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QUALITY FOR LIFE

**Functional Electrical Stimulation and  
EMG Triggered Electrotherapy in motor  
rehabilitation after stroke:  
An Analysis of Scientific Literature**

Literature Survey



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Stroke is the most frequent cause of permanent disability in adults. The incidence within Germany is at approximately 200 000 newly diagnosed patients. In the USA, there are approximately 700 000 strokes annually (1-8). The number of patients who have survived a stroke (prevalence) is about 700 000 to 950 000 within Germany, while it is approximately 3 million in the USA (1-9). Approximately 90 % of these patients suffer from some form of motor loss or disability which requires some form of treatment (7). Large outcome studies have shown that only 5 % of surviving patients regain full use of their arm while 20 % of patients are completely unable to use their arm 3 months after a stroke (10). Regarding ability to walk, 75 % of stroke survivors attain limited walking ability within 12 weeks, while approximately 25 % remain permanently dependent on a wheelchair (11). The best prognosis for recovery of motor functions following stroke is dependent on the extent of the initial motor function failure and the question whether these failures are accompanied by function reducing spasm in the upper and lower extremities (12).

Costs per patient in the first year after a single stroke amount to 18 517 € within Germany (13). Of this, 37 % is spent on rehabilitation, while outpatient treatment accounts for 49 % in the subsequent four years and therefore becomes the main cost factor. Lifelong direct treatment costs average 43 129 € per patient for ischemic stroke. Of this, around 40 % is spent on outpatient treatment, 22 % on inpatient treatment, 21 % on rehabilitation, and 17 % on nursing care (13). The total medical costs for stroke treatment in Germany in 2004 amounted in excess of 7.1 billion € (13). In a multi national study of 16 industrial nations, the lifelong costs of a stroke patient range from 11 787 US dollars for "not further specified" strokes in Australia and 3 035 671 US dollars for a stroke patient with untreated non-rheumatic atrial fibrillation (14). The average lifelong costs for a patient with ischemic stroke lie between 41 257 US dollars in Australia and 104 629 US dollars in Great Britain. The costs are determined mainly by the severity of the stroke (extended hospitalisation), the patient age (higher costs for younger patients) and gender (higher direct costs for women, higher indirect costs for men) (14). These costs for the care of stroke patients underline the high economic significance of this illness for the health systems of developed countries.

The rehabilitation goal for stroke patients is to improve everyday relevant motor functions and allow meaningful contribution to society. Consequently, therapy includes deficit specific training in all categories of motor function (posture control, locomotion, proper use of arms and hands), consolidation and automation of what is learned, as well as transfer of what is learned into everyday life. In patients with functionally relevant motor deficits, 5 weekly 30 – 45 minute deficit specific physiotherapy treatments are indicated (9). Task specific, repetitive training exercises have been shown to be particularly effective. Repetitive sensory motor training, in which simple motions of the arms and hands are repeatedly practised, encourages and speeds up motor function recovery in the upper extremities (15 – 18). Treadmill training with partial weight bearing is of great importance for restoration of walking (19). Also relevant is the selection of the walking speed, which can be improved by specific speed training on the treadmill (20).

In general, physiotherapy and occupational therapy individual treatment remain the preferred option. In moderately affected patients who can and are willing to cooperate, treatment can also take place task specifically in small groups (9). The results of physiotherapeutic treatment can be enhanced by additional intention dependent, EMG triggered functional electrical stimulation (8, 9, 12, 21, 22).

In EMG triggered electrical stimulation, electrical stimulation is voluntarily triggered by the residual muscle activity in the affected muscle. Therefore, the patient is asked to voluntarily tense the paretic muscles. The idea of movement increases electrical activity in the affected musculature (24). Through imagining the activation of the paretic muscle, muscle's EMG activity is increased, which is then registered in the stimulation unit. When EMG activity exceeds a preset level, external electrical stimulation of the muscle takes place which increases or triggers muscle contractions (12). The underlying thought behind intention dependent, EMG triggered functional electrical stimulation is a positive influence on neuronal plasticity of the brain due to proprioceptive and somatosensory feedback from the electrically stimulated, active muscle contraction, due to which the activity of the motoneuron is laid out and the central representation of the damaged extremity is improved. This leads to reorganisation of cerebrally damaged areas as well as physiological learning processes. Marinacci and Horande already proved in 1960 that use of the EMG information brought about improvement in patients' muscular output (25). EMG-triggered functional electrical stimulation is proven to encourage the recovery of motor function. The corresponding clinical studies to prove effectiveness are separately shown and evaluated in the following text. Modern, evidence based guidelines, such as those of the German Association for Neurology (22) and the internationally renowned and independent Stroke Foundation (23), show clearly the positive recommendations for therapeutic electrical stimulation. A high evidence level provides a clear statement in favour of electrical stimulation and EMG biofeedback therapy.

It is of great importance that rehabilitation of stroke patients is not limited to inpatient treatment. Through professional care after discharge from acute and rehabilitation clinics, it is possible to avoid a need for additional care. In a systematic overview work according to the criteria of the Cochrane Collaboration, 14 randomised, controlled studies with 1617 patients with an average age of 70 years (55 to 75.5 years) were evaluated. The study participants mainly suffered from slight to moderate disabilities. Rehabilitative measures usually lasted for at least 12 weeks, while the follow-up took 3 to 12 months. Through the rehabilitative interventions, the risk of no longer being able to handle tasks of daily life was significantly reduced by 28 % (26). Functional electrical stimulation with a battery operated home unit also provides the patients with the option of taking independent action on improving their movement functions.

**Andreas Kannenberg, M.D.**  
*Director Medical Affairs*  
Otto Bock HealthCare GmbH  
Duderstadt/Germany

**Milana Mileusnic, PhD**  
*Clinical Trials Manager*  
Otto Bock HealthCare GmbH  
Vienna/Austria

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Epidemiologische Daten zur Schlaganfallerkrankung. Daten des WHO-MONICA-Projektes in Deutschland.  
Nervenarzt 69 (1998), 1091-1099
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A prospective community-based study of stroke in Germany – the Erlangen Stroke Project (ESPro): incidence and case fatality at 1, 3, and 12 months.  
Stroke 29 (1998), 2501-2506
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The Greater Cincinnati/Northern Kentucky stroke study: preliminary first-ever and total incidence rates of stroke among blacks.  
Stroke 29 (1998), 415-421
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Incidence and occurrence of total (first-ever and recurrent) stroke.  
Stroke 30 (1999), 2523-2528
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Neuromuscular electrical stimulation for motor relearning in hemiparesis.  
Phys Med Rehabil Clin N Am 14 (2003), S93-S109
- 9. Freivogel S, Hummelsheim H**  
Qualitätskriterien und Leitlinien für die motorische Rehabilitation von Patienten mit Hemiparesen.  
Akt Neurol 30 (2003), 401-406
- 10. Nakayama H, Jorgensen HS, Raaschou HO, Olsen TS**  
Recovery of upper extremity function in stroke patients: the Copenhagen study.  
Arch Phys Med Rehabil 75 (1994), 852-857
- 11. Jorgensen HS, Nakayama H, Raaschou HO, Olsen TS**  
Recovery of walking function in stroke patients: the Copenhagen stroke study.  
Arch Phys Med Rehabil 76 (1995), 27-32
- 12. Hesse S, Werner C**  
Poststroke Motor Dysfunction and Spasticity. Novel Pharmacological and Physical Treatment Strategies.  
CNS Drugs 17 (2003), 1093-1107
- 13. Kolominsky-Rabas PL, Reuschmann PU, Marschall P, Emmert M, Baltzer N, Neundörfer B, Schoffski O, Krobot KJ**  
Lifetime cost of ischemic stroke in Germany: results and national projections from a population-based stroke registry: the Erlangen Stroke Project.  
Stroke 37 (2006), 1179-1183

14. **Palmer AJ, Valentine WJ, Roze S, Lammert M, Spiesser J, Gabriel S**  
Overview of costs of stroke from published incidence-based studies spanning 16 industrialized countries.  
Curr Med Res Opin 21 (2005), 19-26
15. **Langhammer B, Stranghelle JK**  
Bobath or motor relearning programme? A comparison of two different approaches of physiotherapy in stroke rehabilitation: a randomized controlled study.  
Clin Rehabil 14 (2000), 361-369
16. **Woldag H, Hummelsheim H**  
Evidence-based physiotherapeutic concepts for improving arm and hand function in stroke patients. A review.  
J Neurol 249 (2002), 518-528
17. **Bütefisch C, Hummelsheim H, Denzler P, Mauritz KH**  
Repetitive training of isolated movements improves the outcome of motor rehabilitation of the centrally paretic hand.  
J Neurol Sci 130 (1995), 59-68
18. **Hummelsheim H, Maier-Loth ML, Eickhof C**  
The functional value of electrical muscle stimulation for the rehabilitation of the hand in stroke patients.  
Scand J Rehabil Med 29 (1997), 3-10
19. **Hesse S, Malezic M, Schaffrin A, Mauritz KH**  
Restoration of gait by combined treadmill training and multichannel electrical stimulation in non-ambulatory hemiparetic patients.  
Scand J Rehabil Med 27 (1995), 199-204
20. **Pohl M, Mehrholz J, Ritschel C, Ruckriem S**  
Speed-dependent treadmill training in ambulatory hemiparetic patients.  
Stroke 33 (2002), 553-558
21. **Platz T**  
Evidenzbasierte Armrehabilitation.  
Nervenarzt 74 (2003), 841-849
22. **Diener HC, Putzki N, Berlit P**  
Leitlinien für Diagnostik und Therapy in der Neurologie: Motorische Rehabilitation nach Schlaganfall.  
3<sup>rd</sup> revised edition, Georg-Thieme-Verlag, Stuttgart, 2005, S. 655-656
23. **National Stroke Foundation**  
Clinical Guidelines for Stroke Rehabilitation and Recovery  
National Stroke Foundation, Melbourne, 2005
24. **Hansen GV**  
EMG-controlled functional electrical stimulation of the paretic hand.  
Scand J Rehabil Med 11 (1979), 189-193
25. **Marinacci AA, Horande M**  
Electromyogram in neuromuscular reeducation.  
Bull Los Angeles Neurol Soc 25 (1960), 57-73
26. **Legg L**  
Outpatient Service Trialists: Rehabilitation therapy services for stroke patients living at home: systematic review of randomised trials.  
Lancet 363 (2004), 352-356

# Individual Representation and Evaluation of the Clinical Studies Regarding Functional Electrical Stimulation

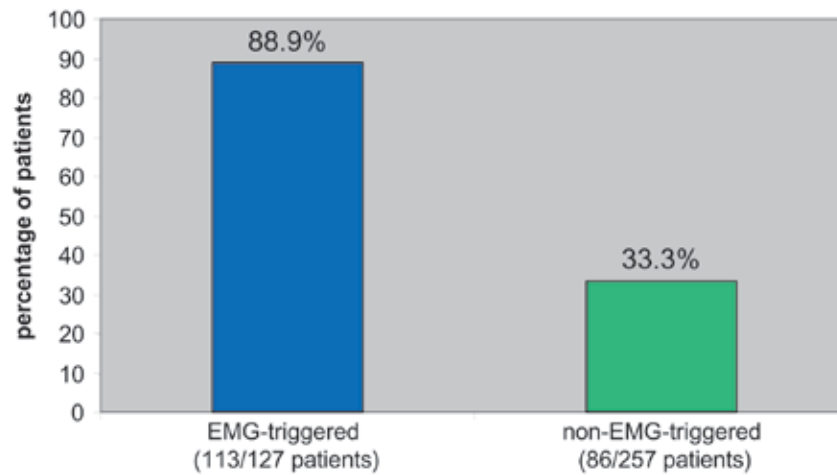
## 1. Reviews and Meta-Analyses of Clinical Studies

### 1.1

<b>Title</b>	de Kroon JR, Ijzerman MJ, Chae J, Lankhorst GJ, Zilvold G Relation between stimulation characteristics and clinical outcome in studies using electrical stimulation to improve motor control of the upper extremity in stroke. J Rehabil Med 37 (2005), 65-74
<b>Study type</b>	Meta-Analysis
<b>Formal evidence category</b>	Ia/IIa
<b>Frame of reference</b>	Treatment of plegia in the upper extremities
<b>Indications</b>	Hemiplegia with participation of the upper extremity
<b>Inquiry / Aim</b>	Examination of the relationship between the characteristics of electrical stimulation and the effect on recovery of motor control of the upper extremity.
<b>Relevant criteria for inclusion and exclusion</b>	<ol style="list-style-type: none"> <li>1. Use of electrical stimulation in rehabilitation of the upper extremities after stroke.</li> <li>2. Use of electrical stimulation with triggering muscle contractions.</li> <li>3. Clinical context – case series, case control studies or randomised controlled studies.</li> <li>4. Relevant outcome parameters for motor control.</li> <li>5. Detailed statement of results for the upper extremity.</li> <li>5. Detailed publication in English, German, French or Dutch from January 1996 to December 2003.</li> </ol>
<b>Tested intervention</b>	Treatment with electrical stimulation
<b>Control intervention</b>	Treatment without electrical stimulation
<b>Possible further treatment groups</b>	None.
<b>Study design</b>	Literature review of 19 studies, of which 12 are randomised controlled clinical studies
<b>Number of centres</b>	n.a.
<b>Randomisation</b>	n.a.
<b>Concealment (masking) of randomisation</b>	n.a.
<b>Blind treatment</b>	n.a.
<b>Observation period</b>	
<b>Primary target criteria</b>	The most relevant outcome parameter of each study was selected. An attempt was made to try to investigate the relationship between the reported effect of electrical stimulation and the parameters such as duration, stimulation method, frequency, amplitude, pulse width, target muscles and stage (acute, subacute, chronic).
<b>Secondary target criteria</b>	n.a.
<b>Number of patients receiving treatment</b>	n.a.

<b>Number and characteristics of included and assessed patients</b>	<p>578 patients (392 electrical stimulation, 186 controls) were included in the review. 4 studies were carried out with patients in the acute phase (within 1 month), 2 studies with patients in the subacute phase (1-6 months), and 10 studies with patients in the chronic phase (&gt;6 months) after stroke. 3 studies had mixed patients with regard to the phase after the stroke. Regarding the severity of the stroke, 7 studies limited inclusion to patients with remaining function in wrist extension (min. 5-20°). 3 studies made no statement about severity. Overall, the severity of the illness was fairly heterogeneous in all studies.</p> <p>The forms of electrical stimulation varied considerably:</p> <ul style="list-style-type: none"> <li>- Neuromuscular electrical stimulation (157 tested intervention, 51 controls)</li> <li>- EMG-triggered electrical stimulation (127 tested intervention, 41 controls)</li> <li>- Positional Feedback electrical stimulation (15 tested intervention, 15 controls)</li> <li>- TENS (26 tested intervention, 18 controls)</li> <li>- Electroacupuncture with surface electrodes (59 tested intervention, 59 controls)</li> <li>- Combined EMG-triggered and neuromuscular electrical stimulation (20 patients)</li> </ul>
<b>Comparability of the treatment groups</b>	<p>n.a.</p>
<b>Results</b>	<p>A relationship was found between the therapy effect and the form of electrical stimulation. 8 of the 9 therapy groups with triggered electrical stimulation showed positive results (88.9%), while only 4 of the 12 therapy groups with non-triggered electrical stimulation showed positive results (33.3%). The ratio of the success rates was 2.7 and was statistically significant (Chi-Square Test, <math>p = 0.024</math>).</p> <p>Regarding the hours of electrical stimulation per week, total number of hours of stimulation, as well as the stimulation frequency, no connection was shown with the therapy effect. The same was true for the stage after the stroke (acute, subacute, chronic).</p>
<b>Undesired therapy effects</b>	<p>None reported.</p>
<b>Authors' conclusion</b>	<p>Triggered or voluntarily activated functional electrical stimulation appears to be superior to non-triggered electrical stimulation with regard to the therapy effect on motor control of the upper extremities. Future clinical studies should carry out a direct comparison of the two forms of electrical stimulation.</p>

### PERCENTAGE OF PATIENT SHOWING POSITIVE RESULTS WHEN TREATED WITH EITHER EMG-TRIGGERED OR NON-TRIGGERED THERAPY



EMG-triggered electrical stimulation is superior in motor control recovery than non-triggered electrostimulation. Meta-analysis involved a total of 588 acute, subacute and chronic patients.

#### Comment

Meta-analysis suggests that triggered electrical stimulation, particularly EMG-triggered electrical stimulation, is superior to non-triggered electrical stimulation.

This literature review forms one of the foundations for a positive recommendation of therapeutic electrical stimulation in the guideline „Motor Rehabilitation after Stroke“ of the German Association for Neurology (22).

#### Included randomised controlled clinical studies

##### **Bowman BR, Baker LL, Waters RL**

Positional feedback and electrical stimulation: an automated treatment for the hemiplegic wrist.

Arch Phys Med Rehabil 60 81979), 497-502

##### **Chae J, Bethoux F, Bohinc T, Dobos L, Davis T, Friedl A**

Neuromuscular stimulation for upper extremity motor and functional recovery in acute hemiplegia.

Stroke 29 (1998), 975-979

##### **Francisco G, Chae J, Chawla H, Kirshblum S, Zorowitz R, Lewis G, Pang S**

Electromyogram-triggered neuromuscular stimulation for improving the arm function of acute stroke survivors: a randomized pilot study.

Arch Phys Med Rehabil 70 (1998), 570-575

**Sonde L, Gip C, Fernaeus SE, Nilsson CG, Viitanen M**

Stimulation with low frequency (1.7 Hz) transcutaneous electric nerve stimulation (low-TENS) increases motor function of the post-stroke paretic arm.

Scand J Rehabil Med 30 (1998), 95-99

**Powell J, Pandyan D, Granat M, Cameron M, Stoff DJ**

Electrical stimulation of wrist extensors in poststroke hemiplegia.

Stroke 30 (1999), 1384-1389

**Wong AMK, Su T, Tang F, Cheng P, Liaw M**

Clinical trial of electrical acupuncture on hemiplegic stroke patients.

Am J Phys Med Rehabil 78 (1999), 117-122

**Cauraugh J, Light K, Kim S, Thigpen M, Behrman A**

Chronic motor dysfunction after stroke: recovering wrist and finger extension by electromyography-triggered neuromuscular stimulation.

Stroke 31 (2000), 1360-1364

**Sonde L, Kalimo H, Fernaeus SE, Viitanen M,**

Low TENS treatment on post-stroke paretic arm: a three year follow-up.

Clin Rehabil 14 (2000), 14-19

**Cauraugh J, Kim S**

Two coupled motor recovery programs are better than one. Electromyography-triggered neuromuscular stimulation and bilateral movements.

Stroke 33 (2002), 1589-1594

**Cauraugh J, Kim SB**

Chronic stroke motor recovery: duration of active neuromuscular stimulation.

J NeuroSci 215 (2003), 13-19

**Cauraugh J, Kim SB**

Stroke motor recovery: active neuromuscular stimulation and repetitive practice schedules.

J Neurol Neurosurg Psychiatry 74 (2003), 1562-1564

**Kimberley TJ, Lewis SM, Auerbach EJ, Dorsey LL, Lojovich JM, Carey JR**

Electrical stimulation driving functional improvements and cortical changes in subjects with stroke.

Exp Brain Res 154 (2004), 450-460

**de Kroon JR, Ijzerman MJ, Lankhorst GJ, Zilvold G**

Electrical stimulation of the upper extremity in stroke: stimulation of the extensors of the hand versus alternate stimulation of flexors and extensors.

