW and Standard acute inpatient rehabilitation groups, which were in favor of the acute inpatient rehabilitation with incorporated EAW group. Changes in LEMS between admission and discharge were approximately 9 points higher in the acute inpatient rehabilitation with incorporated EAW group compared to the Standard acute inpatient rehabilitation group.

Edwards et al.

2022

USA

RCT

PEDro = 5

Level 2

N = 25

Population: 25 patients with chronic motor incomplete SCI, with self-selected gait speed of <0.44 m/s, the ability to take at least one step, and be able to fit into the Ekso device; 18 males and 12 females; mean age 47.2 years; AIS C (n = 9) and AIS D (n = 21); level of injury C1-T10; and mean time since injury 6.8 years. *45 participants were enrolled, of which 33 were randomized to the main study and 12 enrolled as run-in participants. Of the 33 randomized participants, 25 completed the assessments and

- I. There were 3 serious AEs (urinary tract infections unrelated to the device [n = 2]) and one participant in the active group admitted to a hospital with lower extremity numbness and a urinary tract infection).
- 2. From the total sample of 45 participants*, AEs that were deemed "possibly" or "probably" related to the device or training include the

training related to the primary endpoint analysis.

Treatment: Over 12 weeks, participants were randomly assigned to one of three study arms:

- Ekso Robotic Intervention (n = 9):
 Participants performed a 45 min session (standing/up and walking) in the Ekso device, 3 times per week; and if possible, overground training without BWS.
- Active Control (n = 10): Each session comprising 45 min of BWSTT, and if possible, OGT without BWS.
- Passive Control (n = 6): Participants continued with daily activities as normal.

Outcome Measures: Gait speed (10MWT); endurance (6MWT); functional mobility (WISCI II); need of assistance and devices, and safety (AEs and serious AEs). All outcomes were assessed at baseline, at midpoint (6 weeks), at the end of the intervention (12 weeks), and at 12 weeks post-intervention.

- following: 12 (8 Ekso, 4 Active) upper and lower extremity musculoskeletal issues; 4 (3 Ekso, 1 Active) neurological issues; 6 (5 Ekso, 1 Active) skin issues; and 1 (Ekso) visceral issue.
- Self-selected gait speed following the 12-week intervention increased in the Ekso group by 51% (mean, SD; 0.18±0.23 m/s) Active Control by 32% (0.07±0.11 m/s) and Passive Control 14% (0.03±0.03 m/s), within group and between group comparisons (ns).
- 4. The proportion of participants with improvement in clinical ambulation category from home to community speed post-intervention was greatest in the Ekso group (>1/2 Ekso, 1/3 Active Control, 0 Passive Control, p < 0.05).
- 5. The median distance covered in the 6MWT following the 12-week intervention was 538.0 feet (Quartile 268.0–687.3) for the Ekso Group, 346.6 feet (Quartile 219.5–711.5) for the Active Control, and 320.0 feet (Quartile 148.8–466.6) for the Passive Control representing improvements of 34%, 28%, and 18%, respectively (ns).
- 6. Most participants in both the Ekso group and the Active Control group showed no change in type of assistive device used outside the clinic throughout the duration of the protocol; with no changes observed in the Passive Control group.

Tarnacka et al. 2023

Poland RCT **Population:** 105 participants with SCI

- Control group (n = 33):
 28 males, 5 females
 Median age: 36.5 years
 AIS A (n = 14), AIS B (n = 4), AIS C (n =
- There were no significant differences between groups for SCIM-III scores.
- 2. Patients with incomplete SCI assigned to the experimental

PEDro = 5 Level 2 N = 105

- 11), AIS D (n = 4) Level of injury: Cervical (n = 7), thoracic (n = 17), and lumbar (n = 9) Median time since injury: 13 months
- Experimental group (n = 72):
 58 males, 14 females
 Median age: 36.5 years
 AIS A (n = 27), AIS B (n = 7), AIS C (n = 13), AIS D (n = 25)
 Level of injury: Cervical (n = 17), thoracic (n = 32), and lumbar (n = 23)
 Median time since injury: 13 months

Treatment: The therapeutic program consisted of two phases: first, 3 weeks, then, after a 1-week break, 3 weeks in the second phase. The program was conducted six days per week. Participants were allocated into two groups:

- The control group received conventional physiotherapy and 30 min dynamic parapodium training.
- The experimental group received 30 min sessions of RAGT with exoskeleton EKSO-GT or Lokomat Pro with the general exercise program and ground gait training.

