NZSTA Position Paper on
Neuromuscular Electrical Stimulation in Swallowing Rehabilitation

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There is increasing interest regarding the potential application of neuromuscular electrical stimulation (NMES) to dysphagia rehabilitation practices. It is the intent of this position paper to inform NZSTA membership of basic definitions for NMES, to summarise relevant research, to elaborate on professional concerns that arise when discussing NMES as a treatment for dysphagia and to issue an official statement on the application of this technology by members of the NZSTA.

Definition and electrophysiological background
Neuromuscular electrical stimulation (NMES) is defined as "the external control of innervated, but paretic or paralytic, muscles by electrical stimulation of the corresponding intact peripheral nerves" (in Baker, et al., 1993). This control is achieved through the carefully regulated administration of pulsed electrical current at predetermined frequencies and amplitudes to nerves, myoneural junctions or muscles (Ragnarrson, 1994). As this current is passed from the surface electrode through the conductivity medium of the skin and underlying tissue, physiologic processes are altered at many levels. These alternations range from changes in permeability of the cell membrane at the cellular level, to systemic changes such as analgesia (absence of the sense of pain without loss of consciousness) secondary to neurotransmitter release, circulatory changes secondary to vasoactive polypeptide release, and kidney and cardiac changes secondary to modulation of internal organ activity. The therapeutic benefit of electrical stimulation is a consequence of tissue level changes, which are manifested in part by skeletal muscle contraction and subsequent effects on strength, reaction time and stamina (Alon, 1991). The current
administered during electrical stimulation changes the ionic composition of the neural or muscular cell membrane and if of adequate intensity, triggers transmission of a motor unit action potential with a subsequent motor response. The conduction of an action potential and the chemical synaptic transmission created by artificial electrical stimulation involves the same processes of neurosecretion and chemoreception as a naturally occurring excitation. However, the externally stimulated contraction differs from physiologic muscle activity in the ordering of muscle fiber recruitment, the synchronicity of individual motor units and the intensity of stimuli required to produce these changes.

**Application of Neuromuscular Electrical Stimulation in Rehabilitation Medicine**

Therapeutic application of NMES is a complex process and requires a thorough knowledge base in the areas of neural transmission, electrophysiology, biologic impedance and muscle physiology. The effectiveness of the treatment is dependent on precisely chosen stimulation parameters for a selected therapeutic goal. These parameters are critical for treatment effectiveness but also to ensure patient safety. Electrical current can be configured in a complex array of presentation modes by adjusting not only the type of current applied, but also the pulse amplitude, duration, repetition rate and duty cycle of that current. Although certainly knowledge of these concepts can be acquired, they are not typically included in preparatory coursework for a Speech Language Therapy professional degree.

The literature in physical medicine and rehabilitation reports numerous applications for electrical stimulation, including increasing muscle strength and range of motion, correcting contractures from spasticity, increasing sensory awareness and volitional muscle control and decreasing antagonistic spasticity (Kasman, 1994). Some research has documented favourable effects of NMES on muscle function, cortical muscle representation, corticobulbar excitability or motor recovery and thus supports the use of NMES in physical rehabilitation medicine (Glanz et al, 1996; Sullivan et al, 2004; Thompson et al, 2004, Kimberly et al, 2004). Other research has reported no direct benefits from NMES, for example as a training method for elbow strength or as a treatment approach for motor recovery of gait in patients with stroke (Holcomb et al, 2006; Yavuzer et al. 2006). This discrepancy in research findings underscores the need to thoroughly
and systematically investigate the effectiveness of NMES as a rehabilitative treatment tool. Most importantly, there is the need to identify whether the positive effects of NMES on muscles of the upper and lower extremities documented in some research studies can be achieved with NMES of the muscles relevant for swallowing.

**Risks and contraindications**

Electrical stimulators introduce active current into biologic tissue, and at much higher intensity levels than endogenous current; thus, there are potential risks to patient safety. In general rehabilitation practice, NMES is contraindicated in patients with demand type pacemakers, superficial metal implants or orthotics, skin breakdown, cancer, history of cardiac or seizure disorder, impaired peripheral nerve conduction systems and pregnancy.

