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The Orthotic Effect of Functional Electrical Stimulation on the Improvement of Walking in Stroke Patients with a Dropped Foot: A Systematic Review

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Abstract: *Objective* Analysis of the available evidence on the improvement of walking in stroke patients with a dropped foot when using peroneus stimulation. *Methods* A systematic review was performed to identify trials that investigated the orthotic effect of functional electrical stimulation (FES) on walking in stroke patients with a dropped foot. Two independent raters scored the methodological quality of the included articles. Walking speed and physiological cost index (PCI) were selected as the primary outcome measures. Studies that measured walking speed were pooled and a pooled difference including confidence interval was calculated. *Results* Eight studies were included in the review, of which one was a randomized controlled trial. Methodological score ranged from 8 to 18 out of 19. Six studies measured walking speed. The pooled improvement in walking speed was 0.13 m/s (0.07–0.2) or 38% (22.18–53.8). *Conclusions* The present review suggests a positive orthotic effect of functional electrical stimulation on walking speed. **Key Words:** Equinovarus—Peroneal nerve—Electrical stimulation—Hemiplegia—Gait.

Stroke is a major illness in Western countries with huge disabling consequences. The incidence of stroke in the Netherlands is approximately 30 000 (1 : 542) per year and the prevalence is 120 000 patients (1). A stroke causes impairment of the cognitive, sensory, perceptive, and motor functions. A rather common motor impairment is a dropped foot, which is characterized by the inability to dorsiflex the ankle, leading to insufficient toe clearance during walking. This impairment, in combination with commonly seen low selectivity of hip and knee in this patient group results in an abnormal gait, consisting of hip hitching, circumduction, and toe catch, also called equine gait (2). Walking speed is impaired and there is a higher chance of stumbling and falling.

An estimated 20% of the population with partial recovery have a dropfoot (2). Out of 120 000 stroke survivors in the Netherlands, 75% recover only partially, that is 90 000 patients. This group of 90 000 includes approximately 18 000 patients with a dropped foot.

The conventional treatment of drop foot is a splint, usually a custom fitted ankle-foot orthosis (AFO), which is a plastic support worn inside the shoe to maintain the ankle joint in a neutral position, and occasionally a more substantial splint attached to the shoe. This treatment has limitations, being both uncomfortable and awkward to use (3).

In 1961, a new method for correction of dropfoot by means of electrical stimulation was introduced by Liberson (4). The stimulation was applied via electrodes on the skin and was synchronized with the gait phase by a heel-switch worn in the shoe. Stimulation was turned on when the heel was lifted at the beginning of the swing phase. It then produced dorsiflexion and eversion of the ankle joint. Stimulation was turned off when the heel was on the floor again.

A number of (theoretical) advantages of FES in comparison to an orthosis can be mentioned. The active contraction of the muscles stimulates the blood circulation, there is better afferent feedback, walking distance is increased, the stimulator is not custom made like an AFO and thus more applicable

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to a wide range of people, and finally the stimulator is cosmetically better accepted (5). In addition, Merletti mentions that walking with FES implies a more energy efficient use of the hip and knee muscles by avoiding the need for compensatory movements (6). However, the FES system is more sensitive to disturbance and its application requires more time because of the placement of surface electrodes.

FES is not appropriate for all stroke patients with a dropped foot. The patient has to be well motivated, able to stand and walk either alone or with minimal assistance, and the muscles that raise the foot should not be denervated. Contraindications are communication disorders, irritation of the skin, and limited range of movement. The use of FES is not widespread and the total number of patients being treated remains quite small. This can be attributed to several reasons, such as technical limitations and unfamiliarity with FES in many countries. Technical limitations associated with the use of surface stimulators concern the lack of selectivity over the muscles and nerves recruited, the sensitivity of muscle recruitment to electrode placement, and pain and tissue irritation associated with the passage of current through the skin (7).

