CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

In a 55-year-old male with right hemiplegia due to stroke, will walking on a treadmill with a constant posterior force applied to his pelvis be effective at increasing propulsive forces of the affected limb?

AUTHOR

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CLINICAL SCENARIO

A 55-year-old male patient with right-sided hemiplegia following a CVA presents to inpatient rehabilitation. He demonstrates moderate to severe weakness in his right lower extremity and has difficulty walking. In particular, he has difficulty propelling his right leg forward, his step lengths are shorter on the right than the left, and the right leg drags behind him. Patients with hemiplegia due to stroke often struggle with walking, which is why gait training is a large area of focus for rehabilitation. Specifically, rehabilitation focuses on increasing gait speed since it is a predictor of community ambulation and fall risk.[1–10] In order to increase gait speed, an increase in propulsive limb force is required.[6,10] Finding a way to increase the propulsive force of the paretic limb will help patients become more functional and energy efficient in their gait. This will also help increase their gait speed, reducing their risk of falls and improving their ability to ambulate in the community.

SUMMARY OF SEARCH

[Best evidence appraised and key findings]

Four databases were searched, where ten articles were found that met specific inclusion and exclusion criteria. The study design of these 10 articles included: 3 Randomized Controlled Trials (RCT), and 7 cross-sectional repeated measures designs. Three studies: two RCTs and one cross-sectional repeated measures design were selected as "best evidence" to be reviewed and discussed. The key findings from the three studies appraised show that in individuals with hemiplegia due to stroke:

- May have the ability to generate higher lower limb/propulsive forces to help them achieve faster walking speeds. Interventions that include task-specific strengthening for the lower limb to increase propulsive limb force, such as resistive walking, as well as interventions to help increase the range of walking speeds in which individuals are able to perform should be included to improve gait mechanics.
- Applying a controlled resistance or assistance load to the paretic leg while training on a treadmill may help to increase overground gait speed, step length, step cadence, and single-leg support in both the paretic and non-paretic limbs. Applying an assistance load to the paretic leg may help in improving balance: individuals showed improvement in their Berg Balance Scale and Activities Balance Confidence Scale (ABC) scores.
- There are two key factors that contribute to an increase in propulsive limb force during gait: the trailing limb angle (TLA) and ankle moment. TLA is defined as "the angle between the laboratory's vertical axis and the vector joining the greater trochanter with the center of pressure," and ankle moment is defined as the plantarflexion moment.[10(pg. 390)] Specific intervention to help increase paretic ankle moment, such as functional electrical stimulation or other interventions directed at strengthening the ankle plantarflexors, may be necessary to increase the ankle moment, and thus propulsive limb force.

CLINICAL BOTTOM LINE

There is currently no evidence using resisted walking, with a constant force applied at the pelvis, as an intervention to increase propulsive limb force in patients with hemiplegia post-stroke. However, the studies suggest that individuals with chronic stroke have the ability to increase their paretic propulsive limb force through the use of other interventions. The application of a controlled resistive load to the paretic limb during gait training may help to increase gait speed. TLA and ankle moment are key contributors in increasing in propulsive limb force. Rehabilitation interventions directed at strengthening the ankle plantarflexors, such as functional electrical stimulation or resisted walking, may help increase ankle moment. Research currently focuses more on chronic stroke; more research is needed to determine clinical applicability in the inpatient rehabilitation setting and whether resisted walking is effective at increasing paretic propulsive limb force.

This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor

SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)
Stroke CVA Cerebrovascular accident	Resist* walking Resist* treadmill walking Resist* gait Resist* ambulation Gait		Gait Walk* Ambulat* Propulsive limb force Propulsion Paretic limb propulsion Propulsive reserve

Final search strategy:

1. Stroke OR CVA OR cerebrovascular accident
2. Resist* walking OR resist* treadmill walking OR resist* gait OR resist* ambulation
3. Gait OR walk* OR ambulat* OR propulsive limb force OR paretic limb propulsion OR propulsion OR propulsive reserve
4. #1 AND #2 AND #3= 141 results

5. Stroke OR CVA OR cerebrovascular accident
6. Gait OR ambulat*
7. Propulsion OR propulsive limb force OR paretic limb propulsion
8. #6 AND #7 AND #8= 64 results
9. **(#1 AND #2 AND #3) OR (#5 AND #6 AND #7)= 207 results**

Databases and Sites Searched	Number of results	Limits applied, revised number of results (if applicable)
PUBMed	**207**	Two separate searches were conducted in **PubMed**, which returned some duplicate results. The two searches were combined to give a total of 207 results.
CINAHL (first search from above) **CINAHL (second search from above)**	**20** **30**	Removing the outcome and making line 2 of the initial search less specific expanded the initial search in **CINAHL**. However, this returned too many results.
PEDro	**17**	
Web of Science (second search from above)	**110**	**Web of Science:** though this number of results did not require any limits to narrow or expand the search, a second search was also conducted: 1. Stroke OR CVA OR cerebrovascular accident 2. Resist* walking OR resist* gait OR resist* ambulat* 3. #1 AND #2: **19 results**

