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ORIGINAL ARTICLE

Identifying candidates for torque-assisted exoskeleton for gait assistance after stroke: a pre-specified subgroup analysis

Won H. CHANG [1], Tae-Woo KIM [2], Hyoung S. KIM [3], Fazah A. HANAPIAH [4], Jong W. LEE [5], Seung-Hyeon HAN [5], Chai W. JIA [4], Dae H. KIM [1], Deog Y. KIM [5] *

[1]Department of Physical and Rehabilitation Medicine, Center for Prevention and Rehabilitation, Heart Vascular and Stroke Institute, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea; [2]TBI Rehabilitation Center, National Traffic Injury Rehabilitation Hospital, Yangpyeong, South Korea; [3]Department of Rehabilitation Medicine, Pohang Stoke and Spine Hospital, Pohang, South Korea; [4]Faculty of Medicine, Universiti Teknologi MARA, Selangor, Malaysia; [5]Department and Research Institute of Rehabilitation Medicine, Yonsei University College of Medicine, Seoul, South Korea

*Corresponding author: Deog Y. Kim, Department of Rehabilitation Medicine and Research Institute of Rehabilitation Medicine, Yonsei University College of Medicine, 50-1 Yonsei-ro, Seodaemun-gu, Seoul 03722, South Korea. E-mail: kimdy@yuhs.ac

ABSTRACT

BACKGROUND: Wearable robots show promise for gait assistance in stroke patients, yet the clinical characteristics predicting a positive ambulatory response to exoskeletal assistance remain unclear.
AIM: To identify appropriate candidates for torque-assisted exoskeletal wearable robots in stroke patients.
DESIGN: A subgroup analysis using data from an international, multicenter, randomised controlled trial.
SETTING: Inpatient.
POPULATION: Fifty-five early subacute stroke patients who completed four weeks of robot-assisted gait training (RAGT) with the wearable exoskeletal robot (ANGEL LEGS M20, Angel Robotics Co., Ltd.).
METHODS: Immediately after RAGT for the four weeks, ambulatory function with the exoskeleton on and off was evaluated using the 10-Meter Walk Test (10MWT), 6-Minute Walk Test (6MWT), and Physiological Cost Index (PCI). At the same time, additional assessments included the Functional Ambulatory Category (FAC), Fugl-Meyer Assessment-Lower Extremity, Motricity Index-Lower Limb, Trunk Control Test, and Berg Balance Score. Participants were classified as good-responder, no-responder, or negative-responder groups based on changes in walking performance with exoskeletal assistance. Univariate and multivariate ordinal logistic regression analyses identified factors associated with responsiveness.
RESULTS: In the good-responder group, 10MWT, 6MWT and PCI showed significant improvements in the robot-on state compared with the robot-off state, respectively ($P<0.05$). Good responders had significantly lower baseline ambulatory, balance, and lower limb motor function compared to negative-responders ($P<0.05$). Multivariate analysis identified lower FAC as the only independent predictor of positive response to exoskeletal assistance ($P<0.05$).
CONCLUSIONS: Torque-assisted exoskeletal wearable robots may improve ambulatory function in stroke patients with low ambulatory function.
CLINICAL REHABILITATION IMPACT: To achieve meaningful effects through exoskeleton robots, patient selection must be adjusted according to clinical needs.

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Key words: Stroke; Ambulation; Rehabilitation; Robot-assisted gait

Mobility is a fundamental aspect of recovery and quality of life for stroke patients. Regaining mobility after stroke is crucial for achieving independence in activities of daily living, reducing the risk of complications, and improving overall functional outcomes.[1] The ability to regain ambulatory function is often cited as the primary rehabilitation goal among stroke patients, emphasizing its psychological significance beyond mere physical functioning.[2] Despite significant advancements in gait rehabilitation approaches and the continuous development of innovative therapeutic interventions, a substantial percentage of stroke survivors fail to achieve independent mobility.[3, 4] Approximately 25% of stroke survivors do not regain independent walking with persistent deficits in lower limb motor control, balance, and spasticity contributing to long-term disability.[5] The challenges in regaining independent mobility are multifactorial, involving the severity of initial neurological deficits, age, comorbidities, and the timing and intensity of rehabilitation interventions. This therapeutic ceiling emphasizes the critical need for continued research into more effective, personalized rehabilitation approaches and the development of adaptive assistive technologies to improve mobility outcomes for this significant subset of stroke patients for whom current interventions remain insufficient.[6]

