

**The effect of electrical stimulation in the management of muscle tone in people with neurological impairments: a systematic review**

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## Abstract

**Purpose/Introduction:** The purpose of relieving spasticity is to improve function and quality of life.

**Methods:** Sixteen articles met the selection criteria and were included in this systematic review. Each article was then rated on the PEDro scale by each reviewer.

**Results:** Every article that was included in this review showed a significant decrease in muscle tone in people with neurological disorders. This included electric stimulation alone or in combination with orthoses, cycling or botox and TENs alone or with botox.

**Discussion:** The results of this systematic review indicate that electrical stimulation applied alone or as a co-intervention reduces spasticity in people with neuromuscular disorders in the short term. These results are mainly generalizable to people with moderate to severe spasticity that are greater than 3 months post onset.

**Conclusion:** Overall, there was a decrease in tone but there needs to be further research to determine the specific parameters that can be applied to these patients in the clinical setting.

## Introduction

Spasticity can be a debilitating outcome of an upper motor neuron lesion, and is commonly seen in disorders such as cerebral vascular accidents, Parkinson's, traumatic brain injury, spinal cord injury, and multiple sclerosis.<sup>1,2</sup> It is defined as "hypertonia in which one or both of the following signs are present: resistance to externally imposed movement increases with increasing speed of stretch and varies with the direction of joint movement, and/or resistance to externally imposed movement rises rapidly above a threshold speed or joint angle."<sup>3</sup> It has been known for some time that spasticity can cause pain, negatively affecting functional movement and activity performance. Hypertonia can also lead to secondary complications such as contractures, and muscular imbalances, which can result in osteoarthritis, more pain than normal, and skin breakdown. Some 20%-25% of all individuals with first ever stroke present with spasticity, and a prevalence of 12-37% has been reported in people with spinal cord injury.<sup>3-5</sup>

There are many different approaches to managing spasticity. These options include oral medications, implanted pumps, physical therapy, and surgery. Oral medications, baclofen pumps, and botox injections have been shown to significantly reduce spasticity.<sup>2</sup> Oral medications have significant anti-spastic effects but the dosage required to optimally reduce spasticity is not known. One benefit of oral medications is that they do not cause additional muscle weakness. However, there are many adverse side effects that have to be taken into consideration including but not limited to the possibility of bradykinesia, hypotension, dizziness, gastrointestinal issues, and visual symptoms. Intrathecal baclofen

is safer than oral medications with respect to side effects as it bypasses the digestive system. Direct injection into the cerebral spinal fluid drastically reduces the amount of medication needed, and the anti-spastic effects have been noticed for up to 12 months.<sup>3</sup> Botox injections have been shown to significantly reduce spasticity as well. Injections are needed in relatively high doses (300-400U) with the effects of these injections lasting for approximately 6 months. These effects are dose dependent, the higher the dose the more effective the outcomes. It has been shown that antibodies are formed with continued injections, making the treatment less effective as time goes on. Botox injections can be quite expensive, up to \$400 for a vial, with up to 4 vials needed per single treatment session.<sup>3</sup> Surgery for reducing spasticity can be used if conservative treatments are not effective. An example of an effective surgical intervention that may be beneficial in reducing spasticity is a selective posterior rhizotomy. Some complications of this procedure that may occur include dural leakages, sensory or motor deficits, sphincter disturbances, and exacerbation or unmasking of notable muscle weakness, but these have been uncommon. There are also some concerns regarding a possible increased predisposition to skeletal problems such as a hip dislocation or spinal deformity in children.<sup>6</sup>

The purpose of relieving spasticity is to improve function and quality of life.

