

## META-ANALYSIS

# The Therapeutic Effect of Functional and Transcutaneous Electric Stimulation on Improving Gait Speed in Stroke Patients: A Meta-Analysis

Shawn M. Robbins, BScPT, Pamela E. Houghton, PhD, M. Gail Woodbury, PhD, Janet L. Brown, BScPT, MEd

**ABSTRACT.** Robbins SM, Houghton PE, Woodbury MG, Brown JL. The therapeutic effect of functional and transcutaneous electric stimulation on improving gait speed in stroke patients: a meta-analysis. *Arch Phys Med Rehabil* 2006;87:853-9.

**Objective:** To determine the effect of previous treatments of functional electric stimulation (FES) and transcutaneous electric stimulation (TENS) on improving gait speed in subjects poststroke.

**Data Sources:** Relevant articles were obtained through a search of English-language articles cited in Medline, EMBASE, CINAHL, and PubMed databases from January 1966 to May 2005.

**Study Selection:** Prospective clinical studies were included if electric stimulation was used to treat subjects poststroke and gait speed was used as an outcome measure. Excluded studies examined subjects with a variety of neurologic conditions, used implantable electrodes, or combined electric stimulation with treadmill training. A paired consensus between authors produced 8 articles.

**Data Extraction:** Two investigators extracted data independently. The methodologic quality of the studies was assessed with the Downs and Black checklist.

**Data Synthesis:** A fixed-effects model produced a mean difference (.18; 95% confidence interval, .08–.28) that was significant ( $z=3.65$ ,  $P<.01$ ), indicating the effectiveness of FES treatment at increasing gait speed in subjects poststroke. The effect sizes of the studies ranged from  $-.11$  to  $1.43$  for FES and  $.19$  to  $.42$  for TENS. The type of FES and TENS devices, location of electrodes, amount of exposure, and subjects' stages of recovery varied between the studies.

**Conclusions:** FES is effective at improving gait speed in subjects poststroke. Future research should examine the effectiveness of practical and readily available FES units to improve function in subjects in the subacute stages of recovery from a stroke. These studies should attempt to use a randomized controlled design with blinding and standardized outcome measures.

**Key Words:** Cerebrovascular accident; Electric stimulation therapy; Gait; Hemiplegia; Meta-Analysis; Rehabilitation.

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From the School of Physical Therapy, University of Western Ontario, London, ON (Robbins, Houghton, Brown); and Program in Aging, Rehabilitation and Geriatric Care, Lawson Health Research Institute, London, ON (Woodbury), Canada.

No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit upon the author(s) or upon any organization with which the author(s) is/are associated.

Reprint requests to Pamela E. Houghton, PhD, School of Physical Therapy, Rm 1588, Elborn College, University of Western Ontario, London, ON N6G 1H1, Canada, e-mail: [phoughto@uwo.ca](mailto:phoughto@uwo.ca).

0003-9993/06/8706-1044\$32.00/0  
doi:10.1016/j.apmr.2006.02.026

**M**ANY PEOPLE ARE ADMITTED each year to Canadian hospitals as a result of a cerebrovascular accident, more commonly known as a stroke. The crude rate of hospitalization per 100,000 people for cerebrovascular disease was 1199 for men and 748 for women between the ages of 65 and 74 years in 1996 and 1997.<sup>1</sup> After a stroke, people will have resulting motor deficits including decreases in muscle activation, increases in muscle stiffness, and changes in gait patterns.<sup>2,3</sup>

Many different therapeutic techniques have been used to treat motor dysfunctions in patients after a stroke. Functional electric stimulation (FES), also commonly referred to as neuromuscular electric stimulation, and transcutaneous electric stimulation (TENS) are techniques that have been used in the rehabilitation of these patients. Both FES and TENS deliver an electric current through electrodes to muscles. The intensity of the FES current is able to activate motoneurons and produce a muscle contraction. The intensity of the TENS current is below motor threshold, but it is able to produce a pins-and-needles sensation. Some studies<sup>4,5</sup> have examined simple single-channel FES units with 2 electrodes that stimulate along the path of a nerve or a muscle. Other studies<sup>6,7</sup> have examined more complicated multichannel FES units with more than 2 electrodes that stimulate numerous muscles.

