

EFFECTS OF LOKOMAT TRAINING ON GAIT SPEED IN PEOPLE WITH CHRONIC STROKE: A SYSTEMATIC REVIEW

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ABSTRACT

Background: The use of robotics as a tool in physical therapy rehabilitation has grown in popularity over the past decade. The Lokomat is a robotic assisted gait training device used in the rehabilitation of a variety of populations, including people with stroke and spinal cord injury. Although various studies have been completed using the Lokomat, no systematic review has examined this robot's effectiveness in increasing the gait speed of people with stroke. The objective of this systematic review was to compare the effects of the Lokomat robotic gait training to alternative physical therapy on gait speed in people with chronic stroke. **Methods**: A systematic review was completed following PRISMA guidelines. A search was done of PubMed and EMBASE databases. Inclusion criteria consisted of: (1) participants 18 years or older that had a chronic stroke of greater than or equal to 3 months, (2) intervention that included the use of the Lokomat, (3) comparison of robotics to any other physical therapy intervention, and (4) outcomes including gait speed. Two authors screened titles, abstracts, and full articles in a stepwise process with a separate author acting as the tiebreaker at each stage. The senior author performed an independent screening. The reference list of the final articles was also searched to ensure no studies were missed. Risk of bias of the selected studies was assessed using the PEDro database. **Results**: Five studies were selected based on the inclusion criteria with PEDro scores ranging from 4 to 7 on the 10-point scale. Three studies demonstrated a greater improvement in gait speed after Lokomat training (effect size = 2.39, 0.22, and p- value = 0.007) while two studies showed greater improvement in gait speed with alternative rehabilitation (effect size = -0.38 and -0.17). **Discussion**: This systematic review showed conflicting results with three studies demonstrating greater improvement in gait speed with Lokomat training, while two studies showed improved gait speed with use of an alternative intervention. However, one of the studies that reported increased gait speed with the Lokomat group received a PEDro score of 4/10, indicating caution with interpretation. Limitations of this systematic review include the risk of bias associated with included articles, the smaller sample sizes of the included studies, and the exclusion of articles not written in English. Due to conflicting results regarding the effectiveness of gait speed therapy, well-designed randomized control trials are needed to accurately determine the effects of Lokomat in improving gait parameters. Future research should include studies that consist of larger sample sizes, longer periods of Lokomat gait training, and long-term follow up with study participants. Despite the lack of evidence supporting the improvement of gait speed through robotic assisted gait training, the Lokomat may be useful in reducing physical stress on the participant and the therapist during gait training.

Keywords: Lokomat, physical therapy, stroke, gait speed, gait training, robotic training

INTRODUCTION

When treating patients with neurologic deficits, physical therapists often spend a large portion of their time addressing gait impairments. Gait deficits have a significant impact on a patient's functional mobility, which ultimately led to the development of a variety of body weight supported gait training (BWSGT) devices and robot-assisted gait training (RAGT) devices. BWSGT devices are interventional tools used by physical therapists in the treatment of the neurologic and orthopedic patient populations. Through the use of supportive harnesses, BWSGT allows individuals to perform varying gait tasks either over-ground or on a treadmill system with increased safety. These devices also allow for a percentage of the individual's body weight to be supported, making ambulation less difficult.

RAGT further addresses impairments by using robotic exoskeletons to physically assist a person with gait. Various RAGT devices, including the Lokomat, have been developed to help people with gait impairments sense proper gait movements in

the trunk and bilateral lower extremities. Because treadmill training is physically taxing on physical therapists when working with people with severely impaired ambulatory status, these devices have become increasingly more attractive [1]. The Lokomat allows physical therapists to adjust and precisely measure numerous gait parameters as the patient progresses in order to provide more optimized treatments.

Literature has shown that BWSGT has grown more popular for use during gait training to improve ambulation in people that have had a stroke [2]. A stroke, also referred to as a brain attack, is a medical emergency in which blood flow to a portion of the brain is obstructed. Depending on the area of the brain that is affected, a wide variety of residual effects may be seen. Symptoms relating to gait dysfunction include decreased walking speed, decreased cadence, decreased stride length, and increased gait cycles [3].