In order to improve the selectivity upon stimulation responses, implantable systems are being developed (7–9). In contrast to the one-channel implantable stimulator, the two-channel stimulator provides separate control of the dorsiflexion and eversion movement by stimulating both deep and superficial peroneal nerves, respectively. For more information about technical developments the reader is referred to a review by Lyons et al. (10). Preliminary trials have shown that it is possible to balance the foot well between inversion and eversion (8). The principle aim of implantable systems is to establish an orthotic effect rather than producing motor relearning effects. When motor relearning is the main goal, surface stimulators are more indicated.

Although the concept of FES of the peroneus nerve has existed for more than 40 years, there is no hard evidence for the positive clinical effects of this treatment.

Glanz et al. (11) performed a meta-analysis to assess the efficacy of FES on the force of the paretic muscles in the rehabilitation of stroke patients. They concluded that pooling from randomized trials supports FES as promoting recovery of muscle strength after stroke. A second review was carried out by Burridge et al. (12), who focussed on the orthotic and/or therapeutic effect of FES for the correction of dropped foot in subjects suffering from upper motor neuron lesions. However, their review had a descriptive character and study data were not pooled. Another aspect is that only surface stimulators to correct dropped foot were included. Their conclusion was that patients who benefit from FES, experience sufficient improvement in the speed and quality of walking to increase independence significantly.

The present systematic review was carried out to establish the available evidence of the orthotic effect of peroneus nerve stimulation on walking speed. All types of stimulation approaches were included, i.e., surface and one- and two-channel implants. The orthotic effect is defined as the effect that occurs during stimulation while the therapeutic (carry-over) effect is the effect that remains even after the stimulator has been removed (12). The primary outcome measures selected from the present study are walking speed and Physiological Cost Index (PCI), which is a measure for energy cost.

METHODS

Literature search

A literature search was performed in PubMed, in the Database of Abstracts of Reviews of Effectiveness (DARE), Cochrane database, NHS Economic Evaluation Database (NHS EED), and the Health Technology Assessment Database (HTA) from the NHS Centre for Reviews and Dissemination of the University of York, U.K. The PubMed database includes literature from 1966 up to 2003. The following keywords were used separately and combined in PubMed: cerebrovascular accident, electric stimulation, electric stimulation therapy, rehabilitation, recovery of function, peroneal nerve, muscle spasticity, walking, comparative study, cost-benefit analysis, and evaluation study. In the other databases, the previous terms and the following additional terms were used: dropfoot, dropped foot, ankle dorsiflexion, hemiplegia, FES, functional electric stimulation, peroneus, and stroke.

Studies were included if they met the following criteria: (1) functional electrical stimulation of the peroneal nerve should be applied to stroke patients with a dropped foot to improve walking; (2) transcutaneous or implantable stimulators should have been used; (3) comparative trial design, comparing FES with either another treatment or baseline status; (4) studies examining an orthotic effect or both an orthotic and therapeutic effect; and (5) full-length articles in English or Dutch language published between 1966 up to 2003. To support our evidence we also looked for suitable proceedings of FES con-

ferences that reported on the effect of peroneal nerve stimulation on improving walking. Because proceedings have not passed a peer-review process, it was decided not to include them in the pooled analysis. However, suitable proceedings will be described in the discussion section of the present review.

Assessment of methodological quality

As almost no randomized controlled trials with regard to peroneal nerve stimulation have been performed it was not possible to adopt the standard set of methodological criteria. Instead, we adapted the set in order to be able to summarize both controlled and uncontrolled trials. Eventually, a list of 16 criteria was used concerning patient selection, intervention, outcome measurement, and statistics (Appendix 1). Two raters assessed the methodological quality of the included studies independently (AK, LO). In case of disagreement, consensus was reached by consulting a third rater (MY). All criteria that were answered with yes scored 1 point, with the exception of criteria 3, where the score varied from 1 to 3 points. When criteria 3a, b, or c was answered with yes they, respectively, scored 3, 2, and 1 point. By doing so, we accounted for the difference in methodological superiority of controlled vs. noncontrolled trials. This was done because, from a methodological point of view, a randomized controlled trial is better than a crossover design and a crossover design is better than an observational study design. The maximum score that could be reached was 19. Because proceedings failed to meet the criteria that they should be full-length publications, methodological scores were not determined for them.