Studies have shown that FES and TENS can improve strength, decrease spasticity, and improve motor performance.<sup>4-8</sup> Many review articles<sup>9-14</sup> have concluded that electric stimulation can improve gait, functional ability, and motor function in patients who have sustained a stroke; however, they comment that more research is required and future studies should use better methodologic controls. In general, these narrative reviews did not critically appraise the articles using a systematic approach and did not use statistical methods to support their conclusions.

Two meta-analyses have been conducted that have systematically researched the literature and have combined study results. Glanz et al<sup>15</sup> conducted a meta-analysis of the effectiveness of electric stimulation in poststroke rehabilitation. They concluded that electric stimulation significantly improved muscle strength. Kottink et al<sup>16</sup> conducted a meta-analysis examining the ability of FES to improve gait speed in subjects poststroke. They argued that FES can be used as an orthosis, and they pooled the gait speeds of subjects when ambulating with the FES device active. Subjects were treated with FES, with either indwelling or surface electrodes, for 3 weeks to 6 months depending on the study. They determined that gait speed could be significantly improved in people poststroke during FES treatment (orthotic effect). It is not known whether these improvements in walking speed were maintained after the FES machine was removed (therapeutic or carryover effect). The orthotic effect is the ability of the FES device to improve gait while subjects are receiving electric stimulation of the lower-extremity muscles. The therapeutic effect examines changes in gait that have occurred after a series of FES treat-

ments have been applied over a period of weeks or months. Measurements of gait speed for the therapeutic effect are performed without subjects receiving FES during testing.

The purpose of this meta-analysis was to determine the therapeutic effect of lower-extremity FES and TENS with surface electrodes on gait speed in subjects poststroke. This meta-analysis will focus on FES protocols that are clinically feasible (eg, surface electrodes).

### METHODS

A systematic search was conducted to identify all articles published between January 1966 and March 2005 relating to the effectiveness of FES and TENS for the treatment of the lower extremity poststroke. Updates were received from the databases until May 2005. The databases searched included Medline, EMBASE, CINAHL, and PubMed. Search terms and subject headings included *electric stimulation, functional electric stimulation, neuromuscular electric stimulation, transcutaneous electric stimulation, cerebrovascular accident, stroke, hemiplegia, and lower extremity*. We examined the citations and abstracts from the various articles and reviewed controlled trials, before-after trials (noncontrolled with a single group), and literature reviews. Inclusion criteria included prospective studies that (1) used the treatment of FES or TENS with surface electrodes, (2) studied subjects who had sustained a stroke, (3) used gait speed as an outcome measure and assessed without electric stimulation (therapeutic effect), and (4) were written in English. Exclusion criteria included indwelling or implantable electrodes, mixed patient populations (ie, spinal cord injury, acquired brain injury) where the data were not presented separately, retrospective or case study designs, studies repeating previously published data, electric stimulation combined with treadmill training, or sufficient data that were not available (eg, estimates of random variability) despite contacting the authors. Complete articles were retrieved from all relevant citations and from those that were unclear or were missing abstracts from the database citations. In addition, the references from these articles were examined and secondary articles were obtained. A paired consensus between the authors ensured that the articles met the criteria for inclusion.

The methodologic quality of the studies was critically appraised using the Downs and Black checklist.<sup>17</sup> This checklist was developed to assess the quality of randomized and non-randomized studies. The checklist includes 27 items under 5 subscales. The subscales, with the number of items in each subscale in brackets, include reporting (n=10), external validity (n=3), internal validity bias (n=7), internal validity confounding (n=6), and power (n=1). The total score is 32, with a higher score representing a better methodology. The test-retest reliability ( $r=.88$ ), interrater reliability ( $r=.75$ ), and internal consistency (Kuder-Richardson formula 20=.89) of the checklist are good.<sup>17</sup> The articles were rated independently by 2 authors. The authors met to discuss any discrepancies between the scores of each item and to ensure consistency in rating the items. The amount of initial agreement between the raters was calculated for each subscale. During the discussion, a consensus was met between the raters for the scoring on each checklist item. This consensus produced the final ratings for the studies.

