Research Article

Treatment for Lateropulsion in Standard Clinical Practice: A Multicenter Randomized Controlled Trial

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Abstract

Background: Post-stroke lateropulsion with pusher syndrome (LP) severely impacts postural control and daily activities. In Japan, while a knee-ankle-foot orthosis (KAFO) is recommended for LP treatment, a gait exercise assist robot (GEAR) is also used.

Objective: We investigated the effectiveness of gait training using a GEAR and KAFO in improving LP.

Methods: Thirty-six stroke patients with LP were randomly assigned to GEAR or KAFO groups, and received 50-min daily sessions for 2 weeks. Both the GEAR group, using robot assistance, and the KAFO group, with therapist assistance, engaged in gait training with a goal of 30 min per session. Primary outcomes were changes in Burke Lateropulsion Scale (BLS) and Scale for Contraversive Pushing (SCP) scores.

Results: Seventeen participants in each group completed their respective interventions. Both groups showed marked improvements in BLS and SCP scores (all $p < 0.001$). Although the GEAR group achieved greater walking distances and step counts ($p < 0.01$ each), overall BLS and SCP improvements did not significantly differ between the groups ($p = 0.51$ and 0.84, respectively). Both interventions demonstrated comparable LP improvement to previous studies.

Conclusions: We found no significant difference in the treatment effects between the two interventions, indicating both to be effective.

Keywords

Lateropulsion, pusher syndrome, knee-ankle-foot orthosis, gait exercise assist robot, gait training

Introduction

Every year, the incidence of new or recurrent stroke is about 15 million worldwide, (Feigin et al., 2014; Krishnamurthi et al., 2013) and about two-thirds of stroke survivors experience motor deficits associated with diminished quality of life. (Nichols-Larsen et al., 2005) Pusher behavior is a severe postural disorder exhibited by some patients with stroke, and reflects an altered perception of body orientation in space. (Bergmann et al., 2016; Davies, 1985; Karnath, 2007; Karnath et al., 2000; Perennou et al., 2008) This behavior is prevalent in 10–18% of patients undergoing stroke rehabilitation (Abe et al., 2012; Paci et al., 2009; Pedersen et al., 1996) and can considerably hamper treatment, leading to prolonged rehabilitation process. (Danells et al., 2004; Karnath & Broetz, 2003; Krewer et al., 2013b; Paci et al., 2009; Pedersen et al., 1996) While the terms 'pusher syndrome', 'pusher behavior,' and 'contraversive pushing' have previously been used to describe this phenomenon, the term 'lateropulsion' is currently recommended. (Dai & Perennou, 2021; Nolan et al., 2022) In the present study, the term "lateropulsion with pusher behavior" (LP) is used. A recent review article (Paci et al., 2023) of 36 papers that investigated interventions for LP reported that there have been 16 case

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reports, five reports of randomized controlled trials (RCTs), five reports of single subject design trials, three reports of non-RCTs, and two case series. Despite the variety of studies, the lack of substantial and consistent evidence across these methods highlights the need for more definitive research to establish an effective treatment for LP. However, previous RCTs demonstrated higher therapeutic efficacy by robot-assisted gait training (RAGT) using the Lokomat (Hocoma AG, Volketswil, Switzerland) than traditional visual feedback training. (Bergmann et al., 2018; Krewer et al., 2013b; Yun et al., 2018) Multisensory inputs, particularly from visual, vestibular, and somatosensory systems, play important roles in spatial orientation and postural control, and these inputs are integrated in the brain. (Brandt et al., 1994; Dai et al., 2021; Perennou et al., 2008) In post-stroke patients, especially those with LP, this multisensory integration is disrupted due to brain injury, leading to a tilt in the internal model of verticality toward the affected side. (Dai et al., 2021; Perennou et al., 2008) As a result, patients align their body to an erroneous vertical reference. (Dai et al., 2021; Perennou et al., 2008) Regarding treatment for this abnormal body tilt, repetitive corrective gait training using robotic devices has been shown to be effective in improving LP. (Bergmann et al., 2018; Krewer et al., 2013b; Yun et al., 2018) Although the exact neurophysiological mechanisms behind the effects of RAGT has not yet been fully elucidated, repetitive training is considered crucial for improving LP (Bergmann et al., 2018; Yun et al., 2018). The RAGT focuses on the body's verticality by enhancing somatic input in an earth-vertical position. (Krewer et al., 2013b) Forcing the body into an upright position during locomotion seems to be an effective method for immediately reducing LP. (Bergmann et al., 2018)

Similar treatments must be provided in many hospitals to benefit more LP patients. Unfortunately, as of September 2023, the Lokomat is not available in many hospitals in Japan. At the time of writing, only two institutions are equipped; a national research institute and one university hospital. On the other hand, Welwalk®, which is a Gait Exercise Assist Robot (GEAR) developed based on motor learning, is relatively widespread in Japan (Hirano et al., 2017; Katoh et al., 2020; Ogino et al., 2020a, 2020b; Tomida et al., 2019; Wang et al., 2020) GEARs can provide forced correct body posture and reduce body weighted bearing. (Hirano et al., 2017; Katoh et al., 2020; Ogino et al., 2020a, 2020b; Tomida et al., 2019; Wang et al., 2020) Since September 2023, GEARs have been deployed to 103 clinical and welfare facilities in Japan. (http://welwalk.jp/robotics/welwalk/, 2023) GEAR-based gait training has been reported to improve gait in subacute stroke patients, (Hirano et al., 2017; Wang et al., 2020) reduce abnormal patterns, (Katoh et al., 2020) and increase gait speed in chronic stroke patients. (Ogino et al., 2020a) Investigating the effectiveness and outcomes of treatments for LP with robotic devices used in many hospitals is important when considering beneficial medical interventions for LP. Thus, we hypothesized that gait training using a GEAR improves LP more than conventional training.

