The effect of an end-effector type of robot-assisted gait training on patients with Guillain-Barre syndrome: a cross-sectional study [version 1; peer review: 1 approved, 1 approved with reservations]

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**Abstract**

**Background:** Guillain-Barre syndrome (GBS) is a peripheral nerve injury caused by a post-infectious immune response. Although the prognosis of GBS is relatively good, some patients have severe impairments, such as walking disabilities. Robot-assisted gait training (RAGT) is used to improve gait function in various neurologic disorders; however, no studies have reported its effectiveness in GBS patients. We aimed to evaluate the effect of gait training using an end-effector type robotic device on GBS patients.

**Methods:** This was a retrospective study of patients diagnosed with GBS who received RAGT using Morning Walk® at an inpatient department. The main outcome measures evaluated before and after RAGT were: Medical Research Council scale, Functional Ambulation Categories, Modified Barthel Index score, Rivermead Mobility Index, and 2-minute walk test.

**Results:** In total, 15 patients underwent RAGT 24 times. The mean age was 55.7 (±15.3) years and the average time from onset was 3.9 (±3.6) months. When compared to the baseline, all outcome measures associated with gait function were improved after RAGT.

**Conclusions:** RAGT can improve walking ability in GBS patients. RAGT can be considered as one gait training tool to recover gait function in GBS patients.

**Keywords**
Guillain-Barre syndrome, Disability, Robotics, Gait, Rehabilitation
Introduction

Guillain-Barre syndrome (GBS), also known as acute inflammatory demyelinating polyneuropathy, is a rapid-onset immune-mediated polyradiculopathy involving sensory, motor, and autonomic nerves. The most common cause of GBS is post-infectious aberrant immune response that results from peripheral nerve injury. The incidence of GBS is 0.89-1.89 per 100,000 person-years and men have 1.78 times the risk of this syndrome when compared to women. GBS is the most common polyradiculopathy leading to the rapid development of paralysis and sensory loss. The clinical manifestations of GBS can range from mild muscle weakness to complete muscle paralysis, which may lead to severe impairment in walking ability and cause functional deficits. The peak muscle weakness in GBS patients appears 2–4 weeks after the first symptoms and progressively improves over the following weeks and months. Although most GBS patients have recovered from debilitating illness, in some patients, impairments in body functionality remain. It has been estimated that after 6 months, 20% of patients are still not able to walk.

The treatment of GBS is multidisciplinary. It involves supportive care, immunomodulatory therapy using plasma exchange and intravenous immune globulin, and rehabilitation. Rehabilitation in GBS patients is focused on the prevention and reduction of impairments in body function. Several studies have shown that physical rehabilitation in GBS could reduce disability and improve physical abilities and quality of life. Restoration of one’s walking ability is an important rehabilitative treatment goal in patients with various neurological disorders, including GBS. Therefore, it is critical to strengthen muscles and increase endurance through gait training to recover walking ability. This can be achieved using various treatments to assist with gait training, including robot-assisted gait training (RAGT). Based on the findings from various studies, RAGT has many advantages over the conventional methods including early initiation of gait training in severely dependent patients, less effort required from the physiotherapists, a longer duration and higher intensity of gait training, more physiological and reproducible gait patterns, and the possibility to measure a patient’s performance. Additionally, RAGT has potential aerobic benefits with a positive influence on cardiopulmonary fitness, as it was shown in severely disabled spinal cord injury and stroke patients. The feasibility and safety of Morning Walk®, a RAGT device, for patients with various neurologic disorders and the effect of Morning Walk®-assisted gait training on patients with stroke was proven in previous studies. Although RAGT has been shown to be effective in improving gait function in patients with stroke and spinal cord injuries, the effectiveness of RAGT in GBS is not well documented. Therefore, the purpose of this study was to evaluate the effectiveness of RAGT in GBS patients using an end effector type of robotic device.

Methods

We retrospectively analysed patients with GBS who were hospitalized at the National Health Insurance Service Ilsan Hospital from April 2016 to January 2020. Subjects were included if this was their first diagnosis of GBS and were 19 years of age or older. All included patients received RAGT using Morning Walk®. Morning Walk® is an end effector type of robotic device with body support provided via a saddle seat; it was developed in South Korea. The footplates operate independently in the sagittal plane to simulate locomotor activity and guide the feet to reproduce gait trajectories. It also offers ground walking as well as ascending and descending stairs modes.

Figure 1. End-effector Type Robotic device, Morning Walk®.
Subjects received Morning Walk®-assisted gait training for a total of 24 sessions; each session lasting 30 minutes. All participants were assessed using the following tests before and after RAGT: the Medical Research Council (MRC) scale for evaluating muscle strength; the Functional Ambulation Categories (FAC) for measuring functional gait; the Modified Barthel Index Score (MBI) for measuring activities of daily living; the Rivermead Mobility Index (RMI) for testing functional abilities; and the 2-minute walk test (2MWT) for measuring endurance of walking distance\(^\text{18}\). Information was collected from patients medical records, and improvement was measured by calculating differences in the scores before and after RAGT.

SPSS statistics version 25.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analyses. The changes before and after Morning Walk®-assisted gait training for all of the investigated parameters were assessed using paired t-tests. P-values <0.05 were considered statistically significant.

This study was approved by the Institutional Review Board of the Ilsan Hospital (NHIMC 2020-02-008-001). Prior written consent from patients was waived by the IRB because this is a retrospective study.

Results
Sixteen patients diagnosed with GBS underwent RAGT using Morning Walk®, Among them, one participant dropped out of the trial due to pain and discomfort around the saddle seat during the RAGT. Thus, 15 patients (11 males and 4 females) were included; the mean age was 55.7 (±15.3) years and the average time from onset was 3.9 (±3.6) months.

