# Title: Effect of types of ankle-foot orthoses on energy expenditure metrics during walking in individuals with stroke: A systematic review

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## Abstract:

**Purpose:** This systematic review is aimed at evaluating the efficacy of AFO types and comparison between them on the energy expenditure metrics of walking in individuals who had suffered a stroke with (sub)acute or chronic evolution.

**Methods:** The following databases were searched; PubMed, Scopus, ISI Web of Knowledge, Embase and Cochrane Library based on the population intervention comparison outcome (PICO) method.

**Results:** A total of 15 trials involving 195 participants were selected for the final evaluation. All trials, except one, examined individuals in chronic phase. Although the evidence from the selected studies was generally weak, the consensus was that an AFO may have a positive immediate effect on the energy expenditure metrics including energy cost, physiological cost index, mechanical work and vertical center of mass trajectory on the affected leg, in both overground walking and treadmill walking in adults with chronic stroke. There were insufficient studies to evaluate the medium term efficacy of wearing an AFO combined with gait training on metabolic cost parameters during ambulation. There were also insufficient studies for comparison among different designs of AFOs.

**Conclusions:** An AFO can immediately improve energy expenditure metrics of walking in stroke survivors. There is a need for further well-designed randomized trials to evaluate long-term effect of gait training using AFOs and comparison among the different types of orthoses.

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**Keywords:** Energy, Orthotic Devices, Stroke, Walking

**Abbreviations:** AFO: ankle-foot orthosis; PLS-AFO: posterior leaf spring AFO; CAFO: carbon fiber AFO; DAFO: dynamic AFO; RAFO: rigid AFO; AFO-PS: hinged plastic or metal AFO with plantarflexion stop and dorsiflexion free; AFO-PR: AFO with plantarflexion resistance and dorsiflexion free; PAFO: plastic ankle foot orthosis; HR: heart rate; RER: respiratory rate; COM: center of mass; PCI: physiological cost index.

## 1. Introduction

Stroke is a common neurological condition which requires continuing long-term care and rehabilitation[1]. The most common problem secondary to stroke is walking difficulty, including slow velocity, instability, and energy inefficiency [2,3]. The lower walking speed along with the higher energy expenditure disposes patients with stroke to a sedentary life, which affects cardiovascular function and limits ADLs[4]. Generally, the main goals of rehabilitation are to improve gait stability and possibly to reduce energy consumption[5,6]. Orthotic devices, especially ankle foot orthoses (AFOs), can be used to partially improve the gait pattern, reduce metabolic cost and increase walking speed in stroke survivors[7].

Although some walking tests such as computerized gait analysis shows known biomechanical pathologies that can be corrected with an AFO[8], measurements such as oxygen consumption as an energy expenditure index during walking have also been used to evaluate gait economy in stroke populations[9-11]. Moreover, metabolic cost of walking is significantly associated with walking velocity[12,13] and positively associated with fatigue in push-off phase[14,15]. This supports the usage of rehabilitation interventions such as an AFO to appropriately manage impaired joint kinematics and kinetics to positively affect energy expenditure during gait, and lead to increased activity levels during real world tasks. Therefore, we performed a systematic review on the energy expenditure metrics of gait in stroke patients using AFOs.

There is only one previous review which focused on energy cost of walking by various assistive modalities in individuals post stroke[16]. However, it included only gross and net energy cost (ml/kg/min or ml/kg/m and J/kg/min or J/kg/m). This systematic review investigated the energy cost of AFO use, but it did not directly compare the oxygen cost between walking with and without an AFO and did not focus on other energy expenditure indices such as heart rate (HR), physiological cost index (PCI), mechanical work or vertical displacement of center of mass (COM). It should also be noted that different types of AFO with or without articulated joint used in stroke patients constrain plantarflexion and to some extent dorsiflexion depending on the design[17]. However, all AFO designs can improve stroke walking in some way, some of them may make a more positive effect on gait characteristics of stroke;[17] no previous reviews focused on the effects of AFO types on the energy demands of walking. Therefore, the aim of this study was to systematically review the evidence for the impact of AFO designs on energy expenditure metrics during walking in individuals with stroke hemiplegia.

## 2. Methods

### *2.1. Search strategy*

We did the search strategy based on the population intervention comparison outcome (PICO) method and included all relevant articles published from 1990 to December 2019. The procedure was, then, followed by the PRISMA methods (Figure. 1). Five databases including the PubMed, ISI web of knowledge, Cochrane Library, Embase and Scopus were searched. A search strategy for PubMed database was first developed and for other databases was adapted (Supplemental Appendix 1). Literature search was conducted by a reviewer (A.D.). After removing duplications by Endnote X7 software, the titles, abstract, and full texts identified by the database searches were independently reviewed for eligibility by two researchers (A.D. and T.K.).

In case of any dispute for screening and selection process, those were solved by discussion between the two researchers.

### *2.2. Study types*

The review included controlled trials published published in English, which (1) compared walking with an AFO and walking without orthosis (barefoot or with shoes); (2) compared the various AFO designs; (3) included individuals who were clinically diagnosed with stroke; (4) used outcome measures of the indices related to energy expenditure metrics during walking; and (5) reported the statistical analysis of results. Studies that included other type of orthotic devices, such as powered or robotic orthoses were excluded because they are not used as daily-wear device. Case studies and case series without statistical analysis, and studies only published as an abstract were excluded due to the very high risk of bias in such designs. We could not conduct meta-analysis because of the data heterogeneity [18].

### *2.3. Assessment of methodologic quality*

The assessment of the methodologic quality of the included trials was same as our previous study[17]. Briefly, we used the Downs and Black scale which included the sections of study quality, external validity, study bias, and power[19]. For the present review, this scale was modified to 17 items, as it was not possible for some items to be scored due to nonconformity of the items for included studies. Each fulfilled item received “no” (0 point), “unable to determine” (0 point) or “yes” (1 point). The Downs and Black scales for the selected 36 studies are indicated in table 1.

### *2.4. Data extraction*

Data on the trial design, sample size, population recruited (age, gender, time from stroke), inclusion and exclusion criteria, intervention delivered, time with AFO before study (AFO time) and follow-up time during study, outcomes measured, walking velocity and relevant results were extracted from the selected trials shown in table 2. If necessary, we contacted the authors for missing data, clarification, or both.

