

Neuromuscular electrical stimulation and dynamic bracing for the management of upper-extremity spasticity in children with cerebral palsy

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A prospective study was designed to determine whether the combined use of neuromuscular electrical stimulation (NMES) and dynamic bracing was more effective than use of either alone in reducing upper-extremity spasticity in children with spastic hemiplegic cerebral palsy. Twenty-four patients (12 males, 12 females; mean age 8y 7mo [SD 4y 2mo]; age range 3–18y) diagnosed with spastic hemiplegic CP were randomly allocated to three groups: group 1 had two 30-minute sessions of NMES a day applied on the antagonist extensors without bracing; group 2 had two 30-minute sessions of dynamic bracing per day; and group 3 had two 30-minute sessions of NMES and dynamic bracing every day. Treatment was continued for 6 months in all groups and applied only to the affected extremity. Patients were evaluated before therapy, at monthly intervals during the therapy, and 3 months after completion of the therapy. Three measures of outcome were taken: the Melbourne Assessment, grip strength, and posture evaluation with Zancolli's classification. The therapist performing the outcome assessments was blinded as to groups. Statistically significant differences were found in all three measures for only those treated with combined NMES and dynamic bracing. However, this significant effect lasted for only 2 months after discontinuation of the treatment. We conclude that the combined use of NMES and bracing is more effective than either alone but requires continuous application.

†Stephen P Cheshier Sr (1957–2000), the main investigator and the force behind this research, passed away suddenly on 8 September, 2000. He was instrumental in the development of the program, and without him it would not have been possible.

One of the treatment options for spasticity in patients with cerebral palsy (CP) is to 'stretch out' the spastic muscle with an orthosis.¹ Spasticity does not diminish with orthotic bracing, perhaps because of the added resistance to the isotonic contracting muscles, which seems to increase the tone of the spastic muscle.² Upper-limb orthoses are, therefore, temporary expedients and do not seem to be effective in encouraging function or in correcting contractures.³ Orthosis alone as a treatment addresses only the static component of spasticity (muscle shortening), not the dynamic component (abnormal tone and imbalance), thus giving limited improvement to the impaired upper extremity.

Electrical stimulation is another method suggested for the management of spasticity with variable success. As early as 1952, Levine et al. reported that stimulation of the antagonist to a spastic muscle, followed by vigorous range-of-motion exercises, led to a marked decrease in muscle tone.⁴ Alfieri, Hazlewood et al., and Shindo and Jones, in three different studies, also demonstrated an increase in joint range of motion and muscle strength by administering multiple treatment sessions of electrical stimulation to the antagonist of spastic muscles.^{5–7} Later, Sommerfelt et al. found no effect of electrical stimulation after a controlled crossover study.⁸ However, most of these reports and others related to the lower extremity and are not consistent in terms of the application of electrical stimulation (intensity, amplitude, and frequency of delivery).^{5–14} No standard treatment has, therefore, been formulated.

In our previous study we combined neuromuscular electrical stimulation (NMES) with dynamic bracing and applied it in 19 patients diagnosed with CP-induced spastic hemiplegia.¹⁵ In that study, NMES was applied to the wrist and finger extensors. Patients wore a dynamic brace while receiving the NMES and a static brace at night. All patients had significant improvement in posture and showed marked improvement in upper-extremity function within 3 months.

In the present study we sought to investigate whether the improvement in the hand function was due to the effect of NMES, dynamic bracing, or a combination of the two methods.

Method

PATIENTS

This study was approved by the University of Louisville institutional review board, and parental written consent was obtained from all families, together with an oral agreement from each patient.

Thirty-one patients seen at a tertiary hand care clinic between 1997 and 2000 were enrolled in this study. Data were collected at the Center for Orthotic and Prosthetic Care, Louisville, KY, USA. From this initial group, six patients who did not comply with the protocol and one whose family moved out of state were excluded from the study. The remaining 24 patients (12 males, 12 females) met the following inclusion criteria: between 3 and 18 years of age; with truly spastic hemiplegia; with a spasticity in the scapula, shoulder, and elbow region that allowed them to place their hand in the desired position in space; and with Zancolli type 2 to 3 spasticity in the wrist and digits.¹⁶ They had sensation to light touch and demonstrated enough cognition to understand directions and to follow them. The mean age of the children was 8 years 7 months (SD 4y 2mo; age range 3–18y). There were 12 males (six with left hemiplegia and six with right hemiplegia) and 12 females (five with left hemiplegia and seven with right hemiplegia).