Recent engineering advancements have led to new rehabilitation therapies for stroke patients, especially those using robotics.[7] While treadmill-based robotic systems have dominated the clinical field, their fundamental limitation arises from the discrepancy between treadmill walking conditions and actual ground-based walking conditions.[8, 9] Consequently, the field has witnessed an increase in the utilization of exoskeletons for overground gait training, signifying a novel form of robotic rehabilitation.[10, 11] A number of these powered exoskeletons have been proposed for clinical use to support functional walking, and Molteni *et al.*[9] reported that the overground robot-assisted gait training could yield the similar effects to conventional gait training in subacute stroke patients in the recent multicenter randomized controlled trial. Furthermore, the efficacy of gait rehabilitation employing soft exosuit has also been documented.[12]

For stroke patients unable to achieve independent mobility, assisted rehabilitation approaches utilizing gait aids and orthoses have become standard practice; however, these conventional assistive devices present notable limitations in functional outcomes. While ankle-foot orthoses and walking aids like canes or walkers provide some stability and support, studies indicate that patients using traditional assistive devices frequently exhibit compensatory movement patterns, reduced walking speeds, and limited community ambulation capacity.[13, 14] Additionally, these passive devices cannot provide the dynamic, adaptive assistance needed for natural gait patterns or facilitate motor learning and neuroplasticity.

Wearable robots have emerged as a promising intervention for walking assistance in various patient populations, including those with stroke, spinal cord injury, and neurological disorders.[15, 16] These devices such as powered exoskeletons and soft exosuits, assist in restoring walking function by augmenting lower limb movements, thereby improving gait speed, balance, and overall mobility.[16-18] Powered exoskeletons have the potential to offer distinct advantages for clinical rehabilitation, given their enhanced force capability and precise kinematic control, which align with established motor learning principles.[19] Conversely, soft exosuits appear particularly promising for functional daily use, community ambulation, and long-term mobility assistance, primarily due to their portability and reduced obtrusiveness.[20] However, it should be noted that both systems face significant challenges in terms of feasibility and usability, including concerns regarding user acceptance, cognitive load during operation, limited battery life, and difficulties with stairs and uneven terrain.[21] These findings underscore the potential of wearable robots to enhance gait function in stroke patients. Despite the numerous studies that have investigated the effects of gait rehabilitation utilizing wearable exoskeletal robots, there is a lack of literature on appropriate candidates to improve gait function provided by such devices. The objective of this study is to analyze and identify an appropriate target group of stroke patients who would benefit from gait improvement-using a torque-assisted exoskeletal wearable exoskeletal robot.

Materials and methods

Study design

This was a subgroup analysis of a previous international, multicenter, randomized, controlled trial of robot-assisted gait training (RAGT) compared with the conventional gait training to subacute stroke patients (ClinicalTrial.gov Identifier: NCT05157347).[22] Participants were randomly assigned to either group using a custom-written script in R version 4.1.3 (R Core Team. 2021: R: A Language and Environment for Statistical Computing. R Foundation for Statistical Computing, Vienna, Austria). The experimental design entailed the utilization of a block size of 4, along with a treatment assignment ratio of 1:1, which was stratified by each center. Inclusion criteria for this study were as follows: 1) adult patients aged ≥ 19 years who are currently admitted to the rehabilitation unit, 2) hemiparetic patients after ischemic or hemorrhagic stroke, 3) early subacute stage (from day 7 to less than 3 months after onset[23]), 4) severe ambulatory functional impairment with Functional Ambulatory Category (FAC)[24] score = 0 or 1, 5) Trunk Control Test[25] score ≥ 50, and 6) could walk independently and showed no significant disability (modified Rankin Scale[26] ≤1) before stroke onset. Exclusion criteria were as follows: 1) significant difficulty in communication, such as severe cognitive impairment (Mini-Mental State Examination[27] <10) or speech-language impairment, 2) ataxia due to lesion of efferent or afferent pathways of the cerebellum, 3) spasticity of the affected lower extremity (Modified Ashworth Scale ≥2),[28] 4) severe musculoskeletal disorder of the lower limb, 5) a contracture that limited ambulation, 6) apparent leg length discrepancy of 2 cm or more, 7) a lower limb fracture, open wound, or unhealed ulcer, 8) a severe cardiovascular or pulmonary disease, 9) a history of osteoporotic fracture, 10) a neurological disorder that may affect the ambulatory function (*e.g.* Parkinson's disease, multiple sclerosis, etc.), and 11) ineligible by the investigator.