## 3. Results

### *3.1. Description of studies*

In total, data of 15 studies were included for qualitative analyses (Figure. 1). A list of excluded articles along with the reason for their exclusion based on the abstract/ full text has been provided in Supplemental Appendix 2. The quality of the papers had a scientific rigor of 11 (median) out of 17 and ranged from 9 (low) to 13 (high). All papers failed in the items to evaluate the adequacy of population representation, and the blinding of patients or therapists. A non-randomized, controlled, crossover trial was conducted in 5 articles in which walking without an AFO was considered as the control condition, but the order of walking trials was not randomized [20-22]. A randomized, crossover trial was conducted in 5 articles in which walking trial without an AFO was the control trial and the testing order was randomized[23-28]. A randomized, parallel-group controlled design was conducted in 2 studies which one group of the participants was examined with an orthosis and the control group used other orthosis or only shoes[29,30]. We included 3 pilot studies with the statistical analysis of results because COM parameter related to energy expenditure indices was reported in them [31-33]. The most studies recruited habitual AFO users before testing. Only three papers followed up effects of wearing an orthosis after study had started including 1 pilot studies[33] and 2 controlled trials[28,29], while other studies assessed the short-term or immediate effect of an orthosis. Sample sizes were usually small (ranging from 5 to 27 subjects), and only 3 paper reported a sample size calculation (power) [28-30](table 1). Most individuals, were in the chronic phase (>6 months) and did not receive rehabilitation any longer (table 2), but only one paper evaluated the training effect of walking using an AFO in this phase[28]. Only one paper involved the individuals in the early subacute (7 days to 3 months) stage without undergoing rehabilitation[23]. Most studies used non-articulated AFOs (table 2), and only 3 studies evaluated articulated AFOs [24,32,33]. The energy expenditure metrics were assessed during overground walking in 10 studies[21,22,25,26,28,29,31-34], and treadmill walking in 5 studies[20,23,24,27,30]. There were no studies to evaluate the knee-ankle foot orthoses on the energy expenditure variables.

### *3.2. Outcome measures*

Energy expenditure metrics of walking have been measured by evaluating the total energy consumption in ml/kg/min[21-23], net energy consumption in ml/kg/min[20], total energy cost in ml/kg/m[21,22,27,30], net energy cost in ml/kg/m[20,25], net energy cost in J/kg/m[24,26], PCI in beat/min[21,28,29,34], HR in bpm[20-23], RER [20,23], and total mechanical work in J/kg/m[24,25]. No study measured total energy cost in J/kg/m using an AFO in stroke survivors. Furthermore, the vertical displacement of COM has been investigated in relation to the energy cost of walking[35,36]. Therefore, we considered that as one of the energy cost indices[31-33].

### *3.3. Summary of results*

*3.3.1. Effect of AFOs on parameters of energy expenditure metrics of walking*

3.3.1.1. Comparison between orthosis condition and without orthosis condition

**Energy consumption (per min):** Concerning the overground studies, a study with low scientific rigor (score: 9) demonstrated that PAFO use demonstrated a significant improvement in energy consumption ($p<0.05$)[21]. However, no significant effect was found for energy consumption in another study (score: 9)[22]. Regarding the treadmill studies, a significant increase was reported wearing RAFO compared with walking without the AFO for a study (score:10)[23]. However, there was not a significant difference in energy consumption for a study with low scientific rigor ($p>0.05$)[20].

**Energy cost (per meter):** Regarding the overground studies, four studies with low scientific rigor (score: 9-10) reported a significant reduction in total and net energy cost using CAFO[25], PAFO[21], PLS-AFO[26], and a conventional AFO[22]. For the treadmill studies, Bleyenheuft et al. (score: 12) reported that reduction in energy cost (J/kg/m) with PLS-AFO or Chignon AFO was borderline-significant ($p=0.06$)[24]; but two other studies showed that energy cost (ml/kg/m) was significantly reduced by using CAFO[20], and orthosis with elastic straps that guide knee, hip and ankle[27] during treadmill walking (score range: 9-10).

**PCI:** Two studies (score range: 9-12) examined effects of AFOs on PCI using PLS-AFO[21] or DAFO[29] and compared with overground walking without an AFO and reported a significant improvement for this parameter. Another study (score range: 13) demonstrated that using an AFO for 12 weeks had a significant orthotic effect on PCI, but no significant therapeutic effect was found after gait training [28].

**HR and RER:** All studies reported no significant difference on HR and RER by AFOs during treadmill or overground walking [20-23].

**Vertical COM trajectory:** It should be noted that those with drop-foot gait due to stroke hemiplegia are unable to achieve suitable shock absorption at initial contact phase due to not having a heel strike on the paretic leg[37]. This toe-heel foot contact pattern inverts the normal knee moment, producing extensor moments too early in the gait cycle, possibly leading to knee hyperextension. Therefore, the limb is often placed on the ground more slowly than the unaffected limb in post stroke hemiparetic gait. Thus, the peak of the vertical COM in stance phase on the paretic leg is generally lower than that for the nonparetic leg in the same phase in individuals with stroke [36]. Three pilot studies with low scientific rigor showed that peak height of the vertical COM trajectory on the affected leg at stance phase increased by an RAFO or AFO-PR[31-33].

**Mechanical work:** Bleyenheuft et al. reported that total mechanical work (J/kg/m) was similarly improved by chignon AFO and PLS-AFO[24]. Another study (score: 10) reported that the total net work (J/kg/m) at ankle was significantly reduced, however no significant changes in total net work in ankle, knee and hip as a result of wearing the CAFO were found [25].

3.3.1.2. Comparing among AFOs or shoes:

Only three studies with moderate to high scientific rigor evaluated comparison among AFOs or shoes on energy expenditure indices. Bleyenheuft et al. compared PLS-AFO and Chignon AFO and found no significant difference between them for energy cost[24]. Slijper et al. compared AFO-PS and CAFO during overground walking on the PCI and no statistically significant difference was seen between the two AFOs in PCI[34]. Additionally, only one study evaluated the effect of different shoes wearing an AFO on energy cost. Farmani et al. with a high scientific rigor indicated that adding a rocker shoe along with RAFOs improved energy cost (ml/kg/m) [30].

