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Exoskeletal wearable robot on ambulatory function in patients with stroke: a protocol for an international, multicentre, randomised controlled study

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ABSTRACT

Introduction The purpose of this study is to determine the effect of overground gait training using an exoskeletal wearable robot (exoskeleton) on the recovery of ambulatory function in patients with subacute stroke. We also investigate the assistive effects of an exoskeleton on ambulatory function in patients with subacute stroke.

Methods and analysis This study is an international, multicentre, randomised controlled study at five institutions with a total of 150 patients with subacute stroke. Participants will be randomised into two groups (75 patients in the robot-assisted gait training (RAGT) group and 75 patients in the control group). The gait training will be performed with a total of 20 sessions (60 min/session); 5 sessions a week for 4 weeks. The RAGT group will receive 30 min of gait training using an exoskeleton (ANGEL LEGS M20, Angel Robotics) and 30 min of conventional gait training, while the control group will receive 60 min conventional gait training. In all the patients, the functional assessments such as ambulation, motor and balance will be evaluated before and after the intervention. Follow-up monitoring will be performed to verify whether the patient can walk without physical assistance for 3 months. The primary outcome is the improvement of the Functional Ambulatory Category after the gait training. The functional assessments will also be evaluated immediately after the last training session in the RAGT group to assess the assistive effects of an exoskeletal wearable robot. This trial will provide evidence on the effects of an exoskeleton to improve and assist ambulatory function in patients with subacute stroke.

Ethics and dissemination This protocol has been approved by the Institutional Review Board of each hospital and conforms to the Declaration of Helsinki. The results will be disseminated through publication.

Trial registration number Protocol was registered at ClinicalTrials.gov (NCT05157347) on 15 December 2021 and CRIS (KCT0006815) on 19 November 2021.

INTRODUCTION

Stroke is reported as one of the leading causes of disability in adults.[1] Recent advances in hyperacute and acute management have led to

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study is an international, multicentre, randomised controlled study at five institutions.
⇒ This study is to investigate the effect of gait training using exoskeletons with a relatively large number of patients with subacute stroke.
⇒ The post hoc analysis in this study can help stratify participants with application of the exoskeletons for enhancing ambulatory function in patients with stroke.

a significant impact on clinical and functional outcomes of patients with stroke.[2 3] However, hyperacute management such as revascularisation therapy can only be applied to a limited population of patients with stroke[2] and many patients with stroke are still suffering from significant motor impairments and gait disturbance.[1] Especially, the recovery of the ambulatory function in patients with stroke is one of the most important rehabilitation goals because ambulation is a critical factor influencing the patient's home and social activities.[4] Approximately, 80% of patients with stroke showed ambulatory impairment in the acute stroke phase, and many patients with stroke did not fully regain their ambulatory function although the ambulatory function was rapidly restored within 6 months after onset.[1]

Conventional gait training involves a 1:1 training session between a physical therapist and a patient with stroke.[5] Unfortunately, this may not be feasible due to limited rehabilitation facilities, resources and the significant burden imposed on physical therapists. Consequently, many studies have been conducted to develop rehabilitation robots for effective gait

training.[6] A robot could be effective in assisting patients to practice correct and repetitive movements with the adequate quantity and intensity of training.[7] Automated electromechanical gait machines were developed to reduce the dependence on therapists with treadmill training with partial body weight support. They consist of either a robot-driven exoskeleton orthosis or an electromechanical solution, with two driven footplates simulating the phases of gait.[6] The use of robot-assisted gait rehabilitation using a treadmill-based robot for locomotion control has increased in stroke rehabilitation. However, the conditions of treadmill-based robot gait training differ from those of actual overground gait so the increase in gait ability after treadmill-based robot training might not directly translate into the improved overground gait.[8] In addition, the use of a robot for locomotion control could make it difficult to adapt the robotic movements to the patient's effort to move the muscles and to the passive characteristics of the musculoskeletal system.[9]

Overground gait training using an exoskeleton has been proposed to promote the activation of the nervous system by inducing the active participation from the patient who performed active balance control, weight shift and muscle activation.[9] Exoskeletons could enhance gait reconstruction in patients with gait disturbance more safely. These robots allow contact at several main parts of the lower extremity and can therefore control or guide different joints or segments of the lower extremity. In order for the exoskeleton to be functional, their designs offer user-friendliness, mobility and most importantly safety of the patient with central nervous system injuries.[10] Recently, several exoskeletal wearable robots (exoskeletons) have been proposed for clinical use to support functional ambulation in patients with stroke.[9 11–13] Although there are some evidences to support exoskeletons for rehabilitation in patients with stroke, more researches with an international, multicentre trial will be needed to clarify the effect of gait training using an exoskeleton in patients with subacute stroke.

