

CURRENT PERSPECTIVES ON THE USE OF NEUROMUSCULAR ELECTRICAL STIMULATION FOR TREATMENT OF INDIVIDUALS WITH DYSPHAGIA

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Swallowing disorders pose serious health risks, leading to malnutrition, dehydration, and aspiration pneumonia. Further, quality of life can be severely impacted when difficulty and embarrassment arising from a swallowing problem negatively effects the social aspect associated with meal times. Current methods of swallowing treatment include compensatory techniques (e.g., diet modification, postural changes) and rehabilitative techniques (e.g., thermal-tactile stimulation). Surface neuromuscular electrical stimulation applied to the anterior neck is one rehabilitative treatment that is currently being widely used and is of great recent interest. Although this method has been demonstrated to improve swallowing function in some cases, it is not clear *how* this method affects swallowing ability. Unanswered questions regarding this technique have been one source of controversy regarding its clinical use. Future research should focus on elucidating the mechanism by which this treatment acts upon the physiology of swallowing. Meanwhile, clinicians and researchers alike should strive to be informed consumers of the available literature and responsible dispensers when implementing VitalStim® Therapy for the treatment of swallowing disorders.

Neuromuscular Electrical Stimulation (NMES)

What is NMES?

- Application of an electrical current to the lower motor neurons and the muscle fibers they innervate
- Requires intact lower motor neuron, neuromuscular junction, and healthy muscle tissue
- Unlike functional electrical stimulation, the electrical current does not cause or aid in a functional movement; the muscle contractions caused by NMES are considered passive training exercise.

How does NMES work?

- The electrical stimulus excites a peripheral nerve, which leads to the contraction of a motor unit (the neuron and all the muscle fibers it innervates)
- A higher amplitude of stimulation should ideally lead to a larger degree of muscle contraction
- The electrical signal is applied via electrodes, which may include surface, intramuscular, or implanted electrodes.
- The electrical stimulus can be described using several parameters: frequency of the stimulus, amplitude of the signal, pulse width, and shape of waveform.

Why is NMES used therapeutically?

- Improve muscle tone, prevent atrophy

VitalStim® Therapy

How is NMES used for dysphagia treatment?

- For dysphagia, NMES is provided through VitalStim® Therapy, which is currently the only FDA-approved device (for stimulation on the anterior throat) that is available on the market.
- Two pairs of surface electrodes are placed in specific locations on the front of the neck. The stimulator sends the electrical current to the electrodes. The frequency is set to 80Hz and the pulse width is set to 700microseconds, and the waveform is a biphasic square wave, all of which cannot be adjusted. The amplitude can be changed from 0mV to 25mV of current.

- In the traditional use of the device, the electrodes are applied and the amplitude is increase from 0mV until muscle contraction is achieved. The device then cycles through a long contraction/short pause pattern for a period of 60 minutes, during which the patient practices swallowing.
- Five 60-minute treatment sessions per week are recommended.

How long has VitalStim® Therapy been used for dysphagia treatment?

- NMES has been used as a therapy technique by physical therapists since the 1960s. Researchers investigated application of electrical stimulation as a means of stimulating onset of the swallow since 1973 (Larsen, 1973); however, the use of electrical stimulation as a therapeutic intervention was promoted by Marcy Freed beginning in the 1970s.
- Officially, the VitalStim® device was given Class II FDA clearance in 2001 for use on the anterior throat.
 - Freed et al (CITE) published a study that demonstrated safety of the device, as there were concerns for laryngospasms and cardiorespiratory issues due to proximity of the electrical stimulation to carotid artery.

Why does controversy exist regarding VitalStim® Therapy?

- Many clinicians and researchers feel that the method has been used for many years in the absence of adequate evidence for validity, reliability, and treatment effectiveness of the method
- Although anecdotal clinical evidence is important, data from peer-reviewed publications is a necessity for evidence-based practice
- The published evidence regarding VitalStim® Therapy for dysphagia has also caused concerns, due to methodological issues with many of the publications.
- Promotion and marketing of the product initially gave rise to questions of a “pseudoscience.”