## 4. Discussion

Since gait deviation is a common symptom of survivors with stroke, the asymmetric gait pattern increases muscular effort and consequently energy cost is increased. Therefore, information on energy expenditure metrics of walking is clinically important for the assessment of exercise and orthotic interventions or assistive devices[38].

The most studies evaluated immediate, short-term influences of AFOs in the chronic phase of stroke and reported a significant improvement on energy expenditure metrics including energy cost, PCI, mechanical work and vertical COM trajectory on the affected leg, in both overground walking and treadmill walking. However, this review revealed discrepancies in the results of different studies regarding the energy consumption produced by walking with an AFO. One study[21] found a significant reduction while another study[23] repoted a significant increase in the energy consumption with an AFO[20,23], but not significant difference in two other studies[20,22]. Moreover, concerning the RER and HR, the included studies reported no significant difference on both variables with the use of AFOs during treadmill or overground walking [20-23]. This discrepancy among these studies may be due to their low scientific rigor, differences in the subjects' impairments, or AFO stiffness values that were not appropriately optimized to the individual participants. On the other hand, the current review demonstrated the positive effect of an AFO on energy cost and PCI parameters. The reduction of energy cost with an AFO during walking in the included studies may stem from speed increase[38] (table 2), increase of the balance during gait[39], coordinated activities of muscles or from biomechanical effectiveness of AFOs. It should be noted that stroke populations show an increased co-contraction of muscles to keep stability of joints during gait. Increased co-contraction has been reported as being related to increased energy expenditure metrics of walking[40]. AFOs reduce the necessary amount of muscle activity during gait[17,41] thereby this mechanism may reduce energy cost. Additionally, all types of AFOs resulted in a significant improvement in walking speed compared with a control group without the use of an AFO. Another possible explanation of these results is that, when using an AFO, patients have a more normalized gait due to added stability in pelvic motion[42,43] and assist in controlling ankle dorsiflexion[17,41]. Therefore, such changes are likely producing lower levels of muscle recruitment to stabilize the ankle joint during gait, which enhance efficiency and energy cost. The vertical COM displacement has also been studied as a parameter related to energy expenditure metrics of gait[35,36]. Three pilot studies showed that use of an AFO significantly increased the vertical COM trajectory during stance phase of gait on the affected leg[31-33]. As mention above, an AFO could significantly decrease pelvic movements in patients with stroke, helping align the trunk to a more upright position. All these factors could potentially affect the vertical COM displacement. An increase in vertical COM trajectory could imply that an AFO might enable more efficient exchange of potential energy into kinetic energy during stance phase of an affected leg. However, all three studies were pilot with a small sample size. To the best of our knowledge, the relationship between a reduction in energy cost of gait and an improvement in upper body (pelvic and trunk) movements, an increase of the walking balance or coordinated activities of muscles using an AFO in stroke patients have not previously been reported in the literature. Moreover, different types of AFOs might have the different effects on upper body movements [43].

Only one study evaluated patients in the subacute phase after stroke. Hyun found that using Rigid AFO increased VO2 peak during incremental exercise stress testing at variable inclines[23]. Recruiting patients in this phase may be very challenging because it can be hard to convince subjects to walk on the treadmill at a specific speed and breathing through a facemask[44]. Another possible explanation is that clinicians usually focus on the improvement of patients' stability rather than metabolic cost at this stage because gait stability is visually observable in the clinic, and metabolic cost improvements may require weeks of patient acclimation to the AFO, and then expensive equipment to acquire the metabolic data.

In terms of comparison among different AFOs, only 2 studies were found and reported no significant difference between them for energy cost. Regarding the follow-up studies, Thijssen et al. reported more improvement in energy cost after 3 weeks of familiarization to the orthosis than immediate effect[27]. In another study, Erel et al. stated that PCI reduced significantly with a dynamic AFO after three months[29]. Therefore, a training effect is an explanation of the further reduction in these energy expenditure metrics. However, there are limited studies in this regard. On the other hand, one study reported that changes in PCI for walking when not wearing an AFO after a 12-week gait training using an AFO was not significant[28]. Such changes over time measured when not wearing an orthosis have been referred to as a therapeutic effect[28]. Further studies on the therapeutic effect of an AFO based on training should be encouraged.

Regarding the different shoes used with an AFO, one study reported the improvement of energy cost with the use of a rocker shoe compared with a standard shoe in stroke survivors[30]. Another study reported that stiffness of the AFO-Shoe combination was significantly reduced in comparison with the AFO-alone condition, but no significant differences were demonstrated in energy efficiency (ratio of released energy to stored energy) evaluated by a mechanical testing device. However, only one single type of footwear was tested in this study[45]. Various shoes with different hardness of the shoe sole should therefore be evaluated to investigate their effect on energy efficiency. This could be valuable to make the most advantages of the AFO-footwear combination during gait.

Finally, it is reported that the positive ankle power has a great effect on the metabolic cost during walking[14], since the reduced ability to ankle power in push off can be compensated by the hip joint work [46], but is likely to be less economical. As a result, a high metabolic cost of walking is observed in individuals with central neurological disorders who lack adequate ankle push-off energy. Hence, some investigations have been carried out on types of AFO devices to support ankle push-off at the propulsive phase to decrease the metabolic cost of walking. Although some active AFOs could assist push-off function in some cases, all of them are available only in experimental laboratories, and are none currently available for real world clinical use by patients. Among all orthotic devices, passive AFOs are the most popular daily-use application due to simplicity in the design, durability and compactness[47]. Bregman showed that the decrease in energy cost differed from the mechanical changes (increase in hip positive work (and power) [W/kg] and decrease in ankle positive work (and power) [W/kg]) found by the CAFO[25]. Bleyenheuft reported that the relationship between a decrease in energy cost and a reduction in total mechanical work [J/kg/m] with the Chignon AFO and the PLS-AFO [24]. Furthermore, some researchers have investigated the effects of passive AFOs at the propulsive phase; however the improvement in ankle power was insufficient with these AFOs[17]. It is possible that an algorithm to appropriately tune (adjust the resistance to plantarflexion and resistance to dorsiflexion) the

AFO to each individual's ankle push-off needs might hold promise for the future. To the best of our knowledge, this relationship between the improvement in metabolic cost of walking and the positive ankle power generation by an AFO has not been definitively reported in the literature. The exact mechanism for improved energy cost from an AFO requires further research.