*The dynamic parapodium is a piece of individualized uprighting equipment (a combination of thoracolumbosacral orthosis and HKAFO device of the dynamic type) that allows the patient to stand and walk by swinging the trunk. All participants from the Lokomat group with incomplete SCI started with 60% BWS and an initial treadmill speed of 1.5 km/h; patients with complete SCI started with 100-90% BWS. Patients with a thoracic level of injury were mostly enrolled in the EKSO-GT group, and with a cervical level, in the Lokomat group.

Outcome Measures: The AIS Motor Score, SCIM-III, WISCI II, and Barthel Index were conducted before the start of the therapy and after 7 weeks of therapy.

- group achieved significant improvements in motor score [2.58 (SE 1.21, p < 0.05)] and WISCI II [3.07 (SE 1.02, p < 0.01])] scores in comparison with patients assigned to the control group.
- 3. Both the Lokomat group and the Dynamic parapodium group improved on their SCIM-III and AIS motor scores significantly, though the Lokomat group's score difference was slightly greater in X and Y.
- 4.

Hong et al. 2020 USA **Population:** 50 participants with chronic (> 6 months) SCI who were non-ambulatory; 38 males and 12 females;

. There were four "possibly study-related" severe AEs and there were 49 total studyRCT PEDro = 5 Level 2 N = 50 mean (\pm SD) age 38.7 (\pm 14.2) years; AIS A/B (n = 31) and AIS C/D (19); and mean (\pm SD) time since injury 4.69 (\pm 5.18) years.

Treatment: Eligible participants were randomized within site to one of two groups for 12 weeks (3 months):

- Group 1 received EAW first for 12 weeks then crossover to usual activity for a second 12 weeks.
- Group 2 received usual activity first for 12 weeks then crossover to EAW for 12 weeks of training.

Participants were divided by four neurological deficit sub-groups: motor complete tetraplegia (n = 4); motor incomplete tetraplegia (n = 10); motor complete paraplegia (n = 27); and motor incomplete paraplegia (n = 9).

- training, three sessions per week (4–6 h/week) for 36 sessions. Two powered exoskeleton devices were used depending individual characteristics of each participant, namely the ReWalk™ and the Ekso™. Most participants with injury level of T3 or lower used the ReWalk (n = 28) and participants with injury level higher than T3 used the Ekso (n = 22).
- The usual activity arm consisted of the identification of usual activities for each participant and encouragement to continue with these activities throughout the 12week usual activity arm.

Outcome Measures: 10MWT and 6MWT were performed at 12, 24, and 36 sessions.

- related AEs which included 39 skin abrasions/bruising, eight musculoskeletal/edema, and two falls. All study-related skin abrasions and musculoskeletal AEs were resolved, and participants continued in study. There were two falls during EAW, but no injuries occurred.
- 2. There were no order effects for Group 1 (immediate) vs. Group 2 (delayed therapy) for total steps. The number of steps taken per session increased overall sessions for both devices, but participants who used the Ekso took more total overall steps than those who used the ReWalk.
- 3. Participants who used the Rewalk had significantly better performance during the 10MWT and 6MWT than participants using the Ekso at session 36 (p < 0.0001).
- 4. There were significant improvements in the performance of the 10MWT and 6MWT from session 12 to session 36 (p < 0.0001); but there were no significant differences between subgroups in terms of improvements from 12 to 36 sessions on the 10MWT (p = 0.067), and 6MWT (p = 0.339).</p>

2019 Italy Prospective controlled trial

Guanziroli et al.

Level 2 N = 15 **Population:** 15 participants with chronic (< 6 months post-injury) and motor-complete SCI, and with a regular use of a reciprocal gait orthoses or therapeutic standing frame; 11 males and 4 females; mean (± SD) age 39.33 (± 10.31) years; injury level T4 to L1; AIS A-B; and mean (± SD) time since injury 5.47 (± 4.68) years.

- Patients required an average of 21.77 ± 4.68 training sessions to achieve independent walking with ReWalk.
- 2. Group 2 covered more distance in 6 min (+124.52%) (p < 0.01) and required less time (-70.34%) (p = 0.03) to perform 10MWT and to STS-time (-

Treatment: Participants performed 60min sessions 3 times a week for at least 8 weeks with a wearable lower limb powered exoskeleton (ReWalk). The training included sit-stand transfers, stand-sit transfers, stepping skills; and once acquired these underlying skills. the main focus of the training was to improve walking performance with step triggering, coordinating step timing and foot clearance, integrating safe and effective stopping and a full self-control using the wrist pad controller. Participants were divided into two

- groups:
- Group 1 (n = 5): Participants used the first generation of ReWalk software control.
- Group 2 (n = 10): Participants used the second generation software control of the same exoskeleton (which that allowed a better movement pattern based on healthy kinematics and kinetics profiles) with no change in hardware.

