

# E-Stim for Dysphagia: Yes or No?

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*The ASHA Leader*, April 2012, Vol. 17, 12-15. doi:10.1044/leader.FTR2.17052012.12

*In these articles, we hear from both sides on the controversial use of neuromuscular electrical stimulation (e-stim) in dysphagia treatment. Using this treatment, clinicians deliver electrical current through electrodes to stimulate peripheral nerves and evoke a muscle contraction.*

*Jennifer Carter of the Carter Swallowing Center, LLC, presents the case supporting the use of e-stim in swallowing treatment. According to Carter, the evidence shows that, when added to traditional treatment, e-stim makes a statistically significant positive difference.*

*In contrast, lanessa A. Humbert of Johns Hopkins University presents the case against e-stim. She posits that the purpose of e-stim for improving swallowing is not clear, studies do not support e-stim's marketed outcomes, and SLP training is insufficient for its use in most dysphagia treatments.*

*These articles are adapted from the December 2011 issue of Perspectives (<http://sig13perspectives.pubs.asha.org/>) on Swallowing and Swallowing Disorders of ASHA Special Interest Group 13.*

## The Argument for Electrical Stimulation for Dysphagia

by Jennifer Carter

Neuromuscular electrical stimulation (NMES or e-stim) has been added to exercise during rehabilitation by allied health professionals for decades (Hainaut & Duchateau, 1992). In e-stim treatment, clinicians deliver electrical current through externally placed electrodes to stimulate the peripheral nerves that innervate a muscle. In sufficient intensity, this stimulation creates an action potential that travels through the motor neuron and evokes a muscle contraction.

A published review of the physical therapy literature on the use of e-stim during rehabilitation concluded that the addition of e-stim can “optimize recovery of muscle strength” during rehabilitation as it “induces the activity of those motor units which are difficult to activate during voluntary contraction” (Hainaut & Duchateau, 1992). This study and others conclude that e-stim is complementary to voluntary exercise in that it evokes a strength response critical to voluntary exercise and results in shortened rehabilitation time when used in conjunction with voluntary exercise (Hainaut & Duchateau, 1992; Paillard, 2008).

Based on the well-documented experience in physical therapy practice and the supporting evidence on the effectiveness of adding e-stim to exercise during rehabilitation, speech-language pathologists began using e-stim with a device specifically cleared by the Food and Drug Administration in 2002 for use on the anterior neck for dysphagia treatment (U.S. Department of Health and Human Services, VitalStim<sup>®</sup> 510(k) clearance document K023347, 2002).

## E-Stim and Swallowing

Any new medical treatment must be proven to be safe before being used on patients. In the case of e-stim for dysphagia treatment, there are two key safety questions:

- Is it safe to apply electrical current to the anterior portion of the neck?
- Does the addition of e-stim negatively impact swallowing function?

To address general patient safety, Freed (1998) tested for changes in pulse oxymetry readings and cardiac function (heart rate, blood pressure) in the treatment data submitted to the FDA. No adverse reactions to e-stim were noted for any of the 892 patients in the clinical trial. In subsequent published treatment studies that tracked patients for adverse reactions, there have been no reported occurrences of adverse reactions across all patient diagnoses (e.g., Beom, Kim, & Han, 2011; Bogaardt et al., 2009; Cheung et al., 2010).

A frequent argument against the use of e-stim in swallowing treatment is that e-stim is not safe for dysphagia treatment as it can cause a decrease in swallowing function. This assertion may be based on the findings of one physiology study (Ludlow et al., 2007), in which researchers measured hyoid movement during swallowing with e-stim in patients with chronic severe dysphagia to investigate the immediate effect. One of the statistically significant findings of this study was that e-stim applied at the maximum level tolerated by each patient caused hyoid depression at rest in some of the 11 patients with dysphagia in the study.

Since the hyoid normally elevates and protracts during a swallow, it is logical to expect that lowering of the hyoid would increase laryngeal penetration and tracheal aspiration, thereby making swallowing function worse. However, the researchers reported “no group change in aspiration was noted on either [Penetration-Aspiration Scale or NIH Swallowing Safety Scale] scale during swallowing.” Instead, the evidence showed that the patients with the greatest at-rest hyoid depression had the greatest immediate improvements on the scales during swallowing.

