Table 13. Wearable Powered Exoskeletons for Standing Balance

Author Year Country Research Design Score Total Sample Size	Methods	Outcome
Rodríguez-Fernández et al. (2022); Spain RCT Cross-over PEDro=7 Level 1 N=10	**Population:** 10 participants with chronic motor-complete SCI; 9 males and one female; mean (± SD) age 44.10 ± 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: • Knee ankle foot orthosis (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 overground gait training 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 session and the first training session with the crossed-over device. **Outcome Measures:** TUG; 6MWT; 10MWT; and gait kinematics and spatiotemporal parameters (during 6MWT) were assessed at session 10.	1. No serious AEs were reported during the study. 2. The average level of assistance provided by the therapist to the participants was slightly ($p>0.05$) higher for the ABLE group compared to the KAFO group. 3. No significant differences were found between the two groups for 6MWT, 10MWT, and TUG. 4. Linear regression analysis between the outcome metrics of the standardized clinical tests and the level of injury revealed significant, strong correlations for the KAFO group. In contrast, correlations for the ABLE group were low to mild and not statistically significant.
Edwards et al. (2022); USA RCT PEDro=5 Level 2	**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)	1. 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

N=25	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 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, overground without BWS. • Passive Control (n=6): Participants continued with daily activities as normal. **Outcome Measures:** Gait speed (10MWT); functional mobility and balance (TUG); endurance (6MWT); need of assistance and devices (WISCI II); and safety (AEs and serious AEs) were assessed at baseline, at midpoint (6 weeks), at the end of the intervention (12 weeks), and at 12 weeks post-intervention.	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 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. 3. TUG test, self-selected gait speed, maximal gait speed, and median distance covered in the 6MWT following the intervention improved without reaching significant differences ($p>0.05$) for within group and between group comparisons. 4. 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.
Chang et al. (2018); USA RCT PEDro=5 Level 2 N=7	**Population:** 7 participants with SCI and abled to independently stand for 2 min with or without an assistive device. • Exoskeleton-assisted gait training Group (n=4): Mean (SD) age: 56 (17) years; 1 female, 3 males; injury level: C4 (n=1), C7 (n=1), T12 (n=2); AIS: AIS C (n=1), AIS D (n=3); mean (SD) time since injury of 15 (14) years • Conventional physical therapy (CPT) Group (n=3): Mean (SD) age: 60 (2) years; 1 female, 2 males; injury level: C5 (n=1), T12 (n=2); AIS:	1. Only the CPT group showed a statistically significant reduction in TUG time (CPT group: MD −1.6, 95% CI=−2.6, −0.6); Exoskeleton-assisted gait training group: MD − 15.43, 95% CI=(−47.5, 16.6)) between pre- and post-assessments.

	AIS C (n=1), AIS D (n=2); mean (SD) time since injury of 7 (3) years **Treatment:** Participants were randomized into two groups: • Exoskeleton-assisted gait training group (n=4): Participants donned the Ekso exoskeleton and participated in individualized treatment sessions that included sit to stand, static and dynamic standing balance, weight shifting, walking, turning, and stand to sit. Each training session was 60 min long. The training was held 5 days per week for 3 weeks with a total of 15 sessions. • CPT group (n=3): Participants received physical therapy designed to facilitate gait improvement. This included individualized treatment sessions consisting of stretching, strengthening, balance training, standing, sit to stand, stair, and gait training. Each training session lasted 60 min, and the training was held for a total of 15 sessions with 5 days per week for 3 weeks. **Outcome Measures:** TUG test was assessed at baseline and at post-intervention.	
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=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 standing balance exercises, and by a specific	1. After the intervention, no statistical differences were found for any analyzed variables between groups ($p>0.05$). 2. Comparing after training vs. baseline data: a. At baseline, experimental participants were unable to 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.

	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 (spatio-temporal parameters [speed, step length and width, gait cycle time and stance phase percentage] and ground reaction forces [GRFs]) were assessed by using four force plates; clinical outcome measures (6MWT*, 6-min gait speed, fatigue, muscle force [assessed by manual muscle testing of hip, knee and ankle joints], and dynamic balance [assessed by BBS]) 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.	b. For BBS, there was no statistically significant modifications in both groups.
Jang et al. (2022); Korea Pre-post Level 4 N=4	**Population:** 4 participants with gait disturbance because of spinal root dysfunction (patients with previously neurologic deficit after brain or spinal cord disorders were excluded from the study). Mean age: 56.25 years 3M, 1F Causative nerve dysfunction: Right L5 (n=2) and cauda equina (n=2) Duration of weakness: 1 month (n=2), 26 (n=1), and 38 (n=1) months. *All participants had undergone spine surgery for spinal stenosis caused the neurologic deficit and intervention started one week after surgery. **Treatment:** Overground exoskeleton-assisted gait training protocol with ExoAtlet Medy® was scheduled for 4 or 8	1. All participants showed positive changes in gait performance, balance, proximal muscle strength, psychologic state and satisfaction of rehabilitation. 3 participants demonstrated the improvement of TUG test and BBS scores.