Subacute stroke patients who completed RAGT over a period of four weeks in the RAGT group within a previous international, multicenter, randomized, controlled trial underwent the following additional ambulatory functional assessments as scheduled in the initial protocol. Ambulatory function was assessed on the robot-on and the robot-off state at immediate after RAGT for the four weeks. The study has been approved by the Institutional Review Board (IRB) of each hospital (IRB of Severance Hospital, South Korea (IRB no. 1-2021-0031), IRB of National Traffic Injury Rehabilitation Hospital (No. NTRH-21016), IRB of Samsung Medical Center (IRB no. 2021-07-021), IRB of the National Health Insurance Service Ilsan Hospital (No. NHIS- 2021-07-029) and IRB of the Universiti Teknologi MARA (No. REC/04/2021 (MR/26)), and conforms to the Declaration of Helsinki. All the participants provided written informed consent before starting the study procedures.

Functional assessments

Assessment of ambulatory functions

To assess ambulatory function, 10 Meter Walk Test (10MWT),[29] 6-Minute Walk Test (6MWT),[30] and physiological cost index (PCI)[31] were assessed on the robot-on and the robot-off state to investigate the assistive effects of an exoskeletal wearable robot. The 10MWT provides an objective measure of gait speed calculated by dividing the distance walked (10 meters) by the time taken, yielding a result in meters per second (m/s). The 6MWT is used to measure gait endurance by the total distance walked in meters during the test. The minimum clinically important difference (MCID) for the 10MWT was established at 0.06m/s,[32] while for the 6MWT, it was defined as 34.4 m.[33] The PCI is used to estimate the energy expenditure of gait based on the relationship between heart rate and walking speed in various populations. The assessments were performed on the same day and each assessment were conducted in a random order, trying to minimize the effect of interference with each other.

In addition, FAC[24] was assessed on the robot-off state. FAC is a clinical scale used to assess a walking ability based on the amount of physical assistance they require during ambulation.

Assessment of motor and balance functions

To assess motor function of the affected lower limb, the Fugl-Meyer Assessment-Lower Extremity (FMA-LE)[34] and the Motricity Index (MI-LL)[35] were used. The FMA-LE is highly reliable and valid for assessing lower limb motor function in stroke patients with a maximum total score of 34 points indicating normal function. The MI-LL is a standardized clinical tool used to assess motor impairment by measuring muscle strength in the lower limb with a total possible score of 100 for the lower limb.

Balance function was assessed using Trunk Control Test (TCT)[25] and the Berg Balance Score (BBS).[36] The TCT is used to evaluate trunk movement control and sitting balance, and the maximum total score is 100, with higher scores indicating better trunk control. The BBS is used to objectively measure a balance abilities and risk of falls, and the total possible score is 56 points; higher scores indicate better balance and lower risk of falling.

Wearable exoskeletal robot

The wearable exoskeletal robot (ANGEL LEGS M20, Angel Robotics Co., Ltd.) utilized in this study was developed employing a torque-assisted strategy. The system was designed as a wearable orthopedic device that induces correct gait and supports the lower extremities. The device was composed of segmented components that provided precise torque support at the hip, knee, and ankle joints. The device featured adjustable pelvic width/depth and leg length to accommodate various body types. This weighed approximately 20 kg and was recommended for heights between 140 cm and 190 cm and weights up to 90 kg. The exoskeleton employed plantar pressure sensors and inertial measurement units to detect the wearer's intention to walk and the current gait phase. The exoskeleton was equipped with four actuators at the hip and knee joints, which were integrated with two force sensors positioned beneath each ankle-foot orthosis. These actuators generated flexion torque during swing and extension torque during stance, thereby providing optimal support for proper gait and enhancing lower limb functionality synchronized with the user's movements. The level of assistance could be meticulously adjusted and adapted to the individual patient's needs and progress. The integration of a low-inertia motor and an impedance reduction control algorithm served to minimize resistance, thereby ensuring that the robot exhibited natural movement in conjunction with the patient and provided assistance solely when necessary.[22]