The main purpose of this study is to determine the effect of overground gait training using a torque-assisted exoskeleton in patients with subacute stroke on the recovery of ambulatory function. The secondary objective is to investigate the assistive effect of a torque-assisted exoskeleton on ambulatory function in patients with subacute stroke. In addition, the further analysis will be possible to investigate the characteristics of patients with subacute stroke for the appropriate indications for an exoskeleton in this study, because this study is a clinical trial conducted on a relatively large number of patients with subacute stroke subjects. Therefore, the appropriate indication for an exoskeleton in this trial will be determined through a post hoc analysis.

METHODS AND ANALYSIS
Study design
This study is an international, multicentre, randomised controlled study at five institutions with a total of 150 patients with subacute stroke. Participants will be randomised into two groups (75 patients in the robot-assisted gait training (RAGT) group and 75 patients in the control group) in a 1:1 allocation ratio. Written informed consent will be obtained from all the patients prior to enrolment in the study, and the study protocol has been approved by the ethics committees of each hospital.

Study population
Patients with stroke admitted to the rehabilitation departments in four hospitals in Korea and one hospital in Malaysia will be asked to participate in the study. The participating study centres are Severance Hospital, Seoul, Korea; TBI Rehabilitation Center, National Traffic Injury Rehabilitation Hospital, Yangpyeong, Korea; Samsung Medical Center, Seoul, Korea; National Health Insurance Service Ilsan Hospital, Goyang, Korea; and Daehan Rehabilitation Hospital Putrajaya, Putrajaya, Malaysia.

The inclusion criteria are as follows:
1. Adult patients aged ≥19 years.
2. Hemiparetic patients after ischaemic or haemorrhagic stroke.
3. Early subacute stage (from day 7 to less than 3 months after onset[14]).
4. Difficulty of independent gait with Functional Ambulatory Category (FAC) score ≤2.
5. Trunk control test[15] score ≥50.
6. A wearable robot (ANGEL LEGS M20, Angel Robotics) in this trial can be applied.
   A. Height: 140 cm ~190 cm.
   B. Weight: less than 80 kg.
   C. Length of foot: 230 mm ~290 mm.
7. Could ambulate independently and showed no significant disability before stroke onset (modified Rankin scale[16] ≤1).

The exclusion criteria are as follows:
1. Significant difficulty in communication, such as severe cognitive impairment (Mini-Mental State Examination[17] <10) or speech-language impairment.
2. Ataxia due to lesion of the cerebellum.
3. Spasticity of the affected lower extremity (Modified Ashworth Scale ≥2).[18]
4. Severe musculoskeletal disorder in the lower limbs.
5. A contracture that limits the lower limb range of motion.
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 (eg, Parkinson's disease, multiple sclerosis).
11. Ineligible by the investigator.

Box 1 Description of the Functional Ambulatory Category

0: Patient cannot walk.
1: Patient requires physical assistance from one person, contacts are continuous.
2: Patient requires physical assistance as in the previous category, but contact is intermittent or light.
3: Patient requires verbal supervision or stand-by help from one person, without physical contact.
4: Patient can walk independently on level ground but requires help on stairs, slopes or uneven surfaces.
5: Patient can walk independently anywhere.

Interventions

Enrolled participants will be randomly assigned to the RAGT group and the control group. All the participants will receive a total of 20 sessions (60 min/session); 5 sessions a week for 4 weeks. The RAGT group will be given 30 min of conventional gait training and another 30 min (excluding robot attachment and detachment time) of gait training using an exoskeleton (ANGEL LEGS M20, Angel Robotics), while the control group will receive 60 min of conventional gait training in the physical therapy room. An exoskeleton in this study was developed as a wearable walking training orthopaedic exercise device which could provide induction of proper gait and support of the lower limbs with detection of walking intent using built-in sensors. Each RAGT and conventional gait training will be provided by a physical therapist. No other robot-assisted rehabilitation will be provided for all participants in each group.

The gait assistive algorithm of an exoskeleton used in this study consists of the stand-up mode, walking mode and standing mode, all of which are based on passivity-guaranteed control to ensure safety. A physical therapist will perform the continuous support of RAGT for safety. Depending on the functional level of the participant, the level of support ranges from supervision to active assistance. The difficulty of the RAGT will be applied in the form of a gradual reduction of the assistive power of the predetermined 20-step in an exoskeleton according to the performance level of each participant. Nonetheless, there may be an unexpected gear response that disrupts the walking rhythm, causing fatigue and discomfort, and in such cases, the participant can use the emergency switch to stop the gait control and assistive power generation. Participants who are at risk of falling due to loss of balance and potential injuries to the musculoskeletal system and all the physical therapists in this study will be thoroughly trained on how to put on and off the device in an emergency situation prior to RAGT and they are given a fall-proof harness to wear for gait training.