In addition to the general contraindications of NMES, there may be potential specific risks to the use of this technology in the head and neck region, as would be the logical application in swallowing. The USA Food and Drug Administration (FDA) addressed this issue in their specifications for the indications and marketing of these devices. In 1985, FDA documents presented indications for electrical stimulation to include the therapeutic goals of muscle re-education, prevention of disuse atrophy, and maintenance of range of motion. These goals are consistent with some of the therapeutic targets in swallowing management. However, there are several required warning labels on NMES devices that clearly raise concerns for the use of this device in swallowing rehabilitation. One of these states:

"Severe spasm of the laryngeal and pharyngeal muscles may occur when the electrodes are positioned over the neck or mouth. The contractions may be strong enough to close the airway or cause difficulty in breathing" (FDA, 1985).

These early warnings were based not on empirical observation but on a logical concern for patient safety given the proximity of major arteries supplying the brain and of cranial nerves influencing respiratory function. On June 6, 2001 the FDA granted approval for the use of a specific device, the VitalStim™, for use in swallowing rehabilitation. However, this approval came with warnings:
“The long term effects of chronic electrical stimulation are unknown. Stimulation should not be applied over the carotid sinus nerves. If electrodes are placed improperly and the unit is not used with the recommended frequency, intensity and pulse rate, it may cause laryngeal or pharyngeal spasm.” (FDA, 2001)

Further research into the safety of NMES in swallowing rehabilitation is therefore necessary. To date, few well-controlled studies of this technology related to swallowing rehabilitation have been published. A chronology of available literature is summarized below.

**NMES in Swallowing**

Park et al. (1997) investigated the effect of oral electrical stimulation on swallowing function in 4 stroke patients with chronic dysphagia presenting the physiologic abnormality of “delayed swallowing reflex”. Oral stimulation was carried out using stimulation applied to the posterior soft palate through a custom designed palatal prosthesis. Stimulation parameters were set with a duration of 200 µsec, repeated at 1-sec. intervals and intensity at the patients’ individual pain tolerance. In this limited sample of four individuals with swallowing impairment, NMES did not appear to facilitate timely onset of swallowing. Two out of four patients improved in other measures of swallowing biomechanics: specifically, bolus transit time and penetration/aspiration. Although the authors carefully specified the stimulation parameters employed in their work, no clear justification was provided for the selection of these parameters and no comparison treatment was provided. However, this initial work suggests some indication of the effectiveness of this technique on at least some biomechanical features of swallowing.

Freed and colleagues (2001), who are responsible for development of the VitalStim™ device, investigated the clinical effects of NMES on 110 stroke patients with swallowing disorders; time post onset was not specified. 83 patients were enrolled in an electrical stimulation (ES) group while only 36 patients received a ‘standard’ treatment of thermal tactile stimulation (TS). 60 minute treatments was administered by the primary investigator daily for inpatients and 3 times per week for outpatients until the participants achieved a swallowing function score of at least 5
out of 6, or progress plateau. Pre- and post-treatment videofluoroscopic swallowing studies (VFSS) were administered by the primary investigator; however, outcomes were based on a non-standardized scale which documented the ability to safely swallow different food consistencies, rather than being based on biomechanical performance. On the surface, results of this study are promising. 98% of ES patients improved in some way, compared to 69% of TS patients who improved post treatment. Although the results generate considerable excitement and suggest a positive outcome, the methodological design of this study limits the validity of the results in several ways. No justification or experimental control of stimulation parameters was undertaken or reported. Thermal tactile stimulation is problematic as a comparison as it is a poorly understood technique whose effectiveness has not withstood the rigours of empirical research. Outcome measures were based on a non-validated rating scale and ratings were assigned only by the primary investigator, who also provided the treatment. Further, an unspecified number of patients in the NMES group received concomitant dilatation of the upper esophageal sphincter, which is an accepted treatment in its own right. These flaws corrode the validity of the positive results of this study and illustrate the need to interpret the available research with caution.

