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Research Article

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First Insights into the use of an End-Effector RAGT System for Improving Mobility in Patients with Amyotrophic Lateral Sclerosis: A Case Series Study

Ing. Milan Šebek

Head Physiotherapist at ALSA Association, Prague, Czech Republic

Corresponding author
Ing. Milan Šebek, Head Physiotherapist at ALSA Association, Prague, Czech Republic

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ABSTRACT

Background: Amyotrophic lateral sclerosis (ALS) is the most common motor neuron disease in adults. While incurable, managing symptoms is crucial for maintaining quality of life. The loss of walking ability limits independence and inherently results in decreased physical activity, highlighting the need for effective gait rehabilitation. Robot-assisted gait training (RAGT) offers a promising solution by enabling safe, active movement even in later disease stages.

Objective: The objective of this prospective case series study is to explore the potential role of a novel end-effector RAGT device in individuals with ALS who experience gait impairments.

Materials and methods: Two patients with ALS, presenting with varying degrees of gait impairment, completed ten 30-50 minute sessions of end-effector RAGT. Patient progress was evaluated using the 10-Meter Walk Test (10MWT), 6-Minute Walk Test (6MWT), and Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS).

Results: The patient with less advanced ALS showed notable progress, with a 15% increase in walking distance (6MWT) and a 22% increase in gait speed (10MWT). Although the patient with advanced ALS had no significant objective gait improvements, he reported better lower limb mobility, greater confidence while walking, and a higher ALSFRS score post-therapy.

Conclusion: R-Gait therapy may improve gait ability in ALS, especially in earlier stages, with observed objective gains in walking distance and speed. The patient with advanced ALS experienced a subjective improvement, such as increased walking confidence, which may contribute to greater participation in daily activities. In addition, R-Gait provides the opportunity for safe full-body exercise, even for patients in more advanced stages of the disease, allowing them to potentially benefit from active movement, such as preventing contractures and muscle atrophy, improving cardiovascular function, and enhancing overall physical and mental well-being.

Keywords: RAGT, End-Effector, Amyotrophic Lateral Sclerosis, Motor Neuron Disease, Gait Rehabilitation

Introduction

Amyotrophic lateral sclerosis (ALS) is a progressive, incurable, neurodegenerative disease characterized by the degeneration of both upper and lower motor neurons. This leads to weakness, atrophy, and spasticity of voluntary muscles, including those in the limbs and muscles surrounding the spine, as well as those involved in speech and swallowing [1-3]. Muscle weakness typically begins in the distal parts of the limbs in about 70% of cases, while around 25-30% start with bulbar symptoms like dysarthria or dysphagia. In rare cases, breathing difficulties can be an early sign [4,5]. ALS is the most common motor neuron disease in adults, with an incidence of 0.4 to 2.4 cases per 100,000 globally, highest in Europe and North America. The disease is more prevalent in men than women, with a typical onset in their mid-50s [6-8].

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The prognosis of ALS is influenced by factors such as the type of onset, age, progression rate, and respiratory involvement. Bulbar onset and older age are associated with faster progression. The average life expectancy is 2–4 years from symptom onset, with respiratory failure being the leading cause of death [9,10]. Approximately 50% of patients die within 30 months of symptom onset, while 20% survive 5–10 years. Patients with onset before 40 typically survive even ten times longer than those diagnosed after 60 [11].

Currently, only two drugs are approved for slowing the progression of ALS, but they have a moderate effect. The clinical management of ALS is, therefore, primarily focused on managing disease-related symptoms. Multidisciplinary rehabilitation helps patients perform daily activities more independently and safely, boosting self-confidence and allowing them to lead a fulfilling life despite their reduced lifespan [12]. While ALS remains an incurable disease, managing its symptoms can significantly improve quality of life, which, in turn, can positively influence psychological well-being and potentially slow disease progression. Longitudinal studies have shown that psychological distress, including stress, depression, and low self-esteem, is associated with faster disease progression and shorter survival [13,14].