Outcome Measures: 6MWT, 10MWT, and sit to stand time (which measures the time needed to pass from sitting to standing and start to walk) were assessed at the end of the training period while wearing the exoskeleton.

- 38.25%) (p = 0.08) if compared to group 1.
- 3. Group 1 showed a correlation between weight, height, neurological lesion level and the level of performance reached by the participants; instead, group 2, showed correlation only between neurological lesion level and performance.
- 4. Patients of group 2 with lower lesion level, covered longer distance if compared to those with higher lesion, while patients of group 1 with lower distance covered, were characterized by higher weight and height characteristics.

Tamburella et al. 2020b

Italy Prospective controlled trial Level 2 N = 8

Population: 8 participants with incomplete SCI and the ability to walk overground (with aids if necessary); 6 males and 2 females; mean age 53.5 years; injury level C6 (n = 1), C7 (n = 2), T5 (n = 1), T10 (n = 2), and T11 (n = 1); AIS D (n = 1)= 8); and mean (± SD) time since injury 18.3 (± 13.5) months for experimental group and 21.6 (± 11.1) months for control group.

Treatment: All participants performed 10 sessions of 40-min gait training 3 times per week with the main goal of improving comfortable gait speed. Each training session was composed by few min of preparation (performing ankle or knee movements), followed by a specific

- 1. After the intervention, no statistical differences were found for any analyzed variables between groups.
- 2. Comparing after training vs. baseline data:
 - a. Significant improvements in spatiotemporal parameters (gait speed, gait cycle time, and step length) were found only for the experimental group.
 - b. Very minor changes in ground reaction forces and MMT were found for both groups.
 - c. At baseline, experimental participants were unable to

walking training. Participants were divided into two groups:

- Experimental group (n = 4, prospective enrollment): Participants used the NeuroMuscular Controller-controlled Achilles ankle exoskeleton (developed to assists plantar/dorsiflexion during walking).
- Control group (n = 4, case-control matched): Participants didn't use the Achilles exoskeleton.

Outcome Measures: Motion outcome measures (spatiotemporal parameters [speed, step length and width, gait cycle time and stance phase percentage] and ground reaction forces) were assessed by using four force plates; clinical outcome measures (6MWT*, 6-min gait speed, fatigue, muscle force [assessed by MMT of hip, knee and ankle joints] were assessed at baseline and at the end of the training in free walking conditions.

*6MWT was assessed with and without Achilles for the experimental group, and only in free walking condition for control group.

- complete the 6MWT without the support of the Achilles and was easily completed with the Achilles at the end of training; meanwhile only two participants in the control group showed improvements in 6MWT.
- d. For MMT and BBS, there was no statistically significant modifications in both groups.

<u>Tsai et al. 2020</u>

USA Case control Level 3 N = 30 **Population:** 30 patients with acute or subacute SCI (< 6 months post injury) and eligible for LT; 24 males and 6 females; mean age 49.4 years; AIS A (n = 3), AIS B (n = 3), AIS C (n = 13), and AIS D (n = 11); incomplete tetraplegia (n = 12), complete paraplegia (n = 3), and incomplete paraplegia (n = 15); level of injury cervical (n = 12), thoracic (n = 14), and lumbar (n = 4); and mean time since injury 19.3 days.

Treatment: All participants received a minimum of 15 hours of standard of care acute inpatient rehabilitation therapy per week. Two groups were compared:

Intervention group (n = 10)
 (prospective): Participants received
 EAW training for overground
 walking using a powered
 exoskeleton (EksoGT).

- 1. A minor skin abrasion was the only AE recorded.
- 2. Changes from admission to discharge LEMS (14.3±10.1) were significantly greater in the intervention group compared with the control group (4.6±6.1) (P<.01). After adjusting for the days of inpatient stay, a significant difference was found between the groups, with the intervention group having a better change score when compared with the control group (P = .02).
- There was an average of 4.2 ±1.8 sessions of EAW training for each participant.
- 4. Participants using the exoskeleton could stand up

•	Control group (n = 20)
	(retrospective): Participants were
	matched controls and did not
	receive any EAW training.