Subjectively, drug therapy may not accomplish these goals, since it does not always translate into an increase in functionality. Drug therapies and surgeries also have many side effects. So, even though these techniques have been shown to reduce spasticity many people prefer trying a conservative route of treatment before considering them.<sup>7-8</sup>

Electrical stimulation is a conservative tool that physical therapists can utilize in a clinical setting to help manage muscle tone to enhance the effects of daily treatment. It is believed that electrical stimulation can be used to modulate abnormal spinal inhibitory circuits.<sup>9</sup> There are many advantages of electrical stimulation compared to other treatments. Electrical stimulation can modulate the intensity of the intervention, and therefore the intensity of the effect. The spasticity can be modulated versus totally eliminated; therefore individuals can potentially use the residual muscle tone for functional stability. Another advantage is that electrical stimulation is a localized application, therefore targeting specific muscles. It does not affect all muscles in the body, as oral medication might. Disadvantages of electrical stimulation include the potential discomfort of the individual during the application, and the limited duration of the effect.<sup>7</sup>

Despite the use of electrical stimulation world wide, the literature based on its use with regards to managing muscle tone is limited. The research is primarily based on targeting specific muscles with tone and looks primarily at populations of cerebral vascular accident, and spinal cord injury. We would like to combine all approaches and populations in regards to managing muscle spasticity to account for small sample sizes, and the limited available research. The primary aim of this systematic review is to compile the research and determine the effectiveness of electrical stimulation on the management of muscle tone in people with neurological impairments.

## Methods

### Search strategy:

Relevant studies of the effect of electrical stimulation in the management of muscle tone in people with neurological impairments from 1990 to 2012 were obtained through an extensive computerized search of the following bibliographic databases: CINAHL, Pubmed, Science Direct, Google Scholar, Cochrane, PEDRo, and Hooked on Evidence. The key words “tone”, “increased”, “spasticity”, “reduction”, “neurological disorder”, “spinal cord injury”, “cerebral vascular accident”, “stroke”, “electrical stimulation”, “TENS”, “estim” were used in the search, including combinations of these words.

### Study selection and inclusion/exclusion criteria:

Studies that met the following criteria were considered for inclusion: (1) Any article published 1990 and after; (2) Articles with greater than 2 participants; (3) Articles written in the English language; (4) Articles including the adult patient population; (5) Articles with patient populations in an inpatient, outpatient or home care setting; (6) Articles including participants with an acute or chronic neurological disorder that result in increased tone including, but not limited to stroke, spinal cord injury, multiple sclerosis, upper motor neuron syndrome and spasticity; (7) Articles that include treatment with the use of electrical stimulation or TENS unit alone or in combination with orthoses, cycling, or botox. Exclusion criteria for the study were (1) Case studies with 1-2 participants; (2) Articles including the pediatric population; (3) Articles written in a language other than English; (4) Articles published before 1990; (5) Articles using electrical stimulation to strengthen weakened muscles.



### Data extraction and quality assessment

Two of the three reviewers found publications in the databases listed above. Three independent reviewers then screened these abstracts to make sure the publications met the inclusion and exclusion criteria. Each criterion was graded on a “yes” or “no” basis. All three reviewers had to agree that each article met all inclusion and exclusion criteria. If there were any discrepancies between the reviewers, the “yes” or “no” ratings were discussed until a conclusion was reached.

A critical appraisal was conducted to determine the methodological quality of the final selected studies. The PEDro scale was utilized to rate each article on 11 specific categories. The purpose of the PEDro scale is to rapidly identify which of the studies are likely to be internally valid and the reliability of the PEDro scale is fair to good.<sup>8</sup> See Appendix A for a copy of the PEDro Scale.

Each category was awarded one point if the criterion was clearly satisfied but the total score was only rated out of 10. The last question was not used in the scoring since it relates to the external validity or generalizability of the article. The higher the score, the better the article. Two reviewers independently appraised the articles and the results were compared. Any discrepancies were settled through discussion of the scale ratings.

### Data synthesis and analysis

Studies were grouped based upon similar interventions. In this systematic review, electrical stimulation in the management of muscle tone in people with neurological

problems was pooled alone or in combination with orthoses, cycling or botox and TENs alone or with botox. Each group was then compared and the results were combined to see if there was an overall decrease in tone. The quality of the study was determined by the ratings of the PEDro scale. Six and above was considered a high quality study, five was moderate and four and below was a low quality study. This scale was determined by the researchers.