Data extraction

Data was extracted from the articles and categorized using the following items: study design, patients, intervention, training, variables, measurements, statistics, and miscellaneous. Then an inventory was made of the different outcome measures. A selection was made between clinical measures, i.e., walking speed, PCI, and intermediate outcome measures, e.g., gait kinematics and spasticity.

Data analysis

Walking speed at a self-selected pace and PCI were considered to be the primary outcome measures. Walking speed changes in each of the articles were summarized and a pooled difference was estimated using a "random effects"-model (13). This statistical model is used in meta-analyses when both within-study sampling error (variance) and between-studies variation are included in the assessment of the uncertainty (confidence interval) of the results. Random effects models give wider confidence intervals than fixed effects models when there is significant heterogeneity among the results of the included studies.

RESULTS

Selection of literature

The systematic literature search in PubMed resulted in the identification of 33 articles. The search in the other databases did not yield additional articles. Twenty-five studies were excluded from this review. Reasons for exclusion were that the study was not specifically about stroke patients (14–21), the study was not specifically about dropfoot (11,22–27), the study did not report on FES (28,29), and the study was not a comparative trial (3,30–32). Two articles were about the same study and the second article did not yield additional information (33). The publications from Liberson, Buurke, and Zilvold (4,5,34) failed to meet the inclusion criteria that it should have been full-length publications written in Dutch or English between 1966 and 2003.

Eight studies fulfilled the selection criteria and were included in the present review (Table 1) (2,6–8,35–38).

In addition, three proceedings from the IFESS conference (2000) were found that report the effect of peroneal nerve stimulation on walking speed in chronic stroke patients (9,39,40).

Characteristics of the included studies

Patients

The number of patients included in the selected studies ranges from 2 to 56, with a total of 203 patients. In five studies, chronic patients were included (2,7,8,36,38), in one study both chronic and subacute patients were included (6), and in two studies, chronic, subacute, and acute patients were included (35,37). The first 2 weeks after the cerebrovascular accident has been defined as the acute phase, the period between 2 weeks and 6 months after the accident as the subacute phase, and the period after 6 months has been defined as the chronic phase. In total, 10 patients were in the acute stage, 17 patients in the subacute stage, and 176 patients in the chronic stage after stroke.

Two of the studies were carried out in hospitalized patients (35,38). Three patients dropped out in two studies each (37,38). Of 203 patients, 101 were males, 44 were females, and in 58 cases the gender was not