Although little research has been done specifically on the effects of RAGT in people with a history of stroke, research has demonstrated improvements in balance in this population. However, a systematic review did indicate that more research is necessary to determine if these balance improvements are greater than other therapeutic interventions [4]. Furthermore, a systematic review that used the Lokomat showed RAGT results in a greater improvement in mobility related outcomes when compared with over-ground gait training in individuals with incomplete spinal cord injuries [5]. The objective of this systematic review was to compare the effects of the Lokomat robotic gait training device to alternative physical therapy on gait speed in people with chronic stroke.

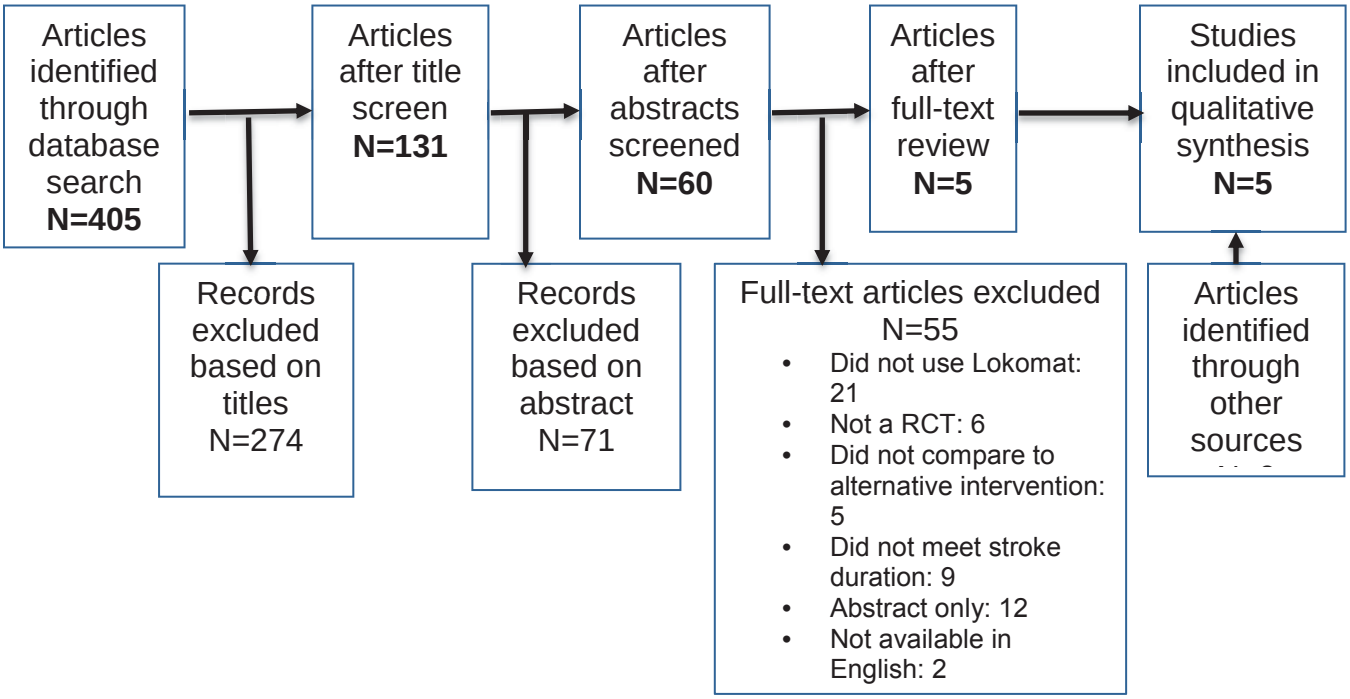
METHODS

Eligibility Criteria: Inclusion criteria consisted of (1) participants 18 years or older that had a chronic stroke of greater than or equal to 3 months, (2) intervention that included the use of the Lokomat, (3) comparison of robotics to any other physical therapy intervention, and (4) outcomes including gait speed. Eligible articles were randomized control trials (RCTs), clinical trials, and pilot studies. Articles were excluded if not available in English, not available in full text, or if it was an abstract from conference presentations.

Information Sources/Search: PubMed and EMBASE were used to search in October, 2017. PubMed used the search: ((stroke) AND gait) AND robotics. EMBASE used the search: ('stroke'/exp OR stroke) AND ('gait'/exp OR gait) AND ('robotics'/exp OR robotics). No filters were placed on the searches, and the search string was completed with help from a university librarian. Another search was performed in October, 2018, using the same search parameters to determine the availability of new publications since the original search. The October, 2018, search did not reveal any additional publications.