	weeks and 2-3 sessions per week. The duration of each session was 60 minutes. Training protocol included sit-to-stand, static standing balance, dynamic standing balance weight shifting, stepping, pivot turns and free walking. **Outcome Measures:** Muscle atrophy (calf circumference), vital sign (heart rate/blood pressure /peak flow), 6-meter walking test, TUG test, BBS, and modified geriatric depression scale were assessed before (T1) and at the end (T2) of the intervention. * The clinical results were not analyzed statistically because of the small sample size.	
Kerdraon et al. (2021); France & USA Pre–post Level 4 N=11	**Population:** 12 participants with chronic complete (AIS A) SCI and able to wear the Atalante exoskeleton; 10 males and 2 females; mean age (± SD) 22.9 (± 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 (± SD) time since injury 88 (± 63.2) months. **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, then maintain a balanced position for at least 5 s; the ability to stand still without support for 2 min; the ability to keep balance in exercise positions, 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.	1. The only treatment-related AEs were skin redness (n=5) and ischial skin abrasion (n=1) with a complete resolution. 2. 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 U-turn 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	**Population:** 10 non-ambulatory patients with SCI with sufficient postural stability to sit independently, ability to transfer from wheelchair to bed independently,	1. There were no severe AEs, but there were three minor events (two skin abrasions and one near fall).

Level 4 N=10	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, TUG test, and Korean version of the FES-I (KFES-I) were assessed at pre-training and post-training. *6MWT and TUG test were also assessed at mid-training (15 sessions).	2. Statistically significant improvement between the pre-training and post-training assessments were reported for the TUG test ($\chi 2$ = 11.400, P = 0.03). 3. 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 was not statistically significant (p=0.475).
Hong et al. (2020); USA Pre-post Level 4 N=50	**Population:** 50 participants with chronic (> 6 months) SCI who were non-ambulatory; 38 males and 12 females; mean (± SD) age 38.7 (± 14.2) years; AIS A/B (n=31) and AIS C/D (19); and mean (± SD) time since injury 4.69 (± 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). • The EAW arm consisted of EAW 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™	1. There were four "possibly study-related" severe AEs and there were 49 total study-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. Participants who used the ReWalk had significantly better performance during the 10MWT, 6MWT and TUG than participants using the Ekso at session 36 (p<0.0001, p<0.0001, p=0.0011, respectively). 3. There were significant improvements in the performance of the 10MWT, 6MWT, and TUG from session 12 to session 36 (p<0.0001*);* but there were no significant differences between sub-groups in terms of improvements from 12 to 36

	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 12-week usual activity arm. **Outcome Measures:** 10MWT, 6MWT and TUG were performed at 12, 24, and 36 sessions.	sessions on the 10MWT, 6MWT, and TUG (p>0.07).
Tefertiller et al. (2017); 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; TUG; and 600-meter walk test were assessed. The 10MWT, 6MWT and TUG 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.	1. A combined total of 66 AEs were reported: a. 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. b. Sixty-four of 66 AEs were minor and were not device-related. c. 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. 2. TUG improved from a midpoint average of 102.1 s (± 28.3) to a final of 83.6 s (± 19.8).
Baunsgaard et al. (2018a; 2018b); 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 injured [TSI ≤	1. All training characteristics (up time, walk time, and steps) increased significantly from TS1 to TS24 (p<0.001), including all sub-groups: recently and

Netherlands, Norway, Spain, Sweden and Switzerland. Pre-post Level 4 N=52	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 walk-mode 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 4 weeks after the last training session. Participants who had or acquired gait function during the training period performed 10MWT, TUG, BBS, and WISCI II at baseline, midway (TS12), at end (TS24) and at follow-up.	chronically injured, paraplegia and tetraplegia, and incomplete and complete injury ($p<0.001$). 2. The recently injured participants significantly improved 10MWT, TUG, BBS, 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; but they showed a significant improvement in TUG and BBS. These changes were retained at follow-up in both groups.
Benson et al. (2016); UK Pre-post Level 4 N=10	**Population:** 10 participants with traumatic SCI; 10 males; age ranged from 23 to 43 years; injury level: C8 to L1; AIS A (n=7) and AIS C (n=3); and time since injury ranged from 15 months to 21 years. **Treatment:** Participants performed 20 exoskeleton (ReWalk™) training sessions over a 10-week training period. Each training session lasted a total of two hours, which included one hour of exoskeleton training and time required for device set up and data collection. Training sessions took place twice weekly. A prespecified training program consisting of progressive training modules was developed. Each training session was tailored to suit the individual's progress and needs. **Outcome Measures:** TUG Test were measured before, during and after the study, with and (where possible) without use of the exoskeleton.	1. Out of 60 candidates, ten (17%) were enrolled and five (8%) completed the training program. Primary reasons for not enrolling were ineligibility (*n*=24, 40%) and limited interest to engage in a 10- week training program (*n*=16, 27%). Five out of ten enrolled participants experienced grade I/II skin aberrations. 2. For TUG with exoskeleton, all 5 participants shown improvements; additionally, only three participants could perform the TUG test without exoskeleton and two of these showed improvements.
Platz et al. (2016); Germany	**Population:** 7 participants with SCI and financial coverage for the inpatient exoskeleton-training; mean (SD) age:	1. All participants who commenced the device-training completed the course