Am J Phys Med Rehabil 83 (2004), 592-600

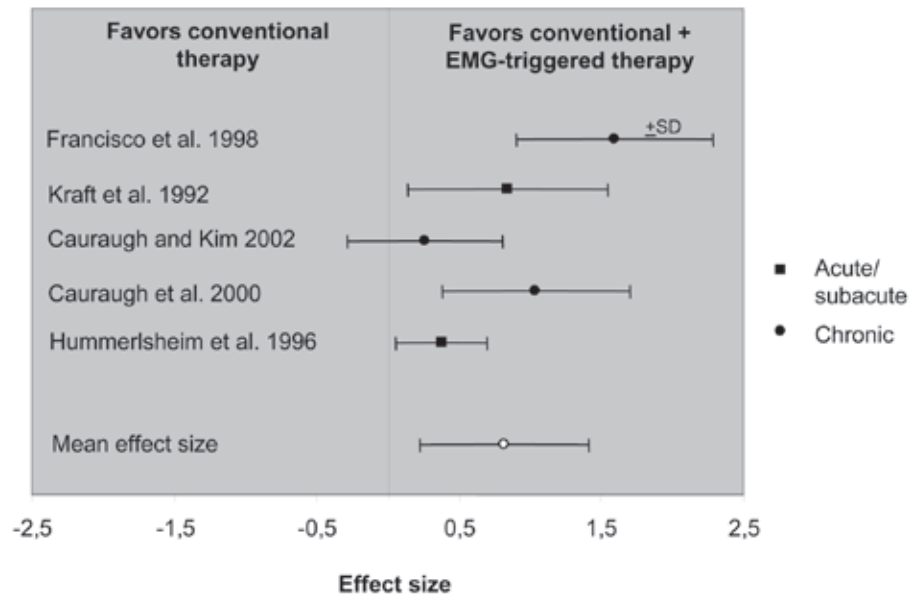
## 1.2

<b>Title</b>	Bolton DAE, Cauraugh JH, Hausenblas HA. Electromyogram triggered neuromuscular stimulation and stroke motor recovery of arm/hand functions: A meta-analysis J Neurol Sci 223 (2004); 121-127
<b>Study type</b>	Meta-analysis of randomised and non-randomised controlled clinical studies
<b>Formal evidence category</b>	Ia / IIa
<b>Frame of reference</b>	Treatment of plegia in the upper extremities
<b>Indications</b>	Hemiplegia of the upper extremities with longer existing stroke
<b>Inquiry / Aim</b>	Effectiveness of functional, EMG triggered electrical stimulation on the function of hands and arms
<b>Relevant criteria for inclusion and exclusion</b>	Inclusion criteria 1. Studies regarding motor function of the upper extremity (however, not solely about strength) 2. Studies regarding EMG triggered electrical stimulation treatment 3. Studies which were published in the English language 4. Studies which had a control group
<b>Tested intervention</b>	EMG triggered electrical stimulation treatment of the upper extremities, treatment duration and frequency varying with the individual studies
<b>Control intervention</b>	Placebo or standard treatment
<b>Possible further treatment groups</b>	n.a.
<b>Study design</b>	3 randomised and 2 non-randomised studies were included (Francisco et al., 1998; Cauraugh et al., 2000; Cauraugh and Kim 2002; as well as Kraft et al., 1992; and Hummelsheim et al., 1996)
<b>Number of centres</b>	n.a.
<b>Randomisation</b>	n.a.
<b>Concealment (masking) of randomisation</b>	n.a.
<b>Blind treatment</b>	n.a.
<b>Observation period</b>	n.a.
<b>Primary target criteria</b>	Functional tests of the upper extremity
<b>Secondary target criteria</b>	n.a.
<b>Number of patients receiving treatment</b>	n.a.
<b>Number and characteristics of included and assessed patients</b>	Altogether 86 patients were included in the 5 studies (of these, 35 in the randomised studies).
<b>Comparability of the treatment groups</b>	n.a.
<b>Results</b>	Functional test: Two studies utilised the box and block test, two utilised Fugl-Meyer test and one utilised Rivermead Motor Assessment tests. The average calculated standardised effectiveness out of the five studies equalled 0.82 (95% confidence interval 0.10 to 1.55). The results were homogeneous between the studies, and there was no difference between randomised and non-randomised studies.
<b>Undesired therapy effects</b>	None reported.

### Authors' conclusion

A standardised effect intensity of 0.82 represents a significant therapy effect. The influence of publication bias cannot explain these results. The effect intensity proves a significant advantage. Based on these results, rehabilitation of chronic plegia after stroke should include EMG triggered electrical stimulation.

### RECOVERY OF ARM/HAND FUNCTION



EMG-triggered electrical stimulation shows large improvements in functional capabilities of arm/hand in acute, subacute and chronic stroke patients.

### Comment

The results of this meta-analysis prove that all previously done comparison studies showed similar advantages of electrotherapy regarding functional improvement of hands and arms. In the overall view of the studies, a significant and clinically relevant superiority of electrotherapy is seen. The quality of the primary studies used in this meta-analysis is regarded as good. This meta-analysis forms one of the foundations for a positive recommendation of therapeutic electrical stimulation in the guideline „Motor Rehabilitation after Stroke“ of the German Association for Neurology (22).

## Included studies

**Kraft G H, Fitts S S, Hammond M C.**

Techniques to Improve Function of the Arm and Hand in Chronic Hemiplegia.  
Arch Phys Med Rehabil 73 (1992), 220-227

**Hummelshein H, Amberger S, Maurtiz KH**

The influence of EMG-initiated electrical muscle stimulation on motor recovery of the centrally paretic hand.  
Eur J Neurol 3 (1996), 245-254

**Francisco G, Chae J, Chawla H, Kirshblum S, Zorowitz R, Lewis G, Pang S**

Electromyogram-triggered neuromuscular stimulation for improving the arm function of acute stroke survivors: a randomized pilot study.  
Arch Phys Med Rehabil 70 (1998), 570-575

**Cauraugh J, Light K, Kim S, Thigpen M, Behrman A**

Chronic motor dysfunction after stroke: recovering wrist and finger extension by electromyography-triggered neuromuscular stimulation.  
Stroke 31 (2000), 1360-1364

**Cauraugh J, Kim S**

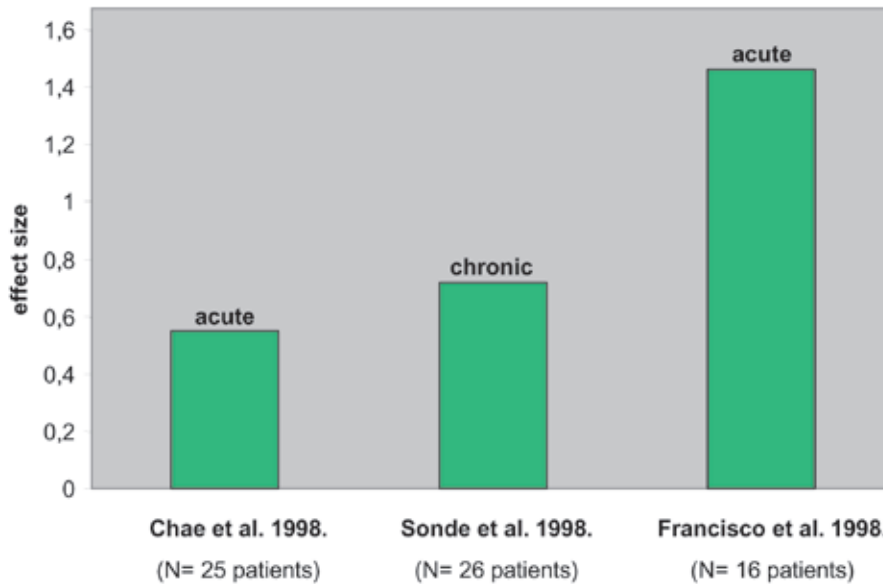
Two coupled motor recovery protocols are better than one: electromyogram-triggered neuromuscular stimulation and bilateral movements.  
Stroke 33 (2002), 1589-1594

## 1.3

<b>Title</b>	De Kroon JR, van der Lee JH, Ijzerman MJ, Lankhorst GJ Therapeutical electrical stimulation to improve motor control and functional abilities of the upper extremity after stroke: A systematic review. Clin Rehabil 16 (2002), 350-360
<b>Study type</b>	Meta-analysis of randomised controlled clinical studies
<b>Formal evidence category</b>	Ia
<b>Frame of reference</b>	Treatment of plegia in the upper extremities
<b>Indications</b>	Hemiplegia with participation of the upper extremity
<b>Inquiry / Aim</b>	Assessment of effectiveness of electrical stimulation with regard to improving motor control and functionality of the paralysed upper extremity after stroke
<b>Relevant criteria for inclusion and exclusion</b>	<ol style="list-style-type: none"> <li>1. Studies about therapeutic electrical stimulation of the upper extremity after stroke with the aim of improving motor control and/or functionality.</li> <li>2. Electrical stimulation with surface electrodes.</li> <li>3. Relevant outcome parameters with regard to motor control and functionality of the upper extremity</li> <li>4. Randomised controlled study</li> <li>5. Detailed publication in English, German, French or Dutch by December 2001</li> </ol>
<b>Tested intervention</b>	Neuromuscular electrical stimulation (2 studies), EMG triggered electrical stimulation (2 studies), Positional Feedback electrical stimulation (1 study) or TENS (2 studies), always in addition to conventional physiotherapy.
<b>Control intervention</b>	Conventional physiotherapy by itself (4 studies) or in combination with sensory stimulation (1 study), or active wrist extensions (1 study)
<b>Possible further treatment groups</b>	None.
<b>Study design</b>	Meta-analysis from 7 randomised controlled clinical studies: Bowman et al., 1979; Chae et al., 1998; Sonde et al., 1998; Francisco et al., 1998; Powell et al., 1999; Sonde et al., 2000; Cauraugh et al., 2000.
<b>Number of centres</b>	n.a.
<b>Randomisation</b>	n.a.
<b>Concealment (masking) of randomisation</b>	n.a.
<b>Blind treatment</b>	n.a.
<b>Observation period</b>	Depending on the study, from 2 weeks to 3 years.
<b>Primary target criteria</b>	Functional tests with regard to motor control and functionality of the upper extremity. A total of 25 different outcome parameters were used in the studies.
<b>Secondary target criteria</b>	n.a.
<b>Number of patients receiving treatment</b>	n.a.
<b>Number and characteristics of included and assessed patients</b>	<p>207 patients were included in the studies (111 electrical stimulation, 96 controls). A total of 30 drop-outs were stated (18 electrical stimulation, 12 controls). Therefore, 177 patients were included in the evaluation.</p> <p>The average patient age ranged from <math>59.4 \pm 11.4</math> years to <math>73.0 \pm 3.5</math> years. 3 studies dealt with patients in the acute phase, one study dealt with patients in the subacute phase, and 2 studies dealt with patients in the chronic phase after stroke. The time after the stroke ranged from <math>17.8 \pm 5.9</math> days to <math>3.49 \pm 2.56</math> years.</p>
<b>Comparability of the treatment groups</b>	n.a.

<b>Results</b>	<p>The quality of the studies was assessed with a score for methodological quality. The score for the included studies ranged from 7 to 16, with a maximum score of 19. The studies were therefore of average to good quality.</p> <p>4 of the 7 studies reported a positive effect of electrical stimulation on motor control of the upper extremity. One of the studies which examined functional outcome parameters reported a positive effect of electrical stimulation on the functionality of the arm. The effect intensity on motor control ranged from 0.55 to 1.46.</p> <p>In two studies, a post-hoc subgroup analysis was done. One study showed a significantly better effect of electrical stimulation in less severely affected patients by comparison to more severely affected patients. The other study reported a significant effect on functionality in the less severely affected group as opposed to no effect in the overall sample.</p> <p>There was no recognisable link between the reported effect and the stage (acute, subacute, chronic) after stroke.</p>
<b>Undesired therapy effects</b>	None reported.
<b>Authors' conclusion</b>	Therapeutic electrical stimulation appears to have a positive effect on motor control of the upper extremity in stroke patients. At the time of the meta-analysis, data were insufficient for proving a positive effect of electrical stimulation on functionality. Differentiation of the effect of various forms of electrical stimulation was not possible. Thus far, there is no indicator that specific forms of electrical stimulation are more effective than others.

## EFFECT OF ELECTRICAL STIMULATION THERAPY ON MOTOR CONTROL



Addition of therapeutic electrical stimulation to conventional physiotherapy has a positive effect on motor control in acute, subacute and chronic stroke patients.

### Comment

The meta-analysis proves a positive effect of electrical stimulation on motor control of the upper extremity in all phases after stroke (acute, subacute, chronic). Furthermore, it was not possible to show that a specific form of electrical stimulation is superior to others, wherein the same authors, in a new review (de Kroon et al., 2005), have meanwhile found clear indicators for superiority of triggered functional electrical stimulation. This meta-analysis forms one of the foundations for a positive recommendation of therapeutic electrical stimulation in the guideline „Motor Rehabilitation after Stroke“ of the German Association for Neurology (22).

## Included studies

**Bowman BR, Baker LL, Waters RL**

Positional feedback and electrical stimulation: an automated treatment for the hemiplegic wrist.  
Arch Phys Med Rehabil 60 (1979), 497-502

**Chae J, Bethoux F, Bohinc T, Dobos L, Davis T, Friedl A**

Neuromuscular stimulation for upper extremity motor and functional recovery in acute hemiplegia.  
Stroke 29 (1998), 975-979

**Francisco G, Chae J, Chawla H, Kirshblum S, Zorowitz R, Lewis G, Pang S**

Electromyogram-triggered neuromuscular stimulation for improving the arm function of acute stroke survivors: a randomized pilot study.  
Arch Phys Med Rehabil 70 (1998), 570-575

**Sonde L, Gip C, Fernaeus SE, Nilsson CG, Viitanen M**

Stimulation with low frequency (1.7 Hz) transcutaneous electric nerve stimulation (low-TENS) increases motor function of the post-stroke paretic arm.  
Scand J Rehabil Med 30 (1998), 95-99

**Powell J, Pandyan D, Granat M, Cameron M, Stoff DJ**

Electrical stimulation of wrist extensors in poststroke hemiplegia.  
Stroke 30 (1999), 1384-1389

**Cauraugh J, Light K, Kim S, Thigpen M, Behrman A**

Chronic motor dysfunction after stroke: recovering wrist and finger extension by electromyography-triggered neuromuscular stimulation.  
Stroke 31 (2000), 1360-1364

**Sonde L, Kalimo H, Fernaeus SE, Viitanen M,**

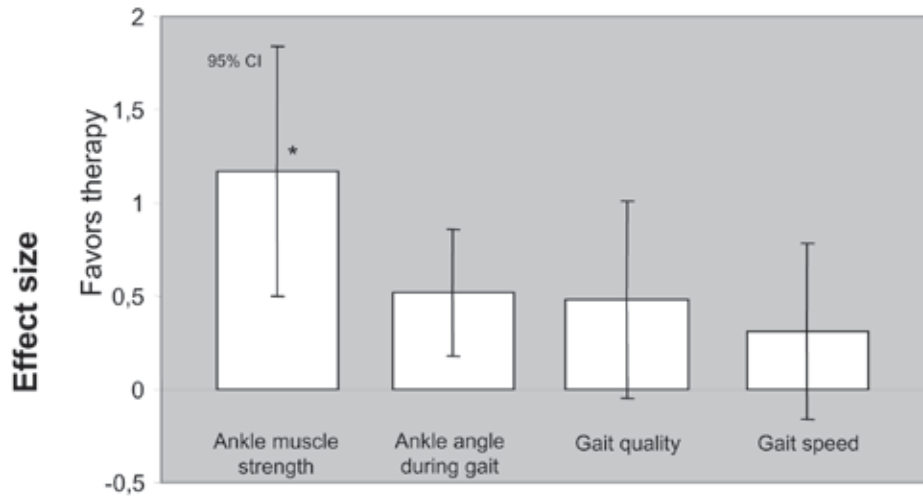
Low TENS treatment on post-stroke paretic arm: a three year follow-up.  
Clin Rehabil 14 (2000), 14-19

## 1.4

<b>Title</b>	Moreland JD, Thomson MA, Fuoco AR Electromyographic biofeedback to improve lower extremity function after stroke: A meta-analysis. Arch Phys Med Rehabil 70 (1998), 134-140
<b>Study type</b>	Meta-analysis
<b>Formal evidence category</b>	Ia
<b>Frame of reference</b>	Treatment of stroke related plegia of the lower extremity
<b>Indications</b>	Hemiplegia with participation of the lower extremity
<b>Inquiry / Aim</b>	Examination of effectiveness of EMG biofeedback by comparison to conventional physiotherapy to improve function of the lower extremity after stroke
<b>Relevant criteria for inclusion and exclusion</b>	Inclusion criteria <ol style="list-style-type: none"> <li>1. Stroke in adults</li> <li>2. Intervention in the treatment group: EMG biofeedback alone or in combination with conventional physiotherapy; in the control group: conventional physiotherapy without any form of feedback and functional electrical stimulation.</li> <li>3. Outcomes: Functional assessment of the lower extremity, including functional tests and walking, stage of recovery of motor function, scope of movement and muscle strength.</li> <li>4. Study design: Exclusively randomised controlled clinical studies</li> <li>5. Study quality: Follow-up in at least 95% of included patients (without deaths), comparability of treatment and control groups regarding age, time since stroke, ability to communicate, sensitivity, baseline values of outcome variables, treatment time and cooperation in both groups, random assignment of therapists to patients, monitoring of treatment protocols with regard to precision and consistency, use of placebo feedback in the control group, avoidance of contamination and parallel treatments, analysis of drop-outs in the respective group to which they were randomised.</li> <li>6. Publication in the English language up to and including December 1995</li> </ol>
<b>Tested intervention</b>	EMG biofeedback alone or in combination with conventional physiotherapy.
<b>Control intervention</b>	Conventional physiotherapy without any form of feedback and with functional electrical stimulation.
<b>Possible further treatment groups</b>	n.a.
<b>Study design</b>	Meta-analysis from 8 randomised controlled clinical studies: Basmajian et al., 1975; Binder et al., 1981; Burnside et al., 1982; John, 1986; Mulder et al., 1986; Cozean et al., 1988; Colborne et al., 1993; Intiso et al., 1994
<b>Number of centres</b>	n.a.
<b>Randomisation</b>	n.a.
<b>Concealment (masking) of randomisation</b>	n.a.
<b>Blind treatment</b>	Assessment of the study quality and extraction of study data for the meta-analysis by 2 evaluators.
<b>Observation period</b>	In the included studies: 4 – 8 weeks
<b>Primary target criteria</b>	Walking speed (6 studies), scope of movement of the ankle joint (4 studies), gait quality (3 studies), ankle angle and double step length (3 studies), strength of ankle movements (2 studies)
<b>Secondary target criteria</b>	n.a.
<b>Number of patients receiving treatment</b>	No statements given.

<b>Number and characteristics of included and assessed patients</b>	No statement of number of patients. The time since the stroke ranged from 0.4 to 144 months.
<b>Comparability of the treatment groups</b>	It is reported that in many studies, too few data were published for a definite assessment of whether the groups are comparable.
<b>Results</b>	<p>97 studies were identified as relevant, 12 studies fulfilled all selection criteria, 4 studies were nonetheless excluded since outcome data were neither published, nor possible to provide by the author. Lastly, 8 studies were included in the meta-analysis.</p> <p>Ankle muscle strength (2 studies): Both studies reported a positive influence of EMG biofeedback on the strength of the ankle muscles. One study reported significant improvements. The combined effect intensity was statistically significant (<math>p = 0.0006</math>) with an average of 1.17 (95% CI 0.60-1.85). In natural units, this means a strength increase of 2.5 kp through EMG biofeedback.</p> <p>Gait quality (3 studies): The average effect intensity was not statistically significant (<math>p = 0.08</math>) with an average of 0.48 (95% CI <math>-0.06 - 1.01</math>).</p> <p>Scope of movement of the ankle joint (4 studies): The effect intensity was negative in two studies and positive in two studies. The average combined effect intensity was non-significant at 0.07 (95% CI <math>-0.42 - 0.57</math>).</p> <p>Ankle angle while walking (3 studies): All 3 studies showed positive effect intensity. The average combined effect intensity was non-significant at 0.51 (95% CI <math>-0.17 - 1.21</math>). The effect intensity corresponds to a change in the ankle angle of <math>5.7^\circ</math> while walking, due to EMG biofeedback.</p> <p>Double step length (3 studies): 2 studies found better results for conventional physiotherapy. The average combined effect intensity was non-significant at 0.09 (95% CI <math>-0.56 - 0.73</math>).</p> <p>Walking speed (6 studies): The effect of EMG biofeedback was negative in 2 studies and positive in 4 studies. The average combined effect intensity was non-significant at 0.31 (95% CI <math>-0.16 - 0.78</math>). This difference corresponds to an 8.4 m increase in the walking distance in 2 minutes due to EMG biofeedback.</p>
<b>Undesired therapy effects</b>	None reported.
<b>Authors' conclusion</b>	The meta-analysis points out the effectiveness of EMG biofeedback for improving the strength of the ankle dorsiflexors. However, generalisation is limited to patients who can walk and whose stroke is more than 3 months ago, who have paresis of the ankle dorsiflexors, and who have a scope of movement of the ankle joint to the neutral position. For the scope of movement of the ankle and the double step length, small, non-significant effect intensities were calculated. Even though not statistically significant, average effect intensities of EMG biofeedback were noted for gait quality, ankle angle while walking, and walking speed. However, the power analysis showed that larger studies are required to confirm these effects.