Study Selection: To identify the articles that were included for review, a stepwise process was used with two authors screening the titles, followed by a review of abstracts and, finally, a review of the full text. A third author was the tiebreaker for the titles and abstracts that were not agreed upon by the first two reviewers. The senior author performed a separate screen of titles, abstracts, and full text articles. For any discrepancies between the screenings, caution was aired on the side of inclusion. A final meeting was held to discuss any discrepancies in final titles to be included, with the ultimate decision being made by the tiebreaker. A final search was completed through the reference list of the final articles to determine any articles that were missed in the original search (see Figure 1 PRISMA Flow Diagram).

Figure 1 PRISMA Flow Diagram



Data Extraction: Two independent reviewers extracted data with input from the senior author. Tiebreakers were broken by a third independent reviewer. The data extracted from each article included: author(s), year of publication, total number of participants, exclusion criteria (per article), gait parameter outcome measures, and assessment intervals (days).

Study Characteristics: There was a total of 124 participants in the five studies, with 63 receiving Lokomat therapy and 61 receiving an alternative form of physical therapy. With regards to the stroke duration, one study required participants to be greater than three months post stroke, three studies required greater than six months post stroke, and one study required greater than 12 months post stroke. The mean age ranged from 53.56 to 66.91 years in the participants receiving Lokomat training and 53.76 to 64.33 years in the participants receiving alternative forms of physical therapy.

For the alternative physical therapy, two studies used body weight supported treadmill training, one study used non-body weight supported treadmill training, one study used over-ground gait training, and one study used home physical therapy with an emphasis on over-ground gait training. The therapy duration ranged from 12 sessions to 40 sessions, with therapy lasting 30 minutes to one hour. All studies varied the therapy intensity by decreasing the amount of body weight supported, decreasing percentage of guidance assistance, increasing gait speed, or increasing ambulation duration [6-10]. Specific characteristics of each study design can be found in Table I: Description of Included Articles.

Outcomes

Three studies showed a faster post-gait speed in individuals in the Lokomat groups when compared to the alternative physical therapy group. This resulted in effect sizes of 2.39 in Bang et al.[6], 0.22 in Westlake et al.[7], and a p-value of 0.007 in Ucar et al[8]. These studies utilized non-body weight supported treadmill training, body weight supported treadmill training, and home physical therapy respectively [6-8]. Two studies showed a faster post-gait speed in individuals in the alternative physical therapy group when compared to the Lokomat group. This resulted in effect sizes of -0.38 in Kelley et al.[9] and -0.17 in Hornby et al[10]. These studies utilized over-ground gait training and body weight supported treadmill training respectively [9-10]. A summary of the results can be found in Table 2.