### *4.3. Limitations*

As previously discussed, the main limitations of the generalizability of current review were related to the nature of the data. The most trials assessed the immediate effects of AFOs in the chronic phase without gait training, had small sample sizes, low to moderate scientific rigor and high risk of bias. Current AFO research lacks high-quality RCTs with appropriate statistical power and high scientific rigor. Statistical power analyses to determine the appropriate sample size for the experiment was calculated in only two papers. There were not any data to evaluate the effect of an AFO with variable plantarflexion resistances on the energy expenditure metrics. Only 2 pilot studies evaluated its effect on the COM displacement. Moreover, the AFO-footwear combination can create different results [30]. However, some studies walked with an AFO only and some studies walked with an AFO associated with a shoe. Finally, few studies investigated the comparison among different types of AFOs and the comparison between the non-articulated and articulated types AFOs on energy expenditure metrics in stroke hemiplegia.

Future investigations should therefore:

- Concentrate on RCTs with high scientific rigor and low risk of bias, specifically by improving participant sampling methods, the blinding of investigators making measurements, similar time periods in all conditions, random allocation, and prevention of losses to follow-up;

- Provide a more detailed physical exam data for the individuals with post stroke in each study, and categorize participants accordingly. For example, if the participant has knee hyperextension, plantarflexor spasticity, or suprapelvic involvement the appropriate AFO would change.

- Utilize a prospective sample size calculation in order to attain a more accurate assessment of orthotic interventions;

- Clarify the relationship between the energy cost of gait and the upper body movements, walking balance, coordinated activities of muscles or positive ankle joint power using an AFO;

- Evaluate long term effect of gait training using AFOs in chronic and (sub) acute phases;

- Investigate the effect of different types of AFOs and a comparison among them on gait after stroke;

- Quantify the mechanical characteristics of the type of AFO used in the study, including torque-angle measurements in dorsiflexion and plantarflexion to document the effect on the participant's gait kinematics, kinetics, muscle activation and energetic cost metrics.

**5. Conclusion**

Although the studies were somewhat weak in scientific rigor and had moderate risks of bias, this review has demonstrated that an AFO can make an immediate, short time improvement in the energy cost of walking phase, while the AFO is worn. Concerning the effects of long-term use of an AFO along with training, there was largely insufficient evidence to reach a valid conclusion. There were also insufficient data for comparison among different designs of AFOs.

Word count: 3593

**Declarations of interest:**

No conflicts of interest

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Table 1. Modified Downs and Black Quality Index Results, and Inter-Rater Reliability for Each Item and Total Score

| | **Report** | | | | | | | | **External Validity** | **Internal Validity- Bias** | | | | **Internal Validity – Confounding** | | | Power | **Total** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Quality Items** | Q1 | Q2 | Q3 | Q4 | Q6 | Q7 | Q9 | Q10 | Q11 | Q14 | Q15 | Q18 | Q20 | Q22 | Q23 | Q26 | Q27 | 17 possible |
| | **Hypothesis/Aim** | **Main Outcomes in Meth/Intro** | **Inclusion/Exclusion Criteria** | **Description of Interventions** | **Main Findings** | **Random Variability** | **Lost to Follow-up** | **Actual Probability Values** | **Representative of the Entire Population** | **Blind Study Subjects** | **blind those measuring** | **Statistical Tests Appropriated** | **Outcome Measures Used Accurate** | **same period of time** | **Random Allocation** | **Losses of Patients to Follow-up** | **Estimate of Statistical Power** | - |
| Farmani[30] | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 1 | 1 | 13 |
| Bleyenheuft[24] | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 1 | 0 | 12 |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kobayashi[31] | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 9 |
| Haruna[33] | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 9 |
| Hyun[23] | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 10 |
| Bregman[25] | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 10 |
| Maeda[21] | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 9 |
| Danielsson[20] | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 10 |
| Bregman[26] | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 9 |
| Thijssen[27] | 1 | 1 | 1 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 9 |
| Kon[32] | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 9 |
| Franceschini[22] | 1 | 1 | 1 | 0 | 1 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 9 |
| Erel[29] | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 1 | 1 | 12 |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Slijper[34] | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 11 |
| Everaert[28] | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 1 | 1 | 13 |

**1=YES, 0= NO, 0= Unable to determine**

Table 2: Characteristics of the Studies on the Effect of the Types of Lower Limb Orthoses on Energy Indices during Walking

| Author / Year | Study design and Samples | AFO Time (habitation before study) | Follow up after study | AFO Type | Walking Surfaces | Outcome Measures | Walking speed (m/s) | Duration (min) | Under SS condition | Main Outcomes |
|---|---|---|---|---|---|---|---|---|---|---|
| Farmani[30] | A randomized, parallel-group controlled design<br>30 individuals with chronic stroke, were able to walk independently without assistive devices, mean age=59.3 y, mean time from stroke=29.1mo, MAS=3<br>2 tests conditions in each group:<br>Group 1(n:15): SSh +RAFO and AFO only<br>Group 2(n:15): RSh+RAFO and AFO only | familiarization just before measurements in the laboratory | not followed up | RAFO | TM | Total energy cost (mL/kg/m) | -Group I:AFO only:29.75(8.07), AFO+SSh:24.14 (7.90)<br>-Group II: * AFO only: 24.6 (9.83), AFO+SSh: 26.34(10.28) | 5 | under SS | For group I, there were no significant changes in O2 cost when subjects wore SSh (*p*>0.05). For group II, oxygen cost (0.42 (0.16) vs. 0.51(0.04)), walking speed (0.71(0.32) vs. 0.60(0.18)) significantly decreased after wearing RSh (p=0.039*). Additionally, a significant difference was found between RSh and SSh in improvement of, energy cost and walking speed. |
| Bleyenheuft[24] | Randomized crossover trial.<br>10 individuals with chronic stroke , able to walk without assistance, mean age = 49 y, time from stroke = 28 mo<br>MAS: 1.5 | wearing a Chignon AFO<br>every day for at least a mo, whereas they just wore a few minutes before the walking tests | not followed up | – Chignon AFO<br>– PLS-AFO | TM | -Total mechanical work(J/kg/m)<br>-Net energy cost (J/kg/m) | -Shoe: 0.64( 0.25)<br>-Chignon AFO:0.81 (0.25)**<br>-PLS-AFO: 0.72 (0.25)** | n/r | under SS | A lower mechanical work was observed with both the Chignon AFO (0.61(0.23)) and the PLS-AFO (0.61(0.2)) than gait without an AFO (0.73(0.25); p=0.003*). The decrease in energy cost during walking by using AFOs (Chignon AFO: 4.8 [4.61 _ 5.41][a] ; PAFO: 4.77 [3.85_5.49][a]) was statistically close to significant compared with shoe only (5.48 [4.82 _ 6.4][a]) (p=0.06). The patients' walking speed was higher with the Chignon AFO (0.81(0.25)) than without it (0.64(0.25); p< 0.001). |