### EFFECT SIZES FOR LOWER EXTREMITY FUNCTIONAL MEASUREMENTS FOLLOWING EMG BIOFEEDBACK THERAPY



EMG biofeedback therapy applied to acute/subacute hemiplegic stroke patients who were able to walk and had some residual movement in the ankle joint resulted in improvements in the strength of the ankle dorsiflexion muscles, gait quality, ankle angle during gait and gait velocity.

#### Comment

EMG biofeedback therapy generates clinically relevant positive effects in hemiplegic patients.

## Included studies

### **Basmajian JV, Kukulka CG, Narayan MG, Takebe K**

Biofeedback treatment of foot-drop after stroke compared with standard rehabilitation technique: effects on voluntary control and strength.

Arch Phys Med Rehabil 56 (1975), 231-236

### **Binder Sa, Moll CB, Wolf SL**

Evaluation of electromyographic biofeedback as an adjunct to therapeutic exercise in treating lower extremities of hemiplegic patients. Phys Ther 61 (1981), 886-893

### **Burnside IG, Tobias S, Bursill D**

Electromyographic feedback in the remobilization of stroke patients: a controlled trial.

Arch Phys Med Rehabil 63 (1982), 217-222

### **John J**

Failure of electrical myofeedback to augment the effects of physiotherapy in stroke.

Int J Rehabil Res 9 (1986), 35-45

### **Mulder T, Hulstijn W, van der Meer J**

EMG feedback and the restoration of motor control.

Am J Phys med Rehabil 65 (1986), 173-187

### **Cozean CD, Pease ES, Hubbell SL**

Biofeedback and functional electrostimulation in stroke rehabilitation.

Arch Phys Med Rehabil 69 (1988), 401-405

### **Colborne GR, Olney SJ, Griffin MP**

Feedback of ankle joint angle and soleus electromyography in the rehabilitation of hemiplegic gait.

Arch Phys Med Rehabil 74 (1993), 1100-1106

### **Intiso D, Santili V, Grasso MG, Rossi R, Caruso I**

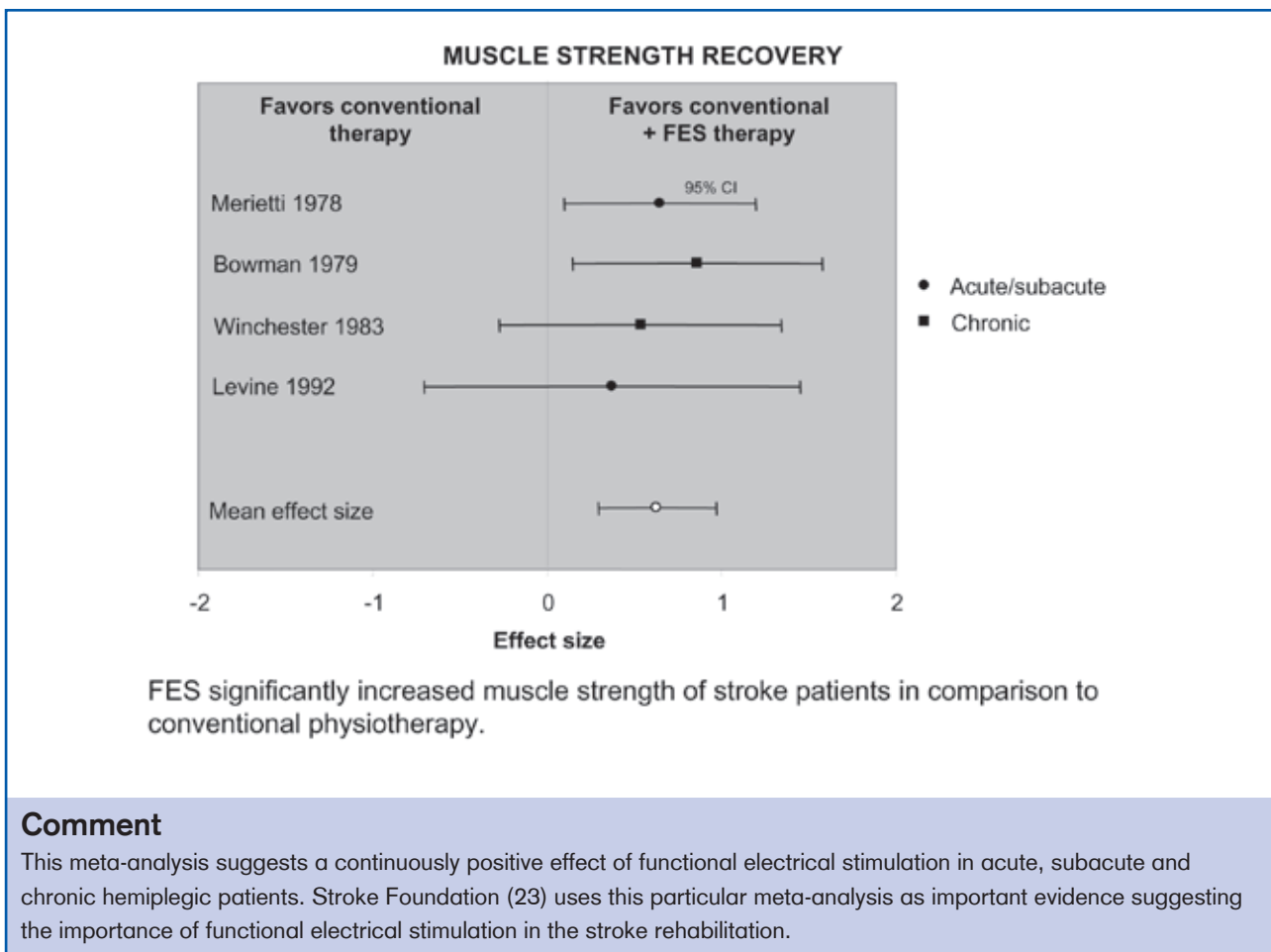
Rehabilitation of walking with electromyographic biofeedback in foot-drop after stroke.

Stroke 25 (1994), 1198-1192

## 1.5

<b>Title</b>	Glanz M, Klawansky S, Stason W, Berkey C Functional electrostimulation in poststroke rehabilitation: A meta-analysis of the randomized controlled trials. Arch Phys Med Rehabil 77 (1996), 549-553
<b>Study type</b>	Meta-analysis of randomised controlled clinical studies
<b>Formal evidence category</b>	Ia
<b>Frame of reference</b>	Treatment of plegia in the upper and lower extremities
<b>Indications</b>	Hemiplegia of the upper or lower extremities with longer existing stroke
<b>Inquiry / Aim</b>	Effectiveness of functional electrical stimulation in rehabilitation after stroke.
<b>Relevant criteria for inclusion and exclusion</b>	Inclusion criteria 1. Randomised controlled clinical study about functional electrical stimulation in rehabilitation after stroke 2. Publication in the English language up to 1994
<b>Tested intervention</b>	Electrical stimulation treatment with (2 studies) or without biofeedback (2 studies). In 3 studies electrical stimulation treatment was combined with conventional physiotherapy, in one study sole electrical stimulation treatment without biofeedback
<b>Control intervention</b>	Conventional physiotherapy (3 studies), in one study only placebo electrical stimulation without accompanying physiotherapy
<b>Possible further treatment groups</b>	n.a.
<b>Study design</b>	4 randomised controlled clinical studies were included (Bowman et al., 1979; Winchester et al., 1983; Merletti et al., 1978; Levin, 1992)
<b>Number of centres</b>	n.a.
<b>Randomisation</b>	n.a.
<b>Concealment (masking) of randomisation</b>	n.a.
<b>Blind treatment</b>	Assessment of study quality by 2 independent evaluators, extraction of outcome data by 2 blinded evaluators
<b>Observation period</b>	3-4 weeks
<b>Primary target criteria</b>	Recovery of muscle strength in the treated body region
<b>Secondary target criteria</b>	n.a.
<b>Number of patients receiving treatment</b>	n.a.
<b>Number and characteristics of included and assessed patients</b>	Altogether 122 patients were included in the 4 studies. The time since stroke ranged from 3 weeks to 46 months.
<b>Comparability of the treatment groups</b>	n.a.

<b>Results</b>	<p>The quality scores of the included studies were relatively low with 0.17 (0.11-0.23). The low scores were primarily due to incomplete documentation of randomisation and absent blinding of patients, treating professionals, and evaluators.</p> <p>All four studies reported a positive effect intensity of functional electrical stimulation on recovery of muscle strength in the treated body regions. The combined effect intensity of functional electrical stimulation in the meta-analysis was 0.63 (95% CI 0.29-0.68).</p>
<b>Undesired therapy effects</b>	None reported.
<b>Authors' conclusion</b>	The meta-analysis demonstrates the effectiveness of functional electrical stimulation in recovery of muscle strength after stroke. However, these results permit no conclusions about the influence on other body functions due to functional electrical stimulation. Overall, the use of functional electrical stimulation is regarded as a promising and cost effective method.



## Included studies

### **Bowman BR, Baker LL, Waters RL**

Positional feedback and electrical stimulation: an automated treatment for the hemiplegic wrist.

Arch Phys Med Rehabil 60 81979), 497-502

### **Winchester P, Montgomery J, Bowman B, Hislop H**

Effects of feedback electrical stimulation training and cyclical electrical stimulation on knee extension in hemiparetic patients.

Phys Ther 63 (1983), 1096-1103

### **Merletti R, Zelaschi F, Latella D, Galli M, Angeli S, Sessa MB**

A control study of muscle force recovery in hemiparetic patients during treatment with functional electrical stimulation.

Scand J Rehabil Med 10 81978), 147-154

### **Levin M**

Relief of hemiparetic by TENS is associated with improvement in voluntary and motor functions.

Electroencephalogr Clin Neurophysiol 85 (1992), 131-142

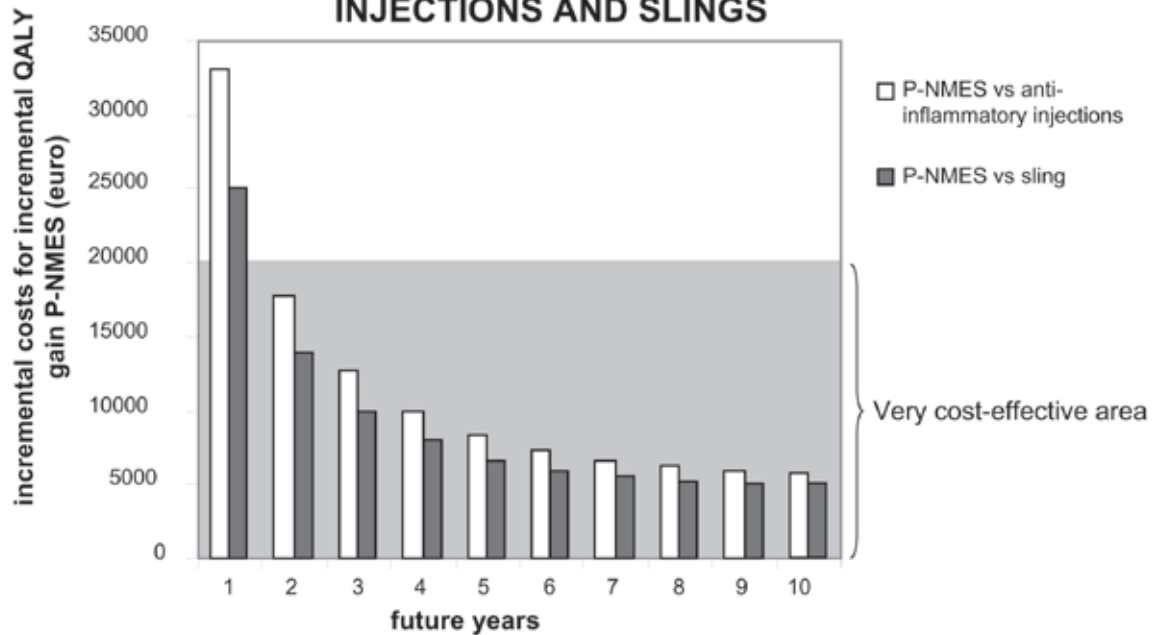
## 2. Economic evaluation studies

### 2.1

<b>Title</b>	Van Til JA, Renzenbrink GJ, Groothuis K, Ijzerman MJ A preliminary economic evaluation of percutaneous neuromuscular electrical stimulation in the treatment of hemiplegic shoulder pain Disability and Rehabilitation 28 (2006), 645-651
<b>Study type identified by the author as</b>	Stage II economic evaluation according to the criteria of Sculpher et al, 1997
<b>Study type according to the evaluator's assessment</b>	Stage II economic evaluation according to the criteria of Sculpher et al, 1997
<b>Formal evidence category</b>	n.a.
<b>Frame of reference</b>	Rehabilitation center in The Netherlands and in the USA
<b>Indications</b>	Chronic hemiplegic shoulder pain in stroke patient
<b>Inquiry / Aim</b>	Preliminary evaluation of the cost-effectiveness of the percutaneous neuromuscular electrical stimulation (P-NMES) in the treatment of chronic hemiplegic shoulder pain (HSP)
<b>Relevant criteria for inclusion and exclusion</b>	1. Chronic hemiplegic shoulder pain
<b>Tested intervention</b>	P-NMES in the treatment of hemiplegic shoulder pain
<b>Control intervention</b>	Sling and anti-inflammatory injections (AI) in the treatment of hemiplegic shoulder pain
<b>Possible further treatment groups</b>	none
<b>Study design</b>	P-NMES: 2 small uncontrolled pilot studies (Yu et al., 2001; Renzenbrink et al., 2001), an uncontrolled trial (Renzenbrink and Ijzerman, 2004) and a randomized controlled trial (Yu et al., 2004); AI injections: unknown design (Snels et al., 2000; Dekker et al., 1997); slings: uncontrolled pilot study (Yu et al., 2001 )
<b>Number of centres</b>	n.a.
<b>Randomisation</b>	n.a.
<b>Concealment (masking) of randomisation</b>	n.a.
<b>Blind treatment</b>	n.a.
<b>Observation period</b>	Data for P-NMES collected from 6 month follow-up; data for AI injections collected from 3 month follow-up; cost-effectiveness of P-NMES vs. AI injections and P-NMES vs. sling was modelled for up to 10 years
<b>Primary target criteria</b>	Not further specified.
<b>Secondary target criteria</b>	Effectiveness of all three treatments and health related quality of life (QoL) for P-NMES were obtained from the literature. These values together with additional data (for ex. QoL for AI injections and slings) were used to calculate: <ul style="list-style-type: none"> <li>•the incremental cost-effectiveness ratio of P-NMES compared to AI injections and sling, and</li> <li>•incremental cost of the first (and subsequent) quality-adjusted life year (cost/QALY) after implantation of the P-NMES device compared to AI injections and slings.</li> </ul>
<b>Number of patients receiving treatment</b>	n.a.

<b>Number and characteristics of included and assessed patients</b>	n.a.
<b>Comparability of the treatment groups</b>	n.a.
<b>Results</b>	<p><b>Short-term analysis</b> (first year following the intervention)</p> <p>The incremental cost-effectiveness ratios (ICER) when P-NMES is compared to AI injections and slings are €6 268 and €4 171, respectively.</p> <p>The incremental cost of the first quality-adjusted year after implantation of the P-NMES device (cost/QALY) compared to AI injections is approx. €33 000 and when compared to slings €27 000.</p> <p>Sensitivity analysis suggests that short-term cost-effectiveness analysis seems to be stable and proof against both changes in costs and changes in effectiveness of the intervention (maximum of €25 additional costs, or approximately 1-2% of additional costs). The range between minimal and maximal effect (QALY gained) is somewhat greater, and the maximum variation can be as great as 25% of additional effects.</p> <p>Long-term analysis</p> <p>Cost-effectiveness (cost/QALY) of P-NMES compared to AI injections and slings decreases to less than €20 000 between 1 and 2 years after the intervention with P-NMES. In the subsequent years the cost-effectiveness continues to drop. For example, 5 years following the intervention cost/QALY is approx. €7 000 and 5 years after that approx. €5 000.</p> <p>The results of long-term cost-effectiveness seem to be stable and proof against both changes in costs and changes in the effectiveness of the intervention.</p>
<b>Undesired therapy effects</b>	None reported
<b>Authors' conclusion</b>	<p>Although more expensive than the alternative interventions, based on both short- and long-term economic evaluations, P-NMES is cost-effective in the treatment of hemiplegic shoulder pain. The incremental cost of P-NMES in the short term analysis falls in the range between</p> <p>€20 000-40 000/QALY (consistent with that of other society-funded medical programs), and falls below the cost-effective threshold of €20 000/QALY (a cost of &lt;€20 000/QALY is considered as particularly cost-effective) between 1 and 2 years following the intervention. Costs of P-NMES are justified for chronic hemiplegic shoulder pain patients. In order to justify it for the subacute patients, future research should try to identify subgroups of those patients that are most likely to develop chronic hemiplegic shoulder pain for which costs of P-NMES would be also justified.</p>

## FUTURE PROJECTIONS OF COST-EFFECTIVENESS OF PERCUTANEOUS NEUROMUSCULAR ELECTRICAL STIMULATION (P-NMES) WHEN COMPARED TO INJECTIONS AND SLINGS



Both short- and long-term economic evaluation study of P-NMES reveals that P-NMES therapy is cost-effective in the treatment of hemiplegic shoulder pain.

### Comment

Although based on data from very small studies, this preliminary economic evaluation study suggests that while more expensive than the alternative interventions, P-NMES is cost-effective in the treatment of hemiplegic shoulder pain.

## Included studies:

**Yu DT, Chae J, Walker ME, Fang ZP.**

Percutaneous intramuscular electric stimulation for the treatment of shoulder subluxation and pain in patients with chronic hemiplegia: A pilot study  
Archives of Physical Medicine & Rehabilitation 82 (2001), 20-25.

**Renzenbrink GJ, Ijzerman MJ**

Percutaneous Neuromuscular Electrical Stimulation (P-NMES) for treating shoulder pain in chronic hemiplegia. Effects on shoulder pain and quality of life  
Clinical Rehabilitation 18 (2004), 359-365.

**Yu DT, Chae J, Walker ME, et al.**

Intramuscular neuromuscular electric stimulation for poststroke shoulder pain: A multicenter randomized clinical trial.  
Archives of Physical Medicine & Rehabilitation 85 (2004), 695-704.

**Renzenbrink GJ, Nijlant JMM, Ijzerman MJ**

StIM system for the treatment of painful shoulder subluxation in chronic hemiplegia; the first European experience.  
Proceedings of 1<sup>st</sup> ISPRM Congress, Bologna; Monduzzi Edit, 2001. pp725-728

**Snels IA, Beckerman H, Twisk JW, et al.**

Effects of triamcinolone acetonide injections on hemiplegic shoulder pain: A randomized clinical trial.  
Stroke 31 (2000), 2396-2401.

**Dekker JH, Wagenaar RC, Lankhorst GJ, de Jong BA**

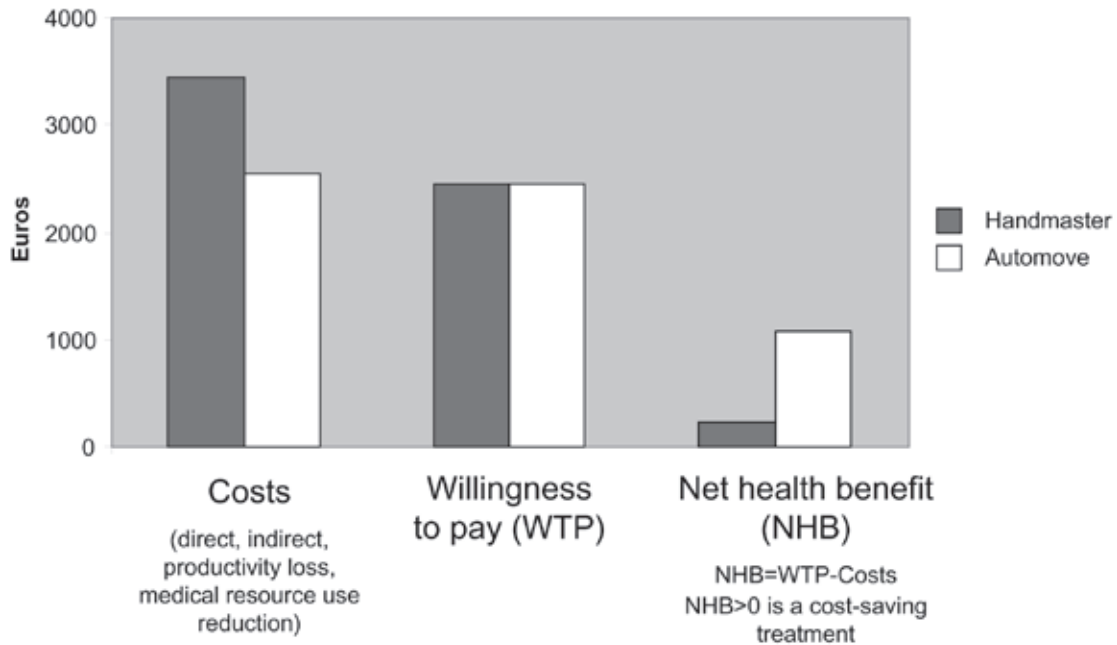
The painful hemiplegic shoulder: Effects of intra-articular triamcinolone acetonide. American Journal of Physical Medicine & Rehabilitation 76 (1997), 43-48.

