

## GUEST EDITORIAL

### Use of neuromuscular electrical stimulation in neurorehabilitation: A challenge to all

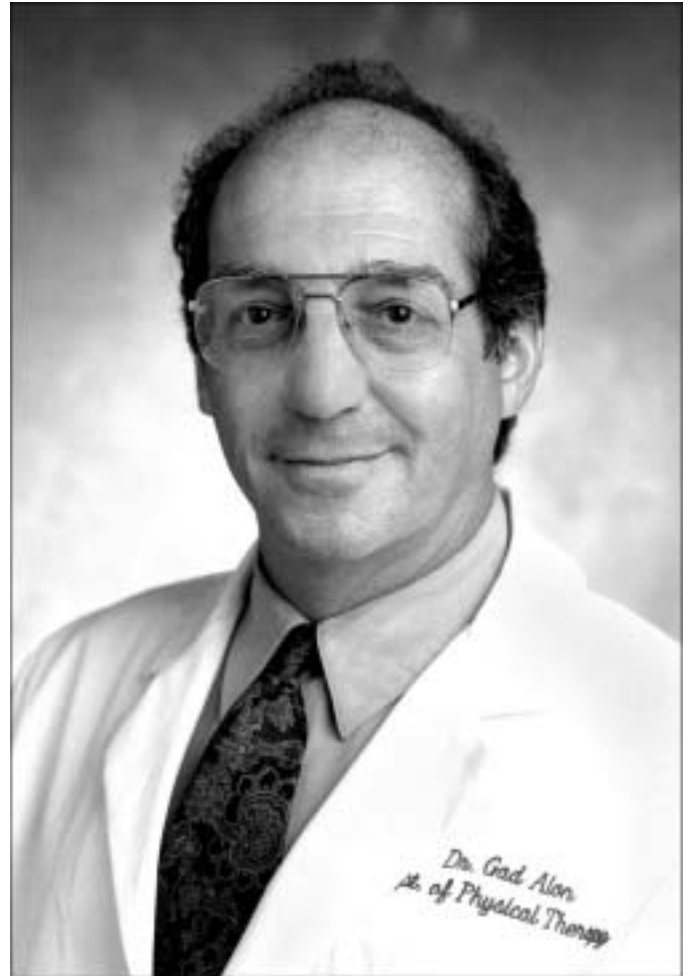
Electrical stimulation, designed to excite peripheral sensory and motor nerves (also called Neuromuscular Electrical Stimulation [NMES]), is gradually becoming a recognized treatment option in neurorehabilitation. Two basic generic paradigms apply:

1. Neuromuscular retraining. This paradigm uses the NMES to minimize impairments and dysfunctions and eventually relearn to perform specific tasks and functions without electrical stimulation.
2. Neuroprosthesis (also termed “neuro-orthosis”). With this paradigm, the NMES enables the patient to perform specific tasks and functions considerably better but only during stimulation.

Growing scientific elucidation of the peripheral and central electrophysiological responses and objective documentation of the clinical benefits that NMES can provide are evident in both scientific inquiries and clinical studies [1–25]. Yet, the use of NMES as part of the everyday rehabilitation programs is uncommon in today’s clinical practice. Regrettably, the majority of subjects who live with damage to the central nervous system (CNS) are currently devoid of the benefits attributed to the evolving NMES technology. Without patients’ experience with the technology, the full spectra of benefits from adding NMES to the neurorehabilitation process remain largely unexplored.

Methodological flaws in current published evidence-based literature may present a major barrier to our ability to transform the ever-growing scientific knowledge into a working technology that serves the needs of the patients. Among the major methodological flaws that one can identify are the timing of NMES initiation, NMES training dose, isolation of the NMES training from the training of specific tasks or functions, and confinement of stimulation to only one to two muscle groups.

Not one paper has been published that provides a medically based rationale for the timing of NMES commencement, the first major flaw. In most pub-



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lished studies [1–4,7–10,15,20,23], initiation of a NMES program was delayed by 3 to 12 months poststroke. Some researchers waited several years before the benefits of NMES were examined in clinical trials [11,19,22]. This classical doctrine of delaying the initiation of NMES no longer seems valid, and recently, investigators have introduced NMES within a mean poststroke onset of 48 hours [17], 15 to 16 days [6,13,21], or 2 to 4 weeks [15,18]. Altogether, these investigators studied 234 patients and none reported any impeding effect on

spontaneous recovery or observed poststroke complications, such as recurrent stroke, Reflex Sympathetic Dystrophy (RSD), or shoulder subluxation. To the contrary, the motor recovery of the stimulated patients was both statistically and clinically superior. The magnitude of spasticity and upper-limb pain was far less in the NMES-treated patients compared to the standard rehabilitation-treated patients. These data provide compelling clinical evidence that early initiation of the NMES program is clearly warranted and delaying the stimulation is unlikely to be medically justified.