An investigator and a research assistant separately extracted data from the studies from the tables or the text of the articles to ensure accurate copying of the data. The data included group means and standard deviations (SDs). The data were analyzed in 2 forms.

First, the results of the controlled studies that examined the effectiveness of FES with an outcome measure of gait speed

were combined. The data were entered into Review Manager 4.2.7.<sup>18,a</sup> The heterogeneity of the studies ( $\chi^2$ ) was calculated and significance determined with  $P$  less than .05.<sup>19</sup> Heterogeneity is a statistical measure of the variability of the treatment difference between the studies.<sup>19</sup> If the studies are not heterogeneous, their results are considered similar and therefore they can be combined. A weighted mean difference with 95% confidence intervals (CIs) was calculated and the fixed-effects model was run to determine the statistical differences of the combined results. A more stringent significance criterion is required with the fixed-effects model to account for artificially narrow CIs.<sup>20,21</sup> Accordingly,  $P$  less than .01 was accepted for statistical significance.

In addition, the effect sizes for the studies were calculated using the following equation<sup>22</sup>:

$$d = \frac{m_t - m_c}{s}$$

where  $d$  is the effect size index;  $m_t$  is the mean change in gait speed in the treatment group (FES, TENS) in the controlled trials, or the posttreatment measure in the before-after (1 group) trials;  $m_c$  is the mean change in gait speed in the control group in controlled trials, or the pretreatment measure in the before-after trials; and  $s$  is the pooled SD between the  $m_t$  and  $m_c$  measures. For before-after trials,  $s$  is equal to the average SD of the  $m_t$  and  $m_c$  groups. For controlled trials,  $s$  is equal to<sup>23</sup>

$$s^2 = \frac{(n_t - 1)(s^t)^2 + (n_c - 1)(s^c)^2}{n_t + n_c - 2}$$

where  $n_t$  and  $n_c$  are the sample sizes of the treatment and control groups and  $s^t$  and  $s^c$  are the SDs of the treatment and control groups. The studies were then grouped and mean effect sizes calculated to make different comparisons. These comparisons and groups included studies examining FES with subjects in the acute and subacute (onset of stroke <6mo) compared with the chronic (onset >6mo) stages of recovery from a stroke, studies examining single-channel FES compared with multichannel FES, and studies examining FES compared with TENS.

### RESULTS

The literature search produced 533 citations from Medline, 230 from CINAHL, 539 from EMBASE, and 438 from PubMed databases. Abstracts were reviewed and secondary references were collected, resulting in 67 full articles that were retrieved. Eighteen review articles were also collected and reference lists were examined for relevant articles. Thirty-seven of the 67 full articles were excluded because they did not meet the inclusion and exclusion criteria. Of the excluded articles, 21 studies included subjects with a variety of neurologic conditions, 1 had repeated data from another study, 7 examined the immediate changes of 1 electric stimulation session and did not involve extended treatment, 5 used indwelling or needle electrodes to deliver the electric stimulation, and 3 were case studies. From the remaining 30 articles, 10 articles used gait speed as an outcome measure. One of these studies<sup>7</sup> was excluded because the researchers measured gait speed for only 3 subjects and presented the results in a case study format. Another article<sup>24</sup> was excluded because subjects were treated only once with FES and the authors of this study believe that a single treatment was unlikely to produce a therapeutic effect. The remaining 8 articles were used in the analyses. Four of the trials are controlled studies, 3 examining FES<sup>25-27</sup> and 1 ex-