Attempting to stand in an upright position from an early stage is recognized as effective in managing LP; Davies emphasized lower limb support to aid standing and walking in hemiparetic patients. (Davies, 1985) Currently, when standing training, a knee-ankle-foot orthosis (KAFO) is utilized in the treatment of patients with severe hemiplegia to prevent the phenomenon of knees bending. (Abe et al., 2021a, 2021b; Boudarham et al., 2013; Maeshima et al., 2015; Ota et al., 2018; Sato et al., 2022; Seki et al., 2023; Tsujimoto et al., 2023; Yamanaka et al., 2004) However, to our knowledge, there have been no studies on the effect of training using a KAFO in patients with LP. Providing aggressive gait training with a KAFO might enhance the improvement of LP more effectively. We therefore decided to investigate the effectiveness of active walking exercises using a KAFO as treatment for LP.

However, it has been assumed that gait training using a KAFO in LP patients might not result in as much increase in step count and walking distance as RAGT due to severe body tilt. In other words, we suspect that gait training using a KAFO may be effective, but less effective than walking training with a GEAR. This is because, as mentioned earlier, repetitive corrective gait training using robotic devices has been shown to be effective in improving LP. If repetition is key, fewer steps during training may result in inferior outcomes. Therefore, in the present study, we hypothesized that RAGT (robot-assisted gait training) would be more effective than KAFO (knee-ankle-foot orthosis) in the treatment of LP. The present study aimed to investigate whether gait training using a GEAR is more effective in improving LP than active training using a KAFO. Therefore, we conducted an RCT to compare the effects of 2-week intensive GEAR training with aggressive KAFO training on gait function improvement in stroke patients with LP.

Methods

Trial Design and Blinding

This study followed a single-blinded, open-label RCT design with two parallel arms. To ensure concealment, pre- and post-intervention measurements of BLS and SCP scoring were performed by scientific staff members not directly involved in the treatment.

Sample Size and Randomization

We calculated the sample size according to a previous study by Bergmann et al. (Bergmann et al., 2018) Based on their

findings, we estimated that a sample size of 15 participants per group would be necessary for an accurate comparison in the present study. for an accurate comparison. Considering a possible dropout rate of 20%, we allocated 18 participants to each group. Therefore, the total number of enrolled participants was 36, who were then randomly allocated to either the i-GEAR or the c-KAFO group. The randomization sequence was computer-generated with a ratio of 1:1, and was done by a scientific staff member who was not directly involved in the assessment or treatment, in order to ensure anonymity.

Participants

Eligibility Criteria for Participants. This study included patients who met the following criteria: hemiparesis after first unilateral ischemic or hemorrhagic stroke, hospitalization for the previous 1–4 weeks, age between 20 and 90 years, presence of LP (Scale for Contraversive Pushing [SCP] score > 0 per component, (Babyar et al., 2009; Baccini et al., 2006, 2008; Karnath et al., 2000) assessed by a physiotherapist and a blinded evaluator), and orthostatic tolerance of passive standing for 30 min.

Patients with severe osteoporosis or unstable fractures, and those with severe higher brain dysfunction or dementia who were unable to understand the instructions of this trial, were excluded from the study. Other exclusion criteria were subarachnoid hemorrhage and acute diseases of the cardiovascular or respiratory system. Due to the configuration limitations of the GEAR system, patients with a height < 140 cm or > 190 cm and those weighing < 35 kg or >90 kg were excluded.

Data collection was conducted at multiple institutions. Participants were inpatients in convalescence rehabilitation wards in Junwakai Memorial Hospital, Zenjyoukai Hospital and Nishinomiya Kyoritsu Rehabilitation Hospital. All procedures in the present study received approval from the ethics committees at each medical institution participating in this research. The study was conducted in accordance with the principles outlined in the Declaration of Helsinki, and written informed consent was obtained from all participating patients before their involvement in the study.

Interventions

Intervention Duration and Frequency. Interventions were provided at least once a day over a 2-week period. All participants underwent at least 14 training sessions during the period. If possible, we provided additional physiotherapy. We counted the cumulative total intervention time for physical therapy in minutes for each patient. Our study protocol is shown in Figure 1.

Format of a Typical Intervention. Inpatients of Japanese convalescence rehabilitation wards typically receive 180 min of individualized rehabilitation, which includes physical therapy (PT), occupational therapy (OT), and speech therapy (ST). (Miyai et al., 2011) OT includes activities of daily living (ADL, referring to daily self-care activities), training, and arm exercises. ST includes training for dysphagia and aphasia. For patients who do not need OT and ST, PT is added instead. Typically, a minimum of 60 min of PT is provided daily. In the present study, intervention using a GEAR (i-GEAR) or treatment using a KAFO (c-KAFO) was conducted during the allocated time for PT. If additional PT was available, we offered various training exercises, including range of motion exercise, transfer exercise, standing and standing exercise, as well as gait training using a KAFO, according to each participant's state. Of the above, the gait training was especially