Lower limb weakness, spasticity, and reduced coordination lead to gait abnormalities, making walking less efficient and more energy-consuming. This forces patients to compensate for muscle imbalances, increasing the risk of tripping and falling. As a result, mobility is compromised, and falls become a significant concern, occurring in about 46% of ALS patients. In 1.7% of cases, a fall was even the cause of death among individuals with ALS [15, 16]. As a secondary effect, compensatory gait patterns may contribute to musculoskeletal pain, including low back pain, and increased fatigue [17]. As a result, patients often become less physically active, leading to deconditioning and muscle atrophy, while joint and muscle spasticity can cause pain, contractures, and further loss of function [18].

The role of exercise in ALS treatment has been debated due to concerns about potential adverse effects on disease progression, but emerging evidence supports its beneficial impact [19]. Appropriately prescribed physical rehabilitation has shown benefits in slowing muscle degeneration, improving respiratory function, and enhancing mobility, including walking. Even in later stages, physical therapy can prevent further decline in strength, reduce fatigue, improve endurance, and promote functional independence [19-22]. Apart from its physical benefits, exercise may positively impact mental health and contribute to an improved quality of life in ALS patients [23,24].

Gait rehabilitation in ALS patients is a dynamic process that adapts to the gradual deterioration of motor functions. The most intensive rehabilitation training typically occurs during the early, ambulatory stages of ALS, with interventions aimed at preserving walking ability, muscle strength, and stability [12]. As the disease progresses, rehabilitation shifts to maximizing the extended benefits of exercise, such as slowing muscle degeneration, preventing joint stiffness, maintaining flexibility, and supporting cardiovascular function. In later stages, these interventions are complemented with compensatory strategies, including the use of assistive devices like orthotics, walkers, or wheelchairs. In addition to conventional therapies, gait rehabilitation may also incorporate treadmill training or body-weight-supported treadmill training (BWSTT), potentially combined with electrical stimulation of the lower limbs to enhance therapeutic outcomes [25,26].

In recent years, the use of robot-assisted gait training (RAGT) in the rehabilitation of patients with neurological disorders has gained increasing attention. Positive effects have been demonstrated in conditions such as stroke, spinal cord injury, and multiple sclerosis [12]. The therapy involves providing repetitive and intensive gait training with the support of robotic devices. The main types of RAGT systems are exoskeletons and end-effector systems. Exoskeletons guide the movement of the extremities by providing external support along the limbs, whereas end-effector systems are connected to the patient's feet, allowing for greater freedom in proximal joints and thereby encouraging more active patient participation (While RAGT systems have the potential to offer an effective and safe intervention, even in the advanced stages of ALS, research on their use in ALS patients is still negligible [27,12].

The present study aims to explore the potential role of a novel end-effector RAGT device in individuals with ALS experiencing gait impairments. The primary focus is to evaluate the effects of the intervention on walking distance, walking speed, and overall functional capacity.

Materials and Methods

Study Design

The study was designed as a prospective case series and conducted between February 2024 and June 2024 at a private rehabilitation facility. In collaboration with the ALSA organization, which was responsible for patient recruitment, gait rehabilitation using the end-effector type of RAGT system (R-Gait, BTL Industries Ltd.) was incorporated as part of the routine multidisciplinary approach to managing ALS symptoms.

Prior to treatment, all participants were fully informed about the study's course, potential side effects, and the possibility of result publication, and provided written informed consent. The study adhered to the ethical principles of the 1975 Declaration of Helsinki and relevant guidelines (Council of Europe, 1997; WMA, 1997–2000).

Participants

Two ALS patients with varying degrees of gait impairment participated in the study.

Inclusion criteria required participants to be adults aged 18 years or older diagnosed with ALS. They had to present with significant gait impairments, either with or without the use of assistive devices, and be in the early to mid-stages of the disease. Only those with sufficient cognitive function, ensuring their ability to cooperate and complete the rehabilitation protocol, were included.

