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Review article

Gait quality after robot therapy compared with physiotherapy in the patient with incomplete spinal cord injured: A systematic review

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ABSTRACT

Background: Spinal cord injury results in the interruption of neuronal conduction in the spinal cord, a condition that occurs in 0.1% of the world's population. This results in severe limitations in autonomy including locomotor function. Its recovery can be pursued through conventional isolated physiotherapeutic rehabilitation (overground walking training - OGT) or associated with Robot-assisted gait training - RAGT (*e.g.*: Lokomat ®).
Aim: The aim of this review is to compare the effectiveness of RAGT combined with conventional physiotherapy.
Methods: The databases consulted, from March 2022 to November 2022, were PubMed, PEDro, Cochrane Central Register of Controlled Trials (Cochrane Library) and CINAHL. RCT studies of people with incomplete spinal cord injuries treated with RAGT and/or OGT with the aim of improving walking were analysed.
Results: Among the 84 RCTs identified, 4 were included in the synthesis, with a total of 258 participants. The outcomes analysed concerned both locomotor function through lower limb muscle strength and the need for assistance in walking, using the WISCI-II scale and the LEMS. Robotic treatment stimulated the greatest improvements in the four studies; however, they were not always statistically significant.
Conclusion: A rehabilitation protocol combining RAGT with conventional physiotherapy is more effective than isolated OGT in improving ambulation in the subacute phase.

1. Introduction

Spinal cord injury is a serious clinical condition, resulting in the interruption of nerve communication of the ascending sensory pathways and descending motor pathways between the brain and the periphery of the body. The spinal cord, which constitutes a portion of the central nervous system, enables the transport of nerve signals in and out of the brain, cooperating with the peripheral nerves and making voluntary and involuntary motor activity, sensory perception and interaction with the external environment possible. When a spinal cord injury occurs, nerve communication is either incompletely or completely interrupted, in the former case some sensations and/or movements remain, at a sublesional level, in the latter case, all function is absent and complete paralysis sets in. There is a subacute phase of a spinal cord injury, which generally refers to the period of time that begins a few days after the injury and lasts up to several weeks or months, depending on the severity of the injury. During this phase, patients may still experience neurological deficits, but their condition is generally more stable than during the acute phase immediately after the injury [1]. The causes of this damage can be non-traumatic, as a consequence of degenerative, inflammatory, infectious, vascular and neoplastic diseases; or they can be traumatic and sudden, *e.g.* due to dislocation or fracture of the vertebra, damage to the ligaments and the intervertebral disc, or penetration of external bodies into the spinal cord itself [1].

The identification of the level of spinal cord injury and its sensemotor consequences is followed by the subdivision of clinical pictures into four different categories:

a. tetraplegia: damage to or loss of motor and/or sensory function of cervical spinal cord segments, with involvement of the lower and upper limbs, trunk and pelvic organs.
b. paraplegia: damage to or loss of motor and/or sensory function in the thoracic, lumbar or sacral segments of the spinal cord; the upper limbs are thus spared, but there may be involvement of the trunk, pelvic organs and lower limbs.
c. tetraparesis: incomplete paralysis of all four limbs;
d. paraparesis: incomplete paralysis of the lower limbs.

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Spinal cord injury leads to the partial or total loss of sense-motor function in the sub-lesional area, in addition to which there are deficits in respiratory function, which is the most common cause of death in the acute phase, bladder, sphincter and gastro-intestinal disorders, which are difficult to treat especially in the long term, impaired sexual function, deficits in thermoregulation and cardio-circulatory function. Furthermore, tertiary damage includes pressure lesions, urinary tract infections and sepsis, osteoporosis and the increased risk of fractures, combined with the formation of para-osteo-arthopathies, spinal deformities, the elevated risk of venous thrombosis and embolisms, severe spasticity with impaired postural maintenance and joint limitations.

Gait represents man's ability to move in and interact with his surroundings through the activation of a sequence of rhythmic and alternating movements of body segments. Unfortunately, the physiological gait pattern may be lost or altered when an incomplete spinal cord injury occurs, a reduced or absent capacity for movement is established. This outlines the need to initiate a neuro-motor rehabilitation activity, combined with the search for suitable aids and orthoses to increase safety and personal autonomy, whenever possible.