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
• Randomized controlled trials, controlled trials, uncontrolled trials, observational studies • Studied a population of older adults age 50 and older who suffered stroke • Measured gait walking on treadmill • Published in English
Exclusion Criteria
• Abstracts, Dissertations, narrative review articles, conference proceedings, letters to the editor • Not published in English • Case studies or case series

RESULTS OF SEARCH

Summary of articles retrieved that met inclusion and exclusion criteria

Author (Year)	Study quality score	Level of Evidence	Study design
Duclos et al[1] (2014)	**11/14 (Downs and Black)**	**2b**	**Cross-sectional repeated measures design (single group)**
Hurt et al[2] (2015)	**11/14 (Downs and Black)** **7/9 (Quality Assessment Tool for Observational Cohort/Cross-Sectional Studies)**	**2b**	**Cross-sectional repeated measures design (two groups)**
Awad et al[3] (2015)	**11/14 (Downs and Black)**	**2b**	**Cross-sectional repeated measures design (single group)**
Wang et al[4] (2015)	**10/14 (Downs and Black)**	**2b**	**Cross-sectional repeated measures design (two groups)**
Bonnyaud et al[5] (2015)	**4/10 (PEDro scale)**	**1b**	**Randomized controlled trial**
Wu[6] (2014)	**5/11 (PEDro scale)**	**1b**	**Randomized controlled trial**
Yen[7] (2015)	**10/14 (Downs and Black)**	**2b**	**Cross-sectional repeated measures design (single group)**
Knarr[8] (2013)	**9/14 (Downs and Black)**	**2b**	**Cross-sectional repeated measures design (single group)**
Phadke[9] (2012)	**10/14 (Downs and Black)**	**2b**	**Cross-sectional repeated measures design (two groups)**
Hsiao et al[10] (2016)	**6/11 (PEDro scale)**	**1b**	**Randomized controlled trial**

BEST EVIDENCE

The following 3 studies were identified as the 'best' evidence and selected for critical appraisal. Reasons for selecting these studies were:

- **Hurt et al. (2015)**[2]: Though this study is observational in design, the information included is relevant to the clinical question. The authors studied the population of interest and used a progressive resistive force during treadmill walking to look at gait parameters in individuals post-stroke. While this study is not interventional, it provides some valid information for clinicians to consider.
- **Wu et al. (2014)[6]:** This RCT was among the highest level of evidence found, proved to be moderate quality (5/11 on PEDro scale), and studied the population of interest. The authors also used resistive forces on the treadmill as an intervention to effect gait parameters, making it relevant to the clinical question.
- **Hsiao et al (2016)[10]:** This RCT was also among the highest level of evidence found, proved to be of moderate quality (6/11 on PEDro scale), and studied the population of interest. The authors studied three groups walking on a treadmill under three different conditions, and looked at how it affected propulsive force.

These three articles were selected because they were among the highest quality evidence available and were the most relevant to the intervention in question: applying a resistive force to help with gait symmetry in patients who have hemiparesis due to stroke. Since the overall evidence of the studies was low, those with the most relevant information were chosen. None of the studies specifically address the clinical question in its entirety, but these studies contain valid information that pertains to at least parts of the clinical question: the population, and either the intervention or outcome of interest.

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of "Effect of progressive horizontal resistive force on the comfortable walking speed of individuals post-stroke" by Hurt CP, Wang J, Capo-Lugo CE, and Brown DA (2015)[2]

Aim/Objective of the Study/Systematic Review:

The purpose of this observational study was to determine whether walking against a progressively increasing horizontal force would influence the walking speed of individuals post-stroke. The findings of this study may assist in the development of different clinical interventions to help improve the gait speed of this specific patient population.

Study Design

[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]

Note: For systematic review, use headings 'search strategy', 'selection criteria', 'methods' etc. For qualitative studies, identify data collection/analyses methods.

This study is a cross-sectional repeated measures design consisting of two groups. Outcomes were measured while the participants walked on a treadmill under 12 different progressive horizontal resistance conditions.

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

This study was conducted at Northwestern University at the Department of Physical Therapy and Human Movement Sciences.

Participants

[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]

Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.

- They used a sample of convenience for the type of sample.
- The study consisted of two groups: healthy individuals and individuals with hemiplegia due to stroke

Participants with hemiplegia

- 3 Female; 11 Male
- Age range: 42-82 (Mean age 55)
- Height ranged from 150cm to 180cm
- Weight ranged from 62kg to 98kg
- Side of paresis: 6 left and 8 right
- Mean months post-stroke= 147 (range 27 months-314 months)
- Berg Balance Scale Score: Mean 51 (range: 46-55)
- Lower extremity Fugl Meyer Score: Mean 19 (range: 15-21)
- Overground comfortable walking speed: Mean 0.9m/s (range: 0.5m/s-1.2m/s)

Healthy participants

- 4 Female; 6 Male
- Age range: 41-61 (Mean age 51)
- Mean height: 174.2cm
- Mean weight: 77.3kg
- Overground comfortable walking speed: Mean= 1.4m/s

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

**Note: Since this study was cross-sectional and not interventional, the two groups received the same exposure, which is described below*

Both Healthy Individuals and Patients with hemiplegia completed the same experimental conditions