Table 1: Description of the Included Studies

Study	n	Methodologic Quality	Stroke Onset (mo)	Intervention	Duration	Study Design	Outcomes
Alon and Ring <sup>27</sup>	C: 9 I: 10	16	C: 51.6 I: 48.6	Multichannel FES	2mo	Control trial	Gait speed and cadence improved
Bogataj et al <sup>25</sup>	C: 10 I: 10	15	C: 3.9	Multichannel FES	3wk	Two group crossover	Gait speed and cadence, step length, and FMA score improved
Burridge et al <sup>26</sup>	C: 16 I: 16	17	C: 59	Single-channel FES	12wk	RCT	Gait speed and PCI not improved
Burridge and McLellan <sup>30</sup>	18	13	35	Single-channel FES	12wk	Before-after trial	Gait speed and PCI improved
Chen et al <sup>28</sup>	C: 12 I: 12	16	12–35*	Single-channel TENS	1mo	RCT	Gait speed and some spasticity measures improved
Granat et al <sup>29</sup>	16	15	7	Single-channel FES	1mo	One group crossover	Gait speed and parameters not improved
Peurala et al <sup>32</sup>	19	14	39.6 <sup>†</sup>	Single-channel TENS	3wk	Before-after trial	Motor scale improved; gait speed and sensation not improved
Sonde et al <sup>31</sup>	13	14	12	Single-channel TENS	3mo	Before-after trial	Gait speed and spasticity improved; FMA not improved

Abbreviations: C, control group; FMA, Fugl-Meyer Assessment; I, intervention group, PCI, Physiological Cost Index; RCT, randomized controlled trial.

\*No mean given; stroke onset range for both the control and intervention groups.

<sup>†</sup>Mean onset includes subjects in both upper-extremity and lower-extremity intervention groups.

aming TENS,<sup>28</sup> with 48 subjects in the treatment group and 47 subjects in the control group. Four of the trials used a before-after or crossover design with a total of 66 subjects receiving treatment. Two of these before-after trials examined FES<sup>29,30</sup> and 2 examined TENS.<sup>31,32</sup> A description of the included studies is provided in table 1.

The 3 controlled trials examining FES differed in methodology and treatment. Bogataj et al<sup>25</sup> used a randomly assigned controlled trial with a crossover. Subjects were treated with multichannel FES over the peroneal nerve, soleus, hamstrings, quadriceps femoris, gluteus maximus, and triceps brachii for 3 weeks while ambulating during therapy. Gait speed was measured over 20m. The mean time from stroke onset for subjects was approximately 3 to 4 months. Burridge et al<sup>26</sup> used a randomized controlled trial (RCT) design. Subjects were treated with a single-channel FES stimulator over the peroneal nerve for 3 months while they ambulated at home. Subjects were instructed to walk briskly for 10m to measure gait speed. Subjects were also permitted 1m at the start and finish for acceleration and deceleration, respectively. Alon and Ring<sup>27</sup> treated subjects with an integrated leg orthosis–stimulation system with electrodes over the peroneus longus, tibialis anterior, and gastrocnemius for 8 weeks. Subjects also received FES treatment to the upper extremity. The program was home based and required subjects to use the stimulators twice a day for 10 to 60 minutes. A non-RCT design was used by the researchers and gait speed was measured with a 10-m walk. Burridge<sup>26</sup> and Alon and Ring<sup>27</sup> used subjects with a mean time since onset of stroke longer than 3 years.

A single-group crossover design was used by Granat et al.<sup>29</sup> Subjects with a drop foot were treated with an FES device with a single set of electrodes over the peroneal nerve for 1 month while they ambulated. Gait speed was measured over 6 or 10m over different surfaces. Subjects were given 1.5m at the begin-

ning and the end of the test to accelerate and decelerate. Only the results for the trials over linoleum are used in the analysis to prevent data from subjects being repeated. Burridge and McLellan<sup>30</sup> performed a before-after trial. Subjects were treated for 3 months with a drop-foot stimulator while they ambulated at home. A 10-m walk test was used to measure gait speed. Both Granat<sup>29</sup> and Burridge and McLellan<sup>30</sup> used subjects in the chronic stage of recovery.

The single RCT examining the effectiveness of TENS was performed by Chen et al.<sup>28</sup> TENS uses electric stimulation with an intensity that is sufficient for sensory level but it is insufficient to produce a tetanic muscle contraction. Subjects received TENS via electrodes placed over the Achilles' tendon and gastrocnemius for 20 minutes, 6 times a week for 1 month. Subjects were instructed to ambulate at a comfortable speed for 10m to measure gait speed. Subjects entered the study 12 to 35 months after the stroke onset.

Two before-after trials examined the effectiveness of TENS on spasticity, motor performance, and gait speed. Sonde et al<sup>31</sup> applied TENS over the lower leg of subjects for 30 minutes every day for 3 months. Peurala et al<sup>32</sup> treated subjects with TENS on the foot and ankle for 30 minutes, twice a day for 3 weeks. Both studies used a 10-m walk test and subjects were in the chronic stage of recovery.