Exclusion criteria included severe cardiovascular disease, unstable orthopedic conditions, epilepsy, cognitive or respiratory impairments, and any condition preventing safe gait training or pain-free harness adjustment.

Patient 1: A 66-year-old male diagnosed with ALS in 2020, presenting with progressive mobility impairment. He uses a walker for short distances and an electric wheelchair for longer distances, which offers improved operability given the patient's upper limb weakness. The patient requires assistance to stand. Neurological examination revealed quadriceps atrophy with fasciculations, lower limb edema, and hyperreflexia. He has difficulty raising his legs beyond the horizontal and is unable to maintain the position. He is fully oriented, cooperative and actively engages in rehabilitation.

Patient 2: A 57-year-old male diagnosed with the spinal form of ALS since September 2022, presenting with upper limb paresis and progressively worsening gait impairments. Since October 2022, the patient has experienced progressive lower limb weakness, cramps, and increasing fatigue. He remains ambulatory, but his walking distance is limited to approximately 400 meters in familiar environments, requiring frequent rest breaks and support when ascending stairs. Spirometry showed preserved ventilatory capacity. The patient is cognitively intact, fully cooperative, and actively participates in rehabilitation.

Interventions

Both patients participated in 10 therapy sessions using the R-Gait device, scheduled approximately once a week. The first session lasted 30 minutes, with the duration gradually increasing up to 50 minutes, based on individual tolerance.

At the start of each therapy session, the patient was secured in a harness, with their feet positioned on the footplates and fastened using adjustable bindings. By securing only the most distal part of the foot, unrestricted movement of the lower limbs and pelvis was maintained throughout the session. The harness was connected to a lift system that facilitated dynamic weight unloading, continuously adjusted based on the gait cycle phase to provide consistent support during movement. The footplates were designed to automatically move the patient's feet in a manner that replicates the push-off phase of the gait cycle, thereby promoting a more natural walking pattern. Integrated sensors monitored foot activity and weight offloading throughout the therapy.

Parameters such as weight support, step length, and gait speed were individualized based on the patient's capabilities. Therapy sessions were progressively extended in duration, with patients encouraged to walk longer distances in each subsequent session while always considering their current physical and psychological condition. At the end of each therapeutic session, the device automatically documented the resulting values for step count and walked distance.

Outcome measures

The clinical efficacy of the therapy was assessed through standardized functional outcome measures, including the Six-Minute Walk Test (6MWT), the Ten-Meter Walk Test (10MWT), and the ALS Functional Rating Scale (ALSFRS). The 6MWT evaluated functional exercise capacity by measuring the total distance walked in six minutes, while the 10MWT assessed gait speed based on the time required to cover a standardized 10-meter distance. Functional status was assessed using the ALSFRS, a questionnaire consisting of 10 domains that measure the ability to perform daily activities, including mobility-related tasks such as walking and stair climbing, as well as breathing, dressing, and more. All outcome measures were collected at baseline and after the final session to assess changes throughout the intervention.

Additionally, therapy parameters (time, distance, step count) were automatically recorded by the device throughout the therapeutic interventions, revealing trends in physical exertion tolerance. These parameters, reflecting the patient's walking performance during each session, showed changes in total distance covered, walking speed and number of steps taken, indicating the patient's ability to tolerate increasing levels of physical activity.

Data analysis

Data were analysed individually for each patient, focusing on pre- and post-therapy values. Values were visualized using graphs to track each patient's progress. For simplicity, the percentage change for each parameter was calculated.

Results

Both recruited patients completed the full series of 10 sessions. No safety issues or adverse events related to the study participation were reported, aside from commonly occurring muscle fatigue. The information about the patients and a summary of the results for the functional outcome measures are provided in Table 1.