TABLE 1. *Characteristics of included studies*

Author	Waters (7)	Merletti (6)	Stefanovska (38)	Bogataj (35)	Granat (37)	Burridge (36)	Burridge (2)	Kenney (8)
Study design	**Before/with**	**Before/with**	**Before/with**	**Crossover**	**Crossover**	**With and without FES**	**Experimental (RCT)**	**Before/with**
Patients								
Number (dropout)	16	50 (3)	8	20	19 (3)	56	32	2 (0)
Type	12/16 CVA	CVA	5/8 CVA	CVA	CVA	50/56 CVA	CVA	CVA
Age (sd) (range)	49.3 (11.3)	57.3 (12.9)	45.4 (5.9)	56.3 (10.4)	57.8 (9.4)	54 (12)	56.8 (16.6)	[31–48]
Stage after stroke	Chronic	Chronic	Subacute + chronic	Acute + subacute + chronic	Acute + subacute + chronic	Chronic	Chronic	Chronic
Gender	8 male 8 female	36 male 14 female	7 male 1 female	11 male 9 female	16 male 3 female	Not mentioned	23 male 9 female	Not mentioned
Paretic side	Not mentioned	14 right 36 left	5 right 3 left	9 right 11 left	12 right, 7 left	27 right 29 left 1 bi	17 right 15 left	Not mentioned
Intervention								
Treatment	FES: implanted	FES: transcutaneous	FES: implanted	FES: transcutaneous	FES: transcutaneous	FES: transcutaneous	FES: transcutaneous	FES: implanted
Control	No control group	No control group	No control group	Conventional therapy	Physiotherapy	No control group	Physiotherapy	No control group
Compared to	AFO	No aid	No aid	No aid	No aid	No aid	No aid	No aid
Training								
Location	At home	Hospital	At home	Hospital	At home	At home	At home	At home
Duration	6 months	1–9 weeks	6 months	3 weeks	4 weeks	3 months	12–13 weeks	20 weeks
Intensity	Daily, individually	5 days/week, mean 14 h	2 h/day	5×/week 30min-1 h	Daily, individually	Daily, individually	Daily, individually	Daily, individually
Outcome measure								
Clinical endpoint	Walking speed			Walking speed	Walking speed	Walking speed PCI	Walking speed PCI	Walking speed
Other outcome	Stride length	Spasticity plantarflexors	Max. isometr. torque:	Distance	Heel strike, inversion	Functional mobility		Endurance
	Cadence, EMG	O_2 consumption	Dorsal/plantarflexion	Number of strides, mean stride time	Symmetry			Isometric torque
		Kendall scale: dorsiflexion, eversion	Resistive torque pas.mov.	Temporal symmetry, mean stance time, Fugl-Meyer ground reaction forces				
Measurements								
Moments	Every 3 months	Every 2 weeks	Every 6 months	Every 3 weeks	0, 6 weeks, 11 weeks	6 weeks, 3 months, every 6 months	0, 4–5 weeks, 12–13 weeks	0, 32 weeks
Baseline	With + without orthosis	Without aids	Surf. stim. 30 min/day, 2–3 week	Not mentioned	Usual aids	With and without FES	Usual aids + FES	With/without Usual aids
Follow-up	With + without FES	With + without FES	Without FES	After MFES + conv therapy	With + without FES	With and without FES	With + without FES	With FES
Statistics	Not mentioned	Student's *t*-test	Not mentioned	MANOVA Friedmans' ANOVA	ANOVA, paired *t*-test Wilcoxon	Paired *t*-test Fisher's exact test	Wilcoxon, Mann–Whitney, Chi-square, Spearman	Not mentioned

mentioned. Paretic side was mentioned in six studies (2,6,35–38). Right hemiparesis was mentioned in 84 patients, left hemiparesis in 101 patients, and in 18 cases the side was not mentioned.

Study designs

Three different designs were used: one randomized controlled trial (RCT) (2), two crossover studies (35,37), and five times a within-subject comparison (6–8,36,38).

The method of FES varied between the studies. In five studies transcutaneous stimulation was used (2,35–38) and in the other three studies implantable stimulation was applied (6–8).

In five studies, the patient could use the stimulator every day at home (2,7,8,36,37). In three studies this was not the case. In the study of Stefanovska patients had a limit of 2 h/day to use the stimulator, Bogataj used treatment sessions of 30 min to 1 h for 5 days per week and the patients in the study of Merletti used the stimulator for 1–4 h for 5 days per week.

Outcome measures

In the eight included studies a total of 20 different outcome measures were used. Walking speed was measured in six studies (2,7,8,35–37) and PCI was measured in two studies (2,36). Both Merletti and Stefanovska do not have walking speed or PCI as outcome parameters in their study.

In the present study, walking speed and PCI are considered to be the primary clinical endpoints. The other outcome measures like endurance, gait kinematics, gait kinetics, torque measurements, spasticity, EMG, and O_2 consumption are considered intermediate outcome measures.

Methodological quality

Scores for methodological quality ranged from 9 to 18 out of 19 (Table 2). There was a disagreement between both raters in 9.9% of the items. Consensus on these items was reached by a third rater. The RCT of Burridge (2) and the cross-over study by Granat (37) were methodologically the best articles both with a score of 18 points. The cross-over study of Bogataj (35) reached the next highest score, which scored 15 out of 19 points.

Effect of functional electrical stimulation on walking speed

Table 3 shows the measured walking speeds with and without FES and the difference between both measurements. Six of the eight studies measured comfortable walking speed (2,7,8,35–37). It was not possible to calculate differences in walking speed for all studies due to insufficient data presentation (8,36). Correspondence with the authors failed to provide the missing data.