The dropout criteria are as follows:
1. Patients who express a desire to dropout of training.
2. Patients who do not comply with the guidelines provided by the investigator.
3. Patients who require treatment outside the scope of the present clinical study.
4. Patients who show a severe injury due to an accident such as a fall.
5. Patients who participate in <80% of the training sessions.
6. Patients who show a new major condition and consequently require absolute rest for recovery (eg, another incidence of stroke, aggravation of stroke, myocardial infarction, any other neurological, internal or musculoskeletal condition).
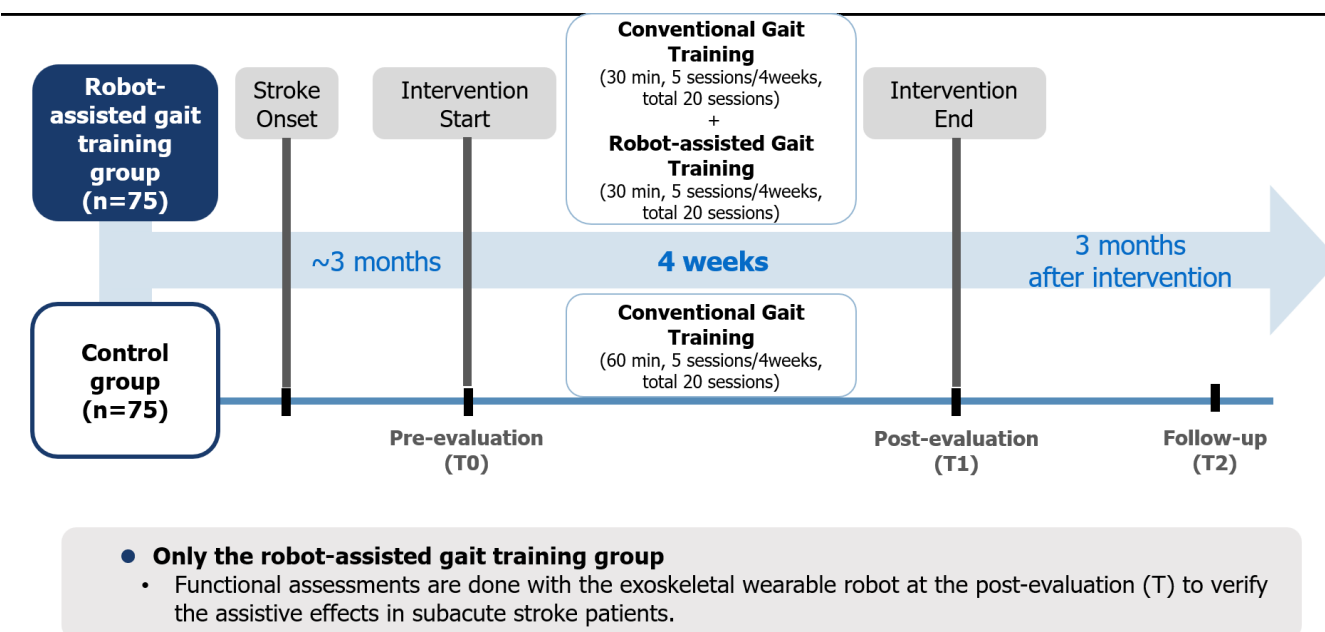
Outcomes

The primary outcome is the change in FAC from T0 to T1 to evaluate the recovery of ambulatory function with RAGT. The FAC is an ordinal scale with six assessment levels of walking disability (from category 0: non-functional ambulation, the patient is unable to walk to category 5: independent ambulation in which the patient is able to walk unaided) (box 1).[19] In addition, we assess the day of regaining gait without physical assistance. Gait without physical assistance is defined as category 3 in the FAC which the individual can walk independently for more than 10 metres without any physical contact but with guidance or monitoring.

Figure 1 depicts a flowchart of the study design. Functional assessments and structured questionnaires in this study are described in table 1. For all the patients in each group, the functional assessments such as ambulation, motor and balance will be evaluated on the robot-off state within 3 days before the first training session (T0) and immediately after the final intervention (T1). A follow-up monitoring will be done to verify whether the patient acquires gait without physical assistance for 3 months from the last day of the intervention. In addition, FAC will be performed 3 months after the intervention (T2) in all the participants (table 2).