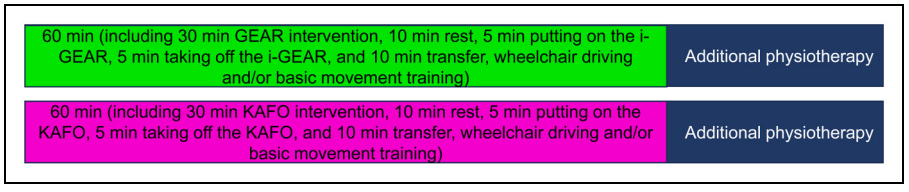

Figure 1. Intervention protocol. Both groups underwent a 60-min physical therapy session consisting of the following activities: 1. Basic movement practice, transfer exercises, and wheelchair driving for 10 min. 2. Attachment of a KAFO/GEAR for 5 min. 3. Walking practice session for 40 min, including a 10-min break. All patients were encouraged to try to walk for 30 min as possible, following standing training to correct their tilted body axis to the midline, The time spent on this standing training was included in the 30-min walking training session. 4. Detachment of a KAFO/GEAR for 5 min. All participants were encouraged to walk for at least 30 min during the 40-min walking sessions, aiming for continuous walking. In addition to the 60-min physical therapy session, 20 min or more of physical therapy was provided as appropriate. Additional physical therapies were provided only when necessary, and frequency and duration were set according to the facility's schedule. Additional physical therapy included exercises tailored to the patient's condition, such as training for basic movements, transfer exercises, joint range of motion expansion for the extremities, and strength training. In particular, gait training using a KAFO was recommended according to the patient's status. When gait training time was included in the additional physical therapy, the total time was added to both the i-GEAR and c-KAFO groups. In addition, the walking distance and step count during walking exercises were summed and recorded. GEAR, Gait Exercise Assist Robot; KAFO, knee–ankle–foot orthosis.

recommended. We recorded the total intervention time for gait training, distance, and number of steps during the standard and additional interventions.

GEAR Intervention. Gait training with a GEAR was conducted using Welwalk WW-1000, (Hirano et al., 2017; Katoh et al., 2020; Ogino et al., 2020a, 2020b; Tomida et al., 2019; Wang et al., 2020) which has been approved as a medical device (Figure 2A). The components of the GEAR system include a wearable KAFO robot, a low-deck-height treadmill, a patient suspension unit, a leg weight suspension unit, a monitor for patient use, and an operation panel. (http://welwalk.jp/robotics/welwalk/, 2023) The KAFO robot is equipped with a motor attached to the knee joint, and a pressure sensor on the plantar region. This allows flexion and extension of the knee joint with the appropriate timing during gait training. Also, it is possible to perform numerous steps efficiently with minimal assistance by performing them on a treadmill.

The knee extension assists and swing assist settings on the lower limb robot connected to i-GEAR cannot be standardized for all patients. Therefore, the assistance levels are tailored to accommodate each patient's status, and the primary physical therapist considers the optimal settings for each individual so that walking training can be sustained over an extended period. Similarly, the harness's load strength is individually adjusted based on the patient's walking ability to facilitate prolonged walking.

The i-GEAR group received GEAR sessions of 50 min, including set-up and rest time. The participant tried to walk as much as possible for at least 30 of the 50 min. If the patient needed to rest, they did so in a standing position with the harness on or a sitting position without the harness.

We recorded the distance and number of steps during each GEAR intervention.

KAFO Intervention. The c-KAFO group underwent gait training using a KAFO with passive assistance from a physical therapist. (Abe et al., 2021a, 2021b; Kobayashi et al., 2022; Maeshima et al., 2015; Miyamoto et al., 2022; Seki et al., 2023; Tsujimoto et al., 2023; Yamanaka et al., 2004) Gait training in patients exhibiting LP is typically difficult. Therefore, the first thing the physical therapist did for each patient was try to correct the tilted standing posture by using a KAFO to provide additional support to the lower limbs. Secondly, the therapist attempted to shift the patient's body weight to the unaffected side of the lower limb. Finally, the therapist tried to have the patient take steps using alternate legs. The patient was encouraged to continue walking as much as possible. In cases of severe LP and difficulty in maintaining continuous walking, the therapist prompted them to proceed more slowly while being cautious to avoid falls. The c-KAFO group underwent KAFO sessions of 50 min. The 50 min included both rest time and the time it took to put on and take off the KAFO, leaving an approximate total of 30 min in which the patient could try to walk as much as possible. We recorded the distance walked and the number of steps taken during each c-KAFO intervention.

Before providing the walking training with i-GEAR or c-KAFO, standing training with visual and auditory feedback was conducted in both groups to ensure smooth

Figure 2. i-GEAR (A) and c-KAFO (B) intervention. Figure 2. **i-GEAR and c-KAFO intervention.** The left panel A shows gait training using a GEAR. When using a GEAR, a motorized KAFO is attached to the affected leg, allowing unrestricted movement of the unaffected lower limb. The right panel B shows a KAFO and gait training using a KAFO. A KAFO is used to supplement the support of the paralyzed lower limb, and the patient walks with the assistance of the primary physical therapist. Since it involves human-assisted support, it is not feasible to sustain walking continuously like a robot. GEAR, Gait Exercise Assist Robot; KAFO, knee–ankle–foot orthosis; i-GEAR; intervention using a GEAR; c-KAFO; control treatment using a KAFO.

walking training. Specifically, the participants practiced shifting their weight to the unaffected side by using mirrors to correct their posture to the midline, as well as receiving feedback from the therapist to adjust and maintain their posture in the midline. These preparatory exercises to maintain the midline were performed for approximately 5–10 min within the 30-min walking training session.