Both the activation of the Spinal Pattern Generator (SPG) [2,3] and the medullary and cortical modifications, enabled by neuroplasticity, are sought through intensive gait training, with the administration of OGT or robot therapy. The latter allows early re-training in the symmetrical gait pattern, progressive load integration and a task-specific approach, all of which reinforce the feedback associated with physiological locomotion [4]. Robotic systems can be composed of mobile 'treadmill' platforms, body weight support (BWS) and exoskeletons that guide the lower limbs during the successive step phases, stimulating the reprogramming of spinal locomotor patterns: an example is Lokomat®. There are also replacement exoskeleton systems that do not require a treadmill, such as the Ekso®: it is worn over clothing and is controlled by a computer in communication with various sensors that detect body weight displacement and allow the step to be initiated, as well as maintaining orthostatism. All this can be done in passive mode, active assisted or active by the subject; always with supervision and assistance from specially trained qualified personnel.

1.1. Aim

The identification of improvements in locomotor function, following the administration of Robot-assisted gait training combined with OGT, compared to the latter applied alone, in persons with incomplete spinal cord injury of any origin.

The aim is, therefore, to compare the effectiveness of robot-assisted therapy, compared to conventional therapy, in recovering or improving gait [4].

2. Material and methods

This systematic review was carried out following the methodological guidance contained in the PRISMA Checklist [5].

The protocol was published in PROSPERO (International Prospective Register of Systematic Reviews) under registration number CRD42022375314.

2.1. Reserch method

"Patients with acquired, incomplete spinal cord injury in the subacute phase".

2.2. Search strategy

An electronic bibliographic search was conducted in eight databases: PubMed, Cochrane Central Register of Controlled Trials, PEDro and, CHINAL database. The P.I.C.O.(M.) strategy was used to formulate the research question of the review. Search was conducted up to November, 30th 2022 with no date restriction and no linguistic limits (Supplementary File 1).

2.3. Study selection criteria

2.3.1. Inclusion criteria

1. The sample must consist of persons with spinal cord injury (whether of traumatic or non-traumatic origin);
2. Robot-assisted gait training (RAGT) should be applied to the experimental group;
3. The use of the treadmill must be included in the RAGT protocol;
4. The intervention to be applied to the control group should be OGT;
5. The main outcome concerns walking and its parameters;
6. The type of study being considered is the randomized controlled clinical trial.

2.3.2. Exclusion criteria

1. The control group is not subject to any treatment or even to robotic therapies;
2. The subject's cognitive integrity is not present;
3. The types of studies are different from randomized controlled clinical trials.

No minimum duration of follow-up or other time criteria are imposed.

2.4. Study selection process

The records retrieved from the databases searching were collected and imported to EndNote V.X9 (Clarivate Analytics). Duplicates were removed through Endnote deduplicator tool. In the screening phase, two reviewers independently read all titles and abstracts, excluding articles that did not answer the research question. A third reviewer intervened to reach a final decision on the list of articles to be read in full text. The study selection process and the reasons for the exclusion were recorded and presented in the PRISMA flow diagram.

2.5. Data extraction and assessment

The methodological quality of the intervention studies included in the review was assessed by the researchers using the Pedro scale tool [6,7]. The results of the assessment were entered in a table, the fulfilment of the criterion was indicated with "Yes" and the absence of the specific item in the analysed study with "No". Two independent reviewers, one an experienced physiotherapist in neurological rehabilitation and a third with research and practice experience, were involved in the quality assessment. Training was provided by a third physiotherapist experienced in research methodology. Summary tables and graphs of the extracted data from all included studies and a narrative summary were provided.

2.6. Data analysis

The reviewers independently extracted data from the studies and summarised them in a summary table. The following data were extracted: author, year, participants, treatment description and outcome.

For the final analysis, we considered the "NA" items as items not reported and described by the authors.

3. Results

The search in the PubMed database produced a total of 32 results. By reading the title and abstract, 31 articles were excluded. The search in the Cochrane Central database produced 24 results, of which only 1 was

relevant to the question. The search on CHINAL database produced 21 results relevant to the question, of which 0 were relevant. The search on PEDro 7 produced results, of which 2 were relevant. The search process is shown in the PRISMA Flow Diagram.

4. Characteristics of the included studies

Alcobendas-Maestro M, Esclarín-Ruz A, Casado-López RM, Muñoz-González A, Pérez-Mateos G, González-Valdizán E, Martín JL. Lokomat robotic-assisted versus overground training within 3 to 6 months of incomplete spinal cord lesion: randomized controlled trial. Neurorehabil Neural Repair, 2012 Nov-Dec; 26(9): 1058–63 [8].