Pre-post Level 4 N=7	48.3 (10.2) years; 2 females and 5 males; AIS: AIS A (n=6) and AIS C (n=1), level of injury: T5-L1, and mean (SD) time since injury: 11.4 (10.1) years. **Treatment:** Participants performed a training with an exoskeleton (ReWalk) for 4-5 weeks during inpatient stay. Each session lasted 60 minutes and was performed from Monday through Friday. Further therapeutic exercises were individually indicated. The skills to be learned during the exoskeleton training included (1) sit-to-stand, (2) stand-to-sit, (3) 2-arm standing balance, (4) 1-arm standing balance, (5) walking straight ahead, (6) walking in a curve, when stable indoor overground walking capability was gained, (7) stair climbing (individual cases), and (8) outdoor walking. **Outcome Measures:** Device-training milestone achievements (the number of device-training sessions until the following milestone were achieved was documented: (a) Sit-to-stand, (b) Stand-to-sit, (c) Standing balance for 1 minute with both crutches, (d) Walk 10 meters straight, (e) Walk 10 meters straight and in curve, (f) Ascend, turn around, and descend a flight of 12 stairs, and (g) Walk 500 meters (outdoors).	of training and achieved basic competences to use the system, that is, the ability to stand up, sit down, keep balance while standing, and walk indoors, at least with a close contact guard.
Sale et al. (2018); Italy Pre-post Level 4 N=8	**Population:** 8 participants with chronic SCI; ability to tolerate upright standing for a minimum of 30 min; joint range of motion within normal functional limits for ambulation; sufficient upper body strength to balance themselves using the walker while wearing the exoskeleton; 6 males, 2 females; mean age: 43.2 years; injury level: T1-L2; and AIS A (n=3), AIS B (n=4), and AIS C (n=1). **Treatment:** Participants underwent a rehabilitation mobility training consisting of a treatment cycle of 20 sessions of robotic training (45 min for 5-4 times per week, for 4-5 weeks) using the Ekso™ system device (exoskeleton), according to individually tailored exercise scheduling.	1. After the training, all participants showed significant (p=0.008) improvements for TUG (T0: 86.83 ± 28.64 s; T1: 58.06 ± 12.7 s).

	Outcome Measures: TUG test was assessed while wearing the exoskeleton at baseline (inclusion) (T0) and after 20 sessions of adaptive training (T1).	
Sale et al. (2016); Italy Pre-post Level 4 N=3	**Population:** 3 participants with chronic SCI; ability to tolerate upright standing for a minimum of 30 min; joint range of motion within normal functional limits for ambulation; sufficient upper body strength to balance themselves using the walker while wearing the exoskeleton; 2 males, 1 female; mean age: 36 years; injury level: T6 (n=1), T10 (n=1), and L1 (n=1); and AIS A (n=2) and AIS C (n=1). **Treatment:** Participants underwent a rehabilitation mobility training consisting of a treatment cycle of 20 sessions of robotic training (50 min for 3/4 times per week) using the Ekso™ system device (exoskeleton), according to individually tailored exercise scheduling. **Outcome Measures:** TUG test was assessed at baseline and after 20 training sessions.	1. The results of TUG test showed a non-significant ($p>0.05$) decrement of −44 % in time (T0 89 ± 24,25 and T1 56,53 ± 9,036).
Kolakowsky-Hayner et al. (2013); USA Pre-post Level 4 N=10	**Population:** 10 participants with complete SCI (AIS A); mean age: 29.8 years; 5 males, 2 females; level of injury: T4-T11; and mean time since injury: 311.3 days. **Treatment:** Participants performed six weekly sessions with graduated time (from 20 to 60 minutes) and less assistance in the Ekso exoskeleton. **Outcome Measures:** Losses of balance and number of falls during the sessions were assessed.	1. Loss of balance and falls were infrequent.