The mean methodologic score using the Downs and Black checklist of the studies was 15 of 32. The mean score of the controlled trials<sup>25-28</sup> was 16, and the mean score of the before-after trials<sup>29-32</sup> was 14. The initial agreement between raters for each subscale, the scores for each subscale, and the total initial agreement and methodologic scores are presented in table 2.

Many of the studies measured gait speed with and without the use of FES and TENS before and after the treatment period. Only the measures of gait speed without FES and TENS were used in the analyses (therapeutic effect). The 3 controlled

**Table 2: Initial Agreement of the Raters and Final Scores for Each Subscale of the Downs and Black Checklist**

Study	Reporting	External Validity	Bias	Confound	Power	Total
Alon and Ring <sup>27</sup>						
Agreement	9/10	3/3	4/7	5/6	1/1	22/27
Score	9	1	3	3	0	16
Bogataj et al <sup>25</sup>						
Agreement	10/10	3/3	6/7	6/6	1/1	26/27
Score	9	0	4	2	0	15
Burridge et al <sup>26</sup>						
Agreement	7/10	3/3	5/7	4/6	1/1	20/27
Score	9	1	4	3	0	17
Burridge and McLellan <sup>30</sup>						
Agreement	7/10	2/3	5/7	4/6	1/1	19/27
Score	8	0	4	1	0	13
Chen et al <sup>28</sup>						
Agreement	7/10	2/3	5/7	4/6	1/1	19/27
Score	8	0	4	4	0	16
Granat et al <sup>29</sup>						
Agreement	10/10	3/3	7/7	5/6	1/1	26/27
Score	8	1	4	2	0	15
Peurala et al <sup>32</sup>						
Agreement	7/10	3/3	6/7	5/6	1/1	22/27
Score	6	1	5	2	0	14
Sonde et al <sup>31</sup>						
Agreement	10/10	3/3	6/7	5/6	1/1	25/27
Score	9	1	3	1	0	14

studies that examined FES were entered into the fixed-effects model.<sup>25-27</sup> Two of the studies produced a positive effect that favored treatment<sup>25,27</sup> and 1 study produced an effect that favored the control.<sup>26</sup> Outcome measures and effect sizes for the studies are shown in table 3. A total of 36 subjects were in the treatment group and 35 subjects were in the control group. The studies were not heterogeneous ( $\chi^2$  test=4.80,  $P=.09$ ). The fixed-effects model produced a mean difference and 95% CI (mean, .18; 95% CI, .08-.28) that were significant ( $z=3.65$ ,  $P<.01$ ) for the effectiveness of FES treatment (fig 1).

The study examining FES using subjects in the acute or subacute stages of recovery from a stroke (onset <6mo)<sup>25</sup> had a larger effect size ( $d=1.43$ ) than the mean effect size ( $d=.40$ ) of the studies examining FES using subjects in the chronic

stage of recovery (onset >6mo).<sup>26,27,29,30</sup> The mean effect size ( $d=1.38$ ) of the studies using multichannel FES<sup>25,27</sup> was larger than the mean effect size ( $d=.09$ ) of the studies examining single-channel FES.<sup>26,29,30</sup> The mean effect size of the FES studies<sup>25-27,29,30</sup> ( $d=.61$ ) was higher than the TENS studies<sup>28,31,32</sup> ( $d=.30$ ).

## DISCUSSION

This meta-analysis supports the conclusion that previous gait training with FES (therapeutic effect) can improve gait speed in subjects poststroke. A total of 4 controlled trials and 4 before-after trials examining the effectiveness of FES or TENS were included. There were an insufficient number of studies examining TENS and an effect model analysis could not be con-