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|---|---|---|---|---|---|---|---|---|---|---|
| Kobayashi[31] | Pilot study<br>5 individuals with chronic stroke, able to walk without assistance, mean age = 36 y, time from stroke = 16 mo, MAS: 1 | Participants' own AFOs, time not<br>reported | not followed up | -PLS-<br>AFO(n:4<br>)<br>-Plastic<br>AFO-<br>PS(n:1) | OG | -Vertical displacement of COM (normalized to weight and body height) | -Shoe: 0.57 (0.30)<br>-AFO:0.76 (0.27)<br>* | - | - | The normalized vertical displacement of the COM on the affected leg during stance phase increased significantly using the AFO (0.56801) compared with footwear (0.56391) (*P* < .05). |
| Haruna[33] | Pilot study<br>5 individuals with chronic stroke, able to walk without assistance, mean age = 36 y, time from stroke = 16 mo<br>MAS: 1-2 | Subject's own AFOs, time: not reported | 3–4 weeks of continuous<br>Use of AFO-PR | 1:Subject's own AFOs<br>(AFO:PLS-AFO(n:4)<br>and AFO with metal<br>uprights(n:1))<br>2:AFO-PR | OG | -Mechanical energy (W/kg) based on the COM information including Power-y, Power-z, Power-ext, and %recovery | -Subject's own<br>Orthosis:0.45(0.026)<br>-Before continuous<br>use of AFO-PR:0.44(0.028)<br>-After continuous<br>use of AFO-PR: 0.51(0.024)* | - | - | An increased exchange rate of the kinetic energy and potential energy was observed for all patients. A larger increase of energy exchange was found on the non-paretic side, and after continuous use of the AFO-PR. A significant increase was noted for gait speed after continuous use of the AFO-PR, but not on the first day. |
| Hyun[23] | Randomized crossover trial<br>15 individuals with subacute stroke, the ability to walk at least 3 minutes with or without an aid, but without standby assistance, mean age = 62.1 y, time from stroke = 34.4days, ankle dorsiflexor muscle weakness grade of "less than fair" | Not reported | not followed up | RAFO | TM | -Total energy consumption or Vo2 (mL/kg/min)<br>-RER(Nu)<br>-HR(bpm)<br>-SBP(mm Hg)<br>-Exercise duration(s) | - | 3 | n/r | Using an AFO significantly decreased peak Vo2 (22.5(6.2) vs. 20.6(6.5)) result during the low-velocity, graded treadmill exercise stress tests relative to walking without an orthosis (p=0.02)*, but did not significantly affect other energy variables (p>0.05). |

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|---|---|---|---|---|---|---|---|---|---|---|
| Bregman [25] | Randomized crossover trial<br><br>4 individuals with chronic stroke, mean age = 51.3y, time from onset = 8.35, MAS ≤1 | CAFO prescribed within the previous three<br><br>years | not followed up | CAFO | OG | -Net energy cost (ml O2kg/m)<br><br>-Total net work (ankle, knee, hip) (J/kg/m) | -Shoe: 0.95 (.22)<br><br>-AFO: 1.04 (.24)<br><br>** | 6 | n/r | A significant decrease of 9.8% was found in energy cost when walking with the AFO (AFO: 0.17 (0.04), without: 0.19 (0.04), p< 0.05.). Net work around the ankle was reduced by 29%, but the total net work performed in the affected leg did not significantly change. |
| Maeda[21] | Non-Randomized crossover trial<br><br>18 individuals with chronic stroke, able to walk without assistance, mean age = 45 y, time from stroke = 19mo, MAS: not reported<br><br>BS: 3-5 | habituated to walking with a PAFO for 8 mo | not followed up | PAFO | OG | -Total energy consumption or VO2 (ml/kg/min)<br><br>-Total energy cost (ml/kg/m)<br><br>- HR(bpm)<br><br>-PCI(beats/m) | -Shoe: 0.38(0.2)<br><br>-AFO: 0.49 (0.2)<br><br>** | 6 | under SS | The difference in the VO2 (per min) and HR were not significant between walking with AFO and walking without AFO (AFO: 11.2(2.3), no AFO: 12.0 (2.3 )), but the reduction of energy cost (per meter) (AFO: 0.41 (0.17), no AFO: 0.63 (0.30)), PCI ) (AFO: 1.16 (0.71), no AFO: 1.53 (0.91)) and the increase of walking distance were significantly observed by AFO application (p<0.01). |
| Danielsson[20] | Non-Randomized crossover trial<br><br>10 individuals with chronic stroke, walking ability for at least 5 minutes without personal assistance, mean age = 52y, time from stroke = 23.2mo<br><br>MAS: 2–4 | habituated to walking with a CAFO for 12 mo | not followed up | CAFO | TM | -Net energy consumption or VO2 ( ml/kg/min)<br><br>-Net energy cost ( ml/kg/m)<br><br>-HR (bpm)<br><br>-RER(Nu) | -Shoe:0.27(0.03)<br><br>-AFO: 0.34 (0.06)<br><br>* | 5 | n/r | The energy cost was significantly lower in walking wearing the AFO (0.51(0.06) ml/kg/m) relative to walking without AFO (0.58(0.07) ml/kg/m) (p= 0.024). HR (AFO: 84.8 (3.9), no AFO: 84.8 (3.8)), RER (AFO: 0.83 (0.01)., no AFO: 0.82 (0.01)) and VO2 (per min) (AFO: 8.8 (0.5), no AFO: 8.6 (0.4)) did not differ significantly between the 2 conditions (p>0.05). |
| Bregman [26] | Randomized crossover trial<br><br>7 individuals with multiple sclerosis and chronic stroke, mean age = 57y, time from onset = 7.85, MAS ≤1 | Received their AFO during the previous three years | not followed up | PLS-<br><br>AFOs | OG | -Net energy cost (J/kg/m) | -Shoe: 0.74(0.36)<br><br>-AFO: 0.84(0.32)<br><br>* | 6 | n/r | The AFO use had a significant improvement in energy cost (AFO: 3.56 (1.78), shoe: 4.16 (1.48)) and walking speed (12%). |