To verify the assistive effect of a torque-assisted exoskeletal wearable robot on ambulatory function, FAC, 10 Metre Walk Test (10MWT),[20] 6-Minute Walk Test[21] and Physiological Cost Index[22] are also assessed on the robot-on state without the help of a physical therapist at T1 in only the RAGT group. Each assessment on the robot-on and robot-off state will be conducted in a random order, trying to minimise the effect of interference with each other on the same day (T1).

Sample size calculation

The sample size was determined a priori, which assumed a two-tailed independent t-test with α equal to 0.05 and power at 95%. The sample size was derived using a recent article[23] that is a similar study design to this study. An estimated sample size of 150 participants was expected to detect a statistically significant difference in primary outcome with a statistical power of 95% based on effect size d=0.961 at α=0.05 with a 25% dropout rate.

Figure 1 Study overview.

Randomisation

Randomisation will be performed using a stratified randomisation algorithm to minimise group imbalance in one key institute. A team member uninvolved in outcome assessment and therapies will be responsible for allocation using a custom-written script in R V.4.1.3 (R Core Team. 2021: R: A Language and Environment for Statistical Computing. R Foundation for Statistical Computing, Vienna, Austria). A block size of 4 will be used, and treatment assignment at the ratio of 1:1 will be stratified by

Table 1 Functional assessments and structured questionnaires for each participant

Domain	Assessments
Ambulatory function	Functional Ambulatory Category Day of Regaining Gait without Physical Assistance 10 Metre Walk Test 6-Minute Walk Test Physiological Cost Index
Balance function	Berg Balance Score Trunk Control Test Postural Assessment Scale for Stroke patients
Lower limb motor function	Fugl-Meyer Assessment-Lower Extremity Motricity Index-Lower Extremity
Lower limb spasticity	Modified Ashworth Scale
Activity of daily living	Functional Independent Measure
Depression scale	Geriatric Depression Scale Short Form
Quality of life	EQ-5D-3L

EQ-5D-3L, European Quality of Life 5 Dimensions 3 Level Version.

each clinical centre. Allocation will be concealed from everyone except the team member who is responsible for the allocation and the investigator who provides gait training according to the group to which a participant is assigned.

Blinding and similarity of interventions

Participants will be aware of their allocated group; however, all functional assessments will be independently performed by a blinded rater to group assignment. To increase and maintain inter-rater reliability and accuracy, all therapists in this study will attend a standardised training programme at the beginning of and every 6 months during the study. In addition, to maintain the similarity of intervention, all the gait trainings in this study will be performed by physical therapists who attend standardised training programmes at the beginning of and every 6 months during the course of the study.

Statistical methods

An independent t-test or Wilcoxon signed-rank test will be used to compare the change in FAC from T0 to T1 (primary outcome) between the two groups and to compare other functional assessments between the two groups depending on the normal distribution of primary outcome. In addition, repeated measures analysis of variance or Friedman test will be used to investigate the change in FAC from T0 to T2.

The post hoc analysis will evaluate the relationship between potential influencing factors and change in FAC from T0 to T2 in the RAGT group. Patients will be stratified into good responders and poor responders, based on whether patients achieved gait without physical assistance (FAC≥3) at T2. The potential influencing factors will be selected for this post hoc analysis because they have been found to have some predictive value in

Table 2 Timetable of study protocol

Phase	Screening	Pre-evaluation (T0) (robot-off)	Intervention	Post-evaluation (T1) (Robot-off)	(Robot-on)*	Tele-visit-1	Tele-visit-2	Follow-up (T2)
Time	Day after stroke onset ≤3 months	±1 day on T0		Within 3 days after the last training session		1 month after the last training session (±7 days)	2 months after the last training session (±7 days)	3 months after the last training session (±14 days)
Visit (tele-visit)	0	1		2	2	(1)	(2)	3
Written informed consent	X							
Inclusion and exclusion criteria	X							
Medical chart review	X			X				
Physical examination	X							
Functional Ambulatory Category	X			X	X			X
Trunk Control Test	X			X				
Modified Ashworth Scale	X	X		X				
Mini-Mental State Examination	X							
Randomisation		X						
Adverse effects			X					
10 Metre Walk Test		X		X	X			
6-Minute Walk Test		X		X	X			
Physiological Cost Index		X		X	X			
Berg Balance Score		X		X	X			
Fugl-Meyer' Assessment-Lower Extremity		X		X	X			
Functional Independent Measure		X		X				
Motricity Index-Lower Extremity		X		X				
Geriatric Depression Scale Short Form		X		X				
EQ-5D-3L		X		X				
Satisfaction questionnaire					X			