## 2.2

<b>Source</b>	Ijzerman MJ, de Kroon JR, Jannink-Nijlant JJM, Renzenbrink GJ, Severens JL Preliminary economic evaluation of electrical stimulation treatment of the upper extremity in post-stroke hemiplegia 7th International Workshop on Functional Electrical Stimulation September 12-15, 2001, Vienna, Austria.
<b>Study type identified by the author as</b>	Economic evaluation
<b>Study type according to the evaluator's assessment</b>	Economic evaluation
<b>Formal evidence category</b>	n.a.
<b>Frame of reference</b>	The Netherlands
<b>Indications</b>	Chronic post-stroke hemiplegia
<b>Inquiry / Aim</b>	To gain insight into economic potential of electrical stimulation (non-triggered) treatment
<b>Relevant criteria for inclusion and exclusion</b>	1. upper-extremity post-stroke hemiplegia
<b>Tested intervention</b>	Electrical stimulation in the treatment of upper-extremity hemiplegia in stroke patients (using one of two commercially available systems: Automove AM800 and NESS Handmaster)
<b>Control intervention</b>	n.a.
<b>Possible further treatment groups</b>	n.a.
<b>Study design</b>	Economic evaluation study (cost-benefit analysis using willingness to pay approach).
<b>Number of centres</b>	n.a.
<b>Randomisation</b>	n.a.
<b>Concealment (masking) of randomisation</b>	n.a.
<b>Blind treatment</b>	n.a.
<b>Observation period</b>	1 year
<b>Primary target criteria</b>	Not further specified
<b>Secondary target criteria</b>	Net health benefit (NHB), where $NHB = costs - willingness-to-pay (WTP)$ . Costs were calculated by using: - Stroke costs from database of the Health Care Insurance Board of the NL (direct and indirect medical costs, productivity loss), - Costs of the electrical stimulation (therapist time and equipment cost), - Costs of reduction in medical resource use (questionnaire to experienced clinicians). Effectiveness was obtained by using willingness to pay (WTP) approach where non-experienced reference population was asked to value treatment (slight to moderate improvement in motor control, reduced oedema, shoulder complaints and spasticity) for three different probabilities (10, 50 and 100%) of a successful outcome.
<b>Number of patients receiving treatment</b>	n.a.
<b>Number and characteristics of included and assessed patients</b>	n.a.

<b>Comparability of the treatment groups</b>	n.a.
<b>Results</b>	<p>Costs: Costs of electrical stimulation therapy do not compensate for reduction in resource use (e.g. prescription of spasmolytics, physiotherapy, occupational therapy etc.) but increase the total costs of treatment of a stroke patient (total costs: €2540 for Automove and €3448 for Handmaster).</p> <p>Benefits (WTP) assuming 100% probability of therapy success : WTP of a reference population was approximately €2450.</p> <p>Net health benefit (NHB) assuming 100% probability of therapy success: NHB was calculated for three scenarios: 1. Average scenario (using average values for costs and benefits): NHB was €-997 and €-89 for the Handmaster and Automove, respectively. 2. Conservative scenario (using lower and upper limit of the willingness to pay values and costs, respectively): NHB was €-2585 and €-1735 for the Handmaster and Automove, respectively. 3. Progressive scenario (using upper and lower limit of the willingness to pay value and costs, respectively): NHB was €228 and €1079 for the Handmaster and Automove, respectively. Note: A NHB&gt;0 implies a cost-saving treatment.</p>
<b>Undesired therapy effects</b>	None
<b>Authors' conclusion</b>	<p>Almost 50% of the reference population values electrical stimulation treatment at €2451 or higher and for those respondents the value of electrical stimulation treatment outweighs the costs. This would suggest that electrical stimulation treatment may be cost-saving for a part of the respondents if the probability of success is nearly 100%. In order to establish a high success rate it is required to critically examine the patient before an electrical stimulation device is prescribed. In the present pilot it was decided to study electrical stimulation treatment as a general entity and it was not the intention to compare two devices. Recently, different reviews have concluded that more fundamental research is required in order to underpin the theoretical foundations of electrical stimulation treatment in general (Chae and Yu 1999; Kroon et al. 2001).</p>

### ECONOMIC EVALUATION OF ELECTRICAL STIMULATION THERAPY IN UPPER EXTREMITY HEMIPLEGIA



Electrical stimulation treatment may be cost-saving if it is ensured that the therapy produces slight to moderate improvement in motor control, reduced oedema, shoulder complaints and spasticity.

Note: The presented results are for the case of progressive scenario.

#### Comment

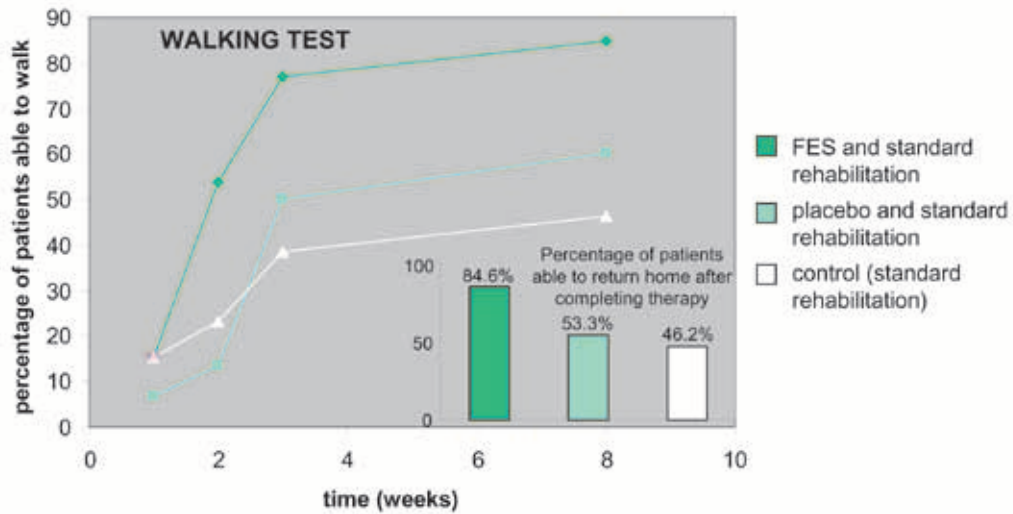
Because EMG-triggered stimulation has been shown to produce larger benefits to a patient than electrical stimulation therapy one would expect that willingness to pay and therefore cost-saving would be larger for such therapy. In this study only an effect of therapy during 1 year were considered. Longer observational period, however, would probably increase the economic value of the therapy.

### 3. Individual studies

#### 3.1

<b>Title</b>	Yan T, Hui-Chan CWY, Li LSW Functional electrical stimulation improves motor recovery of the lower extremity and walking ability of subjects with acute stroke. A randomised placebo-controlled trial. Stroke 36 (2005), 80-85
<b>Study type</b>	Randomised controlled study (RCT)
<b>Formal evidence category</b>	Ib
<b>Frame of reference</b>	Rehabilitation ward of a university clinic in Hong Kong
<b>Indications</b>	Brain infarction with plegia of the lower extremity
<b>Inquiry / Aim</b>	Effectiveness of Functional Electrical Stimulation (FES) to improve functionality and ability to walk
<b>Relevant criteria for inclusion and exclusion</b>	<ol style="list-style-type: none"> <li>1. Fresh hemiparesis (not older than 3 days) with secured cerebral infarction</li> <li>2. Age between 45 and 85 years</li> <li>3. Independent in daily functions prior to stroke</li> <li>4. No relevant mental or physical disabilities (incl. dysphasia or cerebellar damage)</li> </ol>
<b>Tested intervention</b>	15 patients: Surface EMG triggered electrical stimulation therapy of the flexion and extension muscles on the upper and lower leg (0.3 ms pulse, 30 Hz, maximum tolerance intensity 20 to 30 mA), treatment duration 30 minutes per treatment, total of 15 treatments in 3 weeks
<b>Control intervention</b>	15 patients: Placebo treatment with electrodes not connected to the stimulation unit, treatment duration 60 minutes per treatment, total of 15 treatments in 3 weeks
<b>Possible further treatment groups</b>	15 patients: Control group without electrical stimulation therapy
<b>Study design</b>	Three-branched randomised controlled therapy superiority study
<b>Number of centres</b>	Unicentric
<b>Randomisation</b>	Via a computer programme with minimisation of disturbance variables
<b>Concealment (masking) of randomisation</b>	Not explained in further detail
<b>Blind treatment</b>	Blinding of patient and independent evaluator of results
<b>Observation period</b>	7 to 8 weeks
<b>Primary target criteria</b>	Not further specified
<b>Secondary target criteria</b>	Spasticity score as per Levin and Hui-Chan, maximum isometric spontaneous contraction of the talocalcaneal joint flexors and extensors, tests of ability to stand up / walk (tested with regard to validity and reliability), ability to walk, discharge to home
<b>Number of patients receiving treatment</b>	no case number planning mentioned

<b>Number and characteristics of included and assessed patients</b>	<p>45 patients were included. In the progression, 5 patients dropped out due to: gastric bleeding (intervention group), renewed stroke (placebo group), early discharge (placebo group), language communication difficulties (control group) and lack of result measurements (intervention group).</p> <p>Intervention group (13 patients): 11 brain infarctions, 2 haemorrhages, Average age 68 years, spasticity score 7.3</p> <p>Placebo group (15 or 14 patients): 13 brain infarctions, 2 haemorrhages Average age 73 years, spasticity score 5.9</p> <p>Control group (13 patients): 11 brain infarctions, 2 hemorrhages, average age 70 years, spasticity score 6.1</p>
<b>Comparability of the treatment groups</b>	<p>The three groups were similar to each other with regard to age, gender, size, weight, body mass index, age of stroke, type of stroke, side of stroke, spasticity score, mental function, and duration of acute treatment.</p>
<b>Results</b>	<p>Spasticity score: Despite poor starting values, there are tendentially better values in the intervention group, which, however, only show significant difference from the placebo and control groups in week 3. The placebo group shows slightly better results than the control group.</p> <p>Maximum isometric spontaneous contraction: Increase in contraction ability in all three groups, however strongest in the electrical stimulation group with 9.9 Nm after 8 weeks. This is a highly significant advantage (<math>p &lt; 0.01</math>) by comparison to the placebo group (6.8 Nm) and the control group (6.2 Nm).</p> <p>Standing up / walking test: Advantages in favour of the electrical stimulation group, but no determinable significance with large standard deviations.</p> <p>Ability to walk: Significantly higher percentage of patients who are able to walk under electrical stimulation therapy, e.g. 85% (EMS) vs. 60% (placebo) vs. 46% (control group). Furthermore, walking ability was obtained, on average, 2 to 3 days earlier when electrical stimulation treatment was used.</p> <p>Discharge home: Significantly more patients returned to their home environment: 85% (EMS) vs. 53% (placebo) vs. 46% (control group)</p>
<b>Undesired therapy effects</b>	<p>None reported</p>
<b>Authors' conclusion</b>	<p>Early electrical stimulation therapy of the lower extremity improves motor function and ability to walk. The success of the therapy concept is explained by the neuronal plasticity in regeneration and the stimulation, which is specifically adapted to the human gait.</p>



Functional electrical stimulation improved patient's ability to walk and expedited return home.

### Comment

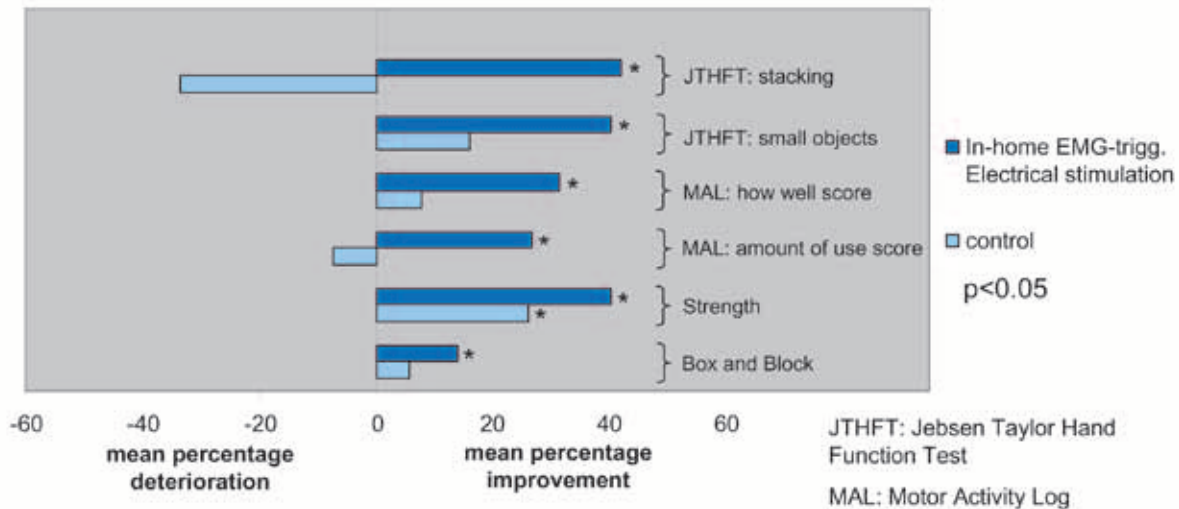
This high-quality study is of interest due to longer subsequent observation times, clinically relevant end points, and the use of two control groups. The accompanying physiotherapy was given for a specified period, and thereby standardised in all three groups. Overall, this study is therefore one of the best and most significant proof forms of the clinical advantages of electrical stimulation therapy with fresh apoplectic paresis of the lower extremity.

### 3.2

<b>Title</b>	Kimberley TJ, Lewis SM, Auerbach EJ, Dorsey LL, Lojovich JM, Carey JR Electrical stimulation driving functional improvements and cortical changes in subjects with stroke. Exp Brain Res 154 (2004), 450-460
<b>Study type</b>	Randomised controlled study (RCT)
<b>Formal evidence category</b>	Ib
<b>Frame of reference</b>	In-home rehabilitation in the USA
<b>Indications</b>	Brain infarction with plegia in the upper extremities
<b>Inquiry / Aim</b>	Effectiveness of EMG triggered electrical stimulation therapy in patients with longer-term paresis of the hand and representation of cerebral activation in the functional NMR
<b>Relevant criteria for inclusion and exclusion</b>	1. Hand paresis due to stroke 6 or more months ago. 2. Remaining hand function present, defined as minimum 10° active flexion and extension in the metacarpophalangeal joint of the index finger. 3. Mental function undisturbed, defined by the Mini-Mental-State questionnaire
<b>Tested intervention</b>	8 test subjects: EMG triggered electrical stimulation therapy, home use by the patient himself, total of 60 treatment hours in 21 days (that is, either one treatment of 6 hours every second day or 3-hour daily therapy)
<b>Control intervention</b>	8 test subjects: Placebo therapy with electrode placement and turning on the unit with the electrode flow not connected to the unit, same treatment intensity and duration as in the intervention group. After the end of placebo therapy, crossover into the tested intervention group.
<b>Possible further treatment groups</b>	None.
<b>Study design</b>	Two-armed randomised controlled therapy superiority study
<b>Number of centres</b>	Evidently unicentric, but followed by in-home therapy
<b>Randomisation</b>	Mentioned, but not described in further detail
<b>Concealment (masking) of randomisation</b>	not described
<b>Blind treatment</b>	The patient and the independent evaluator of results are blinded
<b>Observation period</b>	In the intervention group, about 4 weeks; in the control group, about 8 weeks due to the cross-over phase
<b>Primary target criteria</b>	Not specifically defined
<b>Secondary target criteria</b>	Box-and-Block function test of hand function (consisting of an exercise for gripping, moving and stacking cubes), patient questionnaire about use of the hand in everyday situations (frequency and effectiveness of use), hand function test as per Jebsen and Taylor, strength of finger extension (in Newton), control of finger movements (frequency of conscious movements in mirror learning). Cortical activation in functional core spin tomography (fMRI) with T1 and T2 weighting with 5 mm layer thickness (Voxel number in various ipsi- and contralateral brain areas, such as the gyrus praecentralis and the gyrus postcentralis)
<b>Number of patients receiving treatment</b>	No case number planning mentioned.

<b>Number and characteristics of included and assessed patients</b>	16 patients with stroke an average of 3.0 years ago, average age 60 years, 5 women and 11 men, 8 right and 8 left brain infarctions. Data from all 16 patients were available for the functional target criteria, but assessable fMRI imaging was only obtainable for 12 patients.
<b>Comparability of the treatment groups</b>	Both groups were similar regarding age, gender, age of the stroke, brain localisation of the stroke, side of the stroke, handedness, Mini-Mental-State score, modified Ashworth scale, and all target criteria at the commencement of the study.
<b>Results</b>	<p>Box-and-Block function test: Significant improvement of hand function solely in the intervention group. No statistical testing takes place for the comparison between the intervention and control groups. The difference between 27.0 (SEM 4.8) and 24.3 (SEM 6.1) after 3 weeks is, however, clear.</p> <p>Patient questionnaire regarding use of the hand in everyday situations: Both frequency of hand use and ability to use the hand for everyday activities improved significantly in the electrotherapy group, but not in the control group.</p> <p>Hand function test as per Jebsen and Taylor: Here, some of the tests (e.g. grasping small objects, stacking, or holding heavy containers) showed significant improvements in the intervention group, while there were no observed improvements in the control group.</p> <p>Strength of finger extension: This was the only target criterion for which a significant improvement was also found in the control group. Nevertheless, the therapy effect in the intervention group is greater. 12.9 (SEM 7.9) vs. 8.9 (SEM 2.3)</p> <p>Control of finger movements: Significant differences were not shown at any time here, probably because the scatter rate of the values was very high.</p> <p>Cortical activation in the fMRI: The number of Voxel showed no changes. Borderline significance was found only in the intensity of activation of the ipsilateral gyrus centralis (<math>p=0.046</math>) with electrotherapy.</p>
<b>Undesired therapy effects</b>	None.
<b>Authors' conclusion</b>	In-home intensive EMG triggered electrical stimulation therapy in hand plegia resulted in improved functional hand activity, even though it cannot be stated with certainty whether the statistical significance corresponds to clinical relevance as well. There are several possible reasons for the absence of proof of activation in the fMRI, such as measurements being made at the wrong time.

**PERCENTAGE IMPROVEMENT IN FUNCTIONAL TEST SCORES FOLLOWING  
IN-HOME EMG-TRIGGERED ELECTRICAL STIMULATION THERAPY**



In-home intensive EMG-triggered electrical stimulation therapy of extensor muscles of the hemiplegic forearm of chronic stroke patients resulted in improved functional hand activity (box-and-block test, strength of finger extension, ability to grasp small objects and to stack objects). Patient questionnaires regarding use of the hand in everyday situations also suggest significant improvements in frequency of hand use and ability to use it.

**Comment**

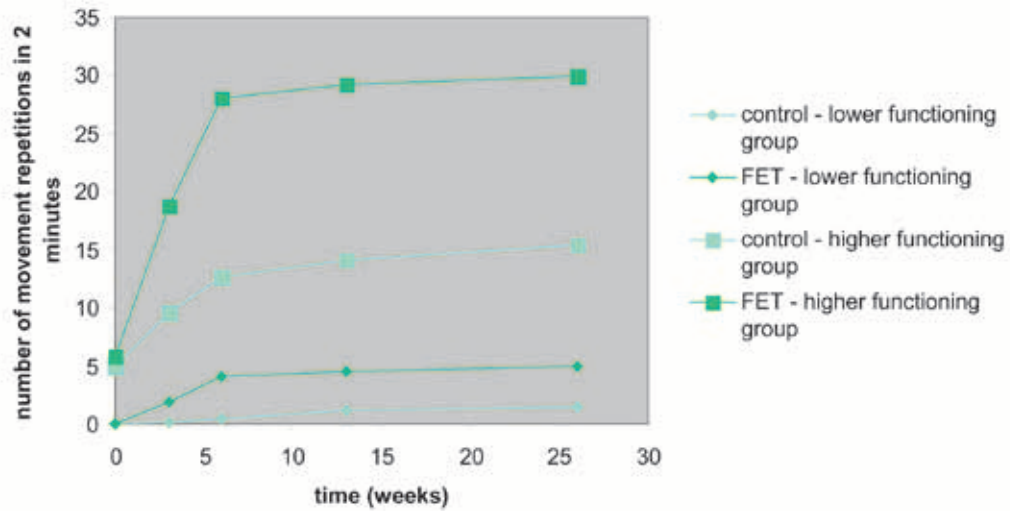
This is a very small study of methodologically high quality with short-term results. The problem of blinding is technically well solved. The emphasis of the statistical analyses lies in the before and after comparisons, even though the group comparisons are actually of greater interest. The study proves good short-term effects of electrical stimulation therapy in patients with longer existing hand plegia.