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|---|---|---|---|---|---|---|---|---|---|---|
| Thijssen[27] | Randomized crossover trial<br><br>27 individuals with chronic stroke, were able to walk 5 minutes or more, mean age = 60y, time from onset = 4.9m, MAS: not reported | 18 subjects used an AFO, time not reported | 3week intervention | Orthosis with elastic straps that guide knee, hip and ankle | TM | Total energy cost per distance: oxygen uptake (mLO2/m) | - | 5 | n/r | Patients walked with three different walking speeds on a TM (PWS, PWS+30%, PWS-30%). The wearing orthosis immediately decreased energy cost during walking at the PWS (AFO: 42 (21), no AFO: 46(25), *P*<0.001). After Three-week familiarization to the orthosis (n=19), energy cost at the PWS and at PWS+30% was lower (*P*<0.05). |
| Kon[32] | A-B-A single-system design, pilot study<br><br>14 individuals with chronic stroke, were able to walk independently, used an AFO routinely on a daily basis, mean age = 59y, time from onset =ns, BS=4 | a three-mo trial period for matching | not followed up | AFO-PR+ heel pad | OG | -Energy conversion efficiency using COM information<br><br>-Vertical displacement of COM (normalized to weight and body height) | - | - | - | A heel pad attached to the AFO led in significant increase the upward energy conversion efficiencies, especially on the non-affected side, along with long-term effects in the affected-side COM height. |
| Franceschini[22] | Non-Randomized crossover trial.<br><br>9 individuals with chronic stroke, were able to walk independently for at<br><br>least 6 min with or without walking aids, mean age = 66.5y, time from onset = 244m, MAS: not reported | Participants' own AFO, time not reported | not followed up | AFO adjusted to<br><br>his or her kinesiological disorder | OG | -Total energy cost (mLO2/kg/m)<br><br>-Total energy consumption (mLO2/kg/min)<br><br>-HR (bpm)<br><br>-RER(Nu) (breaths/min) | -No AFO: 0.25(0.11)<br><br>-AFO:0.35(0.12)<br><br>** | 6 | n/r | The orthosis caused a significant decrease in energy cost (per meter) (0.49 (0.20) vs. 0.76 (0.412) ml O2/kg/m, p<0.01) during walking without a significant effect on cardiorespiratory parameters and energy consumption (per min) (p>0.05). |

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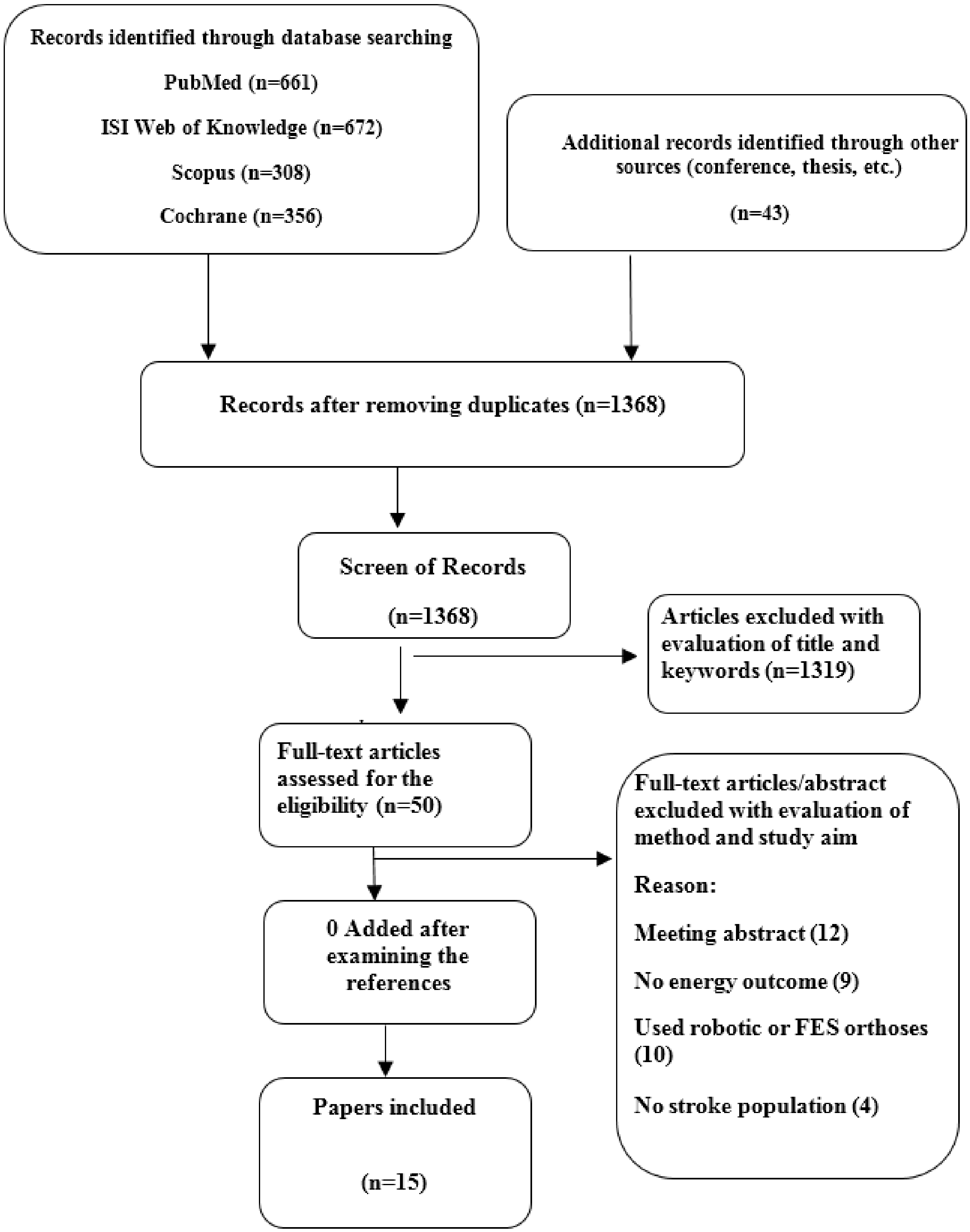
|---|---|---|---|---|---|---|---|---|---|---|
| Erel[29] | A randomized, parallel-group controlled design<br><br>28 individuals with chronic stroke (MAS≤3) were classified 2 groups, CG: age=50.64, time from stroke = 25.36mo,SG: age= 42.50, time from stroke = 30.21mo<br><br>CG: tennis shoe<br><br>SG: tennis shoe +AFO | Not used | three-mo follow-up | DAFO<br><br>(supramalleoler orthosis) based on tone-inhibiting orthosis | OG | -PCI | -CG ;before: 0.65 (0.19)<br><br>-After 3 mo: 0.72 (0.20)<br><br>-SG ;before: 0.84 (0.40)<br><br>-After 3 mo: 0.99 (0.45)* | n/r | n/r | After 3 mo, study group wearing DAFO showed significant improvements in terms of PCI (SG: 0.12(0.06), CG: 0.28(0.13) beats/min, p= 0.001) and walking velocity. |
| Slijper[34] | Non-Randomized crossover trial.<br><br>12 individuals with chronic stroke, able to walk for at least 6 minutes without personal assistance (walking aid was allowed), mean age=56y, mean time from stroke: 25mo, MAS: 0-3 | habituated<br><br>to walking (at least one week) with a DAFO and AFO-PS | not followed up | CAFO<br><br>AFO-PS | OG | -PCI (beats/m) | -CAFO: 0.55 (0.28)<br><br>-AFO-PS: 0.59 (0.25) | 6 | under SS | No statistically significant difference was seen between the two AFOs in PCI (DAFO: 1.08 (1.35), C-AFO: 1.17 (1.35), 95% CI: −0.27−0.95, p=0.320) and walking velocity (95% CI: −0.01−0.10, p=0.127), although the trend favored the AFO-PS in both instances. |
| Everaert[28] | Non-Randomized crossover trial.<br><br>24 individuals with chronic stroke, could ambulate at least 10 m with or without an assistive device, mean age=57y, mean time from stroke: 6.4 mo, MAS: not reported, FAC ≥4 | Not used | 12 weeks | a conventional AFO | OG | -PCI | -No AFO before training: 0.361 (0.264)<br><br>-No AFO after training:<br><br>-With AFO: 0.546(0.326) | 4 | n/r | After 12 weeks of wearing an AFO, PCI had a significant decrease compared with before using an AFO when walking with an AFO. Changes in PCI for walking when not wearing an AFO (therapeutic effect) after 12 weeks of gait training using an AFO was not significant. |