In both studies performed by Burridge (2,36) a 10-m walking test was used to measure walking speed. One meter was allowed at the start and finish of the walkway for acceleration and deceleration. In the study of Granat (37) the length of the recorded walk path was either 6 or 10 m, dependent on the ability of the participating patient. They used a 1.5 m lead-in and run-out of the test walk path instead of 1 m. Also in the study of Kenney (8), a 6-m test was used in both included patients. Bogataj (35) measured walking speed over a distance of 20 m and Waters (7) did not mention how they measured walking speed. All studies measured walking speed three times, with the exception of the study of Granat (37), who measured walking speed five times. Waters (7) again did not give information about this.

In three studies, a significant improvement in walking speed was found (2,7,35). Two other studies only reported the percentage difference without providing a measure of variability (8,36) and the last study did not show a significant change (37). This study, performed by Granat and colleagues, was the only study that found a small decrease in walking speed after the treatment period, from 0.94 to 0.93 m/s.

TABLE 2. *Overview of methodological scores of each of the articles. The scores are separated for each part of the list (maximum methodological score)*

Author	Total (19)	Part 1* (5)	Part 2† (4)	Part 3‡ (6)	Part 4§ (4)	Disagreement
Waters (7)	12	2	3	4	3	2
Merletti (6)	14	3	3	4	4	1
Stefanovska (38)	9	1	3	4	1	2
Bogataj (35)	15	4	3	4	4	1
Granat (37)	18	5	3	6	4	2
Burridge I (36)	13	3	1	6	3	2
Burridge II (2)	18	5	3	6	4	2
Kenney (8)	9	1	2	5	1	3

*Patient selection; †Intervention; ‡Outcome measures; §Statistics.

TABLE 3. *Walking speed*

Author	*n*	Methodological quality	Stimulator	Before (m/s) mean (sd)	After (m/s) mean (sd)	Difference (m/s) mean (sd)	Difference (%) mean (95% CI)
Waters (7)*	16	12	Implanted	0.58 (0.25)	0.79 (0.26)	0.21 (0.1)	36 (16.7–55.7)
Bogataj (35)†							
C	10	15	Transcutaneous	0.23 (0.13)	0.26 (0.11)	0.20 (0.07)	104 (59.4–149.2)
I	10			0.19 (0.09)	0.41 (0.21)		
Granat (37)‡	16	18	Transcutaneous	0.94 (0.63)	0.93 (0.59)	–0.01 (0.21)	–0.8 (–46.2–44.6)
Burridge I (36)§	56	13	Transcutaneous	—	—	—	14
Burridge II (2)#							
C	16	18	Transcutaneous	0.48 (0.25)	0.51 (0.27)	0.1 (0.04)	14 (–36.4–64.5)
I	16			0.64 (0.46)	0.77 (0.43)		
Kenney (8)¶	2	9	Implanted	—	—	—	27

*Before with orthosis, after with stimulation.
†Difference between assessment 1 (baseline) and 2 (C: conv. therapy, I: conv. therapy and FES).
‡Linoleum surface, session 2 is used as before, session 3 with PS as after.
§After 3 months, difference between with and without stimulation.
#Before FES group without stimulation, after FES group with stimulation.
¶Mean of two subjects.
C, control group; I, intervention group.

The pooled improvement in walking speed was 0.13 m/s (0.07–0.2) or 38% (22.18–53.8).

Figure 1 shows the effect of the stimulator on walking speed for each of the articles with its mean and the 95% confidence interval. The methodological score is included in brackets. There seems to be no clear relation between methodological quality of the studies and the reported effect of functional electrical stimulation.

Effect of functional electrical stimulation on Physiological Cost Index (PCI)

Two of eight studies, both carried out by Burridge, measured PCI (2,36). The first study showed a decrease of 39.5% in PCI, comparing PCI with and without stimulation after 3 months. There was no significant change in PCI over 3 months either with or without the stimulator. The second study, which was a RCT, showed an improvement of 24.9% in the FES group when the stimulator was used, in a period of 12–13 weeks. Improvement was also measured in the control group with a reduction of 1% in PCI.