Patients were randomly allocated to three groups by a closed-envelope method. A clinical clerk placed group numbers in closed envelopes before allocation. The envelope remained sealed until each participant had given consent for treatment, understanding the risks and benefits. All patients were evaluated by an upper-extremity surgeon and a therapist, both of whom had taken consents and enrolled patients for non-operative treatment. The treatment was introduced by a therapist. Another therapist, who was blinded to the treatment groups, carried out the outcome measures. The daily treatment regimen included the following: group 1 ($n=8$) followed a course of two 30-minute sessions of NMES applied to the antagonist extensors; group 2 ($n=8$) followed two 30-minute sessions of dynamic bracing; and group 3 ($n=8$) followed a regimen of two 30-minute sessions of NMES of the antagonist extensors and dynamic bracing. Patients in all groups used a static brace at night. Treatment in all groups continued for 6 months and was applied only to the affected extremity. We proposed that the combined therapy of NMES and dynamic bracing would improve limb function more efficiently and more quickly than either alone.

ELECTRICAL STIMULATION DEVICE

The electrical stimulation was delivered by a system consisting of three parts: a stimulator unit (LODE 400 ElectroMed Systems, Louisville, KY, USA), electrodes, and connecting wires (Medi-Stim Inc., Delaware, OH, USA; Fig. 1). The reusable, self-adhering, carbonized rubber electrodes were connected to the stimulator by leads that were snapped to the button of the electrode. The adhesive electrodes were placed on the dorsum of the forearm over the bellies of the wrist and finger extensor muscles (extensor carpi radialis longus and brevis, extensor carpi ulnaris, and extensor digitorum communis muscles) at the distal and proximal positions. The electrical stimulator consisted of a dual-channel battery-powered device with a constant current output of 0 to 100mA. The stimulus waveform consisted of biphasic symmetric rectangular pulses with a 200ms duration. The pulse rate ranged between 40 and 60 pulses/second to produce tetanic muscle contraction. The stimulus amplitude was adjusted to produce tolerable muscle contractions (30–40mA). During the training session with the parents, electrical stimulation was applied first on the clinician's arm, then on one of the parent's arms, and finally on the