Table I: Description of Included Articles

Articles	Population Characteristics	Exclusion Criteria	Lokomat Treatment Session	Alternative PT Treatment Session	Outcome Measure Method
Bang et al. 2016	• Stroke duration >6mo • Males: 9 • Females: 9 • Age: o Lokomat: 53.56 (±3.94) o Alternative: 53.67 (±2.83)	• Condition Preventing Gait Training • Contraindication for Exercise	• 20 Sessions o 1 hour x 5 days x 4 weeks • Initial Session o BWS: up to 40% o Gait Speed: 0.45 m/s • Varying of Intensity o Walking speed o Level of BWS o Duration • Device Initiated Stepping	• 20 Sessions o 1 hour x 5 days x 4 weeks • Treadmill Training w/o BWS • All Sessions o Warm up and cool down o Speed increase every 1-2 min o Pre-determined max speed x 10 seconds • Varying of Intensity o Max speed increased 10%	Gait Speed (m/s) using GaitRite System
Hornby et al. 2008	• Stroke Duration: >6mo • Males: 30 • Females: 18 • Age: o Lokomat: 57 (±10) o Alternative PT: 57 (±11)	• CP or metabolic disease • Condition limiting exercise or locomotion • Excess weight or size for equipment • LE Botox <6mo prior • MMS score <23 • Concurrent PT	• 12 Sessions o 30 min per session • Initial Session o BWS: 30-40% o Gait Speed: 2.0 kmph • Varying of Intensity o BWS decreased 10% each session o Gait speed increased by 0.5 kmph every 10 min o Max Speed: 3.0 kmph • Continuous assist from Lokomat • Individual provides maximum effort	• 12 Sessions o 30 min per session • BWS Treadmill Training • Initial Session o BWS: 30-40% o Gait Speed: 2.0 kmph • Varying of Intensity o BWS decreased 10% each session o Gait speed increased by 0.5 kmph every 10 min o Max Speed: 3.0 kmph • Therapist assists paretic LE as necessary	Gait Speed (m/s) using GaitMat II
Kelley et al. 2013	• Stroke Duration: >3mo • Males: 13 • Females: 7 • Age: o Lokomat: 66.91 (±8.50) o Alternative PT: 64.33 (±10.91)	• Uncontrolled HTN • CP condition • Orthopedic limitations • Claudication while walking • Life expectancy <1year • DVT or PE <6mo • Medical or psychiatric condition affecting participation	• 40 Sessions o 1 hour x 5 days x 8 weeks • Initial Session: o BWS: 40% o Gait Speed: 0.42 m/s o Guidance Force: 100% • Varying of Intensity: o Gait speed o Duration o Guidance Force o BWS • Therapist assists paretic LE as necessary	• 40 Sessions o 1 hour x 5 days x 8 weeks • Over-Ground Gait Training • Emphasis of Training o Gait Speed o Velocity o Safety o Gait Deviations • Additional Interventions o Neuromuscular Reeducation o Therapeutic Exercises o Therapeutic Activities	10-m Walk Test
Ucar et al. 2014	• Stroke Duration: >12mo • Males: 22 • Females: 0 • Age: o Lokomat: 56.2 o Alternative PT: 61.5	• Body weight >300lbs • FAC score <3, unable to ambulate • Cognitive Deficits • CP Conditions • LE Spasticity • Other neurological conditions	• 10 sessions o 30 min x 5 days x 2 weeks • Initial Session: o BWS: 50% o Gait Speed: 1.5 km/hr • Varying of Intensity: o BWS o Guidance Force	• 10 Sessions o 30 min x 5 days x 2 weeks • Home PT • Emphasis of Gait Training o Trunk Stability • Additional interventions o Neuromuscular Reeducation o Therapeutic Exercises	10-m Walk Test
Westlake et al. 2009	• Stroke Duration: >6mo • Males: 13 • Females: 3 • Age: o Lokomat: 58.6 (±16.9) o Alternative PT: 55.1 (±13.6)	• Unstable CP, Orthopedic, or Neurological Conditions • Uncontrolled Diabetes • Significant Cognitive Impairments	• 12 Sessions o 30 min x 3 days x 4 weeks • Initial Session: o BWS: 35% o Gait Speed: below 0.69 m/s for the slow group and above 0.83 m/s for the fast group o Guidance Force: 100% • Varying of Intensity: o BWS decreased by 5% • Continuous assistance from device • Individual provides maximum effort	• 12 Sessions o 30 min x 3 days x 4 weeks • BWS Treadmill Training • Initial Session o BWS: 35% o Gait Speed: below 0.69 m/s for the slow group and above 0.83 m/s for the fast group • Varying of Intensity o BWS decreased by 5% • 1-2 therapists provided assistance to paretic LE and trunk as necessary	Gait Speed (m/s) using GaitRite System

Abbreviations: BWS = Body Weight Support, CP = Cardiopulmonary, Botox = Botulinum Toxin, MMS = Mini Mental Score, HTN = Hypertension, DVT = Deep Vein Thrombosis, PE = Pulmonary Embolus, FAC = Functional Ambulation Categories, w/o = Without, m/s = Meters Per Second, LE = Lower Extremities, PT = Physical Therapy, kmph = Kilometers Per Hour, km = Kilometers, 10-m = 10 Meters

Table 2: PEDro Results

Articles	PEDro Quality Scores	Outcome Measure	Lokomat Group Post-Test Mean (SD)	Alternative Group Post-Test Mean (SD)	P-value (Between group differences)	Effect Size (95% CI)
Bang et al. 2016	7/10	Gait speed (m/s)	0.64 ± 0.04	0.55 ± 0.04	0.002	2.39 (2.37, 2.40)
Hornby et al. 2008	5/10	Self selected gait speed (m/s)	0.52 ± 0.21	0.56 ± 0.28	0.04	-0.17 (-0.23, -0.10)
Kelley et al. 2013	6/10	10-m walk test (m/s)	0.20 ± 0.10	0.27 ± 0.27	-0.06Δ	-0.38 (-0.46, -0.30)
Ucar et al. 2014	4/10	10-m walk test (seconds)	10.6*	16.7*	0.007	†
Westlake et al. 2009	6/10	Self selected gait speed (m/s)	0.72 ± 0.38	0.65 ± 0.29	0.72	0.22 (0.07, 0.38)