Outcomes

Primary Outcome Measures. The primary outcome was changes in LP before and after i-GEAR or c-KAFO. LP was assessed using two major scales, Burke Lateropulsion Scale (BLS) (Babyar et al., 2009; D'Aquila et al., 2004) and SCP (Baccini et al., 2006, 2008; Karnath et al., 2000; Paci et al., 2009), by a blinded evaluator. The BLS rates the patient's resistance to passive supine rolling, passive postural correction while sitting and standing, and assistance during transferring and walking. The greater the resistance, the higher the score (Babyar et al., 2009), with the maximum of 17. The cutoff for the diagnosis of LP was 2 points. (D'Aquila et al., 2004) The BLS shows a high intra- and inter-rater reliability. (Babyar et al., 2009) The SCP has three components: (1) symmetry of spontaneous body posture, (2) use of nonparetic extremities (leg and arm), and (3) resistance to passive correction of tilted posture. (Baccini et al., 2006, 2008; Karnath et al., 2000; Paci et al., 2009) Each component is tested in sitting and standing positions, yielding a maximum score of 2 (1 for sitting and 1 for standing). The total score of the SCP ranges from 0 to 6; the greater the resistance, the higher the score. (Baccini et al., 2006, 2008; Karnath et al., 2000; Paci et al., 2009) The SCP has high interobserver reliability, internal consistency, and moderate-to-high construct validity. (Baccini et al., 2006) To diagnose LP, a cutoff score of >0 was used for each component. (Baccini et al., 2008) We compared changes in BLS and SCP scores (ΔBLS and ΔSCP, respectively) between baseline and post-intervention.

Secondary Outcome Measure. The secondary outcomes were the distance and number of steps walked during both intervention protocols, the number of days until LP resolution, and the improvement of ADL.

During the intervention period, we measured walking distance and step count for both groups. In cases where SCP was 0, indicating resolution of LP, we recorded the number of patients who experienced LP resolution during the inpatient period. Additionally, we recorded the number of days until LP resolution. If the SCP score did not reach 0, the data were considered null. These assessments were performed by the primary physical therapist, who was aware of the treatment allocation. ADL function was assessed using the Functional Independence Measure (FIM) ("Guide for use of the Uniform Data Set for Medical Rehabilitation. version 3.1," 1990) on admission as well as at 1, 2, and 3 months after admission. FIM is an 18-item ordinal measure of disability. Patients were assessed for each item on a 7-point ordinal scale that ranges from complete dependence (value = 7) to complete independence (value = 1). Total FIM scores range from 18 (lowest) to 126 (highest).

The Assessment of Clinical Characteristics at Baseline. The assessment of clinical characteristics at baseline included age, sex, disease type, lesioned hemisphere, number of days from onset to hospitalization in the convalescence rehabilitation ward, lower limb motor function, cognitive function tests, and evaluation of unilateral spatial neglect. Lower limb motor impairments were assessed by using the Fugl-Meyer motor assessment (FMA) (Fugl-Meyer et al., 1975). The FMA consists of five domains: motor, sensory, balance, range of motion, and joint pain. For the present study, the motor domain score was only used to evaluate motor function. The FMA motor domain consists of the upper and lower extremities; the lower extremity score, which ranges from 0 to 34, was employed in the current study. We used Mini-Mental State Examination (MMSE) for evaluation of cognitive function, (Folstein et al., 1975) and the Catherine Bergego Scale (CBS) (Azouvi et al., 2003) and Behavioral Inattention Test (BIT) were used for evaluation of unilateral spatial neglect. (Kato et al., 2012)

Statistical Analysis

Data from participants who completed their respective 2-week interventions were included in the analysis. The primary hypothesis was that patients assigned to i-GEAR would experience a larger improvement in LP (BLS and SCP scores) than those assigned to c-KAFO after the 2-week intervention period (Class II evidence).

The demographic data were summarized using descriptive statistics. An unpaired *t*-test or the Mann-Whitney *U* test was used to compare data between the two groups after confirming their normality. For the main outcomes, time factor changes throughout SCP and BLS, and comparisons between groups, were analyzed using a split-plot design analysis of variance (ANOVA) after applying the aligned rank transform (ATR) method. For the comparison of ordinal data between the two groups, the Mann–Whitney *U* test was used, and the time taken to resolve LP was analyzed by the Kaplan–Meier method using a log-rank test. Furthermore, the $\chi 2$ and Fisher's exact tests were used to compare the nominal data. The relationship between the primary outcome, ΔBLS and ΔSCP, and the clinical characteristics in baseline, FMA, MMSE, CBS, and BIT was investigated using Kendall tau statistics.

Improvement in the FIM scores was analyzed with analysis of variance for split-plot factorial design with training type (i-GEAR or c-KAFO) and time (baseline and 1, 2, and 3 months after admission) as the test factors. Missing outcome values were replaced using the last-observation-carried-forward method.

The statistical analyses were performed using SPSS Statistics for Mac (version 29.0; IBM Corp., Armonk, NY) and R (version 4.4.1). The significance level for α was set at 0.05.

Data Availability

Datasets generated and analyzed during the current study are available in an anonymized form from the corresponding author on reasonable request.

Results

We recruited 36 patients who were undergoing stroke inpatient rehabilitation and met the inclusion criteria. (Figure 3). Thirty-four patients were enrolled in the study between August 2020 and March 2023.

They were randomly assigned to the i-GEAR and c-KAFO groups, with 18 participants each. In each group, one patient abruptly declined in health and necessitated immediate transfer to another hospital before the commencement of the intervention. Consequently, each intervention group included a total of 17 patients. Among the patients in this study, 16 could not complete the 14-day gait training intervention. The total number of days that gait training intervention could not be implemented was 34 days (27 days in the i-GEAR group, 9 days in the c-KAFO group). The main reasons for not being able to receive the intervention were infection with the new coronavirus (COVID-19), fever, feeling unwell, and medical staff shortages due to the COVID-19 outbreak. An $\chi 2$ test showed no difference in the number of days in which gait training could not be conducted in the between both groups ($p = 0.323$). A total of 34 patients received the allocated intervention and were included in the analysis. Due to severe cognitive or language impairment, the MMSE was not completed by seven patients in the i-GEAR group and five in the c-KAFO group, and the BIT test was not completed by four patients in the i-GEAR group and eight in the c-KAFO group.