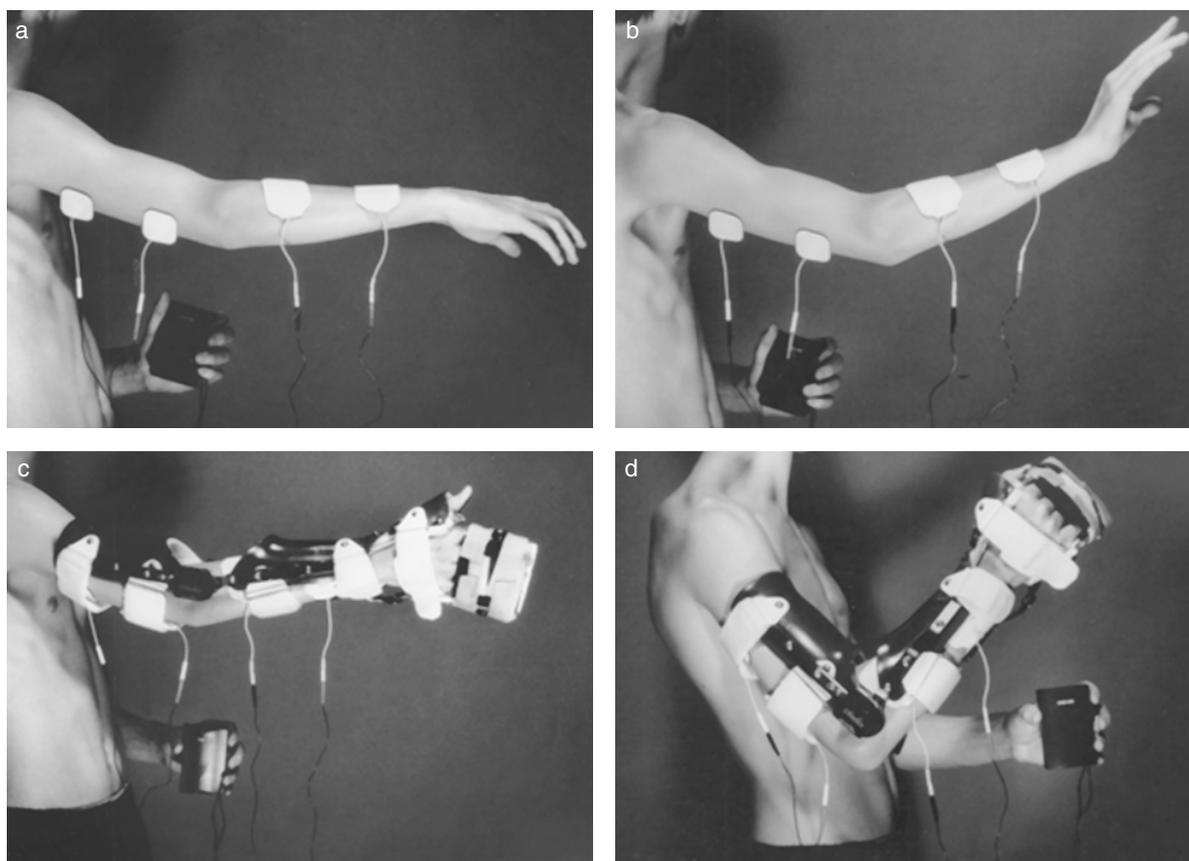


Figure 1: Use of neuromuscular electrical stimulation unit. (a) Portable stimulator unit, two electrodes placed on extensors of forearm, and two electrodes placed on triceps; (b) wrist and finger extension elicited by stimulation of extensors of forearm; (c) electrical stimulation system and orthotic device (dynamic bracing) positioned ready to start therapy; (d) orthotic device allows flexion and extension at elbow joint, locks wrist in an extended position, and also locks proximal interphalangeal and distal interphalangeal joints, permitting resistive finger movement only at metacarpophalangeal joints.

patient's arm. A 5-second ON ramp, 2-second OFF ramp, 10-second ON duty, and 7-second OFF duty cycle was selected to produce rhythmical muscle contraction. The stimulus amplitude threshold was determined by increasing the amplitude of the stimulus until muscles started to contract. The amplitude was then gradually reduced until no contractions were apparent. This amplitude threshold was then doubled and used routinely. If necessary, the amplitude was decreased to make contractions tolerable.

DYNAMIC BRACING

The orthotic device (Ultraflex, Pottstown, PA, USA) consisted of a wrist/hand unit and an elbow unit. The wrist/hand unit had a dynamic dual hinge with adjustable tension (0–12lb) and an adjustable lockout for static tension of the spastic flexor musculature that positions the wrist in the extension described below. This unit also had an adjustable dynamic flat pan that locked the proximal interphalangeal and distal interphalangeal joints in an extended position, allowing resistive finger movement only at the metacarpophalangeal joints (Fig. 1). To resist the spastic muscle without facilitating a spastic response (i.e. a stretch reflex), the wrist unit was positioned 10° short of maximum extension stretch with a flat spreading hand portion to mobilize the metacarpophalangeal joints but block the proximal interphalangeal joints. The elbow unit had a dynamic dual hinge with adjustable tension (0–16lb) and an adjustable lockout. At night, the flat pan was locked up to resist the contracted extrinsic flexors in all groups.

NEUROMUSCULAR ELECTRICAL STIMULATION AND DYNAMIC BRACING PROTOCOL

This home-based program consisted of 1 hour per day of electrical stimulation with dynamic bracing. Treatment time could be divided into two 30-minute sessions or into three 20-minute sessions (once in the morning, once at noon, and once in the evening), depending on parents' schedules. After the parents had been instructed, children were fitted with the wrist and elbow unit. Once the amplitude had been determined, the extensor muscles were stimulated for 10 seconds obtaining a tetanic contraction, followed by 7 seconds of no electrical stimulation. During this period of no stimulation, the patient was told to flex the fingers repeatedly so that the patient learned what muscles to contract to flex the fingers and prevent the co-contraction. At the beginning of the treatment, the tension at the dynamic flat pan of the dynamic brace was strong enough to extend the fingers, and then, as the extensor tendons became stronger, the tension was gradually decreased. After each session, children were allowed to continue with their daily activities. At night, the flat pan was locked up to resist the contracted extrinsic flexors and maintain the range of motion gained during the day.

OUTCOME VARIABLES

Dexterity of the upper extremity was evaluated with the Melbourne Assessment of Unilateral Limb Function, grip and pinch strength were evaluated with a standard dynamometer (JAMAR II), and the posture of the wrist and fingers were evaluated and classified in accordance with the Zancolli classification (Table I).^{16,17} Patients were evaluated before treatment, at monthly intervals during the treatment, and again at the first, second, and third months after completion of the treatment.