*The participants in the intervention group had significantly longer days of inpatient stay than the control group $[39.9 \pm 11.4 \text{ d vs. } 30.9. \pm 12.9 \text{ d}, P < .05]).$

Outcome Measures: LEMS was assessed at baseline and at discharge. For the intervention group only, the number of EAW sessions performed, AEs, total steps, and total up and walk times in each EAW session were recorded as well.

- and walk for about 30 min with 450 steps during each session.
- 5. There is a positive correlation trend between the number of EAW sessions and maximum walking time in the device ($\rho =$ 0.56, large effect size, P = .09).

Population: 18 participants with SCI; who had completed a minimum of one overground exoskeleton gait training session during both inpatient and outpatient therapy Mean (SD) age: 37.4 (15) years

15M, 3F

Paraplegia (n = 9) and tetraplegia (n = 9) ASIA A (n = 5), B (n = 4), C (n = 7), and D (n = 2)

Treatment: A typical overground exoskeleton gait training session in both inpatient rehabilitation and outpatient therapy settings was 45 minutes during which the participant completed standing and walking tasks in the exoskeleton device (Ekso GT).

Outcome Measures: WISCI II was collected during both inpatient and outpatient admissions.

The average number of overground exoskeleton gait training sessions across inpatient and outpatient settings was approximately 19 for both motor complete and motor incomplete SCI groups spanning over an average of 17 to 18 weeks.

- Patients demonstrated improved overground exoskeleton gait training session tolerance on device metrics including "walk" time (motor complete, 7:51 ± 4:42 to 24:50 ± 9:35 minutes; motor incomplete, 12:16 ± 6:01 to 20:01 ± 08:05 minutes), "up" time (motor complete, $16:03 \pm 7:41$ to 29:49 ± 12:44 minutes; motor incomplete, 16:38 ± 4:51 to 23:06 ± 08:50 minutes), and step count (motor complete, 340 ± 295.9 to 840.2 ± 379.4; motor incomplete, 372.3 ± 225.2 to 713.2 ± 272).
- 3. Across therapy settings, patients with motor complete SCI experienced improvement in WISCI II scores from 0 ± 0 at inpatient admission to 3 ± 4.6 by outpatient discharge, whereas the motor incomplete group demonstrated a change of 0.2 ± 0.4 to 9.0 ± 6.4.

Arnold et al. 2024 **USA** Case series Level 4 N = 18

Population: 12 participants with chronic complete (AIS A) SCI and able to wear the Atalante exoskeleton; 10 males and 2 females; mean age (\pm SD) 22.9 (\pm 9.3); injury level T5 (n = 2), T6 (n = 4), T8 (n = 1), T10 (n = 2), T11 (n = 1), and T12 (n = 2); and mean (\pm SD) time since injury 88 (\pm 63.2) months. **Treatment:** Participants received 12

Kerdraon et al. 2021 France & USA Pre – post

Level 4

N = 11

Treatment: Participants received 12 one-hour training sessions for 3 weeks. Patients walked on floor and wore a harness connected to a mobile suspension system (without weight bearing) to prevent from falling, while using the Atalante exoskeleton.

Outcome Measures: The ability to walk 10 m, without human or material assistance; 10MWT; the ability to sit down without human assistance, with intrinsic perturbations such as arm and upper body movements; the ability to turn 180° in less than 3min (U-turn); and the ergonomics of Atalante exoskeleton were assessed at the 6th and at the 12th session.

- The only treatment-related AEs were skin redness (n = 5) and ischial skin abrasion (n = 1) with a complete resolution.
- 2. Walking parameters: Seven out of 11 patients passed the 10MWT unassisted at the 12th session (average speed was 0.13 m/s ± 0.01), representing 63.6% of success. The remaining four patients required human assistance. No relationship was observed with age, gender, height, weight or level of injury.
- 3. Postural parameters: All patients succeeded in standing up, sitting down and standing up for two min at the 6th and 12th session. At the 6th session, all the patients passed the Uturn test with some assistance, whereas during the 12th session two patients performed the U-turn without any help.

Kim et al. 2021

Korea
Pre – post
Level 4
N = 10

Population: 10 non-ambulatory patients with SCI with sufficient postural stability to sit independently, ability to transfer from wheelchair to bed independently, and sufficient bilateral upper extremity strength to manage crutches, among others; 7 males and 3 females; mean age 48.1 years; AIS A (n = 7), AIS B (n = 1), and AIS C (n = 2); level of injury C6 (n = 1), T1 (n = 1), T4 (n = 1), T8 (n = 1), T10 (n = 4), T11 (n = 1), and L1 (n = 1); and mean time since injury 5.7 years.