Table 1: Patient characteristics and functional outcome measures before and after therapy

Subject	Age (years)	FAC	Time since diagnosis (years)	6MWT (m)		10MWT (s)		10MWT (m/s)		ALSFRS	
Patient 1	66	2-3	4	Before	185	Before	13.91	Before	0.71	Before	25
				After	190	After	13.87	After	0.72	After	28
Patient 2	57	4-5	1.5	Before	343	Before	9.32	Before	1.07	Before	32
				After	390	After	7.66	After	1.31	After	29

FAC = Functional Accessibility Classification

Patient 1

Throughout the therapy sessions, Patient 1 demonstrated a progressive increase in exercise tolerance, as reflected in the measured values, up until the sixth session. Thereafter, a decline was observed, reaching its lowest point during the eighth session, followed by a subsequent improvement (Figure 1). The walking speed exhibited variability, with no noticeable trend. observed throughout the treatment course.

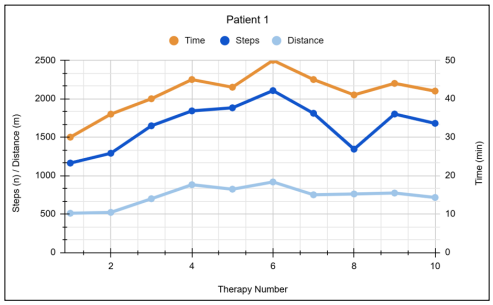

Figure 1: Longitudinal progression of recorded therapy values in Patient 1 across a series of ten therapeutic interventions.

Objective functional gait tests demonstrated no significant differences between pre- and post-therapy values. In the 6MWT, the distance walked increased by only 2.7% following therapy. In the 10MWT, the mean time required to complete the standardized distance and the gait velocity remained almost unchanged, with a percentage change of less than 0.5%. The patient's functional status assessment demonstrated a slight increase in the ALSFRS score, which increased by 12% post-therapy compared to the pre-therapy value (Figure 2).

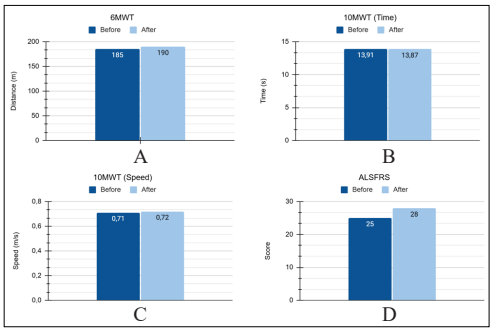

Figure 2: Graphical representation of outcome measures of 6MWT distance (A), 10MWT Time (B), 10MWT Speed (C) and ALSFRS score (D) at baseline (before) and after the last therapy session (after) for Patient 1.

Post-intervention, the patient reported a perceived enhancement in lower limb mobility. Specifically, he expressed reduced anxiety related to knee hyperextension and a subsequent fear of falling, and noted enhanced confidence during supported gait.

Patient 2

Throughout the therapy series, the patient maintained a steady increase in physical effort. However, from the eighth session, progress in the number of steps and distance walked stabilized, coinciding with a reduction in session duration (Figure 3). The patient's walking speed increased from 0.22 m/s achieved during the first RAGT session to 0.33 m/s attained during the final session, representing an improvement of approximately 53.9%.

Following completion of the full therapy regimen, Patient 2 exhibited marked improvements in functional gait assessments compared to baseline values. Specifically, a 14.7% increase in the distance covered during the 6MWT, a 17.8% decrease in the 10-meter walk time, and a 21.5% increase in gait velocity were observed. However, a slight decline of 9% in the ALSFRS score was noted compared to baseline values.

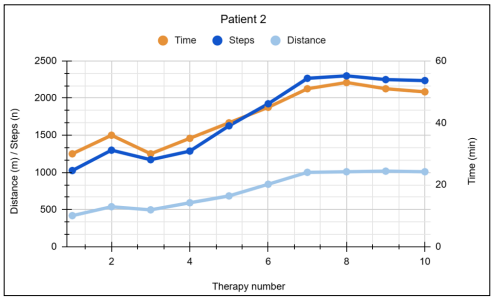

Figure 3: Longitudinal progression of recorded therapy values in Patient 2 across a series of ten therapeutic interventions.