Analyzing EBP literature

Five questions to ask when critically reviewing a clinical method:

1. Independent confirmation and converging evidence
 - Has a well-designed meta-analysis that includes multiple scientifically rigorous studies been published?
2. Experimental Control
 - Is there a control group? Is the control treatment appropriate? Are the groups comparable? Was an experiment conducted, or was it a retrospective review of treatment?
3. Avoidance of subjectivity and bias
 - Was there blinding of participants and/or judges to the treatments? Did the researchers report on all of the participants, not just those that completed the protocol? Is there an adequate explanation for why some participants left the study? Did the researchers discuss potential sources of bias and describe attempts to control for bias? Who provided the treatment and who provided the evaluations?
4. Effect sizes and confidence intervals
 - Were statistics reported? Are effect sizes and confidence intervals provided?
5. Relevance and feasibility
 - Were the participants in the study typical of patients seen clinically? Did the methods in the study represent typical clinical applications of treatment?

Criteria for distinguishing between science and pseudoscience (Finn, Bothe, & Bramlett, 1995)

Pseudoscience Criteria (From Finn, Bothe, & Bramlett, 1995)	A Red Flag for VitalStim® Therapy?
1. Untestable: Is the treatment unable to be tested or disproved?	
2. Unchanged: Does the treatment approach remain unchanged even in the face of contradictory evidence?	
3. Confirming Evidence: Is the rationale for the treatment approach based only on confirming evidence, with disconfirming evidence ignored or minimized?	
4. Anecdotal Evidence: Does the evidence in support of the treatment rely on personal experience and anecdotal accounts?	
5. Inadequate Evidence: Are the treatment claims incommensurate with the level of evidence needed to support those claims?	
6. Avoiding Peer Review: Are treatment claims unsupported by evidence that has undergone critical scrutiny?	
7. Disconnected: Is the treatment approach disconnected from well-established scientific models or paradigms?	
8. New Terms: Is the treatment described by terms that appear to be scientific but upon further examination are found not to be scientific at all?	
9. Grandiose Outcomes: Is the treatment approach based on grandiose claims or poorly specified outcomes?	
10. Holistic: Is the treatment claimed to make sense only within a vaguely described holistic framework?	

Five-phase model for clinical-outcome research (as described by Robey, 2004)

Phase of Research	Description of Phase	Types of studies
Phase I	Identify a therapeutic effect; does the treatment result in a physiological change that is beneficial?	Exploratory studies, case studies, retrospective studies, clinically-oriented single subject studies, chart reviews
Phase II	Determine dimensions of therapeutic effect and prepare for a clinical trial; refine the target population, refine the treatment protocol, determine the optimal dosage, refine measurements	Hypothesis-driven single subject studies, small cohort studies, measurement studies, case-control studies
Phase III	Efficacy testing: in a controlled experiment, are the hypotheses of the treatment supported by the outcomes?	Clinical trials
Phase IV	Effectiveness testing: field research; tests the previously established therapeutic effect of a treatment in day-to-day clinical practice	Meta-analyses of efficacy studies
Phase V	Studies examining who benefits from a treatment, and at what cost; involves policy makers and legislative bodies	Cost-benefit studies

Level of Evidence for Clinical Research (from ASHA)

Level of Evidence	Description
Ia	Well-designed meta-analysis of >1 Randomized Control Trial
Ib	RCT, meta-analysis of <1 RCT, systematic review of case control/cohort studies
IIa	Controlled study without randomization
IIb	Quasi-experimental
III	Non-experimental (correlational, case studies, chart review studies)
IV	Expert committee report, expert opinions

Methodology Ratings Regarding Potential Sources of Bias (adapted from Scottish Intercollegiate Guidelines Network)

Rating	Description
-	High risk of bias; the true effect of the treatment may vary from the reported results (a significant risk that the relationship is not causal).
+	Low risk of bias; the true effect of the treatment is likely to be close to the reported results, but there is a possibility that it is substantially different
++	Very low risk of bias; we are confident that the results reported reflect the true effect (high probability that the relationship is causal).

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