**Table 3: Gait Speed and Effect Sizes of the Included Studies**

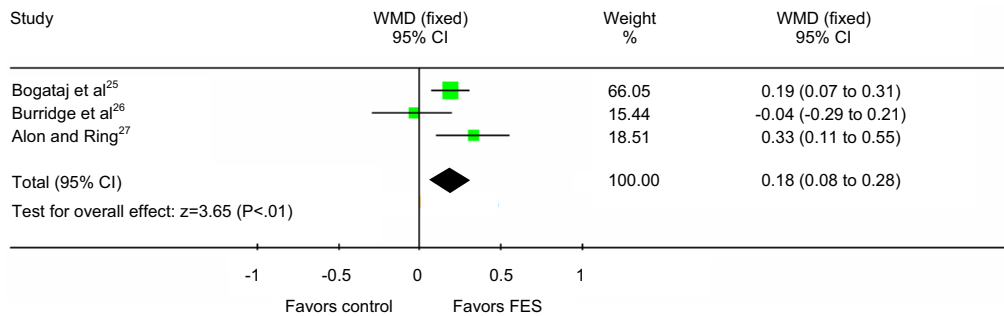
Study	Group	Baseline Gait Speed	Final Gait Speed	Change*	%*	Pooled SD	$d^*$
Alon and Ring <sup>27</sup> (m/s)	C	0.76±0.22	0.75±0.23	-0.01±0.23	-1.32	0.25	1.34
	I	0.88±0.23	1.20±0.30	0.32±0.27	36.36		
Bogataj et al <sup>25</sup> (m/s)	C	0.23±0.13	0.26±0.11	0.03±0.12	13.04	0.13	1.43
	I	0.19±0.08	0.41±0.21	0.22±0.15	115.79		
Burridge et al <sup>26</sup> (m/s)	C	0.48±0.25	0.51±0.27	0.03±0.26	6.25	0.35	-0.11
	I	0.64±0.46	0.63±0.39	-0.01±0.43	-1.56		
Burridge and McLellan <sup>30</sup> (m/s)	I	0.63±0.27	0.74±0.32	0.11±0.30	17.46	0.30	0.37
Chen et al <sup>28</sup> (s)†	C	87.91±23.05	88.05±22.88	-0.14±22.97	-0.16	21.52	0.42
	I	89.75±20.69	80.75±19.23	9.00±19.96	10.03		
Granat et al <sup>29</sup> (m/s)‡	I	0.94±0.63	0.95±0.58	0.01±0.61	1.06	0.61	0.02
Peurala et al <sup>32</sup> (s)†	I	54.7±34.00	48.4±33.00	6.30±33.50	11.52	33.50	0.19
Sonde et al <sup>31</sup> (m/s)	I	0.30±0.33	0.40±0.40	0.10±0.37	33.33	0.37	0.27

NOTE. Values are mean ± SD.

\*Positive values reflect improvement or effect favoring the intervention.

†Time required to ambulate 10m.

‡Converted from m/min.



**Fig 1. A forest plot of the fixed-effects model for the effectiveness of FES on gait speed in subjects who have sustained a stroke. Included are the weights of each study, weighted mean difference (WMD) and 95% CIs of each study, and the combined results.**

ducted to determine the effectiveness of TENS at improving gait speed. The RCT<sup>28</sup> and both before-after trials<sup>31,32</sup> examining the effectiveness of TENS had a positive overall effect. Subjects had an increase in gait speed in 2 of the controlled trials<sup>25,27</sup> and 1 of the before-after trials<sup>30</sup> examining FES. These positive findings are consistent with previous results. FES has been previously shown to improve muscle strength,<sup>4,6,15</sup> muscle recruitment,<sup>5,6</sup> and voluntary motor control<sup>33</sup> in the upper and lower extremities. Glanz et al<sup>15</sup> conducted a meta-analysis and showed that FES could significantly improve strength in subjects poststroke. Kottink et al<sup>16</sup> found in a meta-analysis that FES could increase gait speed while electric stimulation is applied to the lower-extremity muscles (orthotic effect). This meta-analysis shows that previous training using FES can produce sustained improvements in gait speed present even after the FES is turned off (therapeutic effect). These results are important because it is impractical to continue to use FES with surface electrodes indefinitely.