Grouping according to the effects of assistance

In order to analyze the effects of walking assistance using the wearable exoskeletal robot on changes in walking function, 55 stroke patients who performed the 10MWT and 6MWT in either the robot-on or robot-off state were divided into three groups: the good-responder group, the no-responder group, and the negative-responder group, based on the presence or absence of assistance effects. The good-responder group of stroke patients who demonstrated the most favorable outcomes was characterized as those who exhibited an inability to complete the 10MWT and 6MWT in the robot-off state, yet demonstrated capacity to perform these tests in the robot-on state. Furthermore, stroke patients demonstrating improvements that exceeded the MCID threshold when comparing 10MWT and 6MWT scores in the robot-off state to those in the robot-on state were also classified as good responders. The no-responder group was defined as stroke patients where the difference between the 10WMT and 6MWT in the robot-on state and the robot-off state was within the MCID. The negative-responder group was defined as stroke patients where the participant was unable to perform the 10MWT and 6MWT in the robot-on state but performed the 10MWT and 6MWT in the robot-off state, or where the 10WMT and 6MWT in the robot-off state showed a decrease of at least the MCID compared to the 10WMT and 6MWT in the robot-on state.

The potential relating factors were selected for the present analysis on the basis of their demonstrated relevance in prior studies of ambulatory function in stroke patients. The baseline descriptive characteristics included age, sex, body mass index, stroke type, affected side and time since stroke onset in each patient.[3, 37-39] In addition, ambulatory, lower extremity motor and balance functions were selected for this analysis.[3]

Statistical analysis

SPSS version 29.0 (SPSS, Chicago, IL, USA) was used for all statistical analyses. the good-responder group, the no-responder group, and the negative-responder group were compared using one-way ANOVA with post-hoc analysis using Tukey's test for normally distributed variables. Chi-square test was used to compare categorical variables among the three groups. Ordinal Univariate logistic regression was conducted to identify relating factors for identifying a good candidate to the walking assistance using wearable exoskeletal robot and any variables with univariate associations with p-values <0.20 were considered to be potentially associated with the walking assistance using wearable exoskeletal robot and were included in a multivariate model. Ordinal logistic regression models were then developed. A P value <0.05 was considered to be statistically significant.

Availability of data and materials

The data associated with the paper are not publicly available but are available from the corresponding author on reasonable request.

Results

Comparison between the good-, no- and negative-responder groups

A total of 55 subacute stroke patients completed RAGT over a period of four weeks. Table I showed the demographic and functional characteristics in this analysis. Of

TABLE I.—*Baseline characteristics of participants.*

Demographics	Value (N.=55)
Sex (M:F)	33:22
Age (years)	61.2±14.5
Height (cm)	163.3±7.9
Weight (kg)	63.2±8.9
Body mass index	23.7±3.2
Hypertension (yes)	34
Diabetes mellitus (yes)	17
Stroke type (ischemic:hemorrhage)	38:17
Affected side (right:left)	37:18
Stroke duration (days)	57.1±22.1
Functional characteristics	
Functional ambulatory category	2.6±1.3
Trunk Control Test	87.1±13.8
Berg Balance Scale	32.6±14.5
Fugl-Meyer Assessment-Lower Extremity	23.1±7.4
lower limb score of Motricity Index	60.5±19.2
Geriatric Depression Scale-Short Form	5.1±3.9
EuroQal-5D-3L	0.6804±0.1961

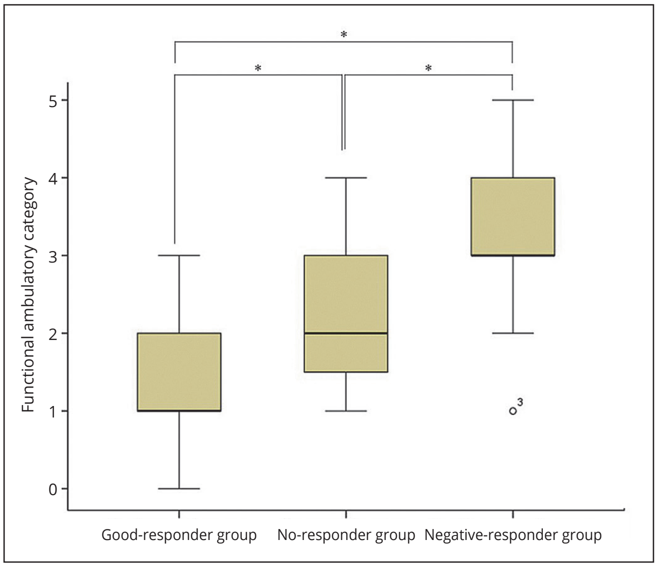

Figure 1.—Functional ambulatory category in the three groups.
*P<0.05 compared between the two groups.