Intervention: . Intervention: Participants received daily conventional physiotherapy OGT including joint mobilisation, muscle strengthening, stretching, postural relaxation techniques, trunk stability and rotation exercises, and self-care practice, along with mobility training to regain ambulation. The experimental group underwent a 40-session (8-week) Lokomat® intervention, with each session lasting one hour, including 30 min on the Lokomat® device. Weight support started at 60% of the subject's weight and decreased to a minimum of 25% based on tolerance. Speed was adjusted according to comfort and necessary orthoses were prescribed.

Esclarín-Ruz A, Alcobendas-Maestro M, Casado-Lopez R, Perez-Mateos G, Florido- Sanchez MA, Gonzalez-Valdizan E, Martin JL. A comparison of robotic walking therapy and conventional walking therapy in individuals with upper versus lower motor neuron lesions: a randomized controlled trial. Arch Phys Med Rehabil, 2014 Jun; 95(6): 1023–31 [9].

Intervention: Participants were selected based on demographic data and lesion characteristics. Groups were divided into upper and lower motor neuron lesions. Experimental groups received 30 min of conventional physiotherapy OGT and 30 min of robot-assisted gait training, while control groups received a 60-min conventional physiotherapy OGT with 30 min of exercises geared towards gait recovery. The usual care included joint mobilisation, muscle strength enhancement, muscle stretching, postural relaxation techniques, stabilisation and trunk rotation exercises, and self-care training. Lokomat® weight support started at 60%, decreasing to 25% based on personal tolerance, while stride speed was adjusted for comfort. No subjects had used Lokomat® before. Orthoses were prescribed and treatments were guided by a physiotherapist.

Shin JC, Kim JY, Park HK, Kim NY. Effect of robotic-assisted gait training in patients with incomplete spinal cord injury. Ann Rehabil Med, 2014 Dec; 38(6): 719–25 [10].

Intervention: The study lasted four weeks and included both an experimental and control group. The experimental group received RAGT three days per week and conventional physiotherapy OGT two days per week (total duration 1 h), while the control group received daily double treatment (duration 30 min each) based on the 'Bobath' physiotherapeutic principles. Treadmill speed was initially set at 1.5 km/h and could be increased to a maximum of 3 km/h; weight support was initially set at 50% and reduced according to personal tolerance without leading to knee instability or toe dragging. Driving force was maintained at 100%. Both groups were allowed to participate in other treatments such as occupational therapy or FES (Functional Electrical Stimulation) during the study.

Mıdık M, Paker N, Buğdaycı D, Mıdık AC. Effects of robot-assisted gait training on lower extremity strength, functional independence, and walking function in men with incomplete traumatic spinal cord injury. Turk J Phys Med Rehabil, 2020 Mar 3; 66(1): 54–59 [11].

Intervention: Subjects underwent conventional physiotherapy treatment OGT five times a week for five weeks. The RAGT group received both conventional and robotic physiotherapy, while the control group received only usual care. RAGT was performed three times a week for 30 min using Lokomat®. Initial weight support was 50%, and the treadmill speed was set at 1.5 km/h. Weight support was gradually decreased, and speed increased based on the participant's tolerance over the weeks.

4.1. Risk of bias

The methodological quality with which the studies were conducted and the risk of bias to which they are subjected are assessed by means of the PEDro Scale, as is shown in Table 2. 'Yes' was indicated as the fulfilment of the criterion, and 'No' as the absence of the specific item in the study analysed. (See Fig. 1.) (See Table 1.)

The first item was included for completeness with respect to the Delphi list [12], but is not included in the final count, which is based on ten, from requirement number 2 to number 11. If the criterion is fulfilled, one point is awarded, otherwise it has a value of zero. The authors of the PEDro scale18 divide clinical studies into four categories, linked to the score obtained: low quality, when it varies between 0 and 3; medium quality, if it is 4 or 5; high quality, if it is 6 to 8; excellent quality, with a score of 9 or 10.

5. Discussion

This systematic review compares the effectiveness of robot-assisted gait training (RAGT) with Lokomat® and OGT for individuals with spinal cord injury during the subacute phase. The Walking Index for Spinal Cord Injury-II scale (WISCI-II) was a common outcome measure used in most studies, and results showed consistent improvements in both control and experimental groups, with statistically significant differences in favor of RAGT in some studies. However, differences in

Table 2
Summary of the PEDro Scale.