### 3.3

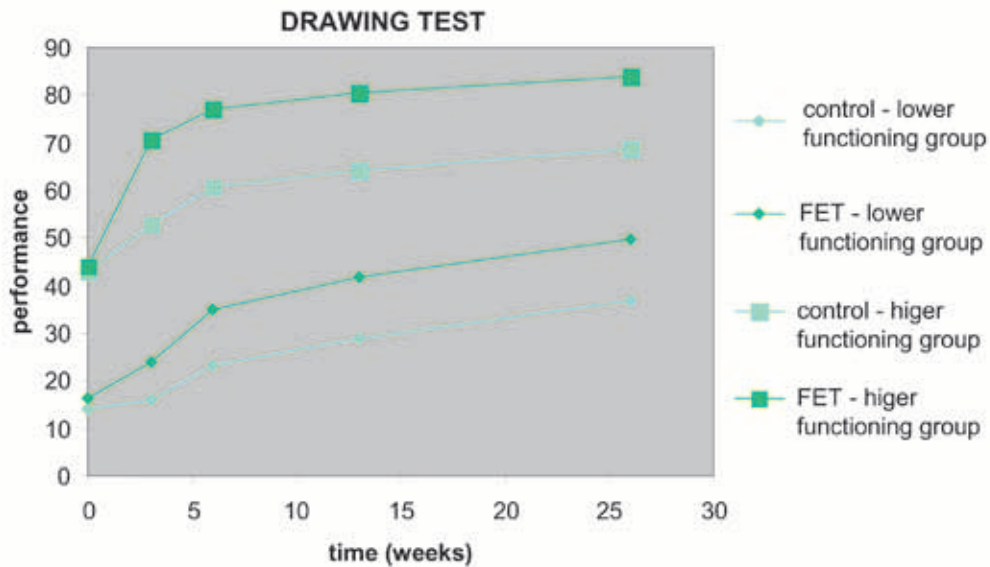
<b>Title</b>	Popovic MB, Popovic DB, Sinkjaer T, Stefanovic A, Schwirtlich L Clinical evaluation of functional electrical therapy in acute hemiplegic subjects. J Rehabil Res Devel 40 (2003), 443-454
<b>Study type</b>	Randomised controlled study (RCT)
<b>Formal evidence category</b>	Ib
<b>Frame of reference</b>	Treatment of plegia in upper extremity (Yugoslavia or Denmark)
<b>Indications</b>	Hemiplegia with paresis of the upper extremity
<b>Inquiry / Aim</b>	Effectiveness of electrotherapy treatment to improve functionality of the upper extremity
<b>Relevant criteria for inclusion and exclusion</b>	<ol style="list-style-type: none"> <li>1. Hemiparesis after ischemic or hemorrhagic insult (diagnosis secured by CT or NMR)</li> <li>2. Time interval between the stroke and the commencement of therapy between 2 weeks and 6 months</li> <li>3. Ability to communicate, vision and hearing, as well as mental functions undisturbed</li> <li>4. Physical independence prior to stroke</li> <li>5. No electrical devices implanted, particularly no cardiac pacemakers</li> <li>6. No relevant injury or prior illness of the upper extremities</li> </ol>
<b>Tested intervention</b>	14 test subjects: in addition to conventional physiotherapy, 30-minute functional electrotherapy of the finger and hand extensors and flexors, total of approximately 20 treatments in 3 weeks (7 x weekly, but partial omission of therapy sessions). In some cases, the patients were able to carry out electrode placement and electrotherapy themselves.
<b>Control intervention</b>	14 test subjects: sole 30-minute physiotherapy as per Bobath, no placebo therapy
<b>Possible further treatment groups</b>	None.
<b>Study design</b>	Two double, two-armed, randomised controlled therapy superiority studies
<b>Number of centres</b>	Unclear
<b>Randomisation</b>	Mentioned and described ("a random generator").
<b>Concealment (masking) of randomisation</b>	Not further specified
<b>Blind treatment</b>	Blinding of result assessment, no blinding of patients
<b>Observation period</b>	26 weeks
<b>Primary target criteria</b>	Not specifically defined
<b>Secondary target criteria</b>	Functional test of the upper extremity, drawing test, spasticity scale modified as per Ashworth, patient questionnaire regarding function of arm and hand
<b>Number of patients receiving treatment</b>	No case number planning mentioned.
<b>Number and characteristics of included and assessed patients</b>	41 patients with stroke, of which 28 were selected as random samples for the study. Of these 28 patients, 16 showed initially better function (higher functioning group - HFG) and 12 showed worse function (lower functioning group - LFG). Average age 60 years; stroke an average of 7 weeks ago, ischemic or hemorrhagic insult in 82 % or 18%, respectively (all values calculated by the authors from raw data)
<b>Comparability of the treatment groups</b>	Both groups were similar regarding age, time since stroke, type of stroke, side of stroke, function test of the upper extremity

<b>Results</b>	<p>Functional tests of the upper extremity: The number of tasks completed in a fixed time period is stated. Significantly better function was found in both intervention groups (that is, good or poor initial function) by comparison to the control groups. The differences correspond to doubling or tripling of function and are significant at all analysis times (3, 6, 13, and 26 weeks).</p> <p>Drawing test: Drawing a 20x20cm square was better accomplished by the patients in the intervention group. The results are significant at all times in the group with poor initial function. In the group with good initial function, significance is only found after 6 and 13 weeks.</p> <p>Spasticity scale modified as per Ashworth: This parameter is only analysed at the study end after 26 weeks. Here, approximately equal values are found for the intervention and control groups of patients with initially poor arm function (2.5 vs. 2.25). In the study in patients with better arm function at the commencement of the study, however, the results differentiate significantly (1.25 vs. 2.25) in favour of the electrotherapy group.</p> <p>Patient questionnaire regarding function: Here, inquiries were made at the 26-week point regarding how well activities can be carried out again with the arm, and how well the arm can be used again. In both questions and in both sub-studies, clearly better results were shown for the electrotherapy group. The values in the patient group with initially better function were about twice as high as the values in the control group (60% vs. 29% of normal functionality, 67% vs. 33% of satisfaction).</p>
<b>Undesired therapy effects</b>	None.
<b>Authors' conclusion</b>	Electrical stimulation therapy of the upper extremity significantly improves functionality after paresis. The results prove several effects by comparison to the control group. Longer therapy appears to be necessary solely in the patients with initially more severely marked paresis. The authors are surprised that improvements were found in the function of the shoulder and elbow as well, even though no electrotherapy was applied in those areas.

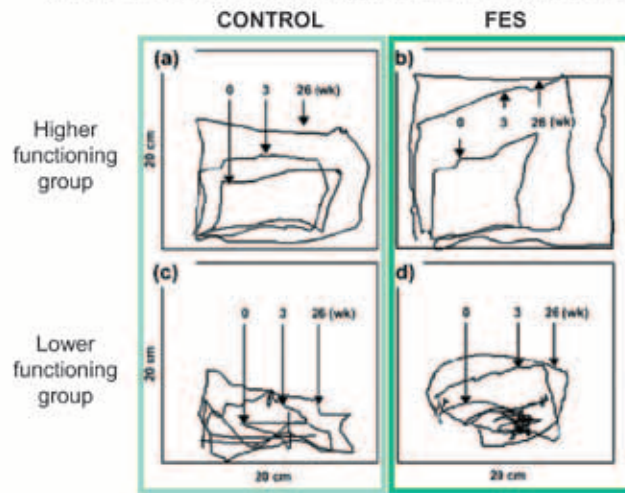
### UPPER EXTREMITY FUNCTION TEST



Functional electrical therapy produces larger short and long-term improvement in upper extremity functionality in comparison to conventional therapy.



#### Improvement in drawing abilities during 26 weeks



Functional electrical therapy produces larger short and long-term improvement in drawing test in comparison to conventional therapy.

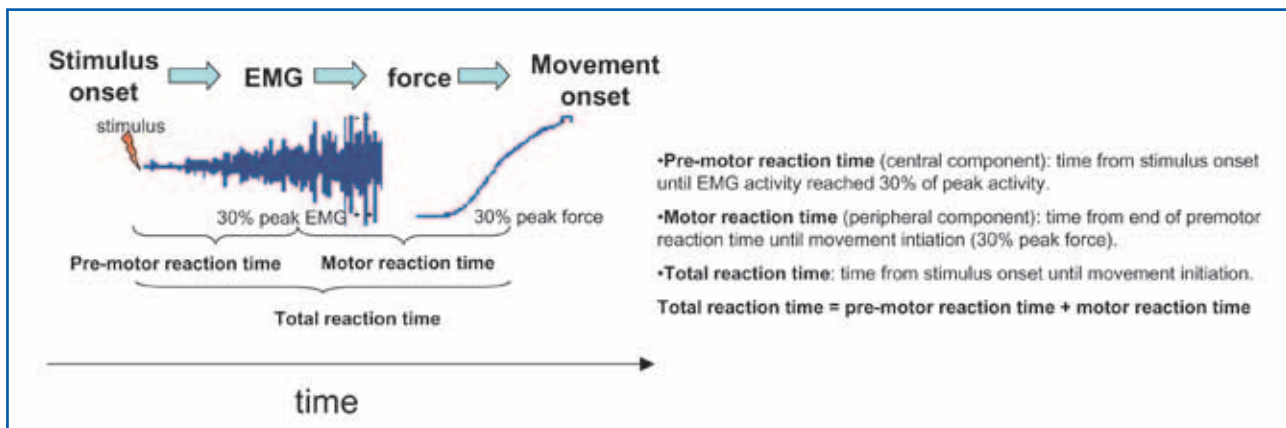
#### Comment

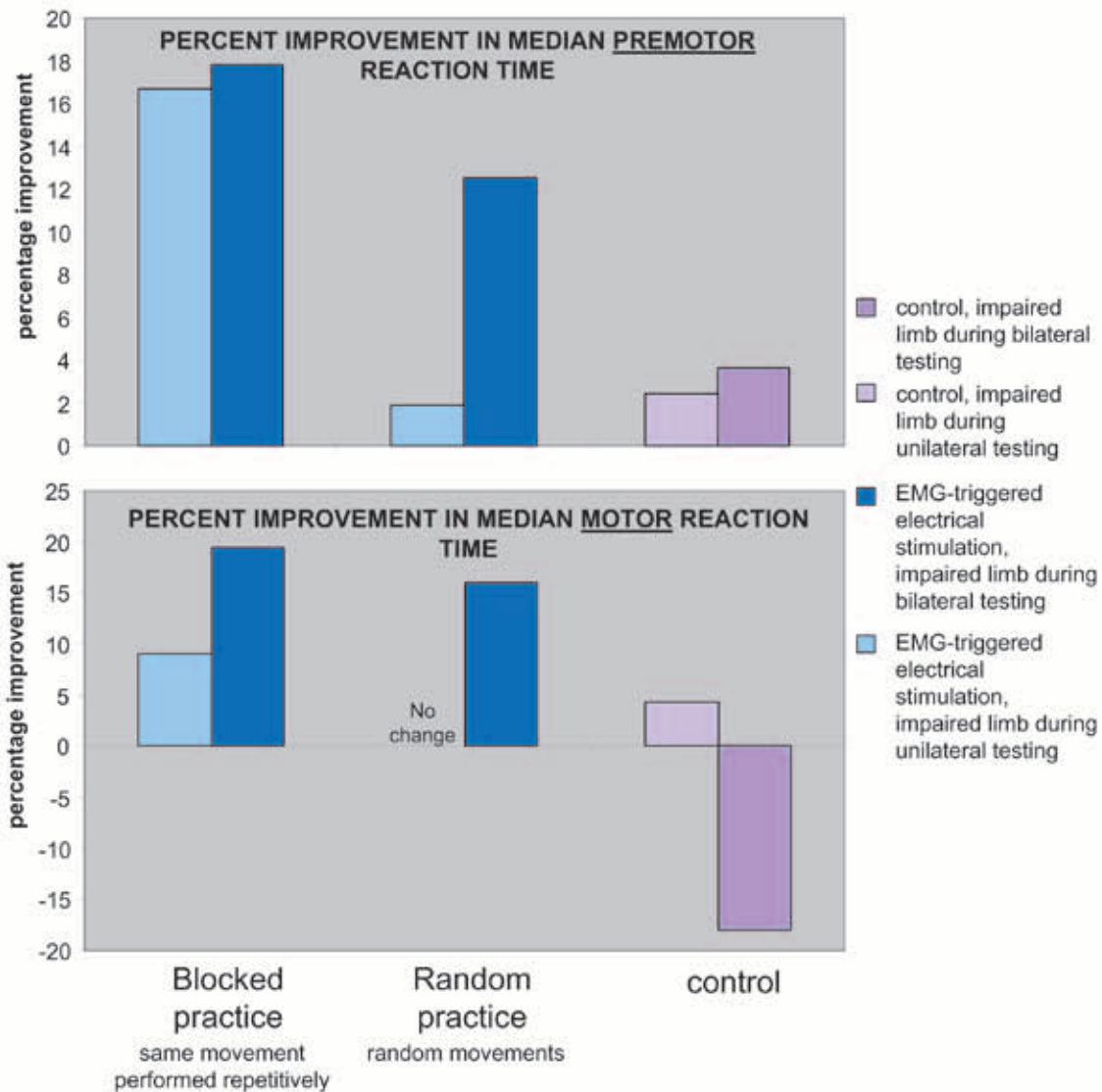
The longer follow-up observation period is positive in this study. The study is able to show major effects of electrical stimulation therapy in patients with residual function of the upper extremity.

### 3.4

<b>Title</b>	Cauraugh JH, Kim SB. Stroke motor recovery: active neuromuscular stimulation and repetitive practice schedules. J Neurol Neurosurg Psychiatry 74 (2003), 1562-1566
<b>Study type</b>	Randomised controlled study (RCT)
<b>Formal evidence category</b>	Ib
<b>Frame of reference</b>	University rehabilitation in the USA
<b>Indications</b>	Chronic hand plegia in status post stroke
<b>Inquiry / Aim</b>	Effectiveness of EMG triggered electrical stimulation therapy to improve hand function
<b>Relevant criteria for inclusion and exclusion</b>	<ol style="list-style-type: none"> <li>1. Status post one or two strokes</li> <li>2. Hand paresis with less than 80% EMG activity by comparison to the other side, however at least 10° extension in the wrist</li> <li>3. No neurological accompanying illnesses</li> <li>4. No participation in another rehabilitation programme</li> </ol>
<b>Tested intervention</b>	<p>14 test subjects: 90-minute surface stimulation of the hand extensors, elbow extensors and shoulder abductors, grouping of stimulation into blocks depending on muscle groups, respectively 5 sec. biphasic stimulation at 50 Hertz, total of 4 treatments in 2 weeks (twice weekly)</p> <p>14 test subjects: as previously, but no grouping of stimulation into blocks by muscle groups – rather, muscle groups are changed after every individual exercise</p>
<b>Control intervention</b>	6 test subjects: 90-minute passive movements of hand and arm, additional attempts to perform movements by himself/herself, no placebo electrotherapy, total 4 treatments in 2 weeks (twice weekly). No reason is given as to why the three groups were so different in the number of patients.
<b>Possible further treatment groups</b>	None.
<b>Study design</b>	Three-armed randomised controlled therapy superiority study
<b>Number of centres</b>	Unicentric
<b>Randomisation</b>	Described and mentioned.
<b>Concealment (masking) of randomisation</b>	Questionable because randomisation took place via a master list, even though the authors emphasize, with a methodological literary reference, that concealment was present.
<b>Blind treatment</b>	None.
<b>Observation period</b>	2 weeks
<b>Primary target criteria</b>	Not specifically defined
<b>Secondary target criteria</b>	Box-and-Block function test of hand function (consisting of an exercise for gripping, moving and stacking cubes), reaction time (subdivided into total, pre-motor and motor reaction times)
<b>Number of patients receiving treatment</b>	No case number planning mentioned.
<b>Number and characteristics of included and assessed patients</b>	34 patients with stroke an average of 3.2 years ago, 30 men and 4 women, multiple strokes present in 8 patients, average age 66 years
<b>Comparability of the treatment groups</b>	The three groups were similar regarding age, gender, time since stroke, side of stroke, number of strokes, as well as the two criteria prior to therapy commencement

<b>Results</b>	<p>Box-and-Block function test:          Significant improvement in both intervention groups by comparison to the control group (<math>p=0.039</math>), however no significant difference between the two intervention groups.</p> <p>Reaction time:          Significant improvements were found between initial and post-therapy values, which, however, are significantly more marked with electrical stimulation than in the control group. The group with a block-like arrangement of exercises showed better results than the group with changing arrangements.</p>
<b>Undesired therapy effects</b>	None.
<b>Authors' conclusion</b>	Regardless of whether the exercises for EMG-triggered electrical stimulation therapy are repeated in blocks or alternate randomly between the muscles, there is a significant increase in hand functions by comparison to conventional physiotherapy.





EMG-triggered electrical stimulation, especially one involving blocked practice, allowed for faster premotor and motor reaction.

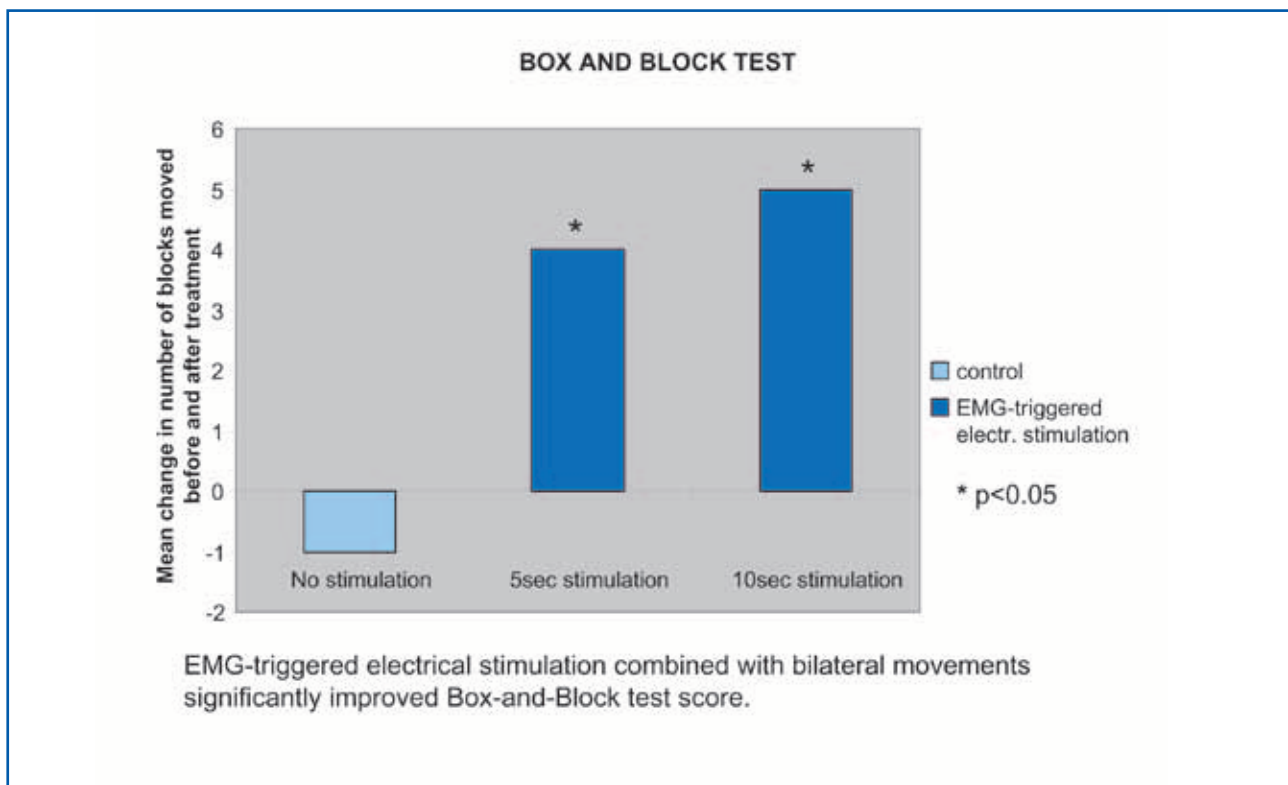
**Comment**

The emphasis of the study lies in examining the two electrotherapy variants as compared to the control group. This study provides good indicators of the superiority of EMG-triggered electrical stimulation therapy.