Y: year, mo: month, MAS: Modified Ashworth Scale, BS: Brunnstrom stage, SSh: standard shoe, RSh: rocker shoe, OG: overground, TM: treadmill, PWS: preferred walking speed, COM: center of mass, SBP: Systolic blood pressure, CG: control group, SG: study group, SS: steady-state, n/r: not reported, Nu: No unit, [a] Nonparametric data: median and interquartile range, values are reported as mean (SD). *p < 0.05. **p< 0.01.

Figure. 1. Flowchart Indicating the Selection of Articles through the PRISMA Method



**Implications for rehabilitation**

- An AFO can immediately improve the energy expenditure metrics during walking after stroke.
- Measurement of energetic parameters of walking wearing a orthotic device such as an AFO can evaluate gait economy in stroke populations.

## Supplementary Material

### Supplemental Appendix 1: Search strategies

### Search strategy for PubMed

((((((stroke) OR cerebrovascular) OR CVA) OR hemi*)) AND ((((((orthos*) OR AFO) OR orthotic) OR caliper) OR orthotic device) OR brace)) AND (((((((((((energy) OR energy cost) OR heart rate) OR energy expenditure) OR metabolic cost) OR center of mass) OR energy efficiency) OR mechanical work) OR oxygen) OR physiological cost index) OR energy consumption)

### Search strategy for Scopus

(ALL("stroke") OR ALL("cerebrovascular") OR ALL("hemi*") OR ALL("CVA")) AND (ALL("orthotic") OR ALL("orthos*") OR ALL("AFO") OR ALL("brace") OR ALL("caliper") OR ALL("orthotic device")) AND (ALL("energy") OR ALL("energy cost") OR ALL("heart rate") OR ALL("energy efficiency") OR ALL("oxygen") OR ALL("energy expenditure") OR ALL("metabolic cost") OR ALL("center of mass") OR ALL("mechanical work") OR ALL("physiological cost index") ALL("energy consumption"))

### Search strategy for Web of Science

(TS=("stroke") OR TS=("cerebrovascular") OR TS=("hemi*") OR TS=("CVA")) AND (TS=("orthotic") OR TS=("orthos*") OR TS=("AFO") OR TS=("brace") OR TS=("caliper") OR TS=("orthotic device")) AND (TS=("energy") OR TS=("energy cost") OR TS=("heart rate") OR TS=("energy efficiency") OR TS=("oxygen") OR TS=("energy expenditure") OR TS=("metabolic cost") OR TS=("center of mass") OR TS=("mechanical work") OR TS=("physiological cost index") OR TS=("COM") OR TS=("energy consumption"))

### Search strategy for Embase

('cerebrovascular' OR 'stroke'/exp OR 'hemiplegia'/exp OR 'hemiparesis'/exp OR hemiparetic OR cerebrovascular) AND ('brace'/exp OR 'orthosis'/exp OR 'orthotics'/exp OR 'ankle foot orthosis'/exp OR afo OR 'caliper'/exp OR orthoses OR 'orthotic device') AND ('energy cost'/exp

OR 'heart rate'/exp OR 'energy expenditure'/exp OR 'metabolic cost'/exp OR 'center of mass'/exp OR 'energy efficiency'/exp OR 'mechanical work' OR 'oxygen'/exp OR 'physiological cost index'/exp OR 'energy consumption'/exp)