	A comparison of robotic walking therapy and conventional walking therapy in upper versus lower motor neuron lesion patients: a randomized clinical trial Esclarín-Ruz A et al., 2014	*Lokomat Robotic-Assisted Versus Overground Training Within 3 to 6 Months of Incomplete Spinal Cord Lesion: Randomized Controlled Trial* Alcobendas-Maestro M et al., 2012	*Effects of robot-assisted gait training on lower extremity strength, functional independence, and walking function in men with incomplete traumatic spinal cord injury* Mıdık M et al., 2020	*Effect of Robotic-Assisted Gait Training in Patients With Incomplete Spinal Cord Injury* Shin JC et al., 2014
1	Yes	Yes	Yes	Yes
2	Yes	Yes	Yes	Yes
3	Yes	Yes	No	No
4	Yes	Yes	Yes	Yes
5	No	No	No	No
6	No	No	Yes	No
7	Yes	Yes	No	No
8	Yes	Yes	Yes	Yes
9	Yes	Yes	No	No
10	Yes	Yes	Yes	Yes
11	Yes	Yes	Yes	Yes
Results	8/10	8/10	6/10	5/10

Legend Pedro Scale: 1 eligibility criteria were specified; 2 subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received); 3 allocation was concealed; 4 the groups were similar at baseline regarding the most important prognostic indicators; 5 there was blinding of all subjects; 6 there was blinding of all therapists who administered the therapy; 7 there was blinding of all assessors who measured at least one key outcome; 8 measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups; 9 all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"; 10 the results of between-group statistical comparisons are reported for at least one key outcome; 11 the study provides both point measures and measures of variability for at least one key outcome.

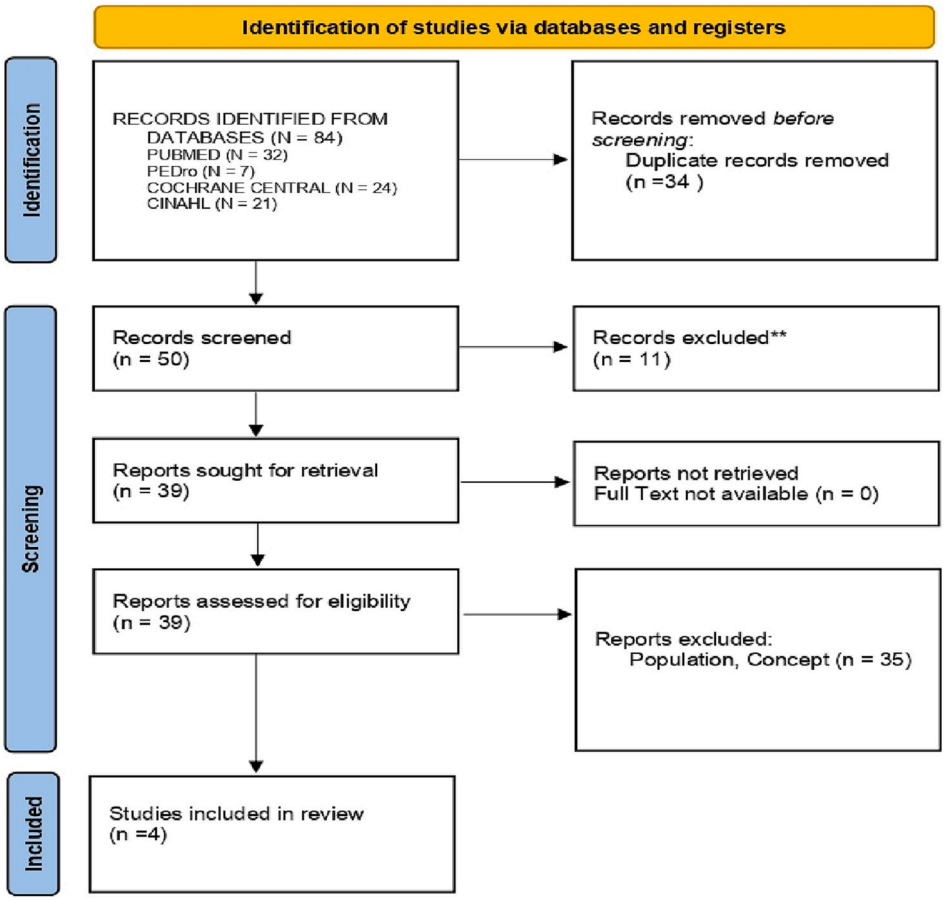

Fig. 1. PRISMA flow-diagram.