Treatment: The program was performed 3 times per week, over 10 weeks. Each training session consisted of standing up from sitting on a chair, walking across a flat floor, and sitting down on a chair with the exoskeleton H-MEX for 60 min.

Outcome Measures: 6MWT and Korean version of FES-I (KFES-I) were assessed at pre-training and post-training.

- There were not severe AEs, but there were several minor events (two skin abrasions and one near fall).
- 2. 6MWT:
 - a. Statistically significant improvement between the pre- and mid- training assessment, and between the mid-training and posttraining assessment (P < 0.014) were reported.
 - b. After training, the mean distance achieved (49.13 ± 15.22 m) was significantly enhanced compared with baseline (20.65 ± 5.55; P = 0.005).
- The mean score in the KFES-I questionnaire was reduced post-training (36.00 ± 9.09) compared to pre-training (37.80 ± 8.40), but this result

	*6MWT were also assessed at mid- training (15 sessions).	was not statistically significant (P = 0.475).
Park et al. 2021 Korea Pre – post Level 4 N = 10	Population: 10 nonambulatory participants with SCI; 7 males and 3 females; mean (± SD) age 48 (± 8.7) years; AIS A (n = 7), AIS B (n = 1), and AIS C (n = 2); injury level C6 (n = 1), Π (n = 1), T4 (n = 1), T8 (n = 1), Π0 (n = 4), Π1 (n = 1), and L1 (n = 1); and mean (± SD) time since injury 5.7 (± 4.8) years. Treatment: The training program was the same as described above in Kim et al. (2021). Outcome Measures: 6MWT was assessed at pre-training (baseline), at mid-training (15 sessions), and post-training (after 30 sessions).	1. In the 6MWT, the participants walked a significantly further distance at mid-training (37.5 ± 10.5 m) than at pre-training (20.7 ± 5.5 m) (p = 0.005) and covered more distance at post-training (49.1 ± 15.2 m) than at pre- and mid-training (p = 0.05 and p = 0.014, respectively).
Xiang et al. 2020 China Pre – post Level 4 N = 28	Population: 28 participants with SCI; 20 males and 8 females, mean (± SD) age 41.3 (± 11.8) year; AIS A (n = 22) and AIS B (n = 6); level of injury beyond T11 (n = 17) and at T11 or lower (n = 11); and median (± IQR) duration of injury 4.0 (± 10.4) years. Treatment: Along with the usual basic rehabilitation therapies, participants performed a gait training protocol (sitting, standing, transitioning between the two, and walking) for 30 min/session, one session/day, 5 days/week for 2 weeks using the new powered lower limb robotic exoskeleton (AIDER). Outcome Measures: Safety indicators, 6MWT, 10MWT, Hoffer walking ability grade, LEMS, and WISCI II were assessed. Walking parameters were assessed at baseline (with the usual orthosis if they had one), at the midterm of the training with the robotic exoskeleton and crutches (week 1), and at the end of the training with those (week 2).	 There were several AEs, (i.e., urinary tract infection [n = 2]; upper respiratory tract infection [n = 2]; conjunctivitis [n = 1]; femoral [n = 1] and foot [n = 1] fracture; skin integrity event [n = 1]; and diabetes [n = 1]). Walking parameters: 6MWT was improved in week 2 (16.2 ± 5.3 m) compared with baseline (0 m). 10MWT at week 1 and week 2 were 0.039 ± 0.016 m/s and 0.045 ± 0.016 m/s in the exoskeleton, respectively with a mean. Participants with higher injuries (T6–T11) demonstrated greater improvements in gait speed and walking distance than those with lower injuries. The same pattern was shown in participants with AIS-A compared to those with AIS-B injuries. Participants showed an improvement in WISCI II and in the Hoffer walking ability grades.