## 3.5

<b>Title</b>	Cauraugh JH, Kim SB. Chronic stroke motor recovery: duration of active neuromuscular stimulation. J Neurol Sci 215 (2003), 13-19
<b>Study type</b>	Randomised controlled study (RCT)
<b>Formal evidence category</b>	Ib
<b>Frame of reference</b>	University rehabilitation in the USA, unclear whether inpatient or outpatient therapy
<b>Indications</b>	Chronic hand plegia following the stroke
<b>Inquiry / Aim</b>	Effectiveness of EMG triggered electrical stimulation therapy in combination with bilateral movement training to improve hand function
<b>Relevant criteria for inclusion and exclusion</b>	<ol style="list-style-type: none"> <li>1. Status post one or two strokes</li> <li>2. Hand paresis with less than 80% EMG activity by comparison to the other side, however at least 10° extension in the wrist</li> <li>3. No neurological accompanying illnesses</li> <li>4. No participation in another rehabilitation programme</li> </ol>
<b>Tested intervention</b>	<p>10 test subjects: 90-minute EMG-triggered surface stimulation of the hand / finger extensors (M. extensor communis digitorum and M. extensor carpi ulnaris), each 5 sec. biphasic stimulation at 50 Hertz, total of 4 treatments in 2 weeks (twice weekly); all exercises also in combination with bilateral movement training in front of a mirror</p> <p>10 test subjects: as previously; however, 10 seconds each of biphasic stimulation</p>
<b>Control intervention</b>	6 test subjects: 90-minute passive movements of hand and arm, additional bilateral movement training, no placebo electrotherapy, total of 4 treatments in 2 weeks (twice weekly). No reason is given as to why the three groups were so different in the number of patients.
<b>Possible further treatment groups</b>	None.
<b>Study design</b>	Three-armed randomised controlled therapy superiority study
<b>Number of centres</b>	Unicentric
<b>Randomisation</b>	Described and mentioned.
<b>Concealment (masking) of randomisation</b>	Randomisation took place via a master list.
<b>Blind treatment</b>	None.
<b>Observation period</b>	2 weeks
<b>Primary target criteria</b>	Not specifically defined
<b>Secondary target criteria</b>	Box-and-Block function test of hand function (consisting of an exercise for gripping, moving and stacking cubes), reaction time (subdivided into total, pre-motor and motor reaction times)
<b>Number of patients receiving treatment</b>	No case number planning mentioned.
<b>Number and characteristics of included and assessed patients</b>	26 patients with stroke an average of 2.8 years ago, 18 men and 8 women, average age 66 years
<b>Comparability of the treatment groups</b>	The three groups were similar in gender distribution and evidently showed similar initial values in the target criteria.

<b>Results</b>	<p>Box-and-Block function test: In the mixed model of variance analysis for measurement value repetitions, a significant difference was found between all three groups, with respectively better results with electrical stimulation and better results in the 10-second group as compared to the 5-second group: 28 vs. 20 vs. 15</p> <p>Reaction time: Significant improvements were observed in the intervention group by comparison to the control group for pre-motor reaction times only, without a recognizable difference between the two intervention groups.</p>
<b>Undesired therapy effects</b>	None mentioned.
<b>Authors' conclusion</b>	By comparison to conventional physiotherapy with bilateral movement training, additive EMG-triggered electrotherapy of the hand muscles produces better hand function. No final statement can be made as yet regarding the stimulation time (5 or 10 seconds), even though the longer stimulation time yielded better results.



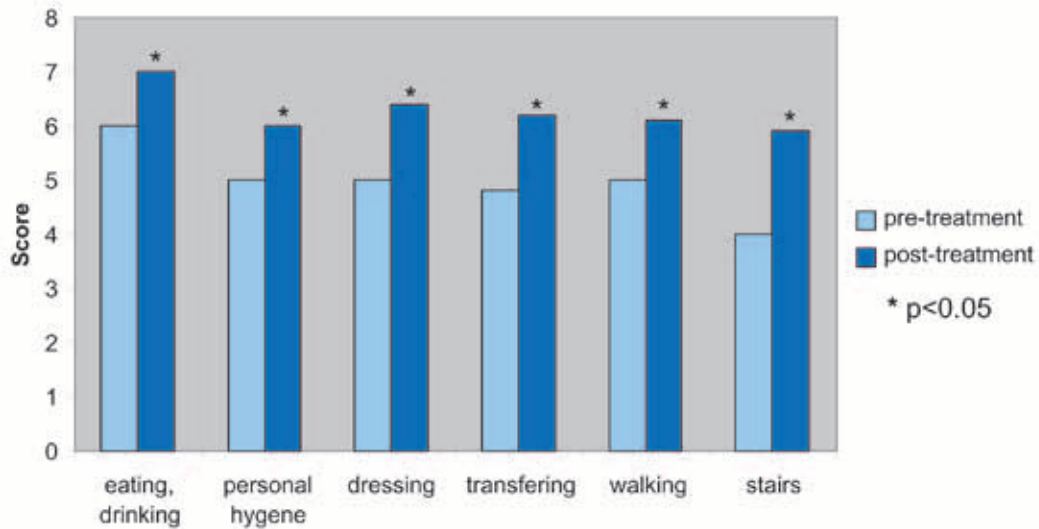
**Comment**  
 This study provides good indicators regarding the superiority of EMG triggered electrical stimulation therapy for chronic hand plegia.

## 3.6

<b>Title</b>	Bocker B, Smolenski UC Motor learning by means of EMG triggered electrostimulation in patients with hemiparesis Phys Med Rehab Kurort 13 (2003), 139-144
<b>Study type</b>	Prospective comparative longitudinal study in the A-B-A design with randomised assignment
<b>Formal evidence category</b>	Ib
<b>Frame of reference</b>	Outpatient follow-up treatment after inpatient rehabilitation
<b>Indications</b>	Leg emphasised hemiparesis after supratentorial cerebrovascular ischemic or hemorrhagic lesion
<b>Inquiry / Aim</b>	Surface EMG triggered electrical stimulation in combination with physiotherapy with regard to movement function and independence
<b>Relevant criteria for inclusion and exclusion</b>	Inclusion: Leg emphasised hemiparesis after supratentorial cerebrovascular ischemic or hemorrhagic lesion Exclusion: Sensory aphasia, dementia, sensitivity disturbances, earlier stroke
<b>Tested intervention</b>	3 months (8 patients) or 6 months (8 patients) of 3 times weekly for 30 minutes physiotherapy as per Bobath; plus twice daily 10 minutes of EMG-triggered electrical stimulation (Automove AM 706-H) of the M. tibialis anterior.
<b>Control intervention</b>	3 months, 3 times weekly, 30 minutes of physiotherapy as per Bobath.
<b>Possible further treatment groups</b>	None.
<b>Study design</b>	After discharge from inpatient rehabilitation, initially 3 months of 30 minutes of physiotherapy as per Bobath 3 times weekly. The patients were assessed before and after this phase. The results provided the baseline and control data (control intervention). After this, randomised assignment to 3 or 6 months, twice daily, 10 minutes of EMG-triggered electrical stimulation (Automove AM 706-H) of the M. tibialis anterior in addition to the above named schema (continuing physiotherapy as per Bobath). After completion of the test intervention, continuation of physiotherapy as per Bobath (3 times weekly, 30 minutes). The evaluation took place every 3 months during the entire study period.
<b>Number of centres</b>	Unicentric
<b>Randomisation</b>	Yes
<b>Concealment (masking) of randomisation</b>	By a draw process
<b>Blind treatment</b>	Blinded evaluation (blinded evaluator), non-blinded treating personnel and patients
<b>Observation period</b>	9 or 12 months. 3 months after completion of EMG-triggered electrical stimulation, physiotherapy as per Bobath continued after completion of the test intervention
<b>Primary target criteria</b>	Active movement of the talocalcaneal joint on the paretic side (range of motion): Foot position in 90° corresponds to 0.
<b>Secondary target criteria</b>	Functional health (specific health): Muscle functions of the paretic extremity (Motoricity Index) and independence (FIM)
<b>Number of patients receiving treatment</b>	16 patients between 47 and 67 years, 9 to 13 months after stroke, strength degrees 1 to 3.
<b>Number and characteristics of included and assessed patients</b>	16 patients. 4 drop-outs are reported (re-insult, myocardial infarction, death of the partner, failure to return).

<b>Comparability of the treatment groups</b>	Relatively few data are reported about the patients. Comparability seems to be given, insofar as assessable. The unclear questions regarding the 4 drop-outs are critical (see above).
<b>Results</b>	<p>Surface EMG-triggered electrical stimulation treatment in combination with physiotherapy as per Bobath produced reduction of pointed foot position and improvements in dorsal foot extension.</p> <ul style="list-style-type: none"> <li>- after 3 months physiotherapy: 4.8°</li> <li>- after 3 months physiotherapy plus electrical stimulation: 19.4°, follow-up: 28.2°</li> <li>- after 6 months physiotherapy plus electrical stimulation: 24.4°, follow-up: 26.2°</li> </ul> <p>The results for each intervention group are significant by comparison to the progression over 3 months of physiotherapy prior to commencement of the intervention. The difference between the intervention groups is non-significant.</p> <p>Improvements in the Motoricity Index:</p> <ul style="list-style-type: none"> <li>- no change after 3 months of physiotherapy</li> <li>- after 3 months of physiotherapy plus electrical stimulation: average 10.1 (from 57.3 to 67.4)</li> <li>- after 6 months of physiotherapy plus electrical stimulation: average 17.7 (from 56.8 to 74.5)</li> </ul> <p>The difference as compared to the 3 months of sole physiotherapy as per Bobath is significant for both intervention groups. The difference is not significant between the intervention groups.</p> <p>The independence (FIM) of all patients increases significantly from the commencement of the test interventions to the end of the study with regard to eating / drinking, body care, dressing, transfer, walking and stair climbing. No significant changes were determined in the 3 months of physiotherapy prior to commencement of the test interventions.</p>
<b>Undesired therapy effects</b>	None.
<b>Authors' conclusion</b>	<p>3 months of surface EMG-triggered electrical stimulation treatment in combination with physiotherapy leads to improved function in the paretic lower extremity, and therefore to improved walking function and activities of daily life. Patient independence is also improved.</p> <p>An additive effect to physiotherapy is assumed. The effectiveness does not result solely from electrical stimulation of paretic muscles, but also from the afferent activity increase after self initiated movement processes, which in turn improves the process of envisioning movement (positive proprioceptive biofeedback). EMG-triggered electrical stimulation remains an adjuvant therapy to necessary physiotherapy.</p> <p>Lengthening combination therapy to 6 months does not produce improved clinical end points. It is possible that functional improvement is triggered in the first 3 months, but that this will not remain effective indefinitely beyond this period.</p>

### FIM SCORES



EMG-triggered electrical stimulation therapy leads to improved patient's walking function and activities of daily life.

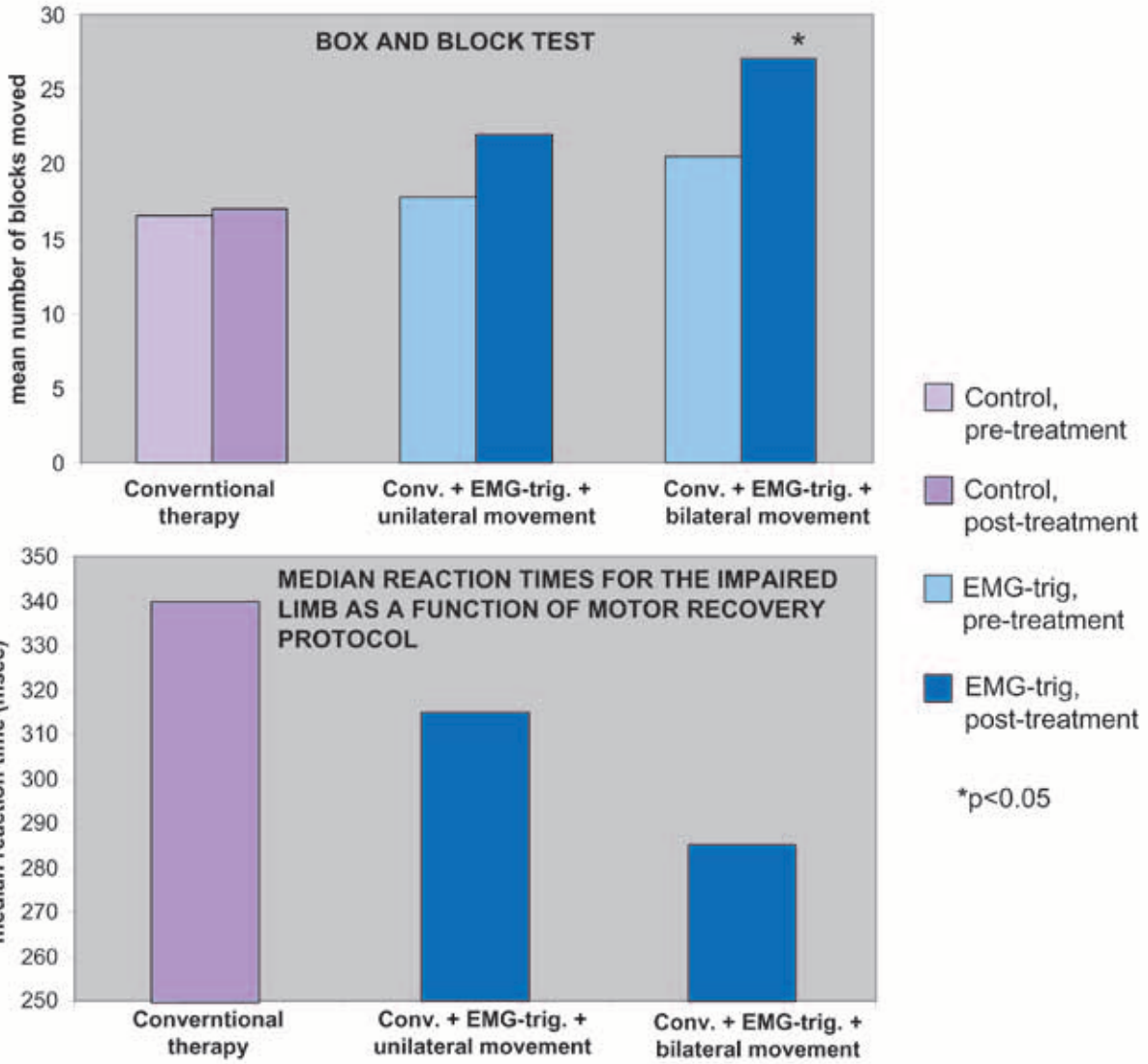
### Comment

This study allows conclusions regarding the presence of a positive-additive effect of EMG-triggered electrical stimulation with physiotherapy. The study furthermore shows that EMG-triggered electrical stimulation is applicable and successful in the outpatient field. It is also impressive that in addition to functional improvements in the directly treated body area, there were also improvements in general body functions.

### 3.7

<b>Title</b>	Cauraugh J, Kim S Two coupled motor recovery protocols are better than one: Electromyogram-triggered neuromuscular stimulation and bilateral movements. Stroke 33 (2002), 1589-1594
<b>Study type</b>	Randomised controlled comparison study (RCT)
<b>Formal evidence category</b>	Ib
<b>Frame of reference</b>	Field study
<b>Indications</b>	Residual hemiparesis symptoms of the upper extremity after stroke
<b>Inquiry / Aim</b>	Effectiveness of surface EMG-triggered electrical stimulation in combination with bilateral coordination training in response to symptoms of chronic hemiparesis at least one year after the stroke
<b>Relevant criteria for inclusion and exclusion</b>	<ol style="list-style-type: none"> <li>1. Cerebrovascular event of at least one year</li> <li>2. Not more than 2 events per hemisphere</li> <li>3. Upper cut-off point: not more than 80% motor recovery (criteria: EMG and direct strength comparison)</li> <li>4. Lower cut-off point: minimum 10° extension ability of the wrist and fingers against gravity, from 90° bending.</li> <li>5. Absence of other neurological deficits</li> <li>6. No anti-spastic medication</li> <li>7. No other rehabilitation programmes</li> </ol>
<b>Tested intervention</b>	10 patients: 3 times 30 EMG-triggered electrical stimulation treatments (Automove AM 800) for 1.5 hours and bilateral movements, 6 hours (=4 days) rehabilitation for 2 weeks
<b>Control intervention</b>	10 patients: 3 times 30 EMG-triggered electrical stimulation treatments (Automove AM 800) for 1.5 hours and unilateral movements, 6 hours (=4 days) rehabilitation for 2 weeks
<b>Possible further treatment groups</b>	5 test subjects: Control group without electrical stimulation, patients asked to do voluntary finger and wrist extensions for 5 seconds with 25 second pauses for 1.5 hours.
<b>Study design</b>	Three-armed comparison study
<b>Number of centres</b>	Unicentric
<b>Randomisation</b>	Yes, method not further specified
<b>Concealment (masking) of randomisation</b>	Not described.
<b>Blind treatment</b>	None.
<b>Observation period</b>	2 weeks
<b>Primary target criteria</b>	<p>Motor ability of the wrist and fingers:</p> <ol style="list-style-type: none"> <li>1. Functional: Moving wood blocks over a separating wall (Box and Block Test).</li> <li>2. Chronometrically: Reaction time to initiation of wrist and finger extension against a measuring cell after an acoustic signal.</li> <li>3. Maintenance and modulation of muscle contraction (contracting the hand and finger extensors for at least 6.5 seconds) by comparison to the healthy upper extremity</li> </ol>
<b>Secondary target criteria</b>	None.
<b>Number of patients receiving treatment</b>	25 patients (average age 63.7 years) with stroke at least one year ago (average value 3.00 years) and chronic paralysis symptoms of the upper extremity, 12 patients with right hemisphere stroke and 13 patients with left hemisphere stroke

<b>Number and characteristics of included and assessed patients</b>	All 25 patients were included in the evaluation of the Box-and-Block tests as well as maintenance of muscle strength. 23 patients were included in the evaluation of reaction latency. 2 patients were excluded from this evaluation due to extreme reaction times.
<b>Comparability of the treatment groups</b>	Restricted. The patient numbers in the control group were only half as many as in the intervention groups. In the reaction times, the unilateral training group was faster from the beginning.
<b>Results</b>	<p>Box-and-Block test: The bilateral training group with EMG-triggered electrical stimulation obtained the best results and was significantly better than the unilateral training group with EMG-triggered electrical stimulation and the control group. Herein, the bilateral training group was 7 times better than the control group. The unilateral training with EMG-triggered electrical stimulation was better than the control group. However, the difference was non-significant.</p> <p>Reaction time: The participants in the unilateral training group had faster reaction times from the beginning. When taking this fact into account in the calculations, the bilateral training group, at 227 ms, remained significantly better than the unilateral training group with 255 ms and the control group with 269 ms.</p> <p>Muscle strength maintenance and strength modulation in a side comparison to the undamaged extremity: The results were so heterogeneous that evaluation only took place within the respective study branch and not in a study branch comparison. The bilateral training group profited most, followed by the unilateral training group and the control group. The improvement in the bilateral training group was statistically significant.</p>
<b>Undesired therapy effects</b>	None.
<b>Authors' conclusion</b>	The "protocol of coupled motor rehabilitation" of active training and EMG-triggered electrical stimulation of the paralysed arm led to a significant expansion of the voluntary motor repertoire in patients whose stroke was at least one year in the past. The results support sensory motor integration therapy as well as dynamic system therapy / the Interlimb theory. Voluntary motor action of the motoneuron is supported by the EMG-triggered electrical stimulation impulse and the activation of the healthy other side. The afferent signals of wrist and finger movements stimulated the somatosensory cortex, therefore also influencing the motor cortex.



Combining EMG-triggered neuromuscular stimulation with bilateral movement therapy yields better Box-and-Block test scores and chronometric reaction times to initiate movements than using EMG-triggered neuromuscular stimulation therapy in combination with unilateral movement or conventional therapy.