sample size, aetiology of injuries, duration and intensity of treatment, and other interventions make it difficult to draw definitive conclusions. Two studies with higher methodological quality suggest that RAGT may not always provide additional benefits compared to conventional physiotherapy alone. One study's potential source of bias was the longer duration of time since injury in the control group compared to the experimental group. In conclusion, the systematic review suggests that robot-assisted gait training (RAGT) can be an effective intervention for improving gait and mobility in individuals with spinal cord injury during the subacute phase. However, it is important to consider the methodological differences among the studies, such as sample size, aetiology of injury, duration and intensity of treatment, and control group characteristics, when interpreting the results. Additionally, high-quality studies, such as those by Alcobendas-Maestro et al. and Esclarín-Ruz et al., provide evidence that RAGT may not always provide additional benefits compared to conventional physiotherapy alone. Therefore, further research is needed to determine the most effective rehabilitation treatment for this population.

5.1. *Strengths and limitations*

This systematic review has several limitations that should be taken into account when interpreting the results. The review was conducted by a single reviewer without peer review, which may have introduced bias. Additionally, the synthesis of the results was qualitative, and no statistical tests were used.

Another limitation is that all studies included in the review had participants who had experienced spinal cord injuries within six months, with only one exception where the control group had a median of 24 months since injury onset. This short timeframe makes it difficult to rule out the possibility of spontaneous improvement due to nerve reorganization, and the observed improvements may be attributed to physiological neuroplasticity.

Finally, it is worth noting that studies conducted on the chronic phase of the disease, where the spinal cord injury had occurred more than two years earlier, did not show significant improvements when compared to OGT. The differences between the two treatments were mainly in the costs and physical exertion of caregivers.

5.2. *Implications for future research and clinical practice*

In summary, the systematic review found that robotic rehabilitation using Lokomat® can be effective in improving walking function and promoting psychological benefits for individuals with incomplete spinal cord injuries in a subacute phase. However, the high cost and size of the system, as well as the need for specialized training, may limit its accessibility. To improve the quality and generalizability of future research, larger and more representative samples should be included, and the chronic phase of the disease should be explored. Additionally, the inclusion of subjective feedback from participants could complement the findings of individual studies.

6. Conclusion

Robot-assisted gait training (RAGT) using the Lokomat® system, in combination with conventional physiotherapy, has been found to improve walking function in individuals with incomplete spinal cord injury (grade C or D) during the sub-acute phase of the injury. Future research is needed to determine the optimal timing for initiating treatment and the types of lesions that would benefit most from this therapy.

Table 1
Characteristics of the included studies.