### Results

Twenty-one articles were originally included in this systematic review. After all three researchers evaluated and critiqued each abstract, five articles were eliminated due to not meeting the inclusion and exclusion criteria. Sixteen studies were ultimately included. Out of these sixteen, there were five randomized controlled trials, four pre-test post test control group design, two repeated measures design, one quasi experiment design, one cross over study, one case control study and one pilot study. The use of electrical stimulation was further broken down into electrical stimulation alone, electrical stimulation with neuroprosthetics, electrical stimulation with botox, electrical stimulation passive locomotion, TENS, or TENS with baclofen. See Table 1 for information on each individual study.

Comparison 1: Hybrid upper extremity functional electrical stimulation (FES) and neuroprosthetic: Two studies<sup>10-11</sup> were included in this comparison. Weingarden et al<sup>10</sup> assessed spasticity at the elbow and wrist at baseline and at discharge in a group of people with hemiplegia. This high quality study scored a 9/10 on the PEDRO scale. Ring

et al<sup>11</sup> measured spasticity at the shoulder, elbow, wrist, and fingers at baseline, 6 weeks, and completion of the study in a group of people with sub acute stroke. This was a lower quality study, which scored a 3/10 on the PEDRO scale. Both studies showed a significant reduction in upper extremity spasticity compared to baseline measurements. These results suggest that functional electrical stimulation combined with a neuroprosthesis plays a role in reducing spasticity in people with moderate to severe spasticity who are greater than 3 months post onset. Further research is required to come to a consensus on the effects of upper extremity hybrid FES and neuroprosthesis.

Comparison 2: Electrical stimulation alone: Six studies<sup>1,4,12-15</sup> were included in this comparison. Seib et al<sup>1</sup> assessed spasticity in the triceps surae muscle at baseline, immediately following the intervention, and 24 hours post intervention. They evaluated the effects of stimulating the agonist versus antagonist muscles in people with traumatic brain injury and spinal cord injury. This study showed that stimulating the antagonist muscle significantly reduces spasticity of the targeted muscles. This was a lower quality study that scored a 4/10 on the PEDRO scale. Van der Salm et al<sup>4</sup> assessed ankle spasticity at baseline, immediately following the intervention, then twice at one-hour intervals following the intervention in people with spinal cord injuries. This study found that stimulating the agonist muscle significantly reduces spasticity in the lower leg. This was an intermediate quality study, which scored a 5/10 on the PEDRO scale. King<sup>12</sup> assessed lower extremity spasticity immediately before, at 0, 5, 10, and 15 minutes after termination of a 30-minute treatment session in participants post stroke. This study found that stimulating the agonist muscle significantly reduces spasticity in the lower leg.

Cheng<sup>13</sup> assessed wrist flexor spasticity before and immediately after the treatment session in participants post stroke. A reduction in spasticity was seen in the extremity that was stimulated as well as the contralateral limb that did not receive stimulation. This was a lower quality study, which scored a 4/10 on the PEDRO scale. Granat et al<sup>14</sup> assessed spasticity of the ankle dorsiflexors at baseline and after each treatment session in people with incomplete spinal cord injuries. The results showed a decrease in spasticity with ambulation and a more symmetrical gait. This was a higher quality study, which scored a 6/10 on the PEDRO scale. Skold et al<sup>15</sup> assessed spasticity of the ankle dorsiflexors at baseline and then 6 months following treatment in people with motor complete tetraplegic spinal cord-injuries. These results showed a significant decrease in dorsiflexor spasticity, which also resulted in an increase in hip flexor, and knee extensor muscle strength, increased upright motor control and an increase in stride length during gait. The results, from these six studies, indicate that the use of electrical stimulation significantly decreases spasticity. Further research is required to come to a consensus on the effects of electrical stimulation, and specific parameters to reduce tone.