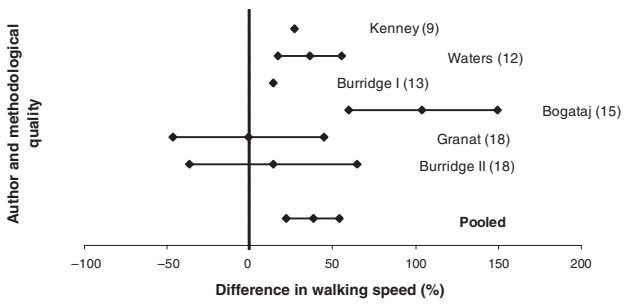

FIG. 1. Methodological quality and difference in walking speed (%). Mean and 95% confidence interval is presented.

DISCUSSION

In the present review, the results of eight studies were analyzed in order to assess the orthotic effect of FES on the improvement of walking in stroke patients with a dropped foot. Six of the eight studies measured walking speed and five of them suggest a positive effect of FES on walking. These studies, with the exception of the study performed by Waters, made a comparison between walking with and without stimulation. Waters and associates made a comparison between walking speed preoperative with an orthosis and walking speed after surgery with stimulation. They found that walking speed was increased significantly (36%) by stimulation (7).

In conclusion, FES seems to have a positive orthotic effect on walking, also when compared with the conventional treatment. The type of stimulator (i.e., transcutaneous or implanted) seems not to influence the walking speed.

Also the proceedings, which were not included in the pooled analysis, showed a positive effect of peroneal nerve stimulation on walking speed. Haugland and colleagues (9) found that the orthotic effect on walking speed seen with an external stimulator was variable, probably depending on the exact placement of the electrodes, but for an implanted stimulator was almost constant and at the level of the strongest effect obtained with the external stimulator. No therapeutic effect was found.

In a study performed by Matsunaga et al. (39), all six patients were able to walk faster and longer when using the stimulator system. Their patients showed a mean improvement of 14.8% in walking speed.

Mann and colleagues (40) also measured the effect of peroneal nerve stimulation alone, but then also in

combination with stimulating a second channel. Selection of the second muscle group was based on clinical observation. Their results indicate a significant therapeutic and orthotic effect on walking speed from using a second channel of stimulation, greater than that achieved with single channel stimulation alone.

Choice of patients

Only 6 of 203 patients dropped out, which is quite remarkable. Two studies described how almost all patients continued to use the stimulator after the trial had ended (2,36). These findings might indicate that the use of the stimulator is not too difficult and patients are satisfied with the effects. Another explanation might be that the selection procedure for patients was successful. It is well known from the literature that "FES" is a useful orthotic device for a selected subpopulation of hemiplegic patients. According to Merletti and colleagues (6) and Gracanin (41), about 20% of the ambulant hemiplegic population benefits from common peroneal nerve stimulation during the rehabilitation period. Granat (37) concludes that a stimulator applied in the late stage of rehabilitation would be helpful to a few patients (2%), particularly in patients with mediolateral instability of the foot and reduced ground clearance in swing leading to forefoot contact. According to Burridge (2) and Waters (7) the stimulator does not work for everyone, although they did not mention which criteria a patient should fulfill to be suitable. Carnstam et al. (14) found that careful selection led to a 94% success rate.

In conclusion, there seems to be no consensus about subgroup-specific effects of peroneal nerve stimulation. There is an idea that people with higher initial walking speed perform better than people with lower initial walking speed. However, this could not be confirmed in the present study, because individual walking speed data was not mentioned in the included studies. Only the study performed by Bogataj and associates (35) reported the individual walking speed data of all participants. These data showed no distinct relation between the initial walking speed of patients and their improvement after the use of FES.