- Research PT performed screening and clinical testing
- Individuals completed:
  - Three trials of overground 10 meter walk test (at self-selected comfortable walking speed)
  - Horizontal resistive force test (in KineAssist Gait and Balance Training System robotic device)
    - Software was created to determine the different levels of horizontal resistive force by determining and manipulating the minimum force required which would cause the treadmill belt to move.
    - A maximum of three trials for each condition were performed until they reached a resistive force that did not allow movement of the treadmill belt. Each trial lasted 90 seconds and every 30 seconds the magnitude of resistance was increased
    - The maximum force value found on this test was used as the upper limit for the range of resistive forces for the next part of the intervention
  - Twelve treadmill walking trials with different levels of horizontal resistive forces.
    - Participants walked at a comfortable walking speed while walking against twelve random and progressive horizontal forces according to the upper limit they reached in the horizontal resistive force test
    - A minimum of 20 steps (continuous) were collected for each of the twelve trials
    - Participants were allowed 30 second rest between each trial

Outcome Measures (Primary and Secondary)

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

- When the participants reached a steady-state speed, they used custom software (MATLAB, MAthWorks, Natick, MA) to determine the coefficient of variation (COV) of the treadmill belt speed for 10-second windows for each trial to measure walking speed. Walking speed was measured in meters/second and was compared between groups.
- The key dependent variable for their hypotheses was the "slope coefficient", to determine the relationship between walking speed and amount of horizontal resistive force (how much walking speed would decrease depending on the amount of horizontal resistive force applied).
- The Berg Balance Scale (max score= 56) and LE Fugl Meyer (LE motor max score= 34) were performed on all of the patient's with hemiplegia before the testing to help give the reader an idea about the level of impairment for the participants.

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable]

- All tests use $p<0.05$ value to determine statistical significance and looked at slope coefficients for both groups
- For overground walking, the individuals with hemiplegia walked at significantly ($p < 0.001$) slower speeds (mean of 0.88 $\pm$ 0.20 m/s) than the non-impaired individuals (mean of 1.36 $\pm$ 0.16 m/s).
- Walking speed at low resistance levels in the KineAssist was also significantly ($p < 0.001$) different between post-stroke (mean of 0.83 $\pm$ 0.18 m/s) and non-impaired (mean of 1.16 $\pm$ 0.14 m/s) individuals.
- A linear relationship was observed for both groups between the horizontal resistive force and walking speed. "The slope coefficients of the linear regression between the observed normalized forces versus the normalized speed relationship"[2] were compared.
  - Slope coefficients were significantly greater ($p < 0.001$) than -1.0, which represents the ideal slope for a constant relative force output; and significantly less ($p <0.001$) than 0.0, which represents the ideal slope for a constant relative speed, for both post-stroke and non-impaired individuals.
- Both groups slowed down in response to increased resistive force (post-stroke individuals more than healthy individuals). The average slope coefficient was statistically different between groups ($P= 0.003$). For individuals post-stroke, it was -0.37 $\pm$ 0.04 and ranged from -0.76 to -0.34, and for the non-impaired individuals it was -0.47 $\pm$ 0.03 and ranged from -0.62 to -0.28.

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

Patients post-stroke seem to have the ability to increase their lower limb propulsive force in order to walk at a faster speed. The results of this study suggest that limb force generation is not the only factor that limits comfortable walking speed in these individuals. Instead, the data provides evidence that there is a "complex interaction in the selection of the comfortable walking speed between targeting a relative force output and the targeting of a particular speed, perhaps related to the amount of reserve capability to generate a wide range of speeds".[2(pg. 7)]

Critical Appraisal

Validity

[Identify the strengths and limitations of the study, including potential sources of bias. Comment on the overall methodological quality (including the score) as you determined from your assessment of the article. Comment on anything you believe was missing in the paper.]

- This study presents level IV evidence, and was scored using the Modified Downs and Black quality checklist and the Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies.
  - All scores for the Modified Downs and Black checklist are out of a possible 28 points. The scored are considered poor if they are below 14 points, a fair score is between 14-18 points, a good score is between 19-23 points, and an excellent score is between 24-28 points[11]. For this study, many of the questions were removed from the checklist, since they were not relevant to the type of study. This study scored 11/14.
  - All scores for the Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies are out of a possible 14 points. This study scored 7/9 as five of the questions were scored as N/A[12]. Items for which this article scored poorly include: Sample size justification (no) and Exposure assessed prior to outcome measurement (no). The items which were answered NA include: Different levels of the exposure of interest, Outcome assessors blinding, exposure assessed more than once over time, timeframe sufficiency, and Follow-up rate.
- The authors used a sample of convenience with no power analysis (due to the study being exploratory) to determine whether the study had enough participants to reach the appropriate power. The exposure and outcomes were measured during the same timeframe, which is to be expected for a cross-sectional design, but will provide weaker evidence regarding a causal relationship between the exposure and outcome. However, the design of this study was appropriate for the objectives of the study and is overall well done for an observational study.

Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

The results of this study suggest that patients post-stroke may have the ability to generate higher lower limb forces to help them achieve faster walking speeds. However, exact reasons why individuals post-stroke may select their particular comfortable walking speeds could not be determined. Both healthy individuals and patients post-stroke show a linear relationship between their walking speed and the amount of horizontal resistive force applied. The authors hypothesized that as the horizontal resistive force increased, the post-stroke individuals would decrease their speed to continue producing a similar force output. Both groups decreased their speed, but the amount of speed reduction was much less than was predicted (slope coefficient was greater than -1.0 for both groups). They also hypothesized that if the post-stroke individuals tried to maintain their "preferred speed of movement"[(page 6)], that they would try and continue with their comfortable walking speed, even as the horizontal resistive force increased. Though there was a linear relationship for these individuals post-stroke, the amount of reduction in walking speed did not demonstrate a "same unit change" according to the horizontal resistive force (slope coefficient was greater than -1.0 and less than 0). More research needs to be done to determine why these individuals select their comfortable walking speed.

Since this study is observational in nature, it is difficult to determine how it can be applied to inform intervention. However, it is difficult to determine a causal effect due to the outcomes being measured in the same timeframe as the exposure. It is also difficult to determine whether there were enough participants in the study to detect if there was truly an association since the authors did not mention a power analysis. Overall, this study did a good job accomplishing its main objectives. The results suggest that interventions to improve gait mechanics in this patient population should include: task-specific strengthening exercises, such as resisted walking, and interventions to help increase the range of speed these individuals are able to walk. However, more evidence is needed to determine how to apply this study to clinical practice.

(2) Description and appraisal of Robotic Resistance/Assistance Training Improves Locomotor Function in Individuals Poststroke: A Randomized Controlled Study by Wu M., Landry J.M., Kim J., Schmit B.D., Yen S.C., MacDonald J. (2014)

Aim/Objective of the Study/Systematic Review:

The purpose of this study was to determine how the application of a controlled resisted force versus assistive force would affect walking speed, balance, and endurance in individuals with hemiplegia post-stroke.

Study Design

[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]

Note: For systematic review, use headings 'search strategy', 'selection criteria', 'methods' etc. For qualitative studies, identify data collection/analyses methods.

This study was a randomized controlled trial with parallel design, consisting of two groups. Outcomes were measured prior to training, 6 weeks after training, and at an 8-week follow-up visit.

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

The study was conducted in research units within different rehabilitation hospitals.

Participants

[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]

Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.

- The study included 30 participants with chronic hemiparetic stroke.

Characteristics of participants

Resistance Group:

- Age (mean ± SD): 53.6 ± 8.9 years
- Sex: 9 Females, 5 males
- Race: 4 white, 10 other
- Paretic side: 7 right, 7 left
- Type of stroke: 6 ischemic, 6 hemorrhagic (*One participant reported unknown cause of stroke and one reported aneurysm)
- Time post-injury (mean ± SD): 7.3 ± 5.6 years
- Ankle foot orthosis: 7 participants
- Assistive device: 7 participants

Assistance Group:

- Age (mean ± SD): 57.4 ± 9.8 years
- Sex: 9 Females, 5 males
- Race: 6 white, 8 other
- Paretic side: 7 right, 7 left
- Type of stroke: 6 ischemic, 6 hemorrhagic (*Two subjects reports unknown cause of stroke)
- Time post-injury (mean ± SD): 7.1 ± 6.0 years
- Ankle foot orthosis: 7 participants
- Assistive device: 9 participants

*****Two participants dropped out of study (one due to poor attendance and the other due to feeling "decreased balance")

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Control

No Control group

Experimental

- Participants were split into two groups based on their gait speed (slow speed: <0.5m/s; fast speed: ≥0.5m/s). These subgroups were then randomly assigned to either a resistance or assistance group.
- All individuals participated in an intensive training program three times per week for 6 weeks. Each training session lasted 45 minutes.
- Training was conducted on the treadmill by licensed physical therapists.
- Body weight support was provided as necessary to prevent the knee from buckling or the toe from dragging.
- The treadmill speed was set at the participant's maximum comfortable walking speed each training session.
- The amount of load (resistance or assistance force) was determined based on the motor performance of the individual, which was measured using a control algorithm:
    - Control algorithm described in previous study: "The amount of force provided is proportional to the kinematic errors between the measured and desired ankle horizontal position and velocity during the swing phase. The desired proportions were determined from the mean recorded ankle trajectory using the position sensor for two healthy subjects walking on the treadmill."[6(pg. 801)]
- For individuals in the resistance group, a "controlled resistance load" was applied to the paretic leg during the swing phase of gait.
- For individuals in the assistance group, a "controlled assistance load" was applied to the paretic leg during the swing phase of gait.

Outcome Measures (Primary and Secondary)

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

Outcome measures were administered by licensed physical therapists before training, after 6 weeks of training, and 8 weeks post-training (at a follow-up examination).

Specific Outcome Measures assessed:

- Self-selected and fast-paced overground walking velocity was assessed using a 10m walkway (GaitMat II).
- The 6-minute walk test was administered to measure walking endurance.
- The Modified Ashworth Scale (0-4)[13] was used to assess muscle tone and spasticity of the knee joint muscle groups.
- The Berg Balance Scale (max score 56; range 0-56)[14] was used to measure balance.
- The Activities Balance Confidence Scale (rating scale ranges from 0-100, lower number meaning they have a lower confidence) and the Medical Outcomes Study 36-Item Short-Form Health Survey (rating scale ranges from 0: negative health to 100: positive health) were also given.