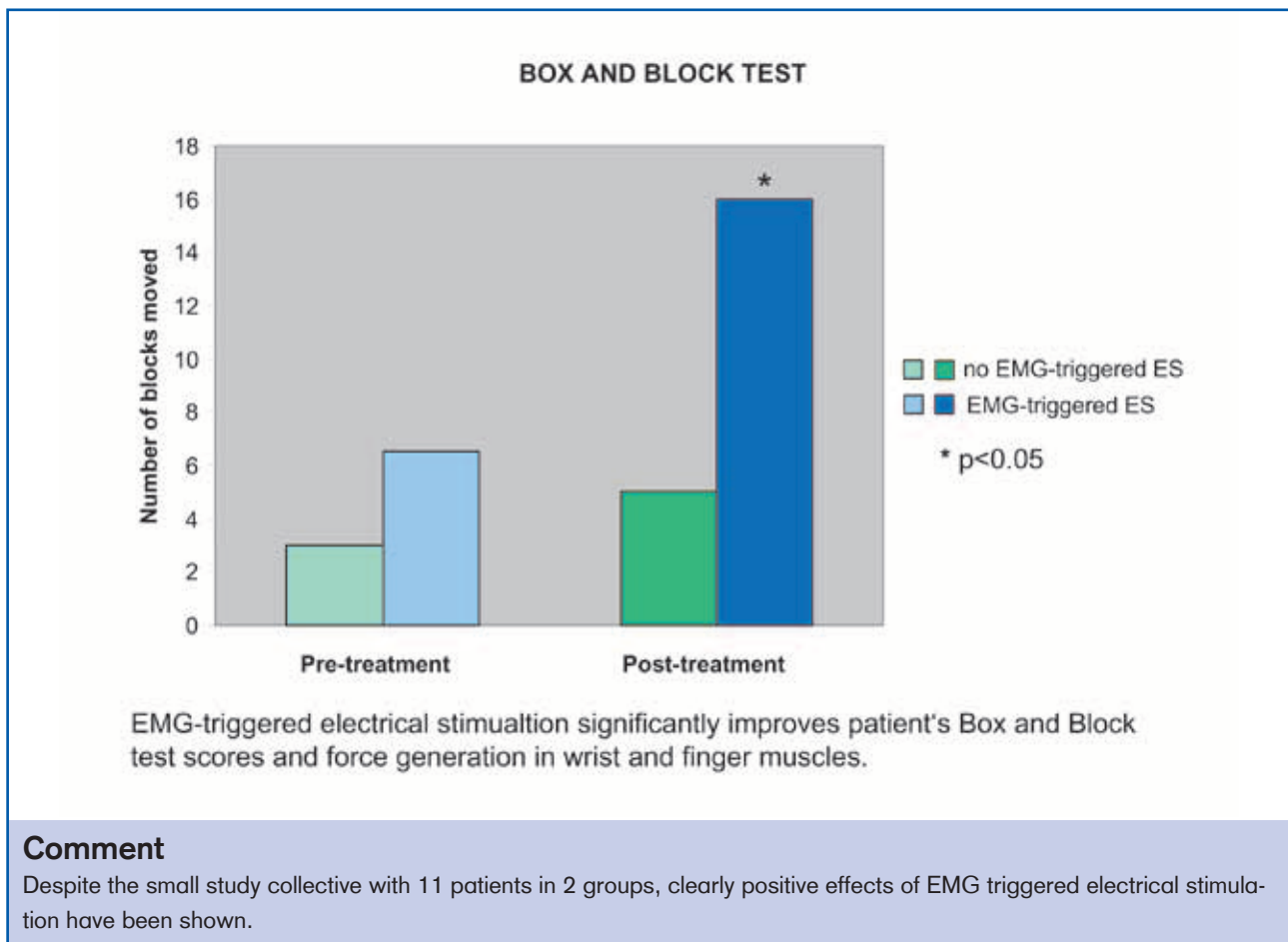
**Comment**

Study shows that the combination of the training programme and EMG-triggered electrical stimulation is better than non-intervention or placebo intervention.

## 3.8

<b>Title</b>	Cauraugh J, Light K, Kim S, Thigpen M, Behrman A Chronic motor dysfunction after stroke: recovering wrist and finger extension by electromyography-triggered neuromuscular stimulation. Stroke 31 (2000), 1360-1364
<b>Study type</b>	Randomised controlled comparison study (RCT)
<b>Formal evidence category</b>	Ib
<b>Frame of reference</b>	Field study
<b>Indications</b>	Residual hemiparesis symptoms of the upper extremity after stroke
<b>Inquiry / Aim</b>	Effectiveness of EMG-triggered electrical stimulation of wrist and finger extensors after stroke at least one year ago
<b>Relevant criteria for inclusion and exclusion</b>	Upper cut-off point: 75% motor recovery of the upper extremity. Lower cut-off point: Remaining ability to extend the wrist by at least 20° against gravity from 90° flexion. No presence of other neurological deficits and no use of another parallel rehabilitation programme.
<b>Tested intervention</b>	First a passive motion of the hemiparetic upper extremity and cautious passive extension of the wrist and finger flexors was performed by a trainer. Then, wrist was positioned at 10° flexion. Placement of surface electrodes to record the EMG of the Mm. extensor communis digitorum and extensor carpi ulnaris, then asking the patient to generate, by means of extension of the underarm musculature, an EMG activity which initiates the electrical impulse for intensification through the Automove (AM 800). There were 2 treatment sessions on 3 days per week in two successive weeks.
<b>Control intervention</b>	Wrist and finger extension without electrical stimulation treatment.
<b>Possible further treatment groups</b>	None.
<b>Study design</b>	After 5 motor tests, randomised assignment to the intervention or control group. The treatment group received 12 therapy sessions of surface EMG triggered electrical stimulation treatment, each session 30 minutes long. The control group is only asked to do active wrist and finger extension without electrical stimulation. After 12 sessions, the control group also receives 12 sessions of surface EMG triggered electrical stimulation.
<b>Number of centres</b>	Unicentric
<b>Randomisation</b>	Yes, method not further specified
<b>Concealment (masking) of randomisation</b>	Not described.
<b>Blind treatment</b>	None.
<b>Observation period</b>	2 weeks
<b>Primary target criteria</b>	Number of moved blocks (2.54 cm <sup>2</sup> cubes) in 60 seconds, isometric strength development
<b>Secondary target criteria</b>	None.
<b>Number of patients receiving treatment</b>	11 patients (average age 61.64 years) with stroke at least one year ago (average value 3.49 years) and chronic paralysis symptoms of the upper extremity, 6 women, 5 men 10 patients with right hemisphere stroke
<b>Number and characteristics of included and assessed patients</b>	11 patients, see above, no drop-outs

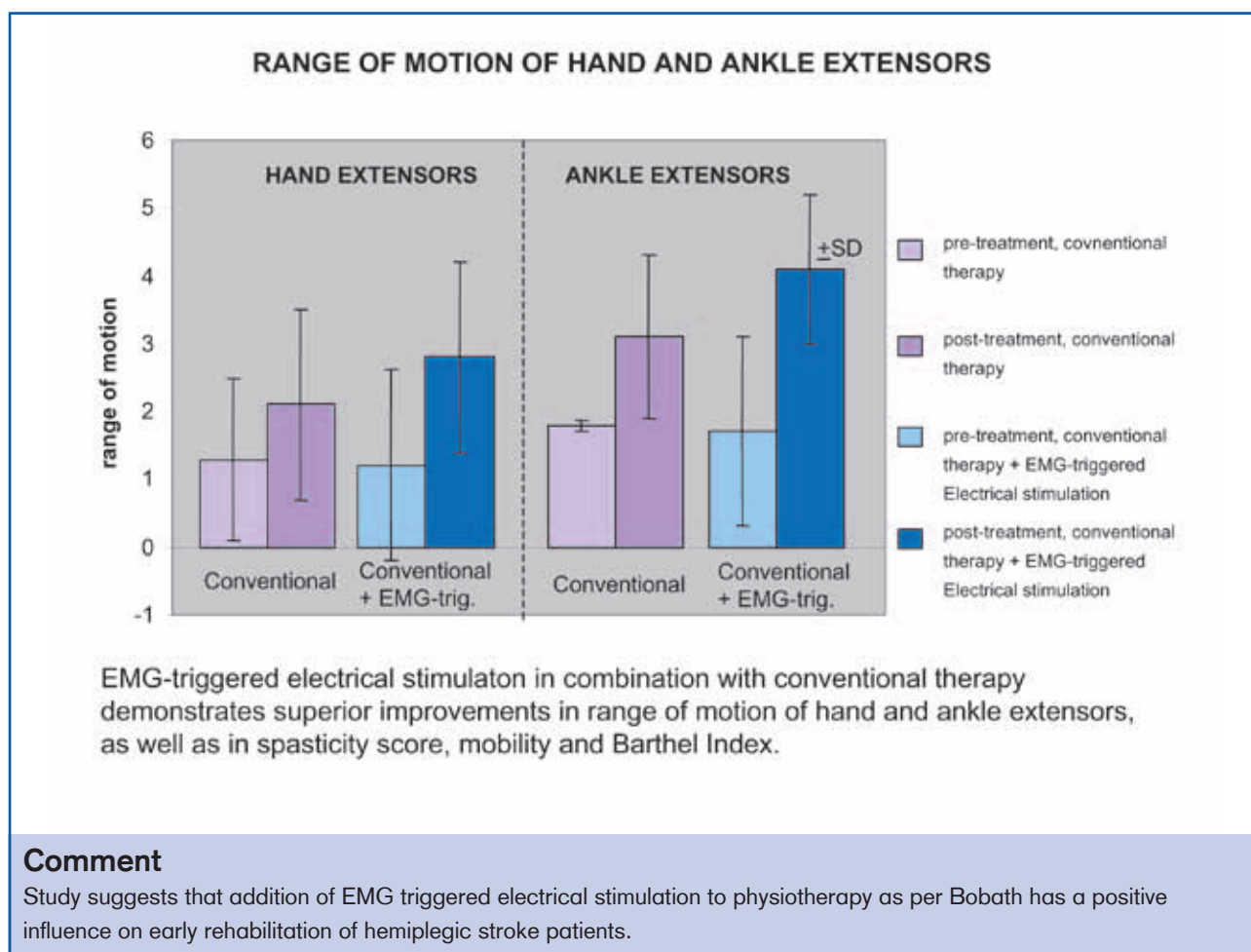
<b>Comparability of the treatment groups</b>	Present
<b>Results</b>	The intervention group moved significantly more wooden blocks (Box and Block test) (9 more than prior to the intervention) and attained greater isometric strength
<b>Undesired therapy effects</b>	None.
<b>Authors' conclusion</b>	Surface EMG triggered electrical stimulation improves the extension movements of the wrist and fingers of hemiparetic patients with stroke at least one year ago. Due to the short training period, the results cannot be linked to the gain in muscle mass. The results support the theory of sensory motor integration; that is, the sensory input of the movement of the paralysed extremity as an afferent signal positively influences the somatosensory cortex and the motor output.



## 3.9

<b>Title</b>	Heckmann J, Mokrusch T, Krockel A, Warnke S, Neundorfer B EMG-triggered electrical muscle stimulation in the treatment of central hemiparesis after a stroke. Eur J Phys Med Rehabil 7 (1997), 138-141
<b>Study type</b>	Randomised controlled study (RCT)
<b>Formal evidence category</b>	Ib
<b>Frame of reference</b>	Neuropsychology department of the regional hospital of Erlangen
<b>Indications</b>	Early rehabilitation after stroke
<b>Inquiry / Aim</b>	To what extent can the rehabilitation of stroke patients in the early phase be improved by surface EMG triggered electrical stimulation?
<b>Relevant criteria for inclusion and exclusion</b>	Inclusion: Right handed persons with large supratentorial cerebrovascular lesion Exclusion: Previous stroke, dementia, bilateral cerebral lesions.
<b>Tested intervention</b>	14 patients: 5 x weekly physiotherapy as per Bobath and surface EMG triggered electrical stimulation by means of PeR-Y rehabilitator of the paretic hand, upper arm and talocalcaneal joint extensors, as well as knee joint flexors, for a total of 4 weeks
<b>Control intervention</b>	14 patients: 5 x weekly physiotherapy as per Bobath, 3 hours weekly ergotherapy, 2 hours weekly group therapy
<b>Possible further treatment groups</b>	None.
<b>Study design</b>	After assignment to intervention and control groups and one week after completion of the testing and control interventions, evaluation of spasticity, active mobility, passive mobility in the pendulum test, and independence in the activities of daily life (Barthel index)
<b>Number of centres</b>	Unicentric
<b>Randomisation</b>	Yes, method not further specified
<b>Concealment (masking) of randomisation</b>	Not described.
<b>Blind treatment</b>	Provided
<b>Observation period</b>	4 weeks
<b>Primary target criteria</b>	Spasticity (spasticity score), active and passive mobility, independence in the activities of daily life (Barthel index)
<b>Secondary target criteria</b>	None.
<b>Number of patients receiving treatment</b>	28 patients (average age 52.1 years), duration of illness in the intervention group 23 to 94 days (average value 56.1 days), in the control group: 26 to 170 days (average value: 61.6 days). Lesion side: Study group 8 right, 6 left; control group 5 right, 9 left
<b>Number and characteristics of included and assessed patients</b>	28 patients, no drop-outs
<b>Comparability of the treatment groups</b>	Provided

<b>Results</b>	Both in the intervention group and in the control group, significant improvements were shown, with the exception of spasticity in the upper arm musculature. The results of the intervention group were significantly better for the mobility of the hand and talocalcanean joint extensors. The results of the intervention group in the spasticity score, in mobility and in the Barthel index were also better, though not of statistical significance.
<b>Undesired therapy effects</b>	None.
<b>Authors' conclusion</b>	Neurophysiologically, frequent, repetitive, actively initiated movements which are increased by means of electrical stimulation impulses strengthen the plastic reorganisation of the brain. Further investigations are required to optimise the therapeutic potential of additional surface EMG triggered electrical stimulation treatments.

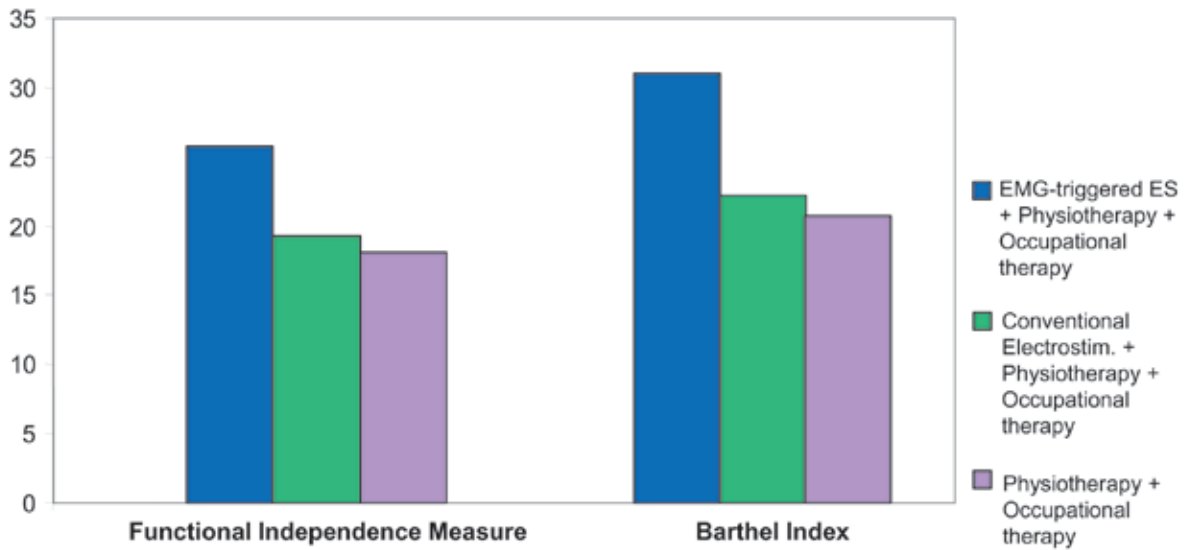


### 3.10

<b>Title</b>	Mokrusch T Treatment of spastic hemiparesis caused by brain infarction with EMG triggered electrostimulation Neurol Rehabil 2 (1997), 82 – 86
<b>Study type</b>	Interim assessment of a randomised controlled clinical study (RCT)
<b>Formal evidence category</b>	Ia
<b>Frame of reference</b>	Study in a neurological rehabilitation clinic
<b>Indications</b>	Spastic hemiparesis after brain infarction
<b>Inquiry / Aim</b>	Effectiveness of EMG triggered electrical stimulation as an additive therapy measure in rehabilitation after stroke.
<b>Relevant criteria for inclusion and exclusion</b>	Inclusion criterion: Spastic hemiparesis of the upper and lower extremity after brain infarction
<b>Tested intervention</b>	22 patients: 5-11 x weekly 1 – 2 daily sessions for 30 minutes of EMG triggered electrical stimulation of the elbow extensors, hand and finger extensors, knee flexors, foot and toe lifters. To trigger the stimulation, the patient had to recruit 50 % of the maximum attainable EMG activity. Basis therapy: 5-11 x physiotherapy (lower extremity) and occupational therapy (upper extremity) weekly.
<b>Control intervention</b>	12 patients: 5-11 x weekly 1 – 2 daily sessions of 30 minutes electrical stimulation in the low-frequency range, without EMG triggering of the elbow extensors, hand and finger extensors, knee flexors, foot and toe lifters. Basis therapy: 5-11 x physiotherapy (lower extremity) and occupational therapy (upper extremity) weekly.
<b>Possible further treatment groups</b>	10 patients: 5-11 x physiotherapy (lower extremity) and occupational therapy (upper extremity) weekly.
<b>Study design</b>	3-armed randomised controlled therapy superiority study
<b>Number of centres</b>	Unicentric
<b>Randomisation</b>	Yes, method not further specified
<b>Concealment (masking) of randomisation</b>	Not described.
<b>Blind treatment</b>	None.
<b>Observation period</b>	Treatment duration 4 – 16 weeks, follow-up observation period not described.
<b>Primary target criteria</b>	Reduction of spasticity (modified Ashworth scale, pendulum test as per Wartenberg, modified as per Bajd) and voluntary contraction strength (myometer measurement) of the elbow and hand extensors, knee flexors and foot extensors (average values of the four muscle groups), mobility and ADL (Barthel index, self-assessment scale B-S as per von Zerssen)
<b>Secondary target criteria</b>	None.
<b>Number of patients receiving treatment</b>	No case number planning described. This is the interim assessment of a larger study which is in progress.

<b>Number and characteristics of included and assessed patients</b>	<p>24 men and 20 women, average age <math>59.8 \pm 8.3</math> years, respectively 22 right and left hemispheric brain infarctions, average time since stroke 6 weeks (1 - 9 weeks).  3 special cases: 1, 2, 5 and 8 years after stroke.  Average treatment period <math>12.3 \pm 3.1</math> weeks (4 – 16 weeks), average number of therapy units weekly:</p> <p>Group with EMG triggered electrical stimulation  FES <math>7.5 \pm 1.2</math> therapy units weekly  Physiotherapy / ergotherapy <math>6.9 \pm 1.2 / 6.8 \pm 1.5</math> therapy units weekly.</p> <p>Group with non-EMG triggered electrical stimulation  FES <math>7.3 \pm 1.1</math> therapy units weekly  Physiotherapy / ergotherapy <math>7.0 \pm 1.3 / 6.8 \pm 1.9</math> therapy units weekly</p> <p>Physiotherapy / ergotherapy group  Physiotherapy / ergotherapy <math>7.4 \pm 1.5 / 7.2 \pm 2.1</math> therapy units weekly</p>
<b>Comparability of the treatment groups</b>	<p>The comparability of the treatment groups with regard to the baseline characteristics of the patients and the weekly therapy intensity appears to be given. However, the group sizes do vary, and no statements are made about the respective total treatment duration of the three groups. Due to the large span of 4 to 16 weeks, non-comparability of the groups cannot be excluded here.</p>
<b>Results</b>	<p>Spasticity: In both electrical stimulation groups, there are significantly stronger improvements in the results than in the control group (EMG triggered FES vs. physiotherapy / ergotherapy <math>p &lt; 0.01</math>, non-EMG triggered FES vs. physiotherapy / ergotherapy <math>p &lt; 0.05</math>). No significant difference was provable between the two forms of FES. In the control group with exclusive physiotherapy / ergotherapy, both in the lower and upper extremities, only moderate improvements in spasticity and pendulum test results by comparison to initial values.</p> <p>Voluntary contraction strength: The voluntary contraction strength increases significantly more in the group with EMG triggered electrical stimulation (<math>p &lt; 0.01</math>) than in the two other groups. There is no significant difference between the groups with non-EMG triggered FES and exclusive physiotherapy / ergotherapy.</p> <p>ADL and wellbeing: Significantly greater improvement in abilities of handling daily life in the group with EMG triggered electrical stimulation (<math>p &lt; 0.05</math>). There is no significant difference between the two other groups, which have also improved by comparison to the initial situation.</p> <p>Special cases: All three patients were treated in the group with EMG triggered electrical stimulation. There was a clear reduction in spasticity and an increase in voluntary contraction strength as well as the abilities of daily life.</p>
<b>Undesired therapy effects</b>	<p>None described.</p>
<b>Authors' conclusion</b>	<p>Electrotherapy with motor effectiveness in the low frequency range can, in itself, reduce spasticity and may furthermore improve the clinical efficiency of conventional movement therapy as an additive measure.</p> <p>EMG triggered electrical stimulation was able to prove that it is able to improve voluntary motor function both in the early phase and in patients with chronic hemiparesis. This does not apply to conventional myostimulation without EMG triggering.</p>

### INCREASE IN ADLs



EMG-triggered electrical stimulation significantly reduces spasticity, increases voluntary contraction strength and improves the abilities of hemiplegic patients to handle daily life.