The following year, Leelamanit et al. (2002) provided synchronized electrical stimulation to 23 patients with moderate to severe dysphagia, specifically those diagnosed with “reduced laryngeal elevation”. Time post onset ranged from 3 to 12 months. NMES was provided through surface electrodes to the thyro-hyoid muscles and presented at a frequency of 60 Hz, with an amplitude of 100 V for 3-30 treatments of 4 hours per day until they demonstrated improved swallow. Treatment outcomes were rated by the primary investigator based on a patient’s ability to swallow more than 3ml water without aspiration, adequate oral intake with weight gain, and improved laryngeal elevation during VFSS. 20 patients demonstrated clinical improvement, whereas 3 patients had no improvement; 6 patients relapsed on follow-up at 2 to 9 months, but regained benefits with another round of treatment. No control group was utilized in this project and, as with the prior study, outcomes measures were by the primary investigator with no control for rater bias.
Burnett et al. (2005) investigated the effects of self-triggered functional electrical stimulation on electromyographic activity of the mylo- and thyrohoid muscles in 9 healthy adults. Electrical stimulation was synchronized to normal swallowing behaviour by each volunteer by pressing a trigger with the thumb. Electrical stimulation was delivered through hooked-wire electrodes at a frequency of 30 Hz and the highest comfortable intensity level. Baseline measures were compared to a placebo swallow which was performed at the end of a series of stimulated swallows and a swallow during which no current was delivered. Rather than relying of subjective measures of treatment outcome, objective measures of muscle activity were calculated to document treatment effects. Analysis of the data revealed no significant change in amplitude or duration of muscle activity after self-triggered electrical stimulation. The authors’ concluded that muscle innervation patterns promoted by the central pattern generator were not affected by electrical stimulation.

Six recent manuscripts have attempted to more critically evaluate NMES when administered using the VitalStim™ device. Suiter, et al. (2006) evaluated the influence of this stimulation using this device on submental muscle activity in normal controls. An AB or BA treatment design revealed that 7 of 8 subjects exhibited no significant gains in myoelectric activity of the submental muscle group following 10 hours of NMES treatment using the treatment protocol described by Freed et al. (2001). Two subjects withdrew from the study due to mild skin irritations after treatment.

Humbert and colleagues at the National Institutes of Health (NIH) (2006) evaluated the effects of stimulation provided through 10 different surface electrode placements on hyolaryngeal movement in normal individuals at rest and during swallowing. Maximum tolerated stimulation was provided using the protocol described by Freed et al. (2001). Blind ratings of VFSS were evaluated using the NIH-Swallowing Safety Scale and specific biomechanical measures of larynx and hyoid movement at rest and during swallowing under the conditions and stimulation and no stimulation. In summary significant hyolaryngeal descent occurred with stimulation at rest. During swallowing, reduced hyolaryngeal elevation occurred during swallowing. Stimulated swallows were also judged to be ‘less safe’ than nonstimulated swallows.
The two prior studies have documented an absence of change or potential worsening of biomechanical function in unimpaired physiology. Although these studies raise significant concerns for long term effects, one can, however, argue that similar effects may not be evidenced in patient with impaired physiology. Therefore, the same NIH research group evaluated the effectiveness of the VitalStim™ device in a population of patients with chronic pharyngeal phase dysphagia (Ludlow et al., 2006). Again, treatment was provided according to the stimulation parameters advocated by the manufacturer of the device. Videofluoroscopy was completed to allow for blinded measurement of hyoid movement and subglottic air column position during no-stim (no current induced), low-stim level (lowest intensity level, at which a participant felt a “tingling” sensation) and high-stim level (highest tolerable intensity without discomfort) conditions. The first primary result was that 8 of 10 participants demonstrated hyoid depression of up to 5-10 mm during stimulation of the muscles at rest, a movement trajectory antagonistic to swallowing. The second primary result was that low levels of stimulation, providing sensory input only, resulted in no improvement in scores on the Aspiration Penetration Scale (Rosenbek, et al., 1996) and slight improvement on the NIH Swallowing Safety scale (unpublished scale). Higher levels of stimulation, which would facilitate muscle contraction, had no effect on aspiration or penetration. Overall the authors conclude that because of interference with hyolaryngeal excursion, “before such a tool is used in therapy, improved understanding of its immediate effects should be gained in the presence of specific types of swallowing difficulties before it is applied widely…” (p. 9).