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable]

<u>Resistance group (6 weeks post treadmill training):</u>

- Self-selected walking speed significantly increased from 0.53 ± 0.25m/s to 0.61 ± 0.28m/s (P= .002).
- Fast walking speed significantly increased from 0.72 ± 0.36m/s to 0.82 ± 0.39m/s (P= .001)
- Step cadence, step length of paretic and non-paretic legs, and time of single-leg support on the paretic leg significantly increased. (See specific results for gait parameters in Table 4 below)
- The 6-minute walk test did not show significant difference (P= .18) but increased from 201 ± 84m to 207± 80m.
- The Berg Balance Scale did not show significant difference (P= .11) but increased from 44.1 ± 8.8 to 45.6 ± 9.3.

<u>Resistance group (at 8-week follow-up):</u>

- Further increase in self-selected and fast walking speeds were partially maintained at follow-up (P= .03

and P= .002)

- The 6-minute walk test was 210 + 82m at follow-up (P= .08).
- The Berg Balance Scale was 44.9 + 9.09 at follow-up (P= .47).

Assistance group (6 weeks post treadmill training):

- Self-selected walking speed significantly increased from 0.47 + 0.24m/s to 0.56 + 0.32m/s (P= .01).
- Fast walking speed significantly increased from 0.65 + 0.38m/s to 0.76 + 0.45m/s (P= .002)
- Step cadence, step length of paretic and non-paretic legs, and time of single-leg support on the paretic leg significantly increased. (See specific results for gait parameters in Table 4 below)
- The 6-minute walk test showed significant increase (P= .002) from 177.4 + 99.9m to 197.5+ 109.5m.
- The Berg Balance Scale significantly increased (P= .02) from 43.6 + 9.0 to 45.5 + 8.8.

Assistance group (at 8-week follow-up):

- Further increase in self-selected and fast walking speeds were partially maintained at follow-up (P= .01 and P= .004)
- The 6-minute walk distance results were partially retained 191.1 + 108.5m at follow-up (P= .02).
- The Berg Balance Scale was 44.1 + 9.6 at follow-up, but was not significant (P= .41).

Differences between groups:

- Self selected walking speed in resistance group increased 0.07 + 0.07m/s and increased 0.09 + .11m/s in the assistance group, with no significant difference between groups (P= .75)
- Fast walking speed in resistance group increased 0.10 + 0.08m/s and increased 0.11 + .12m/s in the assistance group, with no significant difference between groups (P= .73)
- The improvement in the 6-minute walk distance was not significant (P= .06), but was greater in the assistance group (20 + 20m) than the resistance group (6 + 16m).
- The improvement in the Berg Balance Scale score was not significant (P= .63) between the assistance (1.9 + 2.6) and the resistance group (1.4 + 3.1).
- After assistance training, improvements in self-selected walking speed was significantly greater for those who had a faster walking speed (>0.5m/s) than in those who had a slower walking speed (<0.5m/s) initially.
- There was no significant difference in those who had a faster walking speed (>0.5m/s) than in those who had a slower walking speed (<0.5m/s) initially in the resistance group (0.09 + 0.07m/s vs. 0.06 + 0.08m/s for those who had a faster walking speed: >0.5m/s vs. those who had a slower walking speed: <0.5m/s).
- ABC scale scores showed a significant increase (P= .03) for the assistance group, but did not have a significant increase (P=.30) in the resistance group.
- The Medical Outcomes Study 36-Item Short-Form Health Survey showed no significant difference for either group (P= .10-.80)

Table 4 Selected spatial-temporal gait parameters before and after 6 weeks of robotic resistance versus assistance treadmill training, and 8 weeks after the end of training

	Resistance			Assistance		
Outcome Measure	Pre	Post	F/U	Pre	Post	F/U
Single-leg support (%): SSV						
P	21.3±5.5	22.6±5.8*	22.8±5.3*	21.7±5.7	22.9±6.2*	23.8±5.6*
N	36.6±6.4	37.5±5.5	38.9±4.4*	34.0±8.0	35.2±7.7	35.3±8.2
Single-leg support (%): FV						
P	21.0±6.9	23.2±6.4	23.1±7.2	23.0±5.9	24.9±6.6*	25.3±6.3*
N	35.7±6.8	38.1±6.3	39.5±6.8	35.5±8.9	37.9±7.7	37.8±8.0
Step length: SSV (m)						
P	0.48±0.11	0.51±0.12*	0.51±0.11	0.42±0.14	0.45±0.15*	0.45±0.15*
N	0.37±0.15	0.41±0.18*	0.39±0.16	0.33±0.15	0.37±0.16*	0.37±0.17*
Step length: FV (m)						
P	0.55±0.15	0.57±0.17	0.58±0.16*	0.48±0.17	0.52±0.18*	0.52±0.18*
N	0.43±0.18	0.47±0.20*	0.47±0.19*	0.39±0.18	0.43±0.18*	0.43±0.19*
Step asymmetry: SSV	17.0±16.4	14.6±19.2	16.1±19.2	14.8±17.9	14.0±17.8	12.3±13.4
Step asymmetry: FV	15.2±16.6	12.7±16.1	13.1±18.1	14.2±18.4	14.1±18.9	11.9±14.9
Cadence (steps/min): SSV	71.3±17.1	74.7±16.8*	74.3±16.4*	71.4±17.3	76.3±22.5*	76.7±21.8*
Cadence (steps/min): FV	84.1±21.6	87.6±21.0*	86.5±21.2*	86.8±30.3	92.3±32.0*	91.1±33.0

NOTE. Values are mean ± SD.
Abbreviations: FV, faster walking velocity; N, nonparetic leg; P, paretic leg; SSV, self-selected velocity.
* $P<.05$ (within-group comparison, ANOVA).