This meta-analysis has several limitations. Only 3 studies were entered into the fixed-effects model.<sup>25-27</sup> This low number will decrease the strength, generalizability, and external validity of the results. Before-after trials were included in this article to provide a comprehensive review of the topic. Although it is difficult to show the cause-and-effect relation of an intervention with this single-group design, this design does permit subjects who have a history of gait difficulties to act as their own controls. This is a benefit when studying a patient population with such varied levels of lower-extremity weakness and control as a result of a stroke and marked differences in FES protocols. Furthermore, an increase in subjects' gait speed might not represent a significant gain in their overall functional ability. Gait speed was used as an outcome measure because it is among the most commonly used measures in studies examining the effectiveness of FES. More research is needed to determine if FES or TENS can improve the scores on various functional scales such as the Barthel Index or the FIM instrument. The comparison of the effect sizes of the different studies (subacute vs chronic, TENS vs FES) does not hold much statistical validity; however, it can be used to make interesting observations and hopefully help direct future research.

Flansbjerg et al<sup>34</sup> calculated the standard error of measurement percentage to be 7.9% for measuring gait speed in subjects who had sustained a stroke. In other words, an increase of 7.9% is the minimal improvement in gait speed needed to be considered a real change in a group. Three of the 5 FES studies<sup>25,27,30</sup> showed a real improvement in gait speed (see table 3). Thus, FES treatment is capable of improving the gait speed of subjects who have sustained a stroke.

The artificial stimulation of muscles with FES during gait produces repetitive muscle contractions that can increase pro-

prioceptive input to the brain. This effect is shown by changes in the hemodynamic responses to the sensorimotor regions of the brain after electric stimulation in healthy subjects.<sup>35</sup> Carr and Shepherd<sup>36</sup> report that repetitive movements and proprioception are key contributors to motor learning or relearning. In addition, motor patterns will be improved when FES activates a patient's muscles in proper sequence during gait. Activation of the lower-extremity muscles during a functional task (gait) was a strength of many of the included studies.<sup>25-27,29,30</sup> This would assist subjects in improving various aspects of gait and improve functional carryover. A previous study of subjects who sustained a stroke found that a group undergoing a task-orientated intervention to improve gait had greater improvements in gait distance and speed than a similar control group.<sup>37</sup> Ensuring that subjects and patients ambulate while using FES would improve the effectiveness of the intervention for gait retraining.

The methods and amount of exposure to the electric stimulation varied greatly between the studies. Single-channel drop-foot stimulators,<sup>26,29,30</sup> a leg orthosis-stimulation device with 5 electrodes,<sup>27</sup> and a multichannel FES device<sup>25</sup> were used in the various studies. The amount of exposure to FES that subjects received varied between the studies. Some subjects received stimulation throughout the day while they ambulated<sup>26,29,30</sup> and this potentially resulted in large exposure times to FES. In comparison, other studies applied the FES during specific training sessions lasting from 30 to 60 minutes a day.<sup>25,27</sup> Despite this relatively low exposure time to FES, subjects in these studies<sup>25,27</sup> had the largest increase in gait speed. The use of subjects in the subacute stage of recovery is a likely explanation for this result. In addition, compliance was not measured in most of the studies that had subjects use the FES devices at home.<sup>26,30</sup> Low compliance with the devices might have greatly decreased the amount of exposure.

Strong conclusions cannot be made by grouping and comparing the studies based on subject population or treatment technique used; however, interesting trends can be seen when examining these comparisons and the mean effect sizes of these different approaches. Conventional effect sizes are often used to describe a large ( $d=.80$ ), medium ( $d=.50$ ), and small ( $d=.20$ ) effect.<sup>38</sup> The larger the effect size, the larger the magnitude of difference between the control group and the treatment group.<sup>38</sup> The effect size of the study that included subjects in the subacute stage of recovery<sup>25</sup> ( $d=1.43$ ) was large, whereas the mean effect size of the studies that used subjects in the chronic stage of recovery<sup>26,27,29,30</sup> ( $d=.40$ ) was relatively small. Thus, FES appears to be more effective in the subacute stage of stroke recovery. This is supported by research that has determined that most poststroke recovery occurs in patients within the first 6 months after stroke onset.<sup>39</sup>

The mean effect size of the studies examining multichannel FES<sup>25,27</sup> ( $d=1.38$ ) was larger than the mean effect size of the studies examining single-channel FES<sup>26,29,30</sup> ( $d=.09$ ). Multichannel FES might be more effective because it can stimulate a combination of muscles in a specific pattern. However, subjects treated with single-channel FES were in the chronic stage of recovery, and it would be harder to produce changes in these subjects.