the 55 patients, 21 (38.2%) patients who reached to the MCID of 10MWT and 6MWT were classified as the good-responder group. Seven (12.7%) patients were classified as the no-responder group. In addition, 27 (49.1%) patients were classified as the negative-responder group. There was no significant difference in baseline demographics except stroke duration among the three group. The stroke duration was significantly longer in the no-responder group than the negative-responder group (P<0.05). FAC was found to be statistically significant in low in the good-responder group, the no-responder group, and the negative-responder group, in that order (P<0.05, Figure 1). Balance function measured by TCT and BBS in the good-responder group was significantly lower than that in the negative-responder group (P<0.05). Lower extremity motor function assessed by FMA-LE and MI-LL showed a significant lower value in the good-responder group than the negative-responder group (P<0.05, Table II).

Changes of ambulatory functions according to the wearable exoskeletal robot

The good-responder group demonstrated statistically significant improvements across all ambulatory functions in the robot-on state compared to the robot-off state. This included faster walking speed (10MWT, P=0.002), increased endurance (6MWT, P=0.001), and improved metabolic efficiency (lower PCI, P=0.011). The no-responder group exhibited no statistically significant differences between the robot-on and robot-off states for speed (P=0.081), endurance (P=0.333), or efficiency (P=0.269). Conversely, the negative-responder group experienced a detrimental effect when the robot was active. This group showed significantly slower speed, reduced endurance, and significantly worse metabolic efficiency in the robot-on state (P<0.05, Table III).

Relating factors analysis

Table IV showed the results of the univariate and multivariate ordinal logistic regression analysis. In the univariate

Table II.—*Demographics and clinical characteristics of the good-responder, no-responder and negative-responder groups in stroke patients with gait-assisted robot.*

Demographics	Good-responder group (N.=21)	No-responder group (N.=7)	Negative-responder group (N.=27)	P value
Sex (M:F)	10:11	4:3	19:8	0.276
Age (years)	61.4±13.1	60.9±13.8	61.2±16.1	0.997
Height (cm)	161.0±7.1	164.0±8.6	164.9±8.1	0.223
Weight (kg)	62.1±9.7	61.0±12.0	64.7±7.4	0.479
Body mass index	23.9±3.0	22.7±4.2	23.9±3.1	0.659
Hypertension (yes)	14	4	16	0.840
Diabetes mellitus (yes)	7	1	9	0.595
Stroke type (ischemic:hemorrhage)	15:6	5:2	18:9	0.930
Affected side (right:left)	13:8	5:2	19:8	0.800
Stroke duration (days)	58.9±20.8	78.9±30.2†	50.1±17.1	0.006
Functional characteristics				
Functional ambulatory category	1.7±0.9* †	2.3±1.1†	3.4±1.1	<0.001
Trunk Control Test	79.7±13.9†	90.7±14.5	91.9±11.4	0.006
Berg Balance Scale	23.3±12.4†	29.0±17.2	40.8±10.5	<0.001
FMA-LE	18.5±6.5†	25.6±6.6	26.4±6.5	<0.001
MI-LL	53.3±18.4†	58.9±19.4	66.5±18.3	0.056

FAC: functional ambulatory category; TCT: Trunk Control Test; BBS: Berg Balance Scale; FMA-LE: Fugl-Meyer Assessment-Lower Extremity; MI-LL: lower limb score of Motricity Index.
*P<0.05 compared with compared with the no-responder group; †P<0.05 compared with compared with the negative-responder group.