Included studies

Unfortunately, literature justifying the use of stimulation to correct dropped foot is mainly based on case studies, uncontrolled trials, and retrospective reviews. In the present review only one RCT was included (2), which is obviously the most reliable design to separate specific from nonspecific effects. They have become the gold standard for the evaluation of treatment efficacy (42–44). Five of the eight included studies were open label studies, which means that there was no control group (6–8,36,38). The two remaining studies were crossover studies (35,37), whose designs could be a problem in comparative trials using FES, because of a possible carryover effect (45).

For the present review it was assumed that although nonrandomized studies have methodological problems, they could actually produce effect sizes as generated in randomized studies. In this review, most of the patients (176/203) were in the chronic stage after stroke. The chance of spontaneous recovery in these patients is negligible so an observed effect can not easily be attributed to this. Therefore, correction for natural recovery by randomization does not seem to be essential. Two studies measured not only chronic stroke patients, but also acute and subacute patients (35,37). Particularly remarkable is the difference in walking speed measured at baseline between both studies. The difference between Bogataj (35) and Granat (37) is 0.73 m/s or 3.5 times faster (Table 3). Bogataj did not mention details of baseline measurements so the difference cannot be explained by baseline measurement or selection procedure.

The pooled analysis of both controlled and uncontrolled trials showed an improvement of 38% in walking speed with a confidence interval of 22.18–53.8%.

Perry et al. (46) made a classification of walking handicap in the stroke population. They described how the least limited community walkers should walk with a mean velocity of 0.58 m/s. Unlimited community walkers should walk with a mean velocity of 0.8 m/s. So, an improvement of 0.22 m/s is clinically relevant according to Perry. Stroke patients who normally use a peroneus stimulator, especially those who use an implantable stimulator, are relatively good patients and are not very limited in their daily activities. The studies performed by Waters (7) and Bogataj (35) managed to approach this size of improvement. They measured a mean improvement of, respectively, 0.21 m/s and 0.20 m/s.

An alternative way of looking at the results is to consider the percentage change. Burridge et al. (2) decided that a 10% improvement in walking speed was considered to be functionally relevant. In the present study, this improvement is reached by all studies, with the exception of the study performed by Granat (37), who measured a worsening in walking speed of –0.8%.

Orthotic vs. therapeutic benefit

The present review was only focussed on the orthotic effect of FES on walking speed in stroke patients with a dropped foot.

Another interesting aspect to investigate is the possible therapeutic or carryover effect of FES, which can be defined as the benefit gained following a period of stimulation. Liberson and associates noted that when footdrop was corrected in hemiplegic patients by means of electrical stimulation using cutaneous electrodes, some retained the ability to dorsiflex for varying lengths of time after stimulation was stopped (4). Waters et al. (7) observed the same phenomenon in some of their patients. They found an improvement in gait velocity without stimulation, compared with the velocity without an orthosis before surgery. The testing of these patients took place immediately after walking with stimulation. The review of Burridge et al. (12) also concluded that some studies (14,47,48) reported a carryover effect, which consisted of increased voluntary movement and reduced spasticity, but that it is unclear how this occurs, whether this effect is permanent, or how suitable patients can be identified. Many of the included studies were with small samples and few used convincing methodology.

Overall, the literature shows no convincing therapeutic effect of peroneal nerve stimulation. When realization of a therapeutic effect is the main goal, which might especially be the case in acute stroke patients, surface stimulators are more indicated than implantable stimulators. Surface stimulators are therefore useful devices for gait training in acute patients at rehabilitation centers. Due to the difficulties involved in proper electrode placement, training in the home situation is often cumbersome in the beginning. Good instructions from a care professional are needed for this. Another advantage of using the stimulator at home is that therapy duration is not limited, so that patients can practice as much as they want. The prescription of an implantable peroneal nerve stimulator is only a treatment option when the main goal is to realize an orthotic effect for the longterm in drop foot patients. In these patients, an implantable stimulator offers greater comfort when compared to a surface stimulator.