The second critical flaw in current investigational protocols is the absence of evidence-based NMES training dose. Like many other interventions, NMES dosage should be quantified by the type and strength of contraction (stimulation intensity), the number of repetitions (per session, per day), and duration (weeks, months) of application. Therapeutic dose determination should relate to evidence of improvement in the studied impairments or dysfunctions. Conversely, termination of intervention should be linked to lack of improvement (or deterioration) rather than an arbitrary time end point. Regrettably, to date, no clinical studies have been published in neurorehabilitation or other scientific journals that seem to follow this basic concept of training dose.

Researchers made decisions regarding training intensity, duration, and termination without specific rationale, reference to changes in patient progress, or other physiologically or medically sound justification. The majority of studies were limited to three to five sessions a week, for periods of only 20 to 60 minutes in each session without explanation as to why these training intensities were chosen [1–4, 8,13,15,20,21,23]. The total stimulation period had been restricted to 3 to 6 weeks [1–4,8,12,13,15, 17,18,20,23], while only a couple of investigators elected to continue the program up to 3 to 4 months [11,22]. Reconstruction from the data reported in these studies estimates a training dose yield of approximately 12 hours of stimulation in 4.5 weeks of training, a very low dose considering that when not stimulated, the paretic limbs and torso are inactive most of the patient's waking hours. The ten-

dency of the CNS and the peripheral muscular, vascular, and connective tissues systems to adapt to the state of inactivity is well documented. The longer the patient remains inactive, the slower the recovery and the greater the number and severity of residual impairments and functional deficits. Consequently, the existing NMES dosages appear to be severely insufficient and scientifically frail. At the University of Maryland School of Medicine, we are studying NMES training dose in the acute stage poststroke that is 24 times greater than current dosages and we are linking the training dose to functional and motor control gains.

The third major flaw relates to the training paradigm. Most studies that tested the efficacy of NMES in neurorehabilitation applied the stimulation in isolation of the motor task that the patient was trained to relearn. One should not be surprised that significant improvements in isolated impairments (isometric strength, active joint motion) are common and are consistently reported, but improvements in relearning specific tasks or functions are not common [1,2,4,6,8,11,15,17,21,22,26]. A dominant shortcoming in available studies is overlooking the evidence regarding specificity of training. Stated differently, if the goal of NMES training is to regain motor control and functional ability, then the NMES should be combined with the tasks or functional specific activities that are being learned. Only a few researchers have recently recognized the need for a new training paradigm and have demonstrated in chronic stroke patients that appropriate training can result in significant gains of motor control and hand function [19,20,23].

The fourth principle flaw is directed at the application of stimulation to only one [1–4,6–9,12–15,18,20,21,23] and in a few cases two muscle groups [11,22,25]. The rationale for restricted exposure is not typically revealed by authors [1,6,15–18,23,27], but one may assume that the complexity involved in setting up the patient for treatment, the time involved in setting up the patient, assurance of appropriate and reproducible electrode placement, and the uncertainty whether patients can comply with a home-based, multisite stimulation program(s)

constitute four possible reasons why researchers as well as clinicians may have constrained the clinical application of electrical stimulation.

To overcome these cardinal methodological flaws and to maximize the effects of NMES on the physical recovery following stroke, the most urgent clinical research questions should focus on the tentative hypotheses that the stimulation should begin as early as medically possible, that the training doses are likely to be considerably greater than currently reported, and that the NMES must be combined with specific tasks or functions, individually tailored to each patient's ability and continually modified according to patient progress. Another critical question to be answered urgently is, What is the minimum number of electrically stimulated muscle groups that are required to maximize the recovery of upper limb, lower limb, and torso of patients who survive with CNS damage?

To answer the listed and additional research questions, we should challenge the bioengineers to refocus their talent and knowledge and provide stimulation systems, including surface electrodes that are much simpler and "patient friendly." We must use recent advancements in biomaterials and micro- or nanoelectronics to produce a "1-2 push-button" NMES, because patients and their non-professional caregivers, not physician and therapists, will probably be required to apply the stimulation and do so without direct supervision. The stimulation training is likely to continue far beyond the current government or private insurance coverage of standard supervised rehabilitation. Thus, only a very friendly NMES will enable researchers and patients to comply with the training dose needed to maximize the effects of NMES in neurorehabilitation.

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