TABLE III.—*Change of ambulatory function in the good-responder, no-responder and negative-responder groups between the robot-on and robot-off states.*

Characteristics	Subgroup	Robot-on state	Robot-off state	P value
10 Meter Walk Test (m/s)	Good-responder group	0.41±0.20*	0.36±0.20	0.002
	No-responder group	0.50±0.39	0.49±0.39	0.081
	Negative-responder group	0.60±0.39*	0.92±0.56	<0.001
6-Minute Walk Test (m)	Good-responder group	65.2±23.8*	31.5±19.0	0.001
	No-responder group	139.6±151.4	134.8±153.9	0.333
	Negative-responder group	118.3±72.7	173.2±102.7	<0.001
Physiological Cost Index	Good-responder group	1.5±1.6*	3.1±2.8	0.011
	No-responder group	3.0±3.3	5.4±7.8	0.269
	Negative-responder group	1.4±1.3*	0.7±0.7	0.001

*P<0.05 compared with compared gait with robot-off state.

TABLE IV.—*Ordinal logistic regression analysis of the association between potential relating factors and the walking assistance using wearable exoskeletal robot.*

Demographics	Univariate analysis		Multivariate analysis	
	Exp(β) (95% CI)	P value	Exp(β) (95% CI)	P value
characteristics				
Sex	0.850 (-0.196-1.895)	0.111	NT	
Age	0.001 (-0.035~0.036)	0.974		
Body Mass Index	-0.004 (-0.163~0.155)	0.962		
Stroke type	0.205 (-0.892~1.302)	0.715		
Affected side	-0.330 (-1.404~0.743)	0.547		
Stroke duration	0.016 (-0.007~0.040)	0.178	NT	
Functional characteristics				
FAC	-1.309 (-1.932~-0.686)	<0.001	-1.219 (-2.093~-0.345)	0.006
TCT	-0.062 (-0.105~-0.019)	0.005	NT	
BBS	-0.044 (-0.089~0.001)	0.054	NT	
FMA-LE	-0.153 (-0.240~-0.066)	0.001	NT	
MI-LE	-0.035 (-0.065~-0.005)	0.021	NT	

BMI: Body Mass Index; FAC: functional ambulatory category; TCT: Trunk Control Test; BBS: Berg Balance Scale; FMA-LE: Fugl-Meyer Assessment-Lower Extremity; MI-LL: lower limb score of Motricity Index.
*P<0.05.

analysis, sex, stroke duration, FAC, TCT, BBS, FMA-LE and MI-LE demonstrated significant relating factors with the walking assistance using the wearable exoskeletal robot in the univariate ordinal logistic regression analysis. Potential relating factors with a P value <0.2 were then used in the multivariate analysis. In the multivariate analysis, only FAC was a significantly independent factor to the walking assistance using wearable exoskeletal robot (P<0.05, Nagelkerke's R^2 of 0.518).

Discussion

This study presents the first analysis of the proper candidates for an exoskeletal wearable robot for walking assistance in stroke patients. These results suggest that an exoskeletal wearable robot may be effective in subacute stroke patients with lower ambulatory function.

Researches on healthy individuals have demonstrated that wearable exoskeletons can improve ambulatory function through several biomechanical mechanisms.[40-44] Recent articles reported significant reductions in the metabolic cost of walking when using passive or active ankle exoskeletons, leading to improved endurance and reduced fatigue during prolonged walking.[40-42] In addition, the powered hip exoskeleton can enhance walking velocity by 12-15% in healthy adults during level walking and stair climbing tasks.[43] Another article on the hip assist robot suggested the potential to improve trunk stabilization during walking in elderly adults.[44] The findings from studies conducted on healthy individuals have indicated the potential efficacy of robot-assisted gait for various patients with gait disturbances. Recent clinical trials have investigated the immediate effects of wearing exoskeletons on gait function in patients. Awad *et al.*[45] demonstrated that stroke patients experienced significant improvements in gait symmetry, ankle dorsiflexion, and energy efficiency within minutes of wearing a powered soft exosuit. However, given that the participants of the previous study were chronic stroke patients with relatively good walking ability, there is a paucity of research on wearable exoskeletons for assisting bilateral whole lower extremities in stroke patients with very low walking ability. Tan *et al.*[46] examined the effects of wearable exoskeletal robot on ambulation assistance for patients with very low walking ability due to spinal cord injury. A wide range of mobility levels is exhibited by individuals affected by stroke. Consequently, in addition to robots that assist only the ankle or hip, there may be a group of stroke patients who require hip-knee-ankle wearable robots, similar to those used for patients with spinal cord injury.