Blumenfeld et al. (2006) undertook a retrospective study of 40 consecutive patients who underwent traditional dysphagia therapy (intervention included a combination of therapeutic exercise, diet texture modifications and compensatory maneuvers) and 40 consecutive patients who underwent electrical stimulation therapy according to the VitalStim™ treatment paradigm.26 All treatments were administered for 30 minutes per day. Patients were assigned a functional swallowing score, based on the non-validated scale used by Freed et al. (2001); no control was provided for rater bias. In summary, this study documented that both groups increased significantly in regards to their pretreatment swallowing function score. Patients who underwent
electrical stimulation demonstrated significantly greater improvement compared to the traditional therapy group. Important to the interpretation of this study is that the traditional patients were evaluated retrospectively and the stimulated patients evaluated prospectively. Thus an overall advancement in clinical methods between the ensuing years may also account for the change.

Kiger et al. (2006) also investigated the effects of the VitalStim™ therapy protocol compared to traditional swallowing therapy. 22 patients with dysphagia were divided into two groups. One group received what they defined as “traditional dysphagia therapy” (including exercise programs, swallowing maneuvers, thermal stimulation and meal observations) while the other group received VitalStim™ therapy. Patients in the control group had a median of 24 days between onset of symptoms and final assessment, while this was 57 days for the VitalStim™ group. Pre- and post-treatment VFSS or fibreoptic endoscopic evaluation of swallowing (FEES) were used to evaluate swallowing function based on a 7-point ordinal rating scale that described the patients’ biomechanical swallowing functions as well as their ability to swallow different food consistencies. The traditional treatment group improved significantly more in the oral phase than the VitalStim™ group. There were no significant differences in post treatment outcomes for the pharyngeal phase, diet consistency, and oral intake measures between the two groups.

Review of the current literature on the effectiveness of VitalStim™ therapy exposes an interesting observation. Generally, studies using non-blinded subjective outcome measures based on non-validated rating scales, reported potential success of the VitalStim™ treatment (Freed, 2002; Leelaminit, 2002; Blumenfeld, 2006). If, however, blinded and more objective measures such as myoelectric activity (Burnett, 2005; Suiter, 2006), hyoid movement (Ludlow, 2006) or biomechanics (Kiger, 2006) are defined as outcome measures, no positive effect has been reported.

Using a different approach, a careful evaluation of methods was undertaken by a research group in Manchester, UK to systematically investigated the effects of NMES of the pharynx and the faucial pillars, respectively (Fraser et al, 2002; Power et al, 2004). Both studies documented that optimal stimulation parameters exist in terms of frequency, duration and intensity of the provided
stimulus. These optimal NMES parameters increased corticobulbar excitability and, importantly, were specific to the site of stimulation; i.e. optimal parameters for the pharynx (5Hz) were different from optimal stimulation parameters for the faucial pillars (0.2Hz). Most importantly, these studies documented that certain stimulation parameters were inhibitory to neural function underlying swallowing. In other words, corticobulbar excitability was decreased as a direct effect of NMES at non-optimal stimulation parameters. In the Power et al. study (2004), corticobulbar inhibition correlated with radiographically documented evidence of swallowing impairment in normal research participants (Power, 2004). Documentation of adverse effects urges the clinician to respect the obvious risks associated with NMES as a treatment in swallowing rehabilitation. The paucity of research in this area and the subsequent lack of evidence for the effectiveness and safety of this treatment pose a major obstacle in justifying the use of this treatment in swallowing rehabilitation.