#### Comment

Study shows a clear superiority of additive EMG triggered electrical stimulation by comparison to adjunct conventional muscle stimulation and exclusive physiotherapy and occupational therapy as per Bobath.



# Summary of the Shown Clinical Studies, Literature Reviews and Meta-Analyses

The randomised controlled studies (RCT) exploring the effect of electrical stimulation of the upper extremity (Daly et al., 2005; Kimberly et al., 2004; Popovic et al., 2003; Cauraugh et al., 2003 (2), 2002, 2000; Armagan et al., 2003, Bocker et al., 2003; Powell et al. 1999, Heckmann et al. 1997) all saw an overall benefit of EMG triggered electrotherapy. A significant benefit of this therapy form in motor rehabilitation after stroke was also found in several meta-analyses of randomised controlled studies and systematic literature reviews (de Kroon et al., 2005 and 2002; Bolton et al., 2004; Glanz et al; 1996).

Clearly, fewer studies and meta-analyses were carried out in the field of chronic plegia of the lower extremity than in rehabilitation of the upper extremity. The randomised clinical studies (Yan et al., 2005; Heckmann et al, 1997) and the meta-analyses and reviews (Moreland et al., 1998; Glanz et al, 1996) also prove effectiveness of EMG triggered electrical stimulation in motor rehabilitation after stroke in the region of the lower extremity.

Typically, the case numbers in most studies were in the range of only 10 to 30 patients. The proof of statistical significance of the results with small case numbers means that the differences between the examined therapy groups must have been very large. The proof of significant therapeutic benefit in many studies with small case numbers furthermore reduces the likelihood of systematic errors. If one observes the meta-analyses about the subject, which attempt to address the issue of possible bias of randomization and type II error due to small numbers by means of accumulation of data from several studies, the results also show relatively homogeneous positive therapy effects in favour of electrical stimulation.

A critical problem in most studies is the absence of sufficient blinding. In this context, the work of Yan et al., 2005, in which a therapy group, a placebo group and an open control group were maintained, is of interest. Here, tendential differences were shown to the effect that an electrical stimulation unit in itself evidently has a placebo effect. However, this difference is evidently not sufficiently great to explain the overall therapy effect of electrical stimulation. This is in agreement with experiences gathered in other fields of medicine.

The observation period of most studies parallels the treatment period. Popovic et al. (2003) and Kimberly et al. (2004) have shown effects to persist when observed with extended follow-up intervals significantly exceeding the period of therapy.

Overall, EMG triggered electrical stimulation appears to be a procedure which is well proven through study evidence. This applies both to acute, subacute and chronic plegia of both the upper and lower extremities. The quality of the studies is assessed as average to good, and there are few points to criticise in the number of studies and patients as well as in a global assessment of all studies.

**Action Reaction Arm Test (ARAT):** is a performance test of upper extremity motor function which consists of 19 items divided into four hierarchical subtests: Grasp, Grip, Pinch, Gross Movement. Items in each subset are ordered so that: (1) if the subject passes the first test, no more tests need to be administered to that subject and he/she scores top marks for that subtest; (2) if the subject fails the first and fails the second, he scores zero, and again no more tests need to be performed in that subtest; (3) otherwise he needs to complete all tasks within the subtest.

**Activities of Daily Living (ADLs):** are tasks of everyday life. Basic ADLs include eating, dressing, getting into or out of a bed or chair, taking a bath or shower, and using the toilet. Instrumental activities of daily living (IADL) are activities related to independent living and include preparing meals, managing money, shopping, doing housework, and using a telephone. Oftentimes, ability of stroke patient to perform ADLs is measured in order to assess his/her capability to return to his/her own home.

**Arm Motor Ability Test (AMAT):** assesses the motor ability of the hand and arm during activities of daily living. It consists of 13 complex tasks that include one to three components each, with a total of 28 component tasks. Sample tasks are eating with a spoon, drinking from a cup, putting on a sweater, and buttoning it. Functional ability and quality of movement are rated on 6-point scales from video recordings of the patient's performance, while speed of task performance is recorded by a stopwatch. The videotapes of all tests are rated by an observer.

**Ashworth Scale:** is used to grade spasticity. It measures the presence of velocity-dependent resistance on a 0 to 4 scale, with 0 representing normal muscle tone, and 4 representing a limb that is fixed in flexion or extension.

**Barthel Index:** scores the ability of a patient to perform basic (e.g. continence, eating) and more elaborate (e.g. toilet, locomotion) daily tasks. The scoring is based on 10 activities and the maximum score is 100 (a score of 100 indicates that the patient is totally independent). The test items include feeding, moving from wheelchair to bed and return, grooming, transferring to and from a toilet, bathing, walking on level surface, going up and down stairs, dressing, continence of bowels and bladder.

**Bobath concept:** usually known as neuro-developmental treatment (NDT) in the US, is one of the major approaches used to rehabilitate patients following stroke. It is based on the brain's ability to reorganize (neuroplasticity), which means that healthy parts of the brain learn and take on the functions which were previously carried out by the damaged regions of the brain. The main principle of the Bobath concept is to support the affected side of the body as much as is necessary to bring its movements into accord with the less affected side of the body.

**Box-and-Block Test:** is a test of manual dexterity. The test is made up of a box with a partition directly in the centre creating two equal sides. A number of small wooden blocks are placed in one side of the box and the subject being tested is required to grasp one block at a time and transport it over the partition and release it into the opposite side. The subject is given 60 seconds in which to complete the test, and the number of blocks transported to the other side is counted.

**Brunnstrom method:** is a rehabilitation method that emphasizes the synergetic pattern of movement. This therapy encourages development of flexor and extensor synergies during early recovery hoping that synergic activation of muscles would transition into voluntary activation of movements.

**Constrained Induced Movement Therapy (CIMT):** is a therapy where a therapist restrains subject's unaffected arm in a sling. This forces subject to use his/her affected arm repetitively and intensively.

CVA: cerebrovascular accident.

EMG (Electromyography): is a technique for evaluating and recording physiologic properties of muscles at rest and while contracting. EMG is performed using electromyograph (instrument) to produce a record called an electromyogram which detects the electrical potential generated by muscle cells when these cells contract, and also when the cells are at rest.

EMG-biofeedback: by placing electrodes onto skin surface, the remaining EMG signal of contracting weak muscle is recorded and converted into a visual or auditory signal.

EMG-triggered electrical stimulation: the electrical stimulation and contraction of muscles is initiated when EMG-signal of voluntary contraction of the target muscle passes preset threshold.

Fugl-Meyer Scale (FM): is an accurate method of assessing function in patients with hemiparesis. It is a cumulative assessment that measures motor skill, coordination, speed of the upper extremity, balance, sensation, and some joint function in people with hemiparesis.

Functional Electrical Stimulation (FES): muscle contraction is provoked by means of electrical stimulation in order to assist the performance of functional activities. It is an aid for continuous use (example: peroneal stimulator to assist walking).

Functional Independence Measure (FIM): is an 18-item ordinal scale widely used in disability and dependence assessment in rehabilitation medicine. The FIM score ranges from 1 to 7, with 1 (Total Assistance) being the worst possible score and 7 (Complete Independence) being the best possible score. The FIM score is applied to the following areas: eating, grooming, bathing, dressing, toileting, bladder management, bowel management, transferring, locomotion, etc. The FIM score is also used for psychological areas such as comprehension, expression, social interaction, problem solving, and memory.

Jebsen Tylor Hand Function Test (JTHFT): is a functional test and is composed of seven timed testing activities: (1) writing a sentence, (2) turning over cards, (3) picking up small objects (e.g., pennies, paper, clips) and placing them in a container, (4) stacking checkers, (5) simulating eating, (6) moving large empty cans, (7) moving large weighted cans.

Motor Activity Log (MAL): is a structured interview for hemiparetic stroke patients during which patients indicate how often and how well they use their paretic arm and hand in 30 activities of daily living (for example: using fork or spoon for eating, picking up the telephone, using key to unlock a door). For each task being evaluated subject rates the ability of the hemiplegic hand on a 0-5 scale for two categories: one for the amount of use (AS) and one for how well the hand performs (HW). Score 0 means that hemiplegic hand is not used for the specific task, while score 5 indicates that hand performs task as often or as well as before the stroke. A summary score is used, which is the average of all activities for each category.

Motor Reaction Time: also called peripheral component of total reaction time. It is defined as a time from the end of premotor reaction time until movement initiation (30% peak force).

NeuroMuscular Electrical Stimulation (NMES): the electrical stimulation is applied according to a pre-programmed stimulation scheme, resulting in repetitive muscle contractions without active involvement of patient.

Percutaneous NeuroMuscular Electrical Stimulation (P-NMES): the stimulation of the muscle is delivered percutaneously via electrodes implanted through the skin into the muscle.

Positional Feedback Stimulation Training (PFST): the electrical stimulation and contraction of muscles is initiated when joint angle passes preset threshold due to voluntary muscle contraction.

Premotor Reaction Time: also called central component of total reaction time. It is time from stimulus onset until EMG activity reaches 30% of peak activity.

Proprioceptive Neuromuscular Facilitation (PNF): is a strengthening technique used in therapeutic exercise that increases strength, flexibility, and range of motion. It is based on the stretch reflex which is caused by stimulation of the Golgi tendon organs and muscle spindles. The stimulation of these sensors results in activity being sent to the brain, which leads to the contraction and relaxation of muscles. PNF exercises help re-educate the motor units which are lost due to the injury.

Therapeutic Electrical Stimulation (TES): using of electrical stimulation for therapeutic purposes in order to improve impairment after stimulation.

Total reaction time: time from stimulus onset until movement initiation (30% peak force). It is equal to the sum of premotor reaction time and motor reaction time.

Transcutaneous Electrical Nerve Stimulation (TENS): was originally used for the treatment of pain by evoking a sensory reaction without muscle contraction. By adjusting the stimulation parameters, however, muscle contraction can be added to a sensory reaction. The initiation of stimulation does not require voluntary contraction of target muscles. Instead, a pre-programmed stimulation scheme is initiated once the trigger button is pushed.

# Otto Bock worldwide

## Europe



**Otto Bock HealthCare Deutschland GmbH**  
Max-Näder-Str. 15 · D-37115 Duderstadt  
Tel. +49 5527 848-3411 · Fax +49 5527 848-1414  
e-mail: healthcare@ottobock.de · www.ottobock.com



**Otto Bock Healthcare Products GmbH**  
Kaiserstraße 39 · A-1070 Wien  
Tel. +43 1 5269548 · Fax +43 1 5267985  
e-mail: vertrieb.austria@ottobock.com · www.ottobock.at



**Otto Bock Adria Sarajevo D.O.O.**  
Omladinskih radnih brigada 5 · BIH-71000 Sarajevo  
Tel. +387 33 766200 · Fax +387 33 766201  
obadria@bih.net.ba · www.ottobockadria.com.ba



**Otto Bock Suisse AG**  
Pilatusstrasse 2, Postfach 87 · CH-6036 Dierikon  
Tel. +41 41 4556171 · Fax +41 41 4556170  
e-mail: suisse@ottobock.com



**Otto Bock ČR s.r.o.**  
Protetická 460 · CZ-33008 Zruč-Senec  
Tel. +420 37 7825044 · Fax +420 37 7825036  
e-mail: email@ottobock.cz · www.ottobock.cz



**Otto Bock Algérie E.U.R.L.**  
32, rue Ahcène outalab · Coopérative les Mimosas  
Mackle-Ben Aknoun · Alger · DZ-Algérie  
Tel. + 213 21 913863 · Fax + 213 21 913863  
e-mail: information@ottobock.fr · www.ottobock.fr



**Otto Bock Iberica S.A.**  
C/Majada, 1 · E-28760 Tres Cantos (Madrid)  
Tel. +34 91 8063000 · Fax +34 91 8060415  
info@ottobock.es · www.ottobock.es



**Otto Bock Orthopedic Services S.A.E.**  
115 El - Alameen St. · Mohandessein – Giza  
Tel. +20 23 3024390 · Fax +20 23 3024380  
e-mail: info@ottobock.com.eg · www.ottobock.com



**Otto Bock France SNC**  
4 Rue de la Réunion · B.P. 11 · F-91941 Les Ulis Cedex  
Tél. +33 1 69188830 · Fax +33 1 69071802  
e-mail: information@ottobock.fr · www.ottobock.fr



**Otto Bock Healthcare plc**  
32, Parsonage Road · Englefield Green  
GB-Egham, Surrey TW20 0LD  
Tel. +44 1784 744900 · Fax +44 1784 744901  
e-mail: bockuk@ottobock.com · www.ottobock.co.uk



**Otto Bock Hungária Kft.**  
Tatai út 74. · H-1135 Budapest  
Tel. +36 1 4511020 · Fax +36 1 4511021  
e-mail: info@ottobock.hu · www.ottobock.hu



**Otto Bock Adria D.O.O.**  
Dr. Franje Tuđmana 14 · HR-10431 Sveta Nedelja  
Tel. +385 1 3361544 · Fax +385 1 3365986  
e-mail: info@ottobock.hr · www.ottobock.hr



**Otto Bock Italia S.R.L.**  
Via Filippo Turati 5/7 · I-40054 Budrio (BO)  
Tel. +39 051 692-4711 · Fax +39 051 692-4720  
e-mail: info.italia@ottobock.com · www.ottobock.it



**Otto Bock Benelux B.V.**  
Ekkersrijt 1412 · NL-5692 AK-Son en Breugel  
Tel. +31 499 474585 · Fax +31 499 476250  
e-mail: info.benelux@ottobock.com · www.ottobock.nl



**Indústria Ortopédica Otto Bock Unip. Lda.**  
Av. Miguel Bombarda, 21 - 2º Esq. · P-1050-161 Lisboa  
Tel.: +351 21 3535587 · Fax: +351 21 3535590  
e-mail: ottobockportugal@mail.telepac.pt



**Otto Bock Polska Sp. z o. o.**  
Ulica Korolowa 3 · PL-61-029 Poznań  
Tel. +48 61 6538250 · Fax +48 61 6538031  
e-mail: ottobock@ottobock.pl · www.ottobock.pl



**Otto Bock Romania srl**  
Șos de Centura Chitila-Mogoșoia Nr. 3  
RO-Chitila 077405, Jud. Ilfov  
Tel. +40 21 4363110 · Fax +40 21 4363023  
e-mail: Ionut.savescu@ottobock.ro · www.ottobock.ro



**Otto Bock Russia**  
5. Donskoj proezd 15, strojenie 16 · RUS-119334 Moskau  
Tel. +7 495 564-8360 · Fax +7 495 564-8363  
e-mail: info@ottobock.ru · www.ottobock.ru



**Otto Bock Scandinavia AB**  
Koppargatan 3 · Box 623 · S-60114 Norrköping  
Tel. +46 11 280600 · Fax +46 11 312005  
e-mail: info@ottobock.se · www.ottobock.se



**Otto Bock Slovakia s.r.o.**  
Čajáková 25 · SK-81105 Bratislava 1 · Slovenská Republika  
Tel./Fax. 00421 2 52 44 21 88  
e-mail: info@ottobock.sk · www.ottobock.sk



**Otto Bock Sava d.o.o.**  
Maksima Gorkog bb · 18000 Niš, Republika Srbija  
Tel./Fax +381 18 539 191 · e-mail: info@ottobock.rs · www.ottobock.rs



**Otto Bock Ortopedi ve Rehabilitasyon Tekniği Ltd. Şti.**  
Ali Dursun Bey Caddesi · Lati Lokum Sokak  
Meriç Sitesi B Blok No: 6/1  
TR-34387 Mecidiyeköy-İstanbul  
Tel. + 90 212 3565040 · Faks +90 212 3566688  
e-mail: info@ottobock.com.tr · www.ottobock.com.tr

## Americas



**Otto Bock Argentina S.A.**  
Piedras, 1314 - Código Postal:  
RA-1147 Ciudad Autónoma de Buenos Aires  
Tel. + 54 11 4300 0076  
ventas@ottobock.com.ar



**Otto Bock do Brasil Ltda.**  
Rua Jovelino Aparecido Miguel, 32  
BR-13051-030 Campinas-São Paulo  
Tel. +55 19 3729 3500 · Fax +55 19 3269 6061  
ottobock@ottobock.com.br · www.ottobock.com.br



**Otto Bock Healthcare Canada Ltd.**  
5045 S. Service Road · Burlington Ontario L7L 5Y7  
Tel. +1 800 665 3327 · Fax +1 800 463 3659  
e-mail: info@ottobock.ca · www.ottobock.ca



**Otto Bock HealthCare Andina Ltda.**  
Clínica Universitaria Teletón, Autopista Norte km 21  
La Caro · Chia, Cundinamarca, Bogotá/Colombia  
Tel. +57 1 8619988 · Fax +57 1 8619977  
e-mail: ottobock@telesat.com.co



**Otto Bock de Mexico S.A. de C.V.**  
Av. Avila Camacho 2246 · Jardines del Country  
MEX-Guadalajara, Jal. 44210  
Tel. +52 33 38246787 · Fax +52 33 38531935  
e-mail: info@ottobock.com.mx · www.ottobock.com.mx



**Otto Bock HealthCare LP**  
Two Carlson Parkway North, Suite 100  
U.S.A.-Minneapolis, Minnesota 55447  
Phone +1 800 328 4058 · Fax +1 800 962 2549  
e-mail: usa.customerservice@ottobock.com  
www.ottobockus.com

## Asia/Pacific



**Otto Bock Australia Pty. Ltd.**  
Suite 1.01, Century Corporate Centre  
62 Norwest Boulevard · Norwest Business Park  
AUS-Baulkham Hills NSW 2153  
Tel. +61 2 88182800 · Fax +61 2 88182898  
e-mail: healthcare@ottobock.com.au  
www.ottobock.com.au



**Beijing Otto Bock Orthopaedic Industries Co. Ltd.**  
HengXiang Tower · No.15 Tuanjiehu South Road  
Chaoyang District · Beijing 100026 · P.R.China  
Tel. +86 10 85986880 · Fax +86 10 85980040  
china@ottobock.com.cn · www.ottobock.com.cn



**Otto Bock Asia Pacific Ltd.**  
Suite 3218, 32/F., Sun Hung Kai Centre  
30 Harbour Road, Wanchai · Hong Kong  
Tel No. +852 2598 9772 · Fax No. +852 2598 7886  
e-mail: info@ottobock.com.hk



**Otto Bock HealthCare India Pvt. Ltd.**  
Behind Fairlawn Housing Society · Sion Trombay Road  
Chembur · IND-Mumbai 400 071  
Tel. +91 22 2520 1268 · Fax +91 22 2520 1267  
e-mail: information@indiaottobock.com · www.ottobockindia.com



**Otto Bock Japan K. K.**  
Oak Minami-Azabu Bldg. 2F · 3-19-23, Minami-Azabu  
Minato-Ku, J-Tokyo · 106-0047  
Tel. +81 3 5447-1511 · Fax +81 3 5447-1512  
e-mail: ottobock@ottobock.co.jp · www.ottobock.co.jp



**Otto Bock Korea HealthCare Inc.**  
Nongsan B/D 1F, 320-4  
Yangjae - 2 Dong Seocho-Gu · ROK-37-897 Seoul  
Tel. +82 2 577-3831 · Fax +82 2 577-3828  
e-mail: ottobock@korea.com · www.ottobockkorea.com



**Otto Bock South East Asia Co., Ltd.**  
1741 Phaholyothin Road,  
Kwaeng Chatuchark, Khet Chatuchark,  
Bangkok THAILAND 10900  
Tel. +66 2 930-3030 · Fax +66 2 930-3311  
e-mail: obsea@ottobock.co.th · www.ottobock.co.th

*Otto Bock*<sup>®</sup>

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**Otto Bock HealthCare**

Two Carlson Parkway North, Suite 110, Minneapolis, MN 55447-4467  
www.ottobockus.com • 800.328.4058