## Search strategy for Cochrane Central

"( Stroke OR Cerebrovascular accident OR hemi*OR CVA) AND ( Brace OR Orthotic Device OR AFO OR orthos*OR Orthotic caliper ) AND ( Energy OR Oxygen OR Heart Rate OR Oxygen Consumption OR energy cost OR energy expenditure OR metabolic cost OR center of mass OR mechanical work OR mechanical work OR physiological cost index)"

**Supplemental Appendix 2: List of excluded papers**

| Author (year) | Title | Reason for exclusion |
|---|---|---|
| Lee(2018) | A novel hinged ankle foot orthosis for gait performance in chronic hemiplegic stroke survivors: a feasibility study | No energy outcome |
| Moein (2017) | Evaluating the efficacy of an active compression brace on orthostatic cardiovascular responses. | Meeting abstract |
| Kobayashi(2017) | An articulated ankle-foot orthosis with adjustable plantarflexion resistance, dorsiflexion resistance and alignment: A pilot study on mechanical properties and effects on stroke hemiparetic gait | No energy outcome |
| Sarabadani (2017) | Distinctive Steady-State Heart Rate and Blood Pressure Responses to Passive Robotic Leg Exercise during Head-Up Tilt: A Pilot Study in Neurological Patients. | Used robotic or FES orthoses |
| Kobayashi(2017) | Effect of Shoes on Stiffness and Energy Efficiency of Ankle-Foot Orthosis: Bench Testing Analysis | No stroke population |
| Lv (2016) | Experimental Implementation of Underactuated Potential Energy Shaping on a Powered Ankle-Foot Orthosis. | Meeting abstract |
| Awad (2015) | Walking speed and step length asymmetry modify the energy cost of walking after stroke | Meeting abstract |
| Fujii(2015) | Effect of short-term exercise-heat acclimation on ventilatory and cerebral blood flow responses to passive heating at rest in humans. | Meeting abstract |
| Yen (2015) | Using swing resistance and assistance to improve gait symmetry in individuals post-stroke. | Meeting abstract |
| Jeong (2015) | Which type of cane is the most efficient, based on oxygen consumption and balance capacity, in chronic stroke patients? | Meeting abstract |

| | | |
|---|---|---|
| Schiemanck(2015) | .Effects of implantable peroneal nerve stimulation on gait quality, energy expenditure, participation and user satisfaction in patients with post-stroke drop foot using an ankle-foot orthosis | Used robotic or FES orthoses |
| Schiemanck(2015) | Effects of implantable peroneal nerve stimulation on gait quality, energy expenditure, participation and user satisfaction in patients with post-stroke drop foot using an ankle-foot orthosis. | Used robotic or FES orthoses |
| Schiemanck(2015) | peroneal nerve stimulation on gait quality, energy expenditure, participation and user satisfaction in patients with post-stroke drop foot using an ankle-foot orthosis | Used robotic or FES orthoses |
| Schiemanck(2015) | Effects of implantable peroneal nerve stimulation on gait quality, energy expenditure, participation and user satisfaction in patients with post-stroke drop foot using an ankle-foot orthosis. | Used robotic or FES orthoses |
| Rahman(2014) | Asymmetrical Performance and Abnormal Synergies of the Post-Stroke Patient Wearing SCRIPT Passive Orthosis in Calibration, Exercise and Energy Evaluation | Used robotic or FES orthoses |
| Menotti (2014) | Comparison of walking energy cost between an anterior and a posterior ankle-foot orthosis in people with foot drop | No stroke population |
| Kluding (2013) | Foot Drop Stimulation Versus Ankle Foot Orthosis After Stroke | No energy outcome |
| Armstrong (2012) | Heart rate variability and baroreceptor sensitivity following exercise-induced hyperthermia in endurance trained men. | Meeting abstract |
| Lewek(2012) | The Influence of Mechanically and Physiologically Imposed Stiff-Knee Gait Patterns on the Energy Cost of Walking | Meeting abstract |
| Patzkowski (2011) | Can an ankle-foot orthosis change hearts and minds? | No energy outcome |
| Maeshima(2011) | Efficacy of a hybrid assistive limb in post-stroke hemiplegic patients: a preliminary report | Used robotic or FES orthoses |
| Bregman (2011) | The effect of ankle foot orthosis stiffness on the energy cost of walking: A simulation study | No stroke population |
| Ward(2011) | Stroke Survivors' Gait Adaptations to a Powered Ankle Foot Orthosis. | Used robotic or FES orthoses |
| Ibuki (2010) | An investigation of the neurophysiologic effect of tone-reducing AFOs on reflex excitability in subjects with spasticity following stroke while standing | No energy outcome |
| Magagnin(2010) | Effects of robot-driven gait orthosis treadmill training on the autonomic response in rehabilitation-responsive stroke and cervical spondylotic myelopathy patients. | Meeting abstract |
| Stein(2010) | Long-term therapeutic and **orthotic** effects of a foot drop stimulator on walking performance in progressive and nonprogressive neurological disorders. | Used robotic or FES orthoses |
| Tyson (2009) | Assistive Walking Devices in Nonambulant Patients Undergoing Rehabilitation After Stroke: The Effects on | No energy outcome |

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|---|---|---|
| | Functional Mobility, Walking Impairments, and Patients' Opinion | |
| Abe (2009) | Improving gait stability in stroke hemiplegic patients with a plastic ankle-foot orthosis | No energy outcome |
| Roehrig (2008) | Effects of a new orthosis and physical therapy on gait in a subject with longstanding hemiplegia. | No energy outcome |
| Masuki (2007) | Reduced stroke volume during exercise in postural tachycardia syndrome. | No energy outcome |
| Krewer (2007) | The influence of different Lokomat walking conditions on the energy expenditure of hemiparetic patients and healthy subjects | Used robotic or FES orthoses |
| Van Peppen(2004) | The impact of physical therapy on functional outcomes after stroke: what's the evidence? | Meeting abstract |
| Van Peppen(2004) | The impact of physical therapy on functional outcomes after stroke: what's the evidence? | Meeting abstract |
| Chon(2000) | Comparison of Gait Analysis and Energy Consumption between Various Types of Plastic Ankle Foot Orthoses in Hemiplegic Patients. | Meeting abstract |
| Fowler(1993) | Energy cost of ambulation with different methods of foot and ankle immobilization | No stroke population |
| Waters(1999) | The energy expenditure of normal and pathologic gait. | Meeting abstract |