STATISTICAL METHODS

To compare the three groups during the 9 months of measurement (6mo of treatment and 3mo of follow-up after treatment), a repeated-measures analysis of variance was used to determine whether significant differences occurred across treatments, and also across time, with the Mixed Models procedure in SAS (SAS Institute, Cary, NC, USA). Among the three outcome measures, the Melbourne score was used as the primary outcome measure to calculate the sample size. For the outcomes that were statistically significant, comparisons were made with the least-square means.¹⁸ The statistician who performed the analysis for the study was blinded to the treatment groups during the study.

Results

The participants all completed the treatment and follow-ups. Baseline demographic and clinical characteristics are outlined in Table II.

MELBOURNE ASSESSMENT

Patients in the combined treatment group showed a significant improvement during the treatment (Table III). However, this improved function lasted for only 1 month after completion of the treatment. None of the patients reported any pain due to electrical stimulation.

GRIP STRENGTH MEASUREMENTS

Patients treated with the combined treatment of NMES and bracing showed a steady increase in grip strength during the treatment period, which declined once treatment was discontinued (Table IV). A significant improvement in muscle strength was noted as early as 3 months and lasted until 2 months after cessation of the treatment (month 8).

Table I: Zancolli's classification of deformity^a

Type	Definition
I	Complete extension of fingers with wrist in neutral or less than 20° flexion
IIa	Active extension of wrist with fingers in flexion
IIb	No active extension of wrist with fingers flexed
III	No active extension of fingers even with maximal wrist flexion

^aZancolli's classification¹⁷ is widely used as a surgical classification system to guide and evaluate results before and after surgery.

Table II: Baseline values taken at beginning of treatment

Parameter	Group 1, n=8; NMES only	Group 2, n=8; bracing only	Group 3, n=8; NMES + brace
Age, y:m (range)	9:8 (6–18y)	8:10 (4–14y)	7:3 (3–14y)
Sex, M/F	4/4	3/5	5/3
Melbourne score (SD)	52 (5.0)	53 (6.0)	56 (4.0)
Grip strength, lb (SD)	28 (2.0)	25 (2.5)	30 (3.5)

Where errors are shown, results are means (SD). NMES, neuromuscular electrical stimulation.

POSTURE EVALUATION

Criteria presented in Table I were used to evaluate the posture before and after the treatment. None of the patients enrolled in this study had type I deformity before treatment. In group 1, two patients had type IIa deformity, three had type IIb deformity, and three had type III deformity. After 6 months of NMES alone, two patients with type IIa deformity moved to type I, two patients with type III deformity proceeded to type IIb, and others remained in their original categories. In group 2, three patients had type IIa deformity, two had type IIb deformity, and three had type III deformity before 6 months of bracing. Later, only two patients with type III deformity moved to type IIb; others remained in the original categories. Finally, in group 3, two patients with type IIa deformity moved to type I, one patient with type IIb deformity advanced to type I deformity, and two patients with type IIb deformity moved to type IIa. Of three patients with type III deformity, two of them moved to type IIa and one to type I. The change in group 3 was found to be statistically significant compared with the other two groups at the end of the treatment period in 6 months ($p=0.02$). However, this significant change regressed to pretreatment values at 3 months after the treatment, with no significant difference between the groups ($p=0.1$). Comparisons within each individual group also showed a significant difference in group 3 ($p=0.03$), but only a modest improvement with NMES alone (group 1; $p=0.06$) and no difference in bracing alone (group 2; $p=0.1$).

No major complications were noted during the study period.

Discussion

In this study we found that only the combined use of NMES with dynamic bracing is more effective than either treatment alone. The efficacy of the combined treatment method was confirmed by a statistically significant improvement over

time observed in the Melbourne score, grip strength, and posture evaluation. This therapy regimen improved not only the range of motion of the wrist and fingers but also the velocity of movement. Patients obtained better control over their upper extremities.

Patients did not report any significant adverse effects, although a few reported some discomfort from the electrical stimulation at the beginning of the treatment. However, this discomfort was not a limiting factor. Patients quickly learned to tolerate the sensation and found this therapy less demanding and more rewarding than the usual bracing and occupational therapy. They even derived pleasure from seeing the hemiplegic extremity move and were also excited to have a relatively quick response. In most patients we could observe notable improvement after 4 weeks (first evaluation after starting treatment), which encouraged patients and their parents to continue the therapy.