Comparison 3: Electrical stimulation with Botox: Two studies<sup>16-17</sup> were examined in this comparison. Hesse et al<sup>16</sup> assessed upper limb spasticity using Botox A alone, Botox A combined with electrical stimulation, electrical stimulation alone, and placebo electrical stimulation at baseline, at 2, 6, and 12 weeks in people post stroke. This was a higher quality study which scored an 8/10 on the PEDRO scale. Carda et al<sup>17</sup> assessed spasticity and the use of botox with electrical stimulation and botox with taping of at least two of the following muscles: flexor carpi ulnaris, flexor carpi radialis, flexor digitorum

superficialis, or flexor digitorum profundus at baseline, one week later and one month following injection in people post stroke. This was a lower quality study, which scored a 4/10 on the PEDRO scale. Both studies showed a significant decrease in spasticity of the upper limb with the most significant results occurring in the groups that combine Botox with electrical stimulation, and Botox with taping. These results suggest that using electrical stimulation or taping after Botox treatments are beneficial in managing spasticity. Further research is required to come to a consensus on the effects of electrical stimulation with botox.

Comparison 4: Electrical stimulation with passive locomotion: Yamaguchi et al<sup>18</sup> was the only study included in this comparison. This study assessed spasticity in ankle dorsiflexors using electric stimulation combined with passive locomotion both before and after treatment in people with hemiparetic stroke. The results of this study showed the most significant difference in spasticity was in the treatment group receiving both electric stimulation and passive range of motion compared with those just receiving electric stimulation or passive range of motion by itself. This study was a higher quality study as it scored an 8/10 on the PEDRO scale. These results suggest combining passive range of motion with electric stimulation is beneficial in managing spasticity. Further research is required to come to a consensus on the effects of electrical stimulation with passive locomotion.

Comparison 5: Electrical stimulation with lower extremity cycling: Two studies<sup>19-20</sup> were included in this comparison. Krause et al<sup>19</sup> measured spasticity in the quadriceps muscle

at baseline and following lower extremity cycling. The results showed a significant difference in spasticity with electric stimulation combined with active movement compared to that of passive movement. This study was a higher quality study as it scored a 6/10 on the PEDRO scale. Lo et al<sup>20</sup> measured spasticity in the quadriceps and the hamstring muscles at baseline and then following treatment. This study showed a significant decrease in spasticity with passive locomotion combined with electric stimulation compared to just electric stimulation in people post stroke. This study was a higher quality study as it scored a 6/10 on the PEDRO scale. These results from these two studies suggest that a combination of electric stimulation with some form of lower extremity cycling can decrease spasticity. Further research is required to come to a consensus on the effects electrical stimulation with lower extremity cycling.

Comparison 6: TENS: Two studies<sup>21-22</sup> were included in this comparison. Chung et al<sup>21</sup> assessed spasticity in the lower extremity at baseline and immediately following treatment using TENS in people with spinal cord injuries. This was a higher quality study, which scored a 9/10 on the PEDRO scale. Armutlu et al<sup>22</sup> assessed spasticity in the gastrocnemius muscle before, immediately following each treatment and 4 weeks after TENS treatment ended in people with multiple sclerosis. This was a higher quality study, which scored a 6/10 on the PEDRO scale. Both studies showed a statistically significant reduction in spasticity of the lower extremity compared to the placebo group. Further research is required to come to a consensus on the effects of TENS.

Comparison 7: TENS and Baclofen: Only one study<sup>5</sup> was included in this comparison. Aydin et al<sup>5</sup> assessed the effects of baclofen, and baclofen and TENS on lower extremity spasticity 15 minutes after the first application, 15 minutes after the 15<sup>th</sup> session, and 24 hours after the 15<sup>th</sup> session in people with spinal cord injuries. Both treatment groups showed significant improvements but there was no significant difference found between Baclofen alone, and Baclofen with TENS. This study scored 7/10 on the PEDRO scale. TENS may be recommended as a supplement to medical treatment in the management of spasticity. Further research is required to come to a consensus on the effects of TENS and Baclofen.

Electrical stimulation parameters: The parameters for each study are individualized to specific treatments. All of the parameters are inconsistent with each other; therefore no overall consensus can be determined. Throughout our research, there has been no consensus on any one particular set of parameters that will produce the most anti-spastic effect. In fact, each article used a different set of parameters. See Table 1.