We conducted a random two-group allocation; however, a significant age difference was observed between the i-GEAR and c-KAFO groups, with the mean age of the i-GEAR group being approximately 5 years younger ($p < 0.05$). The time from stroke onset to hospitalization was slightly longer in the i-GEAR group, but the difference was not statistically significant. Meanwhile, no significant differences were observed in the other demographics or clinical characteristics at the beginning of the intervention (Table 1).

No adverse events occurred during gait training in either the i-GEAR group or the c-KAFO group, and all patients completed their respective interventions safely. In the BLS, changes in LP for both groups showed improvement, with the i-GEAR group improving from 12 [8–14] before the intervention to 6 [3.0–10.0] after the intervention, and the c-KAFO group improving from 10 [6.5–13] before to

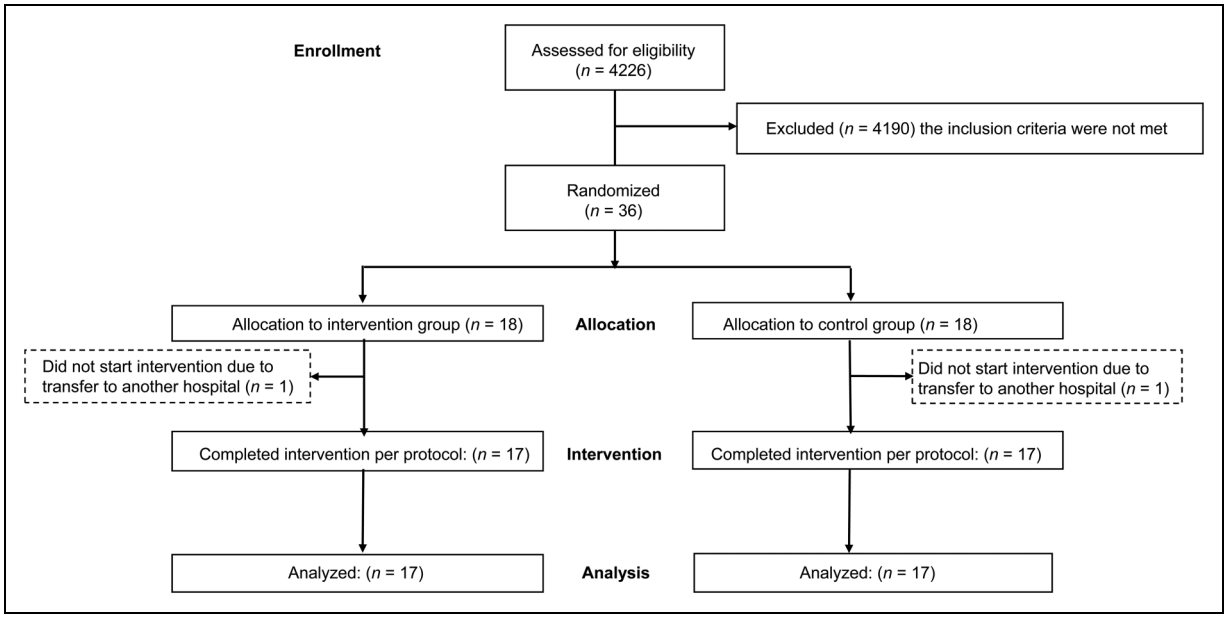

Figure 3. Research flowchart.

Table 1. Comparison of Demographic Data Between the i-GEAR and c-KAFO Groups.

	i-GEAR	Execution rate	c-KAFO	Execution rate	*p*-value
Age*	70.4 ± 10.7	100%	76.1 ± 7.4	100%	0.041
Sex (male/female) †	14/3	100%	11/6	100%	0.438
Disease type (ischemic/hemorrhagic) †	8/9	100%	10/7	100%	0.732
Lesioned hemisphere (right/left) †	9/8	100%	12/5	100%	0.481
Duration from onset to hospitalization (days) **	35.2 ± 19.2	100%	22.7 ± 6.5	100%	0.085
Lower limb FMA**	4 [1.5–4]	100%	4 [2–5.5]	100%	0.259
MMSE**	17.8 ± 8.2	58.5%	23.1 ± 5.5	70.6%	0.228
CBS*	19.2 ± 8.5	100%	15.9 ± 8.1	100%	0.129
BIT**	73.2 ± 47.7	76.5%	106.2 ± 40.5	52.9%	0.186
BLS**	12 [8–14]	100%	10 [6.5–13]	100%	0.375
SCP**	5.5 [5–6]	100%	5.3 [3.4–6]	100%	0.586
Motor FIM**	15.0 [13.0–16.5]	100%	17.00 [13.0–21.5]	100%	0.283
Cognitive FIM**	11.0 [8.50–16.0]	100%	15.0 [10.5–20.5]	100%	0.137
Total FIM**	26.0 [22.0–36.0]	100%	34.0 [24.0–42.0]	100%	0.143

Summary statistics are presented as mean ± standard deviation (normally distributed characteristics), median [first quartile, third quartile] (ordinal scale and characteristics with skewed data), or number (categorical data).

* Unpaired *t* test was used to compare the differences between the i-GEAR and c-KAFO groups.