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

In individuals post-stroke, the application of either a resistance force or an assistance force to the paretic leg while training on a treadmill at maximum comfortable speed may help improve walking speed in individuals poststroke.

Critical Appraisal

Validity

[Identify the strengths and limitations of the study, including potential sources of bias. Comment on the overall methodological quality (including the score) as you determined from your assessment of the article. Comment on anything you believe was missing in the paper.]

Using the PEDro Scale, this study scored 5/11, or 5/10 according to the PEDro database (eligibility criteria item does not contribute to total score). They received points for their strength in random allocation, baseline comparability, adequate follow-up, between-group comparisons, and point estimates and variability. Points were lost due to lack of: blinding (therapists, assessors, and participants), concealed allocation, intention to treat analysis, and eligibility criteria.

The overall quality of this study is moderate. The study lacks external validity as it lacks eligibility criteria for the participants, making it difficult for the reader to understand the characteristics of the participants and how to apply this to a specific patient population. The internal validity of this study is also in question due to lack of blinding of the assessors, therapists, and participants as well as a lack on concealed allocation. Lack of blinding increases the risk of bias; however, they did ensure that the treatment protocol was standardized, and they report lack of blinding as a limitation in their study. The validity of this study is also in question due to lack of "intention-to-treat" analysis, which places the study at risk for post-randomization bias. The study also lacks a control group, which makes it difficult to determine whether the treatment outcomes were actually due to the intervention, and not another factor. The participants were randomly allocated into groups, which helps increase the likelihood that there is no bias in the two groups composition, and that the groups were similar at baseline.

Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

In patients with hemiplegia post-stroke, applying a controlled resistance or assistance load to the paretic leg while walking on the treadmill may help increase overground walking speed. The results of this study showed significant improvement in walking speed for both the resistance and assistance groups. These improvements were also partially retained at the 8-week follow-up visit. There was a significant increase in walking speed for both the resistance and assistance group, but the increase in gait speed was not significantly greater for either group. The reader was unable to determine an MCID for gait speed with the use of the GaitMat II instrument used to measure gait speed. However, the MCID for the 10-m walk test is 0.06 m/s for a small meaningful change and 0.14 m/s for a substantial meaningful change,[15] suggesting that this change in gait speed also was clinically significant for both the resistive and assistive load groups. The assistance group showed significant improvement in their 6-minute walk distance, Berg Balance Scale, and the ABC Scale scores, while the resistance group did not. There was also an increase in step cadence, step length (of both the paretic and non-paretic limbs), and single-leg support time of the paretic leg in both the resistance and assistance groups.

The effect size and confidence intervals were not reported, making it difficult to determine whether these results are clinically meaningful. Additionally, the data that is required to calculate the effect size and confidence intervals are only presented graphically, which prevents the readers from extracting the means and SD's.

The validity of this study is in question due to lack of blinding, lack of allocation concealment, and risk of post-randomization bias. There was also no control group in this study, making it difficult to say whether the change in the outcome measures were actually due to the intervention. More evidence is needed to determine whether the results of this study are clinically meaningful.

(3) Description and appraisal of Mechanisms used to increase peak propulsive force following 12-weeks of gait training in individuals poststroke by Hsiao H.Y., Knarr B.A., Pohlig R.T., Higginson J.S., Binder-Macleod S.A. (2016)

Aim/Objective of the Study/Systematic Review:

The purpose of this study was to determine and quantify how much ankle moment and trailing limb angle (TLA: the angle between the vertical and vector that joins the greater trochanter with the center of pressure[10]) contribute to the increase in propulsive limb force after 12 weeks of gait training on the treadmill in individuals with chronic stroke.

Study Design

[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]

Note: For systematic review, use headings 'search strategy', 'selection criteria', 'methods' etc. For qualitative studies, identify data collection/analyses methods.

This study was a randomized controlled trial consisting of three groups. Outcomes were measured prior to training and after 12 weeks of training.

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

University of Delaware, United States in laboratory.

Participants

[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]

Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.

This study consisted of 45 participants with hemiparesis due to stroke.

- Age: 58.9 ± 12.2 years (Mean ± SD)
- Gender: 14 female, 31 male
- Paretic side: 16 right, 29 left
- Self-selected walking speed: 0.69 ± 0.34m/s (Mean ± SD)
- Time since stroke: Median: 1.7 years; Range: 0.4-30.5 years

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Control

No control group

Experimental

- Participants were randomly assigned to one of three treatment groups:
  - Gait training at self-selected walking speed (SS)
  - Gait training at fastest speed participant is able to maintain for ≥4 minutes (FAST)
  - Gait training at fastest speed participant is able to maintain for ≥4 minutes with functional electrical stimulation applied to dorsiflexor and plantarflexor muscles of the paretic limb. (FastFES)
- Participants in all three groups completed 3 sessions, lasting for 36-minutes each, for 12 weeks.
- Each session consisted of 6 bouts of training, 5 bouts were on a split belt treadmill and the 6th bout was completed overground.
- Functional electrical stimulation for those in the FastFES group was applied for the first, third, and fifth bouts of training. (Authors refer readers to previous publications of their own work for more details[16,17])

- Rest breaks were provided between each walking bout for up to 5 minutes.