Overall, FES produced a medium to large effect<sup>25-27,29,30</sup> ( $d=.61$ ) and TENS<sup>28,31,32</sup> produced a medium to low effect ( $d=.40$ ). FES generates joint movements and stronger muscle contractions than TENS. These repetitive movements and additional sensory information make FES more effective at improving gait speed in subjects poststroke. In general, studies using multichannel FES to treat a subacute population had the largest effect sizes.

Treatments must not only be effective, but they must be readily available and affordable. For these reasons, the effectiveness of FES with implantable electrodes was not examined in this study. Implantable electrodes allow for more precise placement of the electrodes, decrease the discomfort associated with electric stimulation, and decrease the required setup time.<sup>13</sup> However, implantable electrodes are not currently available to most clinicians and they have medical risks that are associated with every invasive treatment. Furthermore, implanting electrodes in patients in the acute or subacute stage of recovery poststroke would be impractical. Patients will respond to treatment and spontaneous recovery will occur, thus potentially making the implantable electrodes unnecessary. Also, multichannel FES is not practical because the devices are unavailable to most health care practitioners and they require complicated and expensive setups. In comparison, single- or dual-channel FES devices are smaller, portable, less expensive, and more readily available, and subjects can take them home to apply treatment. More research regarding the effectiveness of these devices is required to determine if they improve function in patients in the subacute stage of stroke recovery.

The scores of the controlled trials (16/32) were similar to the scores of the before-after trials (14/32) on the Downs and Black checklist. These studies had a similar methodologic quality to those studies used to develop the checklist.<sup>17</sup> Only 1 study used a placebo treatment in its design and made an attempt to blind the assessors.<sup>28</sup> With FES or TENS, it would be very difficult to effectively blind subjects to the treatment because of the sensation experienced with the modalities. Future studies should attempt to blind the assessors to subjects' assignments. In addition, none of the studies adequately described the source population and the recruitment of subjects, and they did not perform a power analysis. Thus, the scores on the external validity and power subscales of the checklist were low.

The scores on the Downs and Black checklist highlight the need for better study design in future research. More RCTs with blinding are needed. Few studies have incorporated a follow-up period in their design. It would be interesting to determine if the improvement in gait speed remains after a period of time when subjects are not receiving treatment. This would help determine if motor patterns were relearned and maintained after the treatment ended. Motion analysis of subjects pretreatment and posttreatment could also help determine if gait and motor patterns have been modified by FES intervention. More studies are needed to examine the effectiveness of FES and TENS in patients in the acute or subacute stages of stroke recovery. Also, more research needs to be performed examining practical FES units. This includes single- or dual-channel FES devices with surface electrodes that are presently

available to purchase, relatively inexpensive, and currently in use in many health care settings.

## CONCLUSIONS

A meta-analysis examining the effectiveness of FES has shown a statistically significant improvement in gait speed. There was insufficient research to make conclusions regarding the effectiveness of TENS. FES can be an effective tool in the rehabilitation of patients after they have sustained a stroke. It has been shown to increase strength<sup>15</sup> and increase gait speed in subjects poststroke. However, studies have not yet shown an improvement in overall functional ability with FES treatment.

The methods of delivery of FES varied greatly between the studies from simple single-channel FES units to more complex multichannel FES units. Different types of delivery will influence the effect of the treatment. In addition, most of the trials used subjects in the chronic stage of stroke recovery.

Future research should examine the effects of practical FES units on patients in the acute or subacute stage of recovery poststroke. In addition, attempts should be made to improve the methodology of the trials. More RCTs are needed in this area with the investigators blinded to the subjects' group assignments.

**Acknowledgments:** We acknowledge Cara Bernier, Sarah Mitchell, Stefan Pagliuso, and Devon Tyler for their initial work in researching the effectiveness of electric stimulation. We thank John MacDougall for his assistance with the data extraction.

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- a. Cochrane Collaboration, PO Box 726, Oxford, OX2 7UX, UK.