** Mann-Whitney *U* test was used to compare the differences between the i-GEAR and c-KAFO groups.

†Chi-square test was used to compare the differences between the i-GEAR and c-KAFO groups.

i-GEAR, intervention using a GEAR; c-KAFO, control treatment using a KAFOFMA, Fugl-Meyer motor assessment; MMSE, Mini-Mental State Examination; CBS, Catherine Bergego Scale; BIT, Behavioral Inattention Test; BLS, Burke Lateropulsion Scale; SCP, Scale for Contraversive Pushing; FIM, Functional Independent Measures

5 [3–9.5] after. The split-plot design ANOVA showed a significant main effect of the time factor ($p < 0.001$). However, no significant difference was found for the training type ($p = 0.56$), and no interaction effect was observed ($p = 0.62$). For SCP, the i-GEAR group changed from 5.5 [5–6] before the intervention to 2.5 [1.75–4.5] after the intervention, and the c-KAFO group changed from 5.3 [3.4–6] before the intervention to 3 [1.125–3.875] after the intervention. The effects of group and time on both BLS and SCP were analyzed using ART mixed effects models. For BLS, the group effect was not significant ($F[1, 32] = 0.46$, $p = 0.505$), indicating no significant differences between the groups, while the time effect was highly significant ($F[1, 32] = 98.96$, $p < 0.001$), indicating a substantial improvement over time. The group × time interaction was not significant ($F[1, 32] = 0.19$, $p = 0.665$), suggesting that both groups showed similar changes over time. Similarly, for SCP, the group effect was not significant ($F[1, 32] = 0.04$, $p = 0.843$), indicating no differences between groups, while the time effect was significant ($F[1, 32] = 78.21$, $p < 0.001$), showing improvement over time. The group × time interaction was also not significant ($F(1, 32) = 0.11$, $p = 0.743$), suggesting similar SCP changes across the groups.

We observed no significant difference between the two groups in BLS after intervention, SCP after intervention, ΔBLS, ΔSCP, number of patients whose LP resolved, and total intervention time. The log-rank test indicated that there was no difference in time taken to resolve LP between i-GEAR and c-KAFO ($p = 0.215$). However, total walking distance and step count were significantly higher in the i-GEAR group than the c-KAFO group. (Table 2)

Similarly, regarding clinical characteristics, there were no significant differences between the two groups in lower limb FMA, MMSE, CBS, BIT, motor FIM, cognitive FIM or total FIM. (Table 1)

No significant correlations were also found between age scores (tau = -0.229, $p = 0.07$), FMA scores (tau = 0.048, $p = 0.72$), MMSE scores (tau = 0.243, $p = 0.14$), BIT scores (tau = 0.079, $p = 0.62$), CBS scores (tau = -0.008, $p = 0.95$), FIM motor scores (tau = 0.195, $p = 0.45$), FIM cognitive scores (tau = 0.002, $p = 0.99$), FIM total scores (tau = 0.085, $p = 0.51$), or ΔBLS over the study period. Similarly, no significant correlations were found between age scores (tau = -0.190, $p = 0.13$), FMA scores (tau = 0.155, $p = 0.24$), MMSE scores (tau = 0.086, $p = 0.59$), BIT scores (tau = 0.090, $p = 0.57$), CBS scores (tau = -0.191, $p = 0.13$), FIM motor scores (tau = 0.243, $p = 0.07$), FIM cognitive scores (tau = 0.023, $p = 0.86$), FIM total scores (tau = 0.154, $p = 0.22$), or ΔSCP over the study period.

In Figure 4, the results of an analysis of variance for split-plot factorial design show that time has a significant large effect ($F = 48.34$, $p < 0.001$). However, training type does not have a large effect on FIM ($F = 1.7052.4$, $p = 0.201$), and no interaction between time and training type ($F = 0.252$, $p = 0.695$) was observed.

Discussion

This study aimed to reveal the therapeutic impact of i-GEAR in treating LP, by comparing with that of c-KAFO. The results showed that i-GEAR was effective

Table 2. Results of Results BLS and SCP at After Intervention, ΔBLS and ΔSCP, Total Walking Distance, and the Number of Walking Steps.

	i-GEAR	c-KAFO	*p*-value
BLS after intervention**	6 [3.0–10.0]	5 [3–9.5]	0.536
SCP after intervention**	2.5 [1.75–4.5]	3 [1.125–3.875]	0.892
ΔBLS*	4.5 ± 2.4	4.1 ± 2.4	0.308
ΔSCP*	2.2 ± 1.2	1.9 ± 1.2	0.196
Total walking distance**	1748.8 ± 925.9	758.6 ± 596.4	0.002
Total step* counts*	6349.5 ± 2279.0	2524.1 ± 2017.7	< 0.001
Total physical therapy time (unit) **	46.1 ± 12.8	44.5 ± 5.5	0.892
Duration from admission to the start of standing exercises (days)**	0.65 ± 0.6	1.2 ± 1.4	0.413

* Unpaired *t* test was used to compare the differences between the i-GEAR and c-KAFO groups.
** Mann-Whitney U test was used to compare the differences between the i-GEAR and c-KAFO groups.
GEAR, Gait Exercise Assist Robot; KAFO, knee–ankle–foot orthosis; i-GEAR; intervention group for using a GEAR; c-KAFO; control treatment group for using KAFO, BLS, Burke Lateropulsion Scale; SCP, Scale for Contraversive Pushing