### Discussion

The results of this systematic review indicate that electrical stimulation applied alone or as a co-intervention reduces spasticity in people with neuromuscular disorders in the short term. These results are mainly generalizable to people with moderate to severe spasticity that are greater than 3 months post onset. Clinically, it is important to find effective modalities to reduce tone and potentially prevent further complications related to spasticity which include contractures, muscle imbalances, osteoarthritis, pain, and skin

breakdown. Due to these complications, it is clear that reducing tone, may potentially improve one's quality of life. It is important to explore conservative options to reduce spasticity because drug therapies and surgeries have many side effects, and most individuals seek alternative treatment before resorting to them.

It is encouraging that every study had positive results in decreasing tone in people with neuromuscular disorders. However, more research is needed to determine whether electrical stimulation is more beneficial alone or in combination with other modalities. Studies that combined electrical stimulation with Botox<sup>5,16</sup>, passive motion<sup>18-19</sup>, or lower extremity cycling<sup>20</sup> showed that these combinations reduced spasticity more than electrical stimulation or its co-intervention alone. These results might suggest that electrical stimulation works best in combination with other therapies. However, at this point in time it is difficult to conclude this due to the small number of studies, small number of high quality studies, and the diverse populations that are being studied. A study would need to be conducted with the same population of people receiving electrical stimulation alone or electrical stimulation combined with botox, neuroprosthetics, passive locomotion, or TENS with baclofen.

In reading the literature, it is also difficult to determine what parameters to use for the most effective results. Each study used a different set of parameters and there is no research comparing different sets of parameters. Four studies used biphasic currents and one study used continuous current. For the remaining studies, parameters differed greatly, and one study did not even state what parameters were used. One commonality between



most studies was that burst durations, ramp time, and/or intensities were individualized to the patient. There needs to be further research determining a specific set of parameters that will reduce tone in people with spasticity. Once this set of parameters is determined, clinicians of all settings will be able to administer an established standardized protocol for using electrical stimulation to reduce spasticity and optimize treatment in people with neurological impairments.

Overall, electrical stimulation appears beneficial in managing spasticity in the short term but studies evaluating long term effects are lacking. Further research is needed to determine if there are any long-term effects. However, due to publication bias, there may be more studies completed that did not result in a significant reduction in spasticity that were not included in this systematic review because they were never published.

Strengths of this systematic review include a clearly stated purpose, detail regarding the search strategy and study selection methods was provided, description of the processes and tools used to assess the quality of the individual studies, and detail about the research validity of studies. Multiple people individually critiqued each potential article included in this study and discussed reasoning for inclusion of each article, which controlled for potential bias. And lastly, the selection criteria for this study were specific and clearly stated, the researchers pooled the results into homogenous categories and a valid and reliable assessment tool was used to critically appraise each article.

The major limitations of this systematic review are that many of the individual studies were not RCTs and most studies had small sample sizes. For each article reviewed, an effect size was unable to be calculated therefore a meta-analysis could not be performed. Parameters were limited in consistency, specifying treatment times, and the effectiveness of a long-term follow up was not determined. Other limitations include the omissions of non-English language publications, the potential for publication bias and no adverse effects were mentioned in the individual articles. Adverse effects that can be seen while using electrical stimulation include skin irritation, discomfort during application, and short-term duration of the effects. It is clinically important to note said adverse effects for one must weigh the pros and cons of the application for each individual person. When evaluating a study, adverse effects are an important component to consider for a clinician's use of electrical stimulation.

For future research, long-term follow-ups are needed, along with a standardization of parameters. These research studies should also be performed with larger sample sizes. Overall, there needs to be much more future research to come to a conclusion on which parameters work the best to decrease tone in patients with neurological disorders.

## Conclusion

Electrical stimulation alone, and included in a multimodal treatment plan seems to produce an anti-spastic effect in individuals with acute and chronic neuromuscular disorders. It may be beneficial for clinicians to utilize electrical stimulation prior to and/or during their treatment session to reduce spasticity. This reduction in spasticity may

potentially optimize the treatment session aiding a person in reaching their goals for physical therapy in a safe and efficient manner. It also has the potential to improve their quality of life

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Table 1.