		There was no change in the LEMS after the program.
Swank et al. 2020 USA Case-control Level 3 N = 59 patients with SCI	Population: 155 patients who had completed inpatient rehabilitation due to stroke (n = 96) or SCI (n = 59). The patients with SCI were 19 males and 12 females, had an average age of 48.2 years; 66.1% were tetraplegic; and 64.4% had cervical level injuries. Treatment: Patients were retrospectively (based on medical records) divided into two groups: • Overground robotic exoskeleton gait training group (n = 31 SCI and 44 stroke): Patient who completed a minimum of one overground robotic exoskeleton gait training session. • Usual care group (n = 28 SCI and 52 stroke): Matched controls who participated in a minimum of one session of usual care gait training interventions. Outcome Measures: FIM motor and WISCI II (for patients with SCI) were assessed at baseline and at discharge. *Only patients with SCI will be assessed here. ** To describe outcomes between patients receiving overground robotic exoskeleton gait training plus usual care and patients receiving usual care only, patients who completed a minimum of 5 overground robotic exoskeleton gait training sessions were included (SCI, n = 18, 58%).	 Dosage: The average overground robotic exoskeleton gait training session count was 6.3 ± 3.8 (range = 1–17). Within the standard 45-min therapy session, the average overall overground robotic exoskeleton gait training session time increased from about 15 min (session 1) to 30 min (sessions 13, 14, and 17) and the time spent 'walking' nearly matched the total 'up' time. C. Patients in the overground robotic exoskeleton gait training group averaged 9.5 more min per day than the usual care group (16.3 ± 8.1 vs. 6.8 ± 6.5 min, P < 0.0001). Functional outcomes: Overground robotic exoskeleton gait training 5+ and usual care groups both showed improvements in WISCI II and FIM motor at baseline compared with at discharge; but without significative differences between groups.
Khan et al. 2019 Canada Pre-post Level 4 N = 12	Population: 12 participants with chronic, non-progressive SCI, using the wheelchair as the primary mode of mobility and able to use forearm crutches; mean (± SD) age 37.5 (± 13.7) years; level of injury C6 (n = 2), C7 (n = 1), T3 (n = 2), T4 (n = 2), T6 (n = 1), T7 (n = 2), T9 (n = 1), T10 (n = 1); AIS A (n = 6), AIS B (n = 2), AIS C (n = 3) and AIS D (n = 1); and mean (± SD) time since injury 7.7 (± 8.1) years.	 AEs and technical issues included two falls (without no injuries sustained by the participants because the trainer could control the fall); skin abrasions which some time away necessary to improve the healing; and some minor injuries in the trainer when he was trying to control the participant's falls. Three participants were able to perform 10MWT, 6MWT

*Uninjured (i.e., control) participants were also recruited for comparison of some physiological measures.

Treatment: Participants used the ReWalk 2.0 (exoskeleton) for training different activities (such as donning and doffing, sit-to-stand, stand-to-sit, balancing in standing and walking) 4 days per week during 12 weeks of training.

Outcome Measures: Walking (10MWT during continuous walking in the ReWalk, 6MWT); manual muscle strength (LEMS); was measured on a force platform) were taken before, during, immediately after, and at follow-up (2–3 months after training).

- without the ReWalk, using their preferred walking aid. All three walked further (but p > 0.05) in the 6MWT and at a lower effort (less physiological cost index) with the ReWalk compared to without the ReWalk.
- 3. All participants required some assistance with donning and doffing the device; however, many walking tasks were possible for most of the participants without assistance.
- 4. Two out of three participants with motor incomplete injuries showed improvements in LEMS.

Population: 11 participants with SCI and with the ability to use the Ekso GT exoskeleton; 8 males and 3 females; mean age 41 years; AIS A (n = 5), AIS C n = 5), and AIS D (n = 1); level of injury C6 (n = 2), T5 (n = 1), T6 (n = 1), T7 (n = 3), T10 (n = 1),T12 (n = 1), L1 (n = 1), and L2 (n = 1); and mean time since injury 9.5 weeks. *Six participants completed all 25 training sessions.

Treatment: The training regime consisted of 25 one-hour walking sessions with the Ekso GT exoskeleton, 3 times per week. Participants progressed through the various walk modes of the device with progressions individually determined.

Outcome Measures: Up time, walk time, number of steps, and AEs (falls, pain and skin integrity) were collected each session; and 6MWT and 10MWT were collected at sessions 2, 13 and 25.

- 1. There were 3 AEs (skin integrity issues [n = 2] and a fall without resulting in injury [n = 1]). Mean visual analogue scale pain scores were low and consistent with mild pain (0-30 mm).
- 2. As participants progressed through the training sessions, up time in the exoskeleton, the proportion of time spent walking, and the number of steps taken increased.
- On the 6MWT, participants consistently covered more distance (117.1 ± 11.7 m) in session 25 compared to session 2 (47.6 ± 6.6 m).
- 4. On the 10MWT, all participants showed consistently improved gait speed, traveling on average 3.2 times faster during their last training session (0.40 ± 0.04 m/s) in comparison to session 2 (0.12 ± 0.01 m/s).
- Participants with AIS C demonstrated greater improvements in gait speed than those with AIS A (0.44 ± 0.05 m/s vs. 0.33 ± 0.09 m/s, respectively) as well as improved distance covered on