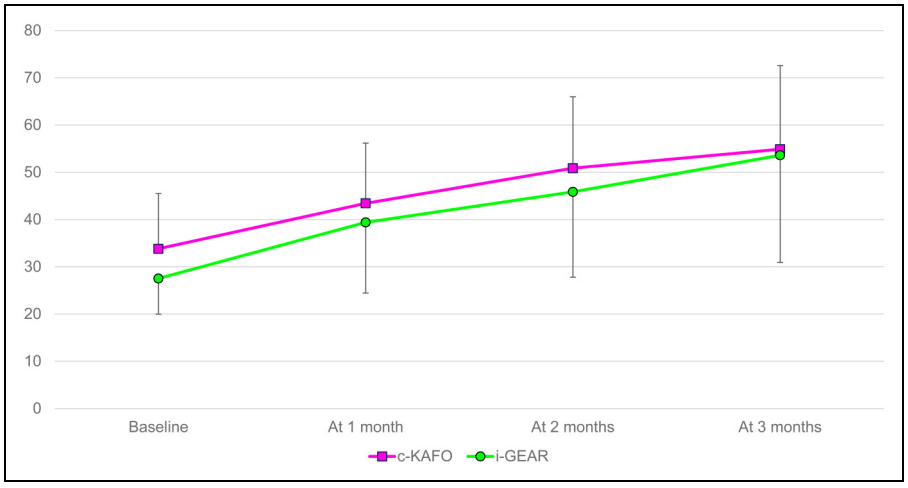

Figure 4. Time course of FIM. FIM, Functional Independence Measure; i-GEAR; intervention using a GEAR; c-KAFO; control treatment using a KAFO.

gait training in terms of longer distance and significantly higher number of steps, compared to c-KAFO. In addition, LP showed a considerable improvement after the intervention in the i-GEAR group. However, the c-KAFO group also demonstrated a substantial improvement in LP, with no significant differences observed in ΔBLS and ΔSCP between the i-GEAR and c-KAFO groups. Likewise, there was no difference between the two groups regarding the number of patients whose LP resolved. No difference in therapeutic effects was also found between the two groups in terms of long-term changes in ADL at 1, 2, and 3 months showed significant improvements compared to baseline data in both groups, with no significant differences observed in long-term therapeutic effects. The c-KAFO group showed a therapeutic effect similar to i-GEAR despite including a more limited walking distance. Our study, which is a multicenter RCT and has higher external validity than previous RCTs, demonstrated substantial therapeutic effects of both i-GEAR and c-KAFO on improvement of LP.

One concern arises from the disparities in the equipment employed between GEAR and Lokomat, as we could not compare using Lokomat, whose effects have already been reported. The Lokomat controls both legs, ensuring a consistent stride length and swing leg position. In contrast, a GEAR involves a robotic device worn solely on the affected leg, allowing unrestricted movement of the unaffected lower limb. In patients with LP, pushing behavior often leads to a markedly outward stepping of the unaffected lower limb, deviating significantly from the body's midline. (Figure 2A) Since a GEAR cannot inhibit LP of the unaffected lower limb or even that in the unaffected upper limb, achieving complete alignment of the body axis to the midline is very difficult. Nevertheless, the BLS scores in the present study showed comparability with previous studies utilizing the Lokomat. These results suggest that maintaining perfect vertical alignment may not be crucial in robot-assisted walking training for treating LP. Similarly, while maintaining vertical alignment during training using a KAFO is difficult, use of a KAFO

demonstrated effects akin to robot-assisted gait training in this regard. This result might suggest that even when achieving a perfect vertical alignment is not feasible, efforts to acquire and maintain perfect alignment may be crucial for effective gait training.

Our multicenter RCT revealed, for the first time, the effects of gait training using a GEAR or KAFO for the same amount of time. Unlike previous studies(Bergmann et al., 2018) where the control group had significantly less gait training time than the RAGT (Lokomat) group, we set the intervention protocol so that both the i-GEAR and c-KAFO groups could undergo 30-min gait training as equally as possible. This adjustment demonstrated the efficacy of modifying walking time, yielding an effect size comparable to those reported previously. This underscores the therapeutic benefits of dedicating sufficient time to gait training to treat LP. Many previous studies (Babyar et al., 2008, 2015; Danells et al., 2004; Davies, 1985; Krewer et al., 2013a; Paci et al., 2009, 2023; Pedersen et al., 1996) have shown that LP deteriorates ADL and also prevents its improvement. In present study, improvements in FIM scores were observed in both groups that underwent walking training. Since walking training likely enhances ADL in patients with LP, it can be regarded as an exceptionally effective intervention.

Bergmann et al. (Bergmann et al., 2018) reported that RAGT (Lokomat) is an active and task-oriented treatment approach, in which the patient's body is in an earth-vertical position, especially beneficial for patients with LP. The harness system and secure connection to the robot might reduce the patient's fear of falling, and they secure and support the patient in an upright standing position(Bergmann et al., 2018). Similarly, in i-GEAR, the body weight loading on the affected lower limb is reduced by a harness, making it easier to support. Such movements promote walking and offer the advantage of inputting stimuli from proprioception. (Bergmann et al., 2018) Previous studies have speculated that these inputs might contribute to correcting the distorted internal reference of verticality. (Bergmann et al., 2018; Yun et al., 2018) The GEAR we used shares similar features with the Lokomat. However, the i-GEAR group did not exhibit a higher effect than the c-KAFO group; there was no significant difference between the two. Notably, the therapeutic efficacy of the i-GEAR was as high as that obtained with the Lokomat, that is, attempting to walk in an upright position demonstrates that improvement in LP can be achieved not only through the support of robotics but also through methods using a KAFO. This suggests that robotics are not necessary for enhancing LP improvement.