The wearable exoskeletal robot utilized in this study was developed to induce proper gait and provide support to the lower extremities; however, it did not demonstrate efficacy in enhancing walking function among all stroke patients. The stroke patients who participated in this study exhibited a wide range of mobility, ranging from FAC 0 to 5. The wearable exoskeletal robot in this study demonstrated efficacy in enhancing walking function in subacute stroke patients, exhibiting a mean FAC of 1.7. Specifically, in cases of stroke patients with reduced mobility, enhancements in walking speed, endurance, and efficiency were documented. These findings corroborate the hypothesis that this exoskeleton confers significant benefits for stroke patients within this demographic. In contrast, the exoskeleton utilized in this study exhibited a deleterious effect on walking ability in patients with higher ambulatory function. Almost half of the patients (49.1%) in this study falls into the negative-responder group. The outcomes observed are thought to be attributable to the properties inherent in the exoskeleton utilized in this study. The exoskeleton in this study has the capacity to assist both the affected hip and knee. The device can be utilized on both lower limbs, concurrently providing balance assistance and lower limb muscle assistance. However, this substantial assistance is accompanied by a significant drawback: the exoskeleton weighs 20 kg. External weight can alter gait by increasing joint loading, changing muscle activation patterns, and modifying both temporal and spatial gait parameters.[47, 48] In addition, the wearable exoskeleton robot utilized in this study features adjustable leg length; however, its design did not prioritize customized fitting for gait assistance. Consequently, it was not optimized for utilization as a personalized ambulatory assistance robot. In patients with high ambulatory function, the discomfort induced by the robot's weight, rather than its assistive effect on ambulation, may have exerted an adverse impact on ambulatory function. The wearable exoskeleton robot used in this study was developed to support the lower limbs for walking and is not intended to improve walking ability in patients with high ambulatory function. Therefore, it is not possible to assert that the adverse effects on stroke patients with high ambulatory function negate the positive effects of the wearable exoskeletal robot on walking function. However, further research is necessary to enhance the accuracy of sensing and assist mechanisms to expand the target population for this robot. Motivation has been identified as a pivotal factor in the utilization of walking assistance robots. A previous study[49] on robotic rehabilitation has also indicated that motivation plays a substantial role in determining the efficacy of functional improvement. Stroke patients with more severe ambulatory impairment might be more motivated and thus achieve better outcomes. Stroke patients with relatively higher superior ambulatory function might exhibit diminished motivation to enhance their abilities, potentially leading to inadequate engagement with robotic assistance. However, the study did not directly assess the participants' motivation, precluding the ability to provide definitive evidence regarding this matter. This was one of the limitations.

Limitations of the study

This study had several limitations that should be considered when interpreting the results. While the four-week training period was sufficient to familiarize participants with the robotic device, it may not have been adequate to achieve optimal adaptation. The sample size was not particularly large, and the relatively small number of non-responders in particular might result in somewhat low statistical power. Consequently, among the various variables, only FAC was analyzed as a significant independent factor. It is acknowledged that, due to the relatively low statistical power, it was possible that other variables in addition to FAC might have influenced the results. A notable limitation was the absence of cognitive function assessment, which precluded analysis of how cognitive status might influence user adaptation and the overall effectiveness of the wearable exoskeletal robot. The underrepresentation of non-ambulatory patients in the sample under consideration serves to limit the generalizability of the findings to this important subgroup, who might particularly benefit from robotic assistance. This study did not evaluate the effects of long-term continuous wear of a wearable exoskeletal robot at home or in the community; therefore, the walking assistance effects of wearable exoskeletal robots in reallife settings could not be verified. Therefore, no changes in quality of life associated with the use of wearable exoskeletons could be identified. Moreover, the study's design did not encompass a comparative analysis with conventional orthoses or other assistive devices. Consequently, it was not feasible to ascertain the relative merits or drawbacks of the wearable exoskeletal robot in comparison to existing, potentially more economical or less sophisticated alternatives. Future research should be needed to elucidate these limitations.

Conclusions

The findings of this study indicate that subacute stroke patients with lower ambulatory function may be appropriate candidates for this type of the wearable exoskeleton robot designed to assist in enhancing ambulatory function. Careful patient selection based on functional status is imperative for optimizing the use of wearable exoskeleton robots.

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Conflicts of interest
The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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