Study	Country	Dx	N	Study Arms	Outcomes	Follow-up	Treatment	Results	Strengths and limitations	Parameters
Weingarden et al. (1998)		TBI CVA	10	Upper extremity FES orthosis system	Passive range of motion (goniometric measurements) Posture measurements of the wrists and elbow joints at rest (with improvement being toward neutral)	6 month	All participants received electrical stimulation 30 minutes 2x/day and gradually increased to a total of several hours per day for 6 months. AROM was initiated during the first 2 weeks of the protocol. FES functional training was initiated during the 3 <sup>rd</sup> week.	Significant improvements in PROM measurements and posture of the upper extremity. Improvement in MAS, but not significant	MAS is reliable and valid No control group No blinding	36pps, 40% duty cycle, burst duration was individualized, pulse duration ranged from 0.1-0.5ms, ramp of the stimulation was individualized

Ring et al. (2005)	Israel	CVA	22	Control group + physical therapy Neuroprosthesis group + physical therapy	MAS Active range of motion (goniometric measurements)	None	All participants attended 3 therapy days per week 3 hours/day. They received functional training to improve ADLs. The neuroprosthesis group used the Handmaster system 10 minutes twice a day, progressed to 50 minutes 3 times a day over the first 2 weeks then remained at this level of use until the end of the 6-week study	Significant reduction in shoulder and finger spasticity was demonstrated in the neuroprosthesis group	Randomized Parameters were individualized  Small sample size	Stimulation parameters were individually adjusted as to pulse duration and amplitude based on muscle response to achieve a full arc of finger motion, and patient tolerance.
Seib et al. (1994)	US	TBI SCI	10	Electrical Stimulation	SMS (spasticity measurement system) Subjective spasticity assessment form	None	10 subjects received electric stimulation with the electrode placed on the tibialis anterior for a 20 minute treatment session	Significant reduction in spasticity in 8 participants at 24hrs post treatment	No control group No blinding	2 second ramp up, 15 seconds on, 20 seconds off , 30 pps, intensity set to individual tolerance



Van der Salm (2006)	The Netherlands	SCI	10	Placebo Agonist stimulation Antagonist stimulation Dermatome stimulation	MAS Clonus score H-reflex measurement Reflex initiating angle	None	Each participant received all 4 interventions on 4 separate days with a minimum of 72 hours between 2 subsequent interventions	Significant reduction in spasticity when stimulating the agonist and antagonist muscles	Blinding Participants were used as their own controls	300us, 30Hz
King (1996)	US	CVA	21	NMES Passive stretch	Torque meter	None	10 patients received NMES while 11 patients received passive stretching. 2 electrodes placed on the volar side of the forearm both proximally and distally.	Significant improvement in NMES group.	Randomized Baseline taken No attrition Standardized  Small Sample	Synchronous mode 45 Hz, 250us, ramp up: down 3:0s on/off 10 sec amplitude 15-20mA

Cheng et al. (2010)	China	CVA	15	Electrical stimulation + rocker board + ambulation training Control + general exercises + ambulation training	MMT (dynamometer) EMG Electronic goniometer Balance master system EFEP (timed walking test)	None	7 patients in control group received 30 min of general exercise and 15 min of ambulation training 8 patients in experimental group received 30 minutes of rocker board training with e-stim and 15 mins of ambulation training	Significant decrease in spasticity with ambulation seen in the experimental group	Randomized Attrition Small Sample size	40Hz, intensity adjusted per person, 10s on/10s off
Granat et al. (1993)	Scotland	SCI	6	PRE + stimulation	MMT (Dynamometer) MAS Pendulum Test Modified Barthel Test	6 month	3 dependent on wheelchair, 3 independent of a wheelchair Individualized strengthening program using electric stimulation.	Significant decrease in spasticity and increase in strength overall	No attrition Reliable and Valid outcome measures Small sample size	25Hz, 300us, duty cycle: 4sec on 8 sec off