Gait training using a KAFO is a novel intervention, and has not been incorporated in previous studies. To date, gait training has not been a common approach in the treatment of LP because patients with LP have severely impaired postural control, and improvement of gait is rarely a therapeutic objective. Indeed, active intervention using a KAFO for stroke patients is generally not recommended in North America. (Hurley, 2006) On the other hand, walking practice using a KAFO is strongly recommended in Japan, (Abe et al., 2021a, 2021b; Kobayashi et al., 2022; Maeshima et al., 2015; Ota et al., 2018; Sato et al., 2022; Seki et al., 2023; Tsujimoto et al., 2023; Yamanaka et al., 2004) which is explicitly stated in the Japan Stroke Society Guideline 2021 for the Treatment of Stroke. (Miyamoto et al., 2022) There have been multiple reports on the effects of intervention using a KAFO, and it has been established as one of the recommended rehabilitation methods in Japan. This may be due to the difference in the length of hospital stay in the two regions. In Japan, there are facilities called convalescent rehabilitation wards (Miyai et al., 2011), where the length of stay there is approximately 60 to 180 days. (Kamo et al., 2019) If a medical system that supports long-term rehabilitation is not available, recommending gait training with a KAFO may not be possible. During the course of treatment, KAFO eventually stops being used, and is replaced with an AFO. Therefore, walking practice with a KAFO, which immobilizes the knees, may seem inefficient. However, recent Japanese studies have suggested that long-term walking training with knee immobilization using a KAFO enhances walking independence more than early transition to an AFO. (Abe et al., 2021a, 2021b) Because gait training with a KAFO is mainly recommended in Japan, and it would have been difficult to conduct this study outside of a Japanese convalescent rehabilitation hospital, the present study conducted in Japan represents the first report on the treatment of LP demonstrating the effectiveness of gait training with a KAFO.

The mechanisms by which gait training with i-GEAR or c-KAFO improves LP has yet to be elucidated. Many LP patients exhibit multiple impairments, such as motor paresis, sensory disturbance and unilateral spatial neglect. Furthermore, in such cases, mild consciousness disorders are often observed. In patients with these disorders, standing and walking training offer appropriate sensory input, which is then transmitted to the reticular activating system in the brainstem and distributed to various brain regions, possibly leading to increased awareness. By shifting weight to the unaffected side during gait training in this heightened state of arousal, the patients are able to correct their tilted posture. Thus, gait training in patients with improved consciousness may have contributed to improving the posture and LP of said patients.

There are some limitations to the present study. First, we were not able to investigate the effectiveness of the Lokomat. Previous studies have reported that Lokomat therapy is the only treatment that shows clear evidence of therapeutic efficacy in improving LP. However, since only two units have been introduced in Japan, confirming their effectiveness has been challenging. Our study lacks a direct comparison, and we cannot rule out the possibility

that results using the Lokomat could differ from those using i-GEAR. Second, the present study did not compare among i-GEAR, c-KAFO, and traditional physical therapy with regard to factors visual feedback balance training. Based on previous studies, comparing the effectiveness of interventions utilizing Locomat or visual feedback could have yielded a more evident differentiation between the present study and prior research.

Third, the post-intervention BLS evaluation period of our study was limited to 2 weeks. Yun et al. assessed the effectiveness of RAGT (Lokomat) intervention, which showed greater ΔBLS immediately and at 1-month post-intervention, compared to conventional physical therapy (non-RAGT). (Yun et al., 2018) However, in an RCT study by Bergmann et al., the RAGT intervention using Lokomat showed no significant difference in ΔBLS between baseline and the 2-week follow-up compared to the control group, despite a significant decrease in BLS score immediately post-intervention.(Bergmann et al., 2018) Although the investigation of long-term prognosis in our study was less detailed than those of previous studies (Bergmann et al., 2018; Yun et al., 2018), we examined the duration until LP resolution, and found no differences in the duration or frequency of resolution. Additionally, post-intervention follow-up was performed regarding ADL. As a result, there was no difference in recovery of ADL between the c-KAFO and i-GEAR groups, indicating no difference in the effect on LP during the follow-up phase. Therefore, although long-term BLS evaluation was not conducted in the present study, our results indicate that there was no difference regarding long-term improvement in LP between the i-GEAR group and the c-KAFO group.

Fourth, although it was shown that a subject's cognitive function was not related to the degree of improvement in BLS, the MMSE of the i-GEAR group was 18.83 ± 9.326, and that of the c-KAFO group was 23.90 ± 5.152. These MMSE scores may be considered relatively low, particularly when evaluating recovery from LP, because the patient is expected to relearn the ability to maintain proper posture. Thus, there is a possibility that the potential decline in cognitive function observed in the present study may have influenced the treatment outcomes for LP. Fifth, we suspect that LP is caused by a disturbance in the convergence of multimodality inputs, such as visual, vestibular, and somatosensory information. However, these sensory systems were not assessed in our study. Although the present study was a randomized controlled trial designed to control for inequalities between groups, the exact differences in various sensory inputs between the two groups were not examined.

Conclusion

In conclusion, the results of the present study indicate that i-GEAR effectively improved LP in subacute stroke patients. Similarly, c-KAFO also led to improvement in LP. The therapeutic effects were comparable to those reported in previous studies using the Lokomat. Therefore, i-GEAR is recommended as a beneficial treatment contributing to LP improvement. Furthermore, i-GEAR is advantageous as a treatment capable of providing a sufficient walking distance and step count "Even in facilities without GEARs, aggressive gait training using a KAFO is an effective treatment to improve post-stroke LP, although it reduces walking distance and step count.

Clinical Trial Registration

This study is registered in the UMIN Clinical Trial Registry (UMIN ID: 000045593).

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Statements and Declarations

Disclosures

None.

Author Contributions

Conceptualization, HA, SU, YK and ST; methodology, HA and SU; data analysis, HA; projection administration, HA, SU, YK, ST, NM and NN; data collection and subjects recruitment, SU, YK and ST; investigation, HA, SU, and ST; writing—original draft preparation, HA; writing—review and editing, HA SU, YK, ST, NM and NN; visualization, HA, SU, YK and ST; supervision, HA and US. All authors have read and agreed to the final version of the manuscript.

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