McIntosh et al. 2019

Canada Pre – post Level 4 N = 11

		the 6MWT (128.1 \pm 17.3 m vs. 102.7 \pm 13.1 m, respectively).
Tefertiller et al. 2018 USA Pre-post Level 4 N = 32	Population: 32 non-ambulatory participants with SCI; 27 males and 5 females; mean age 37 years; injury level T4-L2; and AIS A (n = 21), AIS B (n = 5), and AIS C (n = 6). Time since injury not stated. Treatment: The participants completed 24 training sessions at a frequency of 3 times per week for 8 weeks. Throughout the trial, participants were asked to perform various gait-related tasks while wearing the Indego exoskeleton. Outcome Measures: 10MWT (indoor and outdoor assessments); 6MWT; and 600-meter walk test were assessed. The 10MWT and 6MWT were completed midway (session 11, 12, or 13) and during the final walking sessions (session 24 or 25) utilizing the device and an appropriate assistive device. The 600-meter walk test was completed once during the trial on indoor surfaces between the midway and final assessments.	 A combined total of 66 AEs were reported: Eleven of these AEs were directly device related and were reported on six participants. The majority (9/11) of the device-related AEs were skin redness, small abrasions, mild joint edema, or mild bruising on the lower legs and hips that were resolved with improved padding and pressure relief. Sixty-four of 66 AEs were minor and were not device-related. Two events were categorized as moderate (right greater trochanteric blister due to pressure and friction while walking in the device, and ankle sprain while walking in the device), without interruption in training for either participant. 10MWT: Final indoor and outdoor walking speeds among all participants significantly (p < 0.05) improved to 0.37 m/s (± 0.08 and ± 0.09, respectively). 6MWT: For all participants, average distance completed during the initial 6MWT was 92.0 m and an average distance of 107.5 m (± 28.3) was completed during the final evaluation period. The average time it took all participants to walk 600 m was 35 min 24 s (± 13.44 s).
Baunsgaard et al. (<u>2018a;</u> <u>2018b</u>) Denmark, Germany, the	Population: 52 participants with SCI; 36 males and 16 females; mean age 47.0 years; injury level C5–L2; AIS A-B-C (n = 33) and AIS D (n = 19); and time since injury were subgrouped (recently	All training characteristics (up time, walk time and steps) increased significantly from TS1 to TS24 (P < 0.001), including all sub-groups: recently and chronically injured, paraplegia

Netherlands, Norway, Spain, Sweden and Switzerland.

Pre-post Level 4 N = 52 injured [TSI \leq 1 year], n = 25; chronically injured [TSI > 1 year], n = 27).

Treatment: The training protocol consisted of gait training three times per week for eight weeks, as an "add on" to existing training. Two exoskeletons were used, the Ekso (n = 8) and the Ekso GT (n = 44).

Outcome Measures: Total up time (time standing plus time walking), walk time (time in walk motion) and number of steps, recorded by the device during the training session, alongside the walkmode and the assistive device used. LEMS and SCIM-III mobility subscore were assessed at baseline, at end of the training period (TS24) and at a follow-up session. Participants who had or acquired gait function during the training period performed 10MWT, and WISCI II at baseline, midway (TS12), at end (TS24) and at follow-up.

- and tetraplegia, and incomplete and complete injury (P < 0.001).
- 2. In the recently injured group, five participants (20%) had gait function at baseline which increased to 14 (56%) at TS24, (P = 0.004) and to 15 participants (60%) at follow-up (P = 1.00). In the chronically injured group, 11 participants (41%) had gait function at baseline which increased to 12 (44%) at TS24 and at follow-up.
- 3. The recently injured participants significantly improved 10MWT, LEMS, and mobility subscore of SCIM-III but not WISCI II from baseline to TS24. The chronically injured participants did not significantly improve 10MWT, WISCI II, mobility subscore of SCIM-III or LEMS from baseline to TS24. These changes were retained at follow-up in both groups.

<u>Gagnon et al.</u> 2018

Canada Pre-post Level 4 N = 13 **Population:** 14 participants with a motor complete SCI who use a wheelchair as their primary mode of mobility; 9 males and 5 females; mean $(\pm SD)$ age 38.7 (± 10.9) years; injury level C6 (n = 1), T3 (n = 1), T4 (n = 2), T6 (n = 6), T8 (n = 1), T9 (n = 1), and T10 (n = 2); AIS A (n = 13) and AIS B (n = 1); and mean $(\pm SD)$ time since injury 7.4 (± 7.8) years.