Skold et al. (2002)	US	SCI	15	FES cycling Control group	Body weight BMI MAS Isokinetic kin-com EMG VAS	6 month	30 min/sessions: 8 patients received FES cycling 3x/week for 6 months	No significant changes	Randomized No attrition  Small sample size	Not stated
Hesse et al. (1998)	Germany	CVA	24	Botox +electrical stim Botox Placebo + electrical stim Placebo	MAS Goniometric measurement ADL subjective data	2, 6, 12 weeks	Patients that received botox received 2 injections per muscle (FCU, FCR, FDP) electrical stimulation groups received stim of both arms and forearm for 30 minutes 3x/day during 3 days following injection	No significant decrease in spasticity across groups. Muscle tone reduction was most prominent in bottom +e-stim group	Randomized Blinding  Outcome measures (with the exception of MAS) may not be valid	20 Hz, 200us, 50- 90mA
Carda et al. (2005)	Italy	CVA	65	Botulinm +functional taping Botulinum + Estim	MAS	1 month	90 minutes a day for 5 days	Botulinum and taping was more significant	Large sample size  Not randomized	Continuous 10s 50Hz 300ms

Yamaguchi et al. (2001)	Japan	CVA	27	Electric stimulation + passive locomotion Electric stimulation only Passive locomotion only	MAS	None	9 patients per group. 20 minutes/session; e-stim was applied to end plate zone of the tibialis anterior.	Significant improvement in electrical stimulation combined with passive locomotion	Randomized Tx allocation concealed Small sample size	Biphasic current ; 30Hz, 0.3us
Krause et al. (2008)	Germany	SCI	5	Active movement +FES Passive movement	MAS Pendulum test/ relaxation index	None	All subjects received both treatments	Significant increase in relaxation index after the active session + FES	Randomized Assessor blinded Small sample size	Biphasic Pulse width 500ms Frequency 20Hz
Lo et al. (2009)	Taiwan	CVA	17	Functional electrical stimulation assisted leg cycling wheelchair	MAS H-reflex measurement Pendulum test	None	8 subjects as a control group used a leg cycling WC 7 subjects used FES-LW This was performed for 10 days	There was a significant reduction in spasticity with use of the FES-LW	Reliable tests and measures No long term follow up Not randomized	Biphasic 20 Hz frequency pulse duration of 300ns

Chung et al. (2010)	China	SCI	18	Active TENS Placebo TENS	Composite spasticity score	None	Electrodes were placed over the common peroneal nerve posterior to the head of the fibula to the limb with dominant spasticity for 60 minutes	Significant reduction in spasticity in the active TENS group	Randomized Blinding Reliable and valid outcome measure  Small sample size	PRO-TENS 0.25ms, 100Hz, 15mA
Armutlu et al. (2003)	Turkey	MS	10	TENS	Enraf nonius myomed electromyographic feedback apparatus MAS Ambulation index	None	All participants received TENS treatment 20min/day for 4 weeks Electrodes placed at middle of gastroc/soleus, and laterally to plantar surface of the foot	Significant reduction in spasticity	Randomized No attrition Reliable outcome measures  Small sample No control	100Hz, 0.3us

Aydin et al. (2005)	Turkey	SCI	21	1. Baclofen + exercise 2. TENS + exercise	MAS SFS(spasticity frequency scale): self report DTR Electrophysiologic investigations	None	10 participants received baclofen and 11 received TENS. Baclofen group dosage was increased by 5mg every 3-5 days until a max of 80mg was reached. In TENS group, electrodes were placed on bilateral tibial nerves. 15 sessions lasting 15 minutes	Significant improvements in both treatment groups No significant difference between groups	Blinding to evaluation	Biphasic square waves ; 50 mA (not causing contraction) 100Hz, 100us
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## Appendix A

**PEDro scale**

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1. eligibility criteria were specified
  2. subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)
  3. allocation was concealed
  4. the groups were similar at baseline regarding the most important prognostic indicators
  5. there was blinding of all subjects
  6. there was blinding of all therapists who administered the therapy
  7. there was blinding of all assessors who measured at least one key outcome
  8. measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups
  9. all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”
- no  yes  where: no  yes  where:
- no  yes  where:
- no  yes  where: no  yes  where: no  yes  where: no  yes  where:
- no  yes  where:
- no  yes  where: 10. the results of between-group statistical comparisons are reported for at least one
- key outcome no  yes  where: 11. the study provides both point measures and measures of variability for at
- least one key outcome no  yes  where