However, this study has certain limitations. Owing to the nature of the treatment, participants are not blinded to the method of treatment. The statistical power is low as a result of limited number of children in each group. The comparisons between groups should, therefore, be interpreted cautiously. The study also lacks a control group not undergoing treatment. The improvement in function can, therefore, only be assumed to be due to the treatment, given no spontaneous improvement without the treatment in a period of 9 months. In addition, the effect of combined therapy lasted only 1 or 2 months after discontinuation of the treatment. Whether a longer-lasting effect can be achieved with longer treatment durations is not clear without further investigation.

The number of studies reporting the effect of electrical stimulation on upper extremity spasticity is limited. Pape et al. applied therapeutic electrical stimulation to the triceps and wrist extensors of 26 children with hemiplegia, but no measurable change in function was reported.¹⁹ Baker et al. reported an increase in wrist and finger extension in 16 adult

Table III: Melbourne Assessment¹⁶ scores

Group	Month during treatment						Month after treatment		
	1	2	3	4	5	6	7	8	9
1 NMES only	52 (4)	53 (8)	55 (7)	54 (4)	54 (8)	51 (4)	52 (5)	50 (4)	49 (5)
2 Brace only	51 (3)	50 (4)	53 (7)	51 (3)	52 (5)	49 (4)	52 (6)	48 (5)	48 (6)
3 NMES + brace	57 (6)	57 (5)	70 (6)	69 (5)	68 (7)	70 (3)	65 (4)	55 (5)	50 (7)
<i>p</i> value	0.2	0.2	0.01	0.01	0.02	0.02	0.05	0.07	0.08

Statistically significant *p* values are shown in bold; values are means (SD) at 95% confidence intervals. NMES, neuromuscular electrical stimulation.

Table IV: Grip strength testing presented as a percentage of contralateral extremity

Group	Month during treatment						Month after treatment		
	1	2	3	4	5	6	7	8	9
1 NMES only	30 (3.0)	28 (8.0)	24 (5.0)	29 (4.0)	27 (7.0)	27 (3.0)	29 (4.0)	28 (5.0)	25 (4.0)
2 Brace only	25 (3.5)	22 (5.0)	23 (4.0)	21 (3.0)	20 (6.5)	20 (4.0)	19 (5.0)	18 (2.0)	20 (3.0)
3 NMES + brace	33 (5.0)	38 (1.5)	44 (3.8)	39 (2.6)	36 (4.3)	35 (5.0)	38 (3.0)	29 (2.0)	28 (3.0)
<i>p</i> value	0.09	0.03	0.001	0.02	0.03	0.03	0.01	0.1	0.09

Statistically significant *p* values are shown in bold; values are means (SD) at 95% confidence intervals. NMES, neuromuscular electrical stimulation.

patients with hemiplegia with unilateral flexor spasticity.²⁰ Three 30-minute periods of electrical stimulation per day were applied for a period of 4 weeks. However, patients seen at 1 and 2 months after the cessation of electrical stimulation had developed increased flexor contractures despite attempts to maintain range of motion with passive exercise and splinting. Later, Carmick applied electrical stimulation to upper extremity spasticity in two children and noted a significant improvement.²¹ Larger series have been published on two recent studies. Wright and Granat used 3 minutes of daily functional electrical stimulation to forearm extensors on eight children with CP and demonstrated an improved outcome during the treatment period for 6 weeks.²² Maenpaa et al. used electrical stimulation at a sensory level on 12 children with upper-extremity spasticity and reported a significant improvement in function within the treatment period (4–5wks) and afterwards as far as 3 months.²³ However, this improvement gradually returned to baseline after cessation of the treatment. All of these studies show many differences in terms of application of the electrical stimulation (such as frequency and duration), supplemental treatments (bracing and occupational therapy), patient population (adults vs children), and evaluation criteria of functional outcomes. However, one finding in common is that the improvement in function is temporary and lasts for only a limited period after cessation of the treatment, as we have demonstrated in the present study.

Conclusion

In summary, the combined use of electrical stimulation and dynamic bracing presented in this study represents a quick and effective method of management and could potentially reduce the need for multiple surgical procedures. However, more research is needed to determine the ideal method of application for electrical stimulation and other supplemental treatment modalities.

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