Continued

Table 2 Continued

Phase	Screening	Pre-evaluation (T0) (robot-off)	Intervention	Post-evaluation (T1)		Tele-visit-1	Tele-visit-2	Follow-up (T2)
				(Robot-off)	(Robot-on)*			
Time	Day after stroke onset ≤3 months	±1 day on T0		Within 3 days after the last training session		1 month after the last training session (±7 days)	2 months after the last training session (±7 days)	3 months after the last training session (±14 days)
Visit (tele-visit)	0	1		2	2	(1)	(2)	3
Day of Regaining Gait without Physical Assistance	X	X	X	X	X	X	X	X

*In only the robot-assisted gait training group.
EQ-5D-3L, European Quality of Life 5 Dimensions 3 Level Version.

previous studies on ambulatory recovery in patients with stroke. Univariate logistic regression will be conducted to identify possible factors and these possible factors will be included in a multivariate model. Multivariate logistic regression models will be then developed. In addition, to investigate the associated factors for assistive effects of the exoskeleton in this study, another post hoc analysis will be done to evaluate the difference in 10MWT between the robot-on state and the robot-off state.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

DISCUSSION

This international, multicentre, randomised controlled study is the first to investigate the effects of exoskeletons for improving ambulatory function and assistance of gait in a larger number of patients with subacute stroke. Advances in robotic technology have made it possible to apply the RAGT to improve ambulatory function in patients with stroke. Most of the studies using RAGT in patients with stroke have used treadmill-based robots, and a recent review article showed that RAGT with physiotherapy was more beneficial for independent walking than physiotherapy alone.[24] However, there might be some limitations of treadmill-based robots in improving ambulatory function because gait training with the trunk passively supported by a harness in treadmill-based robots implies less need for active dynamic stabilisation.[25] To overcome these limitations, overground gait training using an exoskeleton may provide a better opportunity for patients with stroke to improve ambulatory function. Although several studies have investigated the effects of RAGT using an exoskeleton in patients with stroke, most studies were conducted on a relatively small number of patients with stroke at a single institution[26 27] and were case series without a control group.[9 28] Recently, Louie *et al*[11] reported that an exoskeleton-based physical therapy programme did not show greater improvements in walking independence compared with conventional physical therapy in patients with subacute stroke. However, the limitation was that a clear comparison could not be performed due to a relatively high number of dropouts in the exoskeleton-based physical therapy group. In addition, Molteni *et al*[12] reported that the efficacy of overground RAGT was similar to that of conventional gait training in patients with subacute stroke. Because most of the participants might walk before intervention in the study, there is a lack of clarification on the effects of overground RAGT for patients with subacute stroke on the recovery of ambulatory function. Therefore, a multicentre study with a relatively larger number of participants is needed to clarify the training effects of overground gait training using an exoskeletal wearable robot.

Most of the exoskeletons were first developed for patients with spinal cord injury to assist mobilisation, and have been shown to reduce immobility and spasticity, and improve cardiopulmonary, bowel and bladder autonomic function, resulting in improved quality of life.[29] Recently, an exoskeleton has been shown to enhance ambulatory function in patients with cerebral palsy,[10] and the elderly population.[30 31] Stroke is the second leading cause of mortality worldwide and is the most common cause of long-term disability.[1] Ambulation is a critical factor influencing independence in patients with stroke.[4] Therefore, if the exoskeleton can improve ambulatory function in patients with stroke, it is also considered a potential approach for reducing social burden. In this study, the gait assistive effects of the exoskeleton could be identified in patients with stroke after the aforementioned total of 20 sessions of RAGT.

In addition, the post hoc analysis in this study will help stratify participants best suited for RAGT with the exoskeleton and application of the exoskeleton for enhancing ambulatory function in patients with stroke. If successful, proper prescription of the exoskeleton may have the potential to enhance stroke ambulatory recovery and ambulatory function beyond the conventional gait training.

There are some limitations in this trial. An exoskeletal wearable robot (ANGEL LEGS M20, Angel Robotics) used in this study was developed in a torque-assisted strategy. Due to the limitations of the robot's torque, the development company recommended that a patient weighing less than 80 kg would be suitable to expect a therapeutic effect. Through additional research and development in the future, it can be used for patients with stroke weighing 80 kg or more.

ETHICS AND DISSEMINATION

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 provide written informed consent before starting the study procedures. The study is registered on ClinicalTrials.gov and Clinical Research Information Service (CRiS). This trial is ongoing since October 2021. The results will be disseminated through international publications in peer-reviewed journals, in addition to international conference presentations.

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