Scope of Clinical Practice
The emergence of new treatment modalities may have substantial ramifications that are more far-reaching than the immediate potential effects on the patient. There are implications for the profession as a whole and the individual clinician. Speech and language therapists in New Zealand and throughout the world hold the professional responsibility to confine their clinical practice and educational offerings to methods that have undergone empirical scrutiny under the auspices of human subjects oversight and peer review, particularly when potential risks are imposed by the method. The New Zealand Speech-Language Therapists Association’s Code of Ethics states that:

1.4: “Members shall evaluate the effectiveness of services rendered and/or equipment dispensed and shall provide services or equipment only when benefit can be reasonably expected.”

1.12 “Members shall take every possible precaution to avoid causing injury to clients.”

For any emerging technique, particularly those of an invasive nature, nonjudicious use of the modality outside of the protection of approved human subjects research may not only
compromise the safety of dysphagic patients, but may also place the treating speech language therapist in legal and ethical jeopardy. If patient injury were to occur, no accepted documentation exists that could support one’s best intentions.

The application of neuromuscular electrical stimulation in the management of the dysphagia patient is a hotly debated topic internationally and has divided the community of clinicians and researchers into two camps with very little “shades of grey” between. There are vehement supporters of the technique and its clinical effectiveness that may not be willing to carefully review the literature with critical eye: “…significant progress with VitalStim Therapy, the first FDA-cleared method for safely re-educating the pharyngeal muscles with electrical stimulation” (Vitalstim™). There are equally staunch critics that perhaps are not as open to the potential positive evidence that may indicate the effectiveness and safety of this treatment approach: “The producers of VitalStim have not faced their responsibility to the clinical research world and patients with dysphagia who are desperate of additional treatment procedures…. Clinicians and patients – beware” (Logemann, 2006). In this context, the intent of this position paper is not to discourage investigation or experimental consideration of this technique, rather to caution against its premature clinical application, an application that is heavily driven by industry.

In a chapter on neuromuscular electrical stimulation, Alon (1991) comments that:

“The present disarray, and the natural tendency to accept nonscientific, subjective and commercially motivated claims….may threaten the substantive potential that electrical stimulation can offer as an objective clinical modality”.

This comment was offered in reference to NMES applications in physiotherapy but certainly rings true for swallowing rehabilitation as well. By presenting an unbiased review of existing research and encouraging active discussion around this topic we hope to spark new, well-controlled investigations that will advance our clinical work, rather than polarizing the clinical and research communities.
Prior research in this area of swallowing rehabilitation has not withstood the rigors of peer review. Given this, reports of efficacy and the absence of associated complications have to be critically questioned. As new techniques and technologies surface in the approach to dysphagia management, particularly those which are invasive and with potential patient safety issues, certain criteria have to be followed before incorporating these into clinical practice. The process of peer review is a necessary step in the scientific process and assures thorough review of methodological design and statistical analysis. Nevertheless, critical evaluation of any kind of information, even of that published in journals, is vital. Replications of the research that supports a technique will provide valuable information about the results of earlier research studies. In general, professional and personal implications of utilization of the technique need to be considered as being equally important as the possible implications for patient care.

It is the responsibility of researchers world wide to identify safe, effective treatment approaches for the rehabilitation of swallowing disorders based on systematic, ethical research. It is the responsibility of clinicians to limit their practice to evidence-based, safe treatment approaches. Although it is important to seek alternative therapies for the growing numbers of patients with dysphagia, each new technique must undergo the scrutiny of sound scientific research before it is applied in the clinical setting.

**NZSTA position on NMES in Dysphagia Management - Summary**

There is preliminary evidence that application of neuromuscular electrical stimulation in swallowing rehabilitation may ultimately present as a viable approach for swallowing impairment under some limited conditions, however this information is not yet confirmed. Based on available published literature and the ethical guidelines that govern clinical practice, it is thus the position of the New Zealand Speech-Language Therapists Association that application of this treatment modality in swallowing rehabilitation cannot be supported by empirical evidence, has the under-evaluated potential to cause harm and does not meet the expectations for evidence-based practice. Application of this technique in the patient population is considered premature and should therefore not be utilized in the treatment of swallowing disorders until further evidence is available.
NZSTA position paper on NMES

References


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