		Effect of Robotic-Assisted Gait Training in Patients With Incomplete Spinal Cord Injury		Effects of robot-assisted gait training on lower extremity strength, functional independence, and walking function in men with incomplete traumatic spinal cord injury		Lokomat Robotic-Assisted *Versus* Overground Training Within 3 to 6 Months of Incomplete Spinal Cord Lesion: Randomized Controlled Trial		A comparison of robotic walking therapy and conventional walking therapy in upper *versus* lower motor neuron lesion patients: a randomized clinical trial			
		Ji Cheol Shin et al., 2014		Melike Mıdık et al., 2020		Mónica Alcobendas-Maestro et al., 2012		Ana Esclarín-Ruz et al., 2014			
Participants		Experimental group	**Control Greoup**	Experimental group	Control group	Experimental group	Control group	Experimental group MN superior	Experimental group MN inferior	Control group MN superior	Control group MN inferior
	N°	30 DO 3	30 DO 4	15	15	40 DO 3	40 DO 2	22 DO 1	22 DO 2	22 DO 1	22 DO 1
	Age	43.15 ± 14.37	48.15 ± 11.49	35.4 ± 12.1	37.9 ± 10.0	45.2 (SD 15.5)	49.5 (SD 12.8)	43.6 (12)	36.4 (12)	44.9 (7)	42.7 (18)
	Time since spinal cord injury	3.33 months (±2.02 SD)	2.73 months (±1.97 SD)	5 months (4.30)	24 months (17.44)	120 days (87.5–145) = 4 months	135 gg (93.7–180) = 4.5 months	125.6 days (65.2) = 4.18 months	117.9 days (25.6) = 3.93 months	140.3 days (45.5) = 4.68 months	109 days (50.5) = 3.63 months
	Aetiology traumatic	66.7%	73.1%	100%	100%	49%	47%	57%	70%	57%	71%
	Non-traumatic aetiology	33.3%	26.1%	0%	0%	51%	53%	43%	30%	43%	29%
	ASIA	D	D	C-D	C-D	C-D	C-D	C-D		C-D	
				13.7 ± 1.1	13.6 ± 1.0						
Measuring scales	**WISCI II**	11 (0–19)	9 (0−20)	14.1 ± 1.1	13.6 ± 1.0	16 (8.5–19)	9 (8–16)	13.47 (5.65)	12.45 (4.17)	11.04 (5.09)	10.8 (4.54)
	Baseline	3 (0–14)	4 (0–16)	9.8 ± 1.4	11.0 ± 1.1	4(3–8)	4(2.3–6)	5.9 ± 4.5	6 ± 3.2	4.9 ± 4.1	5 ± 3.7
				28.9 ± 3.6	24.4 ± 2.2						
	LEMS	37 (20–49)	37 (20–48)	29.1 ± 3.7	24.4 ± 2.2	40 (35–45.5)	35 (29.7–40)	38.33 (10.6)	27.15 (11.10)	32.28 (11.04)	22.57 (10.8)
	Baseline	31 (12–40)	33 (20–40)	27.1 ± 3.3	23.8 ± 2.3	33 (24.5–38.9)	30 (23.7–36)	30 ± 10.4	21 ± 10.3	27 ± 10.9	20 ± 9.9
Intervention		4 weeks total; 40 min/day for 3 days RAGT + conventional physiotherapy 1 h/day for 2 days conventional physiotherapy - for week-	4 weeks total; 1 h/day for 5 days conventional physiotherapy -for week-	5 weeks total; 5 times/week OGT + 3 time/week for 30 min RAGT	5 weeks total; 5 times/ week OGT	8 weeks total; daily physiotherapyOGT for 1 h + 30 min/day for 5 days per week of RAGT and 30 min/ day of re-education walking re-education	8 weeks total; daily conventional physiotherapy for 1 h + 1 h/day for 5 days per week of gait re-education walking re-education	8 weeks total; 30 min conventional physiotherapy +30 min RAGT for day, 5 days per week		8 weeks total; 1 h/day of traditional physiotherapy for 5 days per week	
Results		On the LEMS, AMI, SCIM-M and WISCI-II scales the greatest improvement occurs in the experimental group; neither LEMS nor SCIM-M show a statistically significant inter-group difference, unlike of AMI and WISCI-II.		There was a statistically significant improvement in LEMS, WISCI-II and SCIM-III scores after the experimental treatment. There were no significant differences at WISCI-II between the two groups.		The WISCI II, 6MWS, FIM-L and LEMS scales achieve a greater improvement in the experimental group. No statistically significant differences are identified at the 10MWT, as well as at the Ashworth scale and at the VAS.		At 6MWT, better results were obtained in groups A1 and B1 compared to those undergoing conventional treatment, as well as on the LEMS and FIM-L. Strength and walking ability did not differ between subjects with a lower MN lesion when comparing the comparison of the two groups.			

Legend: AMI = Ambulation Motor Index; ASIA = American Spinal Injury Association; BWS = Body Weight Support; CPG = Central Pattern Generator; DO = Drop Out; FIM-L = Functional Independence Measure – Locomotor; ISNCSCI = International Standards for Neurological Classification of Spinal Cord Injury; LEMS = Lower Extremity Motor Score; MRC = Medical Research Council; OGT = Overground gait training; RAGT = Robot-assisted gait training; RCT = Randomized Controlled Trial; SCIM3 (−M) = Spinal Cord Independence Measurement 3 (− Mobility); SPG = Spinal Pattern Generator; VAS = Visual Analog Scale; WISCI II = Walking Index for Spinal Cord Injury – II; 6MWT o 6MWS = 6-min walking test/scale; 10MWT = 10-m walking test.

Additionally, further investigation is necessary to evaluate the psychological effects of standing and walking simulation during recovery and therapy.

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Authors' contributions

IF wrote the initial draft of the manuscript, drafted the manuscript and devised the form. FB co-authored the manuscript, revised it and provided feedback. RT and FB contributed to the critical revision for important intellectual content. All authors read and approved the final version of the manuscript.

CRediT authorship contribution statement

Isabella Fabbri: Conceptualization, Investigation. **Fabio Betti:** Investigation, Supervision. **Roberto Tedeschi:** Methodology, Supervision, Writing – original draft, Writing – review & editing.

Declaration of Competing Interest

The authors report no declarations of interest.

Data availability

The protocol and the dataset analysed during the current study is available from the corresponding author on reasonable request.

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Ethical approval was not sought for the present study because not required

Appendix A. Supplementary data

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