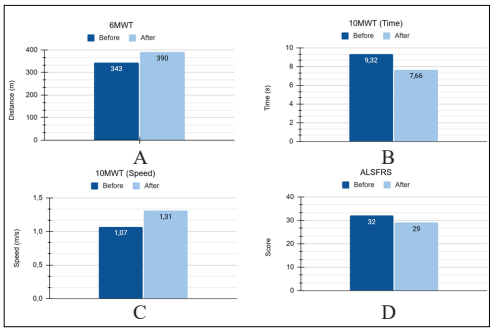

Figure 4: Graphical representation of outcome measures of 6MWT distance (A), 10MWT Time (B), 10MWT Speed (C) and ALSFRS score (D) at baseline (before) and after the last therapy session (after) for Patient 2.

According to the patient's subjective assessment, he consistently felt well after each therapeutic session without experiencing increased fatigue. Upon completing the full course of therapy, he reported improved walking confidence and reduced fatigue over longer distances.

Discussion

Given the inherent progressive nature of ALS, where a gradual decline in motor function is expected, the primary goal of therapeutic interventions increasingly focuses on managing symptoms, slowing the rate of functional decline, and maximizing the preservation of independence and participation in daily life to maintain the best possible quality of life (12). One key factor affecting patients' independence and well-being is walking ability, which is an important aspect of rehabilitation programs for individuals with ALS. Existing literature examining physical exercise in ALS patients indicate that resistance or/and aerobic interventions, conducted up to three times a week for less than 60 minutes, can slow functional decline, enhance quality of life, preserve muscle strength, and alleviate fatigue. However, it is crucial that these interventions be individualized to avoid overexertion, which may have detrimental effects [19-22].

The aim of this study was to explore the impact of an end-effector-based RAGT system on walking ability in two patients with ALS exhibiting varying degrees of gait impairment. The therapy's effects were evaluated using objective functional gait tests (6MWT and 10MWT) and ALS severity through the ALSFRS score. To assess the patients' ability to increase the physical demands of therapy, data from the device tracking distance, step count, and walking speed were analysed. To the best of the authors' knowledge, no previous study has evaluated the impact of an end-effector type RAGT system on lower limb function in ALS patients.

After completing a series of 10 therapy sessions, the patients exhibited varied outcomes. While Patient 1 demonstrated limited progress in objective gait parameters, Patient 2 showed a 14.7% increase in distance covered during the 6MWT, a 17.8% reduction in the 10-meter walk time, and a 21.5% increase in gait velocity. Patient 2 also exhibited a superior ability to tolerate incrementally increased physical exertion, resulting in progressive lengthening of sessions and increased walking distance with each subsequent session. Interestingly, despite these contrasting objective findings, both patients reported a perceived enhancement in lower limb mobility and increased confidence during ambulation, highlighting a potential benefit of RAGT beyond purely measurable gait improvements. The ALSFRS score showed a slight improvement for Patient 1, while Patient 2 experienced a 9% decline. This discrepancy between the objective results and ALSFRS scores may be due to the fact that ALSFRS assesses not only ambulation but also other functional domains affected by ALS, such as speech, swallowing, and writing, which are unrelated to the intervention, but may impact the overall ALSFRS score. Furthermore, existing literature investigating the effects of exercise in ALS patients also reports a decline in ALSFRS-R scores over a 3-month period, even within intervention groups, albeit less pronounced compared to control groups [28,29].

Objective results may suggest that RAGT has a greater positive effect in patients with less impaired walking ability, as demonstrated in this study by Patient 2 (FAC score of 4-5), compared to Patient 1 (FAC score of 2-3). A potential explanation for this phenomenon lies in the possibility that patients in earlier stages of the disease may have a greater preservation of neuroplasticity, which is crucial for the efficacy of RAGT [30]. Furthermore, preserved motor functions allow for active movements that can be strengthened and optimized through RAGT [6]. On the other hand, in Patient 1, who exhibited more advanced impairment, even maintaining the current level of function can be considered a meaningful therapeutic outcome, especially when combined with the patient's subjective sense of improvement, given the progressive nature of this neurodegenerative disease.