Δ P-value was not reported. Value reported is mean difference between protocols
*No standard deviation was reported.
† Unable to calculate effect size due to no standard deviation reported.

DISCUSSION

Based on the results of this systematic review, there is some evidence that suggests the Lokomat may improve gait speed in people with a history of a previous stroke. However, there were conflicting results when all studies were compared. Two of the included studies showed a greater improvement in gait speed with use of an alternative physical therapy intervention. In comparison, the remaining studies showed a greater improvement in gait speed with use of Lokomat training. However, one of the studies that showed better results with the Lokomat received a PEDro score of 4/10, indicating caution with interpretation. Because of this, there is no conclusive evidence to support Lokomat training over alternative physical therapy interventions when comparing improvement in gait speed in people with a history of chronic stroke.

While this study did not definitively show that the use of the Lokomat is a better intervention than alternative physical therapy intervention, other studies that did not meet this study's criteria have shown that Lokomat can improve different gait parameters, functional skills, and generic activities of daily living more than alternative interventions. In Taveggia et al. [11], patients that were included in the trial had an average of less than 3 months between the stroke and intervention. This study concluded that the experimental group, which received Lokomat training along with alternative intervention, showed greater improvements in gait function and generic activities of daily living. The experimental group also showed a significant increase in gait speed at the end of treatments as well as at the follow-up appointment, and it was the only group to show functional improvements. Other studies that have included a stroke duration of less than three months have shown significant improvements in outcome measures such as the Functional Independence Measure, Timed-Up and Go, endurance, and stair negotiation for the group receiving Lokomat treatment [12][13]. All of these studies concluded that Lokomat can be very beneficial for people who have had a stroke within 3 months of treatment as compared to only receiving alternative intervention.

The Lokomat, while expensive and not proven to be a superior treatment option, will decrease the physical demands of the physical therapist during gait training [1]. Both the Lokomat and alternative interventions have shown overall gait and functional improvement in people with a history of a stroke. Until further research is done, both are considered to be acceptable and beneficial treatment options to improve overall function for this patient population.

Limitations of this Systematic Review: One of the limitations to this study was the risk of bias associated with the included articles. Each article measured gait speed in a different way with two using a GaitRite System, one using the GaitMat II, and two using the 10-meter walk test. Of the three articles that showed greater improvement of gait speed with use of the Lokomat, two of those studies used the 10-meter walk test to determine gait speed while the other used the GaitRite System. Use of the 10-meter walk test in these two studies demonstrates intra-rater reliability and observer expectation bias. The use of a pressure sensitive walkway to measure gait parameters, such as the GaitRite or GaitMat II systems, could eliminate this risk of bias by providing conclusive data.

Another limitation to this study is the use of smaller sample sizes in all of the included studies with the largest sample size being 48 participants in Hornby et al. [10]. The average sample size between all of the studies was 25 participants. The last limitation to this study was the exclusion of two articles that were not available in English.

Suggestions for Future Research: Despite the use of robotics being a new area of intervention in rehabilitation, there is a shortage of research on the benefits in using robotics to improve outcomes. Because of this, well-designed randomized control trials comparing Lokomat to alternative physical therapy interventions with larger sample sizes are needed. These studies should include people in the acute or subacute stage of a stroke and longer periods of training with both the Lokomat and alternative physical therapy interventions. Long-term follow up with study participants should be included to determine the long-term outcome after treatment with either intervention.

CONCLUSION

Based on this research, there is no definitive evidence supporting the use of Lokomat to improve gait speed. Because of this, physical therapy clinics that cannot afford a Lokomat can continue to use alternative physical therapy interventions to help improve gait deviations in people recovering from a stroke with confidence that evidence-based treatment is provided.

DISCLOSURES

The authors have no financial interests to disclose and no conflicts of interest are present.

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