Conventional treatment

In the present review, only three of the eight studies included a control group (2,35,37). The control group in the study of Burridge (2) and Granat (37) both received physiotherapy. As only Granat described the patients as receiving their normal physiotherapy during the control period, it was not possible to examine if there was a difference in treatment intensity between both studies. The conventional treatment in the study of Bogataj (35) was much more comprehensive, consisting of physical therapy, medical treatment, occupational therapy, speech therapy, sessions with a psychologist, sessions with a social worker, and a cultural program. These studies show that different conventional treatments exist with a large variation in intensity to treat stroke patients with a dropped foot, which makes it difficult to compare their results.

Dropped foot is conventionally corrected by splinting. As far as we know, only one (placebo-controlled) randomized clinical trial (49) has been performed to examine the effect of an AFO on walking ability in stroke patients. Beckerman et al. included 60 patients and they combined treatment with a polypropylene AFO, thermocoagulation (TH), placebo-AFO, and placebo-TH treatment, which resulted in four groups. The results show that the efficacy of both therapeutic interventions appears to be neither statistically significant nor clinically relevant. Only in the AFO group was there a small but clinically irrelevant increase of 0.1 m/s in comfortable and maximum walking speed in comparison with the placebo-AFO group. Also, two thirds of all included patients were unsatisfied with the use of the AFO, as measured with the Sickness Impact Profile.

An interesting aspect that has not been clarified yet is the additional value of a peroneus stimulator in comparison with an AFO. Numerous (observational) studies have reported the effect of using an AFO or FES separately, but Mann et al. (50) has made a comparison between both treatments. In this study chronic stroke patients were randomly assi-gned to use either an AFO or a surface stimulator for 12 weeks to manage their dropped foot. Significant improvements in walking speed, endurance, and mobility were observed after 12 weeks in both groups. The FES group showed a significant carryover effect in their unaided walking past 12 weeks, which was not observed in the AFO group. Also a larger trend towards improved PCI was observed in the FES group compared to the AFO group. These results support the hypothesis that FES may have a greater training effect than simply using an AFO to correct a dropped foot in chronic stroke patients. However, further work is required to investigate this more comprehensively.

CONCLUSION

FES seems to have a positive orthotic effect on walking speed and PCI. The pooled effect size for

walking speed was 0.13 m/s (0.07–0.2 m/s) or 38%(22.18–53.8%).

Walking speed seems also to increase when FES is compared with an AFO. In the literature it is not clear what proportion might benefit from FES. Future studies should report on suitability criteria for patients.

PCI was found to decrease in two studies (2,36). In one study, there was a significant decrease in PCI with and without stimulation after 3 months (36). No significant changes were found when comparing PCI before and after treatment. Although patients often reported that walking was less fatiguing, this seemed to be a psychological effect.

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APPENDIX I. CRITERIA LIST FOR ASSESSMENT OF METHODOLOGICAL QUALITY

Patient selection	
1. Were the eligibility criteria specified?	Yes/No/Don't know
2. Was the selection procedure described?	Yes/No/Don't know
3. Was the design of the study:	
a) a randomized controlled trial?	Yes: score 3
No	
b) a crossover?	Yes: score 2
No	
c) open label?	Yes: score 1
Intervention	
4. Was the index intervention explicitly described?	Yes/No/Don't know
5. Were cointerventions avoided of comparable?	Yes/No/Don't know
6. Was the compliance acceptable in all groups?	Yes/No/Don't know
7. Was the baseline described?	Yes/No/Don't know
Outcome measurements	
8. Were the outcome measures relevant?	Yes/No/Don't know
9. Were adverse effects described?	Yes/No/Don't know
10. Was the withdrawal/dropout rate described and acceptable?	Yes/No/Don't know
11. 1) Was a short-term follow-up measurement described?	Yes/No/Don't know
Short-term ≤2 months	
2) Was a long-term follow-up measurement described?	Yes/No/Don't know
Long-term ≥2 months	
12. Were outcomes standardized?	Yes/No/Don't know
Statistics	
13. Was the sample size for each group described?	Yes/No/Don't know
14. Is the number of patients at least 15?	Yes/No/Don't know
15. Were point estimates and measures of variability presented for the primary outcome measures?	Yes/No/Don't know
16. Were statistical tests performed and described?	Yes/No/Don't know