Compared to the baseline measurements, all the outcome measures were improved after Morning Walk®-assisted gait training. There were significant improvements in muscle power of the hip, knee, and ankle, FAC, MBI, 2MWT, and RMI (Table 1).

<table>
<thead>
<tr>
<th>Table 1. Outcome measures before and after RAGT.</th>
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<tr>
<td>Before</td>
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<td>Muscle power</td>
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<td>Ankle Ext.</td>
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<tr>
<td>Functional Ambulation Categories</td>
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<td>Modified Barthel Index Score</td>
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<tr>
<td>2-minute walk test</td>
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<td>Rivermead Mobility Index</td>
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Flx.: Flexor, Ext.: Extensor, *p<0.05

Discussion
This study demonstrated that RAGT was beneficial and effective in patients with GBS. The patients with GBS who received Morning Walk®-assisted gait training showed significant improvements in the motor power of their lower limbs, gait function, gait endurance, and activities of daily living.

GBS is associated with residual physical disability such as stroke, spinal cord injury, or traumatic brain injury. The effectiveness of rehabilitation treatment in patients with brain lesions or spinal cord injuries has been discussed in several studies\(^{19-21}\). However, the effectiveness of rehabilitative treatment in patients with GBS is still poor\(^{22}\). Some studies concluded that rehabilitation treatment for GBS patients was effective and improved body functionality and quality of life\(^{20,21}\). However, these studies do not strongly support the effect of rehabilitation in patients with GBS due to their limitations, including small sample sizes or the lack of a control group.

RAGT was proven to be a significant method to improve the locomotor function of patients with various neurologic disorders\(^{23,24}\). However, to our knowledge, the efficacy of RAGT in GBS patients has not been reported to date. This was the first preliminary study to investigate the effects of RAGT among patients with GBS. We found that Morning Walk®-assisted gait training improved the MRC scale. These findings suggest that RAGT might assist in strengthening the muscle power in the lower limbs. There were also improvements in the FAC and 2MWT after RAGT, suggesting that RAGT is beneficial in improving functional gait and walking endurance. We believe that the improvements in the lower limb muscle strength were related to the improvements in functional gait and walking endurance. Finally, the MBI and RMI scores also improved after RAGT, suggesting that RAGT improves activities of daily living and functional abilities. RAGT using an end-effector type device improved walking and functional abilities in GBS patients and it can be considered as one of the gait training tools to assist in the recovery of gait function in patients with GBS.

This study had several limitations. Firstly, the sample size was small; only 15 patients from a single medical center were enrolled. Secondly, there was no control group in this study; thus, we were not able to determine if RAGT is better than conventional rehabilitative therapy. Finally, this study only assessed outcomes at the beginning and end of RAGT. Thus, we were not able to determine the persistence of treatment effects over time. Future studies with larger sample sizes and a control group are needed to evaluate the persistence of treatment effects.

Data availability
Underlying data
Dryad: The Effect of an End-Effector Type of Robot-Assisted Gait Training on Patients with Guillain-Barre Syndrome, https://doi.org/10.5061/dryad.hqbzkhl1d\(^{25}\).

Data are available under the terms of the Creative Commons Zero “No rights reserved” data waiver (CC0 1.0 Public domain dedication).
References


Introduction:
The authors should provide a proper state of art analysis with previous rehabilitation results with this population defining the experimental condition. Additionally, it is required to reference studies of rehabilitation outcomes with this population or other affected populations by other pathologies with Morning Walk Device.

Methodology:
There are many missing experimental details, such as the location of the hospital, the preparation and the experimental set-up, the description of the population and the clinical levels of every involved patient, the measurements, and the procedure of the clinical evaluation.

Results:
There are also many missing information details, such as the units in Table 1, details of the results. According to the patient or the level of affectation, it is also required to analyze the kinematics results.

Discussion:
This section is also fragile. The authors should compare with other works about the results following similar intervention with the same or similar set-up even though with other population to have a reference of comparison.

Is the work clearly and accurately presented and does it cite the current literature?
Partly

Is the study design appropriate and is the work technically sound?
Partly

Are sufficient details of methods and analysis provided to allow replication by others?
Partly

If applicable, is the statistical analysis and its interpretation appropriate?
Partly

Are all the source data underlying the results available to ensure full reproducibility?
No

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Healthcare Robotics, Rehabilitation Robotics, Human-Robot Interaction

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 12 January 2021

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I think this paper is a meaningful study with clear meaning, despite the limitations of no control group.

However, as mentioned in the paper, GBM often improves to spontaneous, and GBM's onset is important in determining this. It would be nice to provide information on the onset of inclusion patients.

It would be nice if a description of a specific method using RAGT was added. For example, it would be nice if information such as 1) the patient proceeds with treatment to walk as quickly as
possible; 2) uses the stair function; and 3) how much body weight support is used.

For statistical analysis 15 patients are non-parametric, so Wilcoxon signed rank test would be more suitable than paired t-test.

**Is the work clearly and accurately presented and does it cite the current literature?**
Yes

**Is the study design appropriate and is the work technically sound?**
Yes

**Are sufficient details of methods and analysis provided to allow replication by others?**
Partly

**If applicable, is the statistical analysis and its interpretation appropriate?**
Partly

**Are all the source data underlying the results available to ensure full reproducibility?**
Yes

**Are the conclusions drawn adequately supported by the results?**
Yes

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Description of a specific method using RAGT, Information on the onset of inclusion patients, Wilcoxon signed rank test analysis

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.
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