Treatment: Participants began a six-week progressive LT program that encompassed a total of 18 training sessions (three sessions/week; 60 min/session) with the EKSO GT robotic exoskeleton. Depending on the level of each participant's proficiency, on the participant's tolerance, and on the activities planned for the session (e.g., instructions and basic training to initiate sit-stand transfers, walking and turning with forearm crutches), the workload was periodically adjusted using walking

- I. Five participants reported training-related pain or stiffness in the upper extremities during the program, six participants experienced orthostatic hypotension with systolic blood pressure drops of ≥ 20 mmHg during a training session, and one participant sustained bilateral calcaneal fractures and stopped the program.
- On average, during the LT program, the standing time, the walking time, and the number of steps taken per session were 49.7 ± 12.7 min, 33.4 ± 12.5 min, and 1190 ± 561 steps, respectively; and were progressed by 45.3%, 102.1%, and 248.7%, respectively,

	distance, duration, and speed parameter progressions. Outcome Measures: After each session, all training parameters and other relevant information (e.g., total standing time, total walking time, and total number of steps) were recorded. Also, the performance when walking with the exoskeleton at self-selected comfortable walking speed measured using the 10MWT was assessed at the start (within the first 5 sessions) and at the end of the program.	3.	between the start and the end of the program. Walking speed increased significantly (p ≤ 0.0001; + 66.8%) between the start (0.15 ± 0.02 m/s) and end (0.25 ± 0.05 m/s) of the training program.
Hartigan et al. 2015 USA Pre-Post Level 4 N = 16	Population: 16 participants - 13 males and 3 females; SCI ranging from C5 complete to L1 incomplete; age range= 18-51 years. Treatment: To assess how quickly each participant could achieve proficiency in walking, each participant was trained in the system (Indego exoskeleton) for 5 sessions, each session lasting approximately 1.5 hours. Following these 5 sessions, each participant performed a 10MWT and a 6MWT. Outcome Measures: 10MWT, 6MWT, donning and doffing times, ability to walk on various surfaces.	2.	At the end of 5 sessions (1.5 hours per session), average walking speed was 0.22 m/s for persons with C5-6 motor complete tetraplegia, 0.26 m/s for TI-8 motor complete paraplegia, and 0.45 m/s for T9-L1 paraplegia. Distances covered in 6 min averaged 64 m for those with C5-6, 74 m for TI-8, and 121 m for T9-L1. Additionally, all participants were able to walk on both indoor and outdoor surfaces.
Yang et al. 2015 USA Post Test Level 4 N = 12	Population: 12 participants - 10 males and 2 females; 9 AIS A, 2 AIS B and 1 AIS C; Level of injury between C8 to T11; age range= 31 to 75. Treatment: Twelve participants with SCI ≥1.5 years who were wheelchair users participated. They wore a powered exoskeleton (ReWalk) with crutches to complete 10-meter (10MWT) and 6MWT walk tests. Level of assistance was defined as modified independence, supervision, minimal assistance, and moderate assistance. Best effort EAW velocity, level of assistance, and observational gait analysis were recorded. Outcome Measures: 10MWT, 6MWT, level of assistance, degree of hip flexion, degree of knee flexion, step time.	2.	7 of 12 participants ambulated ≥0.40 m/s. 5 participants walked with modified independence, 3 with supervision, 3 with minimal assistance, and 1 with moderate assistance. Significant inverse relationships were noted between level of assistance and EAW velocity for both 6MWT and 10MWT. There were 13 episodes of mild skin abrasions. Modified independence and supervision groups ambulated with 2-point alternating crutch pattern, whereas the minimal assistance and moderate

			assistance groups favored 3- point crutch gait.
Esquenazi et al. 2012 USA Pre-post Level 4 N = 12	Population: 12 participants with chronic SCI (8M 4F); 18-55 yrs old; all motor-complete cervical and thoracic; >6 months post-injury. Treatment: All participants had gait training using the ReWalk powered exoskeleton; participants were trained for up to 24 sessions of 60-90 min duration over approximately 8 weeks. Outcome Measures: 6MWT; 10MWT; gait laboratory evaluation; dynamic electromyogram; survey containing questions about comfort and confidence using the ReWalk; assessment of spasticity and pain; physical examination; Short Form-36 v2 Health Survey Questionnaire.	 2. 4. 5. 	considerably reduced walking abilities, average distances and average walking speed significantly improved. Average walking speed was 0.25m/s (0.03-0.45m/s). (No significance testing done). Three participants reported their overall spasticity improved after training. All participants had strong positive comments regarding the emotional/psychosocial benefits of the use of ReWalk.