Outcome Measures (Primary and Secondary)

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

- A gait evaluation was conducted at baseline and after 12 weeks of gait training by using an 8-camera motion analysis system while patient walked at comfortable walking speed on a treadmill. (The authors refer readers to previous publications of their own work for more details[16–18])
- The peak anterior component of the ground reaction force (AGRF) was calculated prior to training and 12-weeks post training to determine the change in propulsive force. (The authors refer readers to previous publications of their own work for more details on the biomechanical-based model[19])
- For those who showed an increase in their AGRF following training, the authors then determined the contribution of the changes in TLA (angle between the laboratory's vertical axis and the vector joining the greater trochanter with the center of pressure)[10(pg. 390)] and in ankle moment (ankle plantarflexion moment resolved into the shank coordinate system and normalized to body weight)[10(pg. 390)] to propulsive force. All data was averaged within 30-second trials.
- The authors also performed a two-way mixed design analysis of covariance (ANCOVA) comparing the pre-training vs. post-training and the group (SS vs. Fast vs. FastFES) in order to analyse any change in TLA or ankle moment.

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable]

45 participants completed the 12-week training, but only 39 participants' data were analysed due to technical issues.

- Walking speed increased from 0.69 to 0.82 m/s following 12-weeks of training on average for all of the groups.
- Paretic propulsive force increased 23% and non-paretic propulsive force increased 17%. The change in propulsive force of the paretic limb contributed to 52% of the variance in self-selected walking speed and the change in propulsive force of the non-paretic limb contributed 36% of the variance.
- There was no significant difference between the predicted and the actual measured changes in propulsive forces for the paretic or non-paretic side.
  - Mean predicted paretic propulsive force: 16.15 N; Measured paretic propulsive force: 15.69 N ($p = 0.85$, $t = 0.19$)
  - Mean predicted non-paretic propulsive force: 21.98 N; Measured non-paretic propulsive force: 20.26 N ($p = 0.66$, $t = -0.52$)
- 26/39 participants increased propulsive force in the paretic limb: 9 from the SS group, 9 in the FAST group, and 8 in the FastFES group.
- In 21 of the participants, there was a greater contribution from changes in TLA than ankle moment to the propulsive force in the paretic limb. In 10 of the participants, there was no contribution from changes in ankle moment, and in 4 of the participants, there was no contribution from changes in TLA.
- 3 of the 26 participants who showed improvement in propulsive force of their paretic limb did not show an increase in the propulsive force of their non-paretic limb. 13 of the participants who did show an increase in the propulsive force of their non-paretic limb showed greater contribution from TLA than ankle moment. In 6 of the participants, there was no contribution from changes in TLA for the increase in the non-paretic propulsive force.
- There was a significant increase in paretic ankle moment for the FastFES group when the comparison of pre-training vs. post-training and the group: SS ($p = 0.38$) vs. FAST ($p = 0.14$) vs. FastFES ($p=0.03$). In the non-paretic limb, no significant interactions between the pre-training vs. post-training and group were found for TLA or ankle moment.

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

Trailing limb angle (TLA) is the primary contributor to increases in propulsive force in patients with hemiplegia due to stroke. TLA increased in all three groups but there was no significant difference between groups. There was only an increase in the paretic ankle moment in the FastFES group, meaning that specific targeting may be required in order to increase ankle moment.