There are only a few studies specifically focused on gait rehabilitation in ALS patients, and only one addresses robot-assisted therapy. Morioka et al. investigated the effects of the Hybrid Assistive Limb (HAL) in 11 patients [12]. The results demonstrated a 21% increase in the distance covered during the 2MWT and a 9.5% increase in speed on the 10MWT. In another study by Sanjak et al., involving 9 participants, a 21% improvement in the distance covered during the 6MWT and a 26.5% increase in speed on the 25-foot walk test (25FWT) were observed after 24 treadmill training sessions [26]. These findings are almost in agreement with the results of the present study. The differences may be attributed to the larger sample size and varying levels of gait dysfunction. Additionally, the study with better results for the 6MWT protocol involved more than twice the number of therapy sessions.

Despite objectively poorer results in gait tests, RAGT can still offer benefits even to patients in later stages of the disease which is also supported by the subjective report of the Patient 1. Standard rehabilitation exercises in ALS patients carry a risk of falls. For example, a study by Clawson et al., which examined the effects of stretching, resistance, and endurance exercises in ALS patients, found that falls accounted for 42.5% of all adverse events. During the study, 40 falls occurred in 25 patients [31]. RAGT employs a body weight support system, facilitates active, full-body exercise for patients with varying degrees of mobility impairment within a controlled environment that minimizes fall risk. Furthermore, active movement during RAGT may provide broader benefits beyond improvements in measurable gait parameters. These include psychological advantages, prevention of complications such as muscle atrophy and contractures, as well as enhancement of cardiorespiratory factors and maintaining motor activity [22,27] Moreover, from a physiological standpoint, exercise, especially endurance activities, can significantly influence ALS progression. It optimizes glucose utilization in muscles, reducing metabolic and oxidative stress, protecting mitochondria, and maintaining muscle endurance. Additionally, by regulating blood sugar levels and minimizing lipid oxidation and free radical production, exercise may potentially slow neurodegeneration [32].

This case series study has several limitations that should be considered when interpreting the results. First, due to the small sample size (n=2), the findings cannot be generalized to the broader ALS patient population. Another limitation is the heterogeneity of the patients, who differed in the severity of their condition (FAC score), which may have influenced their response to therapy. The absence of a control group further complicates the interpretation, as it prevents comparisons with the natural progression of the disease or with other rehabilitation approaches. Additionally, the ALSFRS scale may not be the most appropriate evaluation tool in this context. Since the ALSFRS assesses a wide range of functional aspects, such as speech and swallowing, it may not accurately capture subtle changes in gait. Therefore, objective gait tests like the 10MWT and 6MWT should be complemented by additional assessment methods or questionnaires that capture broader benefits of RAGT, such as improvements in quality of life and overall mobility beyond gait enhancements, to provide a more comprehensive evaluation of its effects in ALS patients undergoing rehabilitation.

Despite the mentioned limitations, this study provides valuable insight, particularly as it is the first to suggest a potential positive effect of end-effector RAGT therapy on gait quality in ALS patients. Future research with larger, more diverse samples and more robust study designs is needed to better illuminate the effect of the RAGT system across different stages of ALS and to confirm the effectiveness of this intervention for improving gait, overall physical condition and quality of life in ALS patients.

Conclusion

The study suggests that R-Gait therapy may positively impact gait ability, particularly in the earlier stages of ALS, where notable improvements in walking distance and speed were observed. Even for a patient with more advanced ALS, subjective improvements such as increased walking confidence were reported, which may have a meaningful clinical impact on quality of life by promoting greater physical activity and social participation. Additionally, RAGT provides an opportunity for full-body exercise in a safe environment, even for individuals in later stages of the disease, and may offer further benefits,

such as slowing neurodegeneration, preventing muscle atrophy and contractures, and improving circulation. Due to the study's limitations, these findings should be considered exploratory and require further validation

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