Critical Appraisal
Validity [Identify the strengths and limitations of the study, including potential sources of bias. Comment on the overall methodological quality (including the score) as you determined from your assessment of the article. Comment on anything you believe was missing in the paper.]
Using the PEDro Scale, this study scored 6/11, or 5/10 according to the PEDro database (eligibility criteria item does not contribute to total score). They received points for their strength in random allocation, adequate follow-up, between-group comparisons, intention-to-treat analysis, and point estimates and variability. Points were lost due to lack of: blinding (therapists, assessors, and participants), concealed allocation, and baseline comparability. The overall quality of this study is moderate. The internal validity of this study is also in question due to lack of blinding of the assessors, therapists, and participants as well as a lack on concealed allocation. Lack of blinding increases the risk of bias; however, they did ensure that the treatment protocol was standardized. All of the participants received the treatment intervention, which helps prevent post-randomization bias. However, this study lacks a control group, which makes it difficult to determine whether the treatment outcomes were actually due to the intervention, and not another factor. The participants were randomly allocated into groups, which helps increase the likelihood that there is no bias in the three groups composition. However, the authors did not include information that would allow us to determine baseline characteristics, which makes it difficult for us to determine who would respond to the intervention.
Interpretation of Results [This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]
TLA seems to be the main contributor to increases in propulsive limb force after a 12-week gait-training program. There does not seem to be a difference between groups for the TLA. However, there was a significant increase in the paretic ankle moment in the FastFES group. As stated above, the paretic ankle moment is described as the ankle plantarflexion moment. This suggests that specifically targeting the ankle plantarflexors in rehab interventions may help to increase ankle moment, and therefore augment propulsive force in patients post-stroke. In addition to increasing ankle moment, increasing the paretic limb extension, or the TLA is also very important to increase propulsive force. All three training interventions: walking on a treadmill at a self-selected speed, at a fast speed, and at a fast speed with the addition of functional electrical stimulation all helped to increase the TLA. However, there were large variations in the individuals as well as paretic versus non-paretic limbs, making it difficult to determine which individuals would be likely to respond to this intervention. The effect size and confidence intervals were not reported, making it difficult to determine whether the increases in TLA and ankle moment are clinically meaningful. The authors also did not include enough information for the reader to calculate the effect size or confidence interval. The average increase in gait speed for those who increased their propulsive limb force was 0.2m/s, as determined by the 10-m walk test (MCID: 0.14 m/s= substantial meaningful change).[15] For the FAST group, the mean change was 0.24 m/s, the FastFES group was 0.17 m/s, and the SS group was 0.16 m/s. All of the groups showed a clinically meaningful increase in gait speed, with the FAST group showing the largest increase. Since the changes in gait speed are considered clinically significant in this patient population, any of these training interventions may be effective in increasing gait speed and be clinically meaningful. However, this study lacks baseline characteristics of their participants, making it difficult to determine who would respond to this intervention. More research is needed to determine whether the specific patient population of interest would benefit from this intervention.

EVIDENCE SYNTHESIS AND IMPLICATIONS

<u>**Clinical Implications**</u>
The evidence reviewed in this paper suggests that individuals with hemiparesis post-stroke have the ability to increase their paretic propulsive limb force,[2] thereby increasing their gait speed and community ambulation. There is not any current evidence that supports the use of resisted treadmill training at the pelvis to specifically increase propulsive limb force; however, the included studies offer some useful clinical information to help improve gait. Hurt et al discusses that therapeutic interventions should focus on lower limb strengthening, such as walking against resistance in addition to attempting to increase patient's gait speed.[2] However, since this

study design is observational, clinicians should also use clinical reasoning and other evidence to support their decisions for utilizing this intervention. Treadmill training with both a resistive and assistive load was shown to increase gait speed when applied to the paretic limb; however, a resistive load was not more effective than an assistive load.[6] Instead, the two different interventions seem to utilize different motor learning mechanisms, which both may result in an increase in gait speed.[6] The increase in gait speed was also partially retained at follow-up, and was clinically meaningful according to the MCID for the 10-m walk test.[15] The evidence appraised in this paper also discusses the key contributors to propulsive limb force, which was determined in previous articles,[19] and includes the TLA and ankle moment. Interventions directed at improving these two key factors may help to increase propulsive limb force. TLA seems to contribute the most, and the use of interventions directed at helping to increase the paretic leg extension may help in increasing the TLA component of propulsive limb force.[10] The ability to increase ankle moment appears to require a more targeted intervention, such as specific strengthening of the ankle plantarflexors.[10] Functional electrical stimulation during treadmill gait training seems to be effective in increasing the ankle moment, though there were large variations in improvement between individuals.[10] Clinicians should recognize this limitation, since the study did not include baseline characteristics of the individuals to determine who would respond to this intervention. This limits the generalizability of study findings, further emphasizing the importance of utilizing clinical judgment.

All of the evidence appraised included patients with chronic stroke (mean of ~7 years[6], mean of ~12 years[2], and range of 0.4-30.5 years[10] post-stroke). Clinicians should utilize clinical judgment when considering these interventions for use in patients with acute stroke, or in the inpatient rehabilitation setting, as with this clinical scenario. In the study by Wu et al, body weight support was provided (as needed) to prevent knee buckling or toe drag[6], which may prove necessary for those with acute stroke. Based on the evidence discussed along with the use of clinical judgment, using resisted walking as an intervention with the patient in this clinical scenario may help to increase gait speed. Resisted walking on the treadmill seems to be safe, and may help to increase gait speed.

It appears that treadmill training may be effective in increasing paretic propulsive limb forces for individuals post-stroke, specifically by increasing the TLA. The addition of functional electrical stimulation may be helpful to increase ankle moment, and the addition of either a resistive or assistive load to the paretic leg was also shown to be effective in improving gait speed.

Future Research

Based on the current evidence available, future research demands more high quality randomized controlled trials to determine which interventions will help increase propulsive limb force in the paretic limb of individuals post-stroke. The majority of articles relevant to the clinical question are observational studies, making it difficult to determine an answer to the clinical question due to lack of interventional studies. However, these observational studies help clinicians understand the types of interventions that should be tested to determine effectiveness on specific patient populations. The current randomized controlled trials available do not score above 6, out of 10, on the PEDro scale, primarily due to either: lack of blinding, risk of post-randomization bias, or neglecting to determine baseline characteristics. The articles reviewed discuss the need for larger sample sizes as well as specific baseline characteristics of individuals due to the large variations between individuals. Future research should also look at the use of these interventions in patients with acute stroke to determine the effectiveness of these interventions early on rather than in the chronic phases.

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