Despite the evidence showing that aspiration did not increase—and in some cases actually improved—the study authors conclude that e-stim may put patients at a greater risk of aspiration. Based on the findings from this study and the absence of any published studies showing e-stim to have a statistically significant negative impact on swallowing function in patients with dysphagia, the assertion that e-stim puts patients at greater risk during swallowing trials is not strongly supported by the evidence.

## Improved Swallowing Function

It is well supported in the physical therapy literature that e-stim is not a stand-alone treatment and is “not a substitute for but a complement of voluntary exercise for disused muscles” (Hainaut & Duchateau, 1992). Accepting that e-stim is an addition to—rather than a replacement for—traditional treatment techniques, the most appropriate question in discussing the validity of using e-stim in dysphagia treatment is, “Does the addition of e-stim to traditional dysphagia treatment make a significant difference?”

Randomized controlled trials are regarded as the gold standard of research and can be designed to address this specific question. A review of research published prior to September 2011 finds six randomized controlled trials of e-stim and dysphagia treatment (Bulow, Speyer, Baijens, Woisard, & Ekberg, 2008; Lim et al., 2009; Lin et al., 2009; Permsirivanich et al., 2009; Ryu et al., 2008; Xia et al., 2011).

In the largest of these trials (Xia et al., 2011), researchers assessed 120 patients with dysphagia who were post-stroke and randomly assigned to one of three groups: traditional swallowing treatment alone, e-stim alone, or e-stim plus traditional swallowing treatment. The experimental group that added e-stim to traditional

treatment made significantly greater improvements in all four outcome measures than the traditional treatment alone group or the e-stim alone group. The authors thus concluded that the addition of e-stim to traditional treatment resulted in better patient outcomes than traditional treatment alone.

It is beyond the scope and size of this article to review each of the published studies about dysphagia treatment and e-stim. As with all research, the studies published to date have strengths and weaknesses, and readers are encouraged to examine the literature for themselves. In general, the vast majority of the published treatment studies about the use of e-stim in dysphagia treatment have shown e-stim to have significantly positive effects on treatment outcomes.

Do clinicians have to wait for the publication of a perfectly designed, large, randomized controlled study before adopting a treatment intervention? Much of the debate about the use of e-stim in dysphagia treatment stems from differences in opinion on how much research is needed before adopting this modality. In an examination of evidence-based practice in general, Dollaghan (2004) notes that because “few studies meet all the critical appraisal criteria, reasonable people can disagree about the quality of evidence from a particular study, making it important for individuals to think independently about the validity, importance, and precision of results from empirical studies as a prelude to applying them to clinical care.”

Given the limited research supporting many other widely used traditional treatment techniques, clinicians have needed to apply all elements of evidence-based practice to make therapeutic decisions; research, clinician experience, and patient experience all help to guide decisions. E-stim for dysphagia treatment should be held to the same standard as other treatment interventions for it to be considered evidence-based practice.

Given the nature of e-stim as an adjunctive modality, perhaps most important for the clinician is to define the best treatment to provide while the e-stim is being applied. The wide range of treatments that have been used in e-stim research thus far is likely a reflection of the fact that no single best or most effective dysphagia treatment has been determined. However, the broad range of interventions applied during e-stim in the studies showing a statistically significant difference in outcomes suggests that adding e-stim to a variety of different treatments can increase the effectiveness of that treatment. The use of e-stim in treatment, therefore, does not need to wait for the ideal research study to document the perfect treatment to use in conjunction with e-stim.

This argument supporting the use of e-stim as a treatment tool for dysphagia in no way suggests that e-stim should be used with all patients. Like all other speech-language pathology treatment tools, the use of e-stim is not a panacea that works for all patient types. As with all interventions, regardless of how sound the evidence supporting their use, clinicians must apply clinical judgment to the decision-making process. In the case of e-stim, the clinician must evaluate the published evidence as well as the patient's condition, symptoms, and needs in determining how—or if—e-stim can provide benefit to that patient.

## **The Argument Against Electrical Stimulation for Dysphagia**

*by lanessa A. Humbert*

What is the intended use of e-stim for dysphagia? Can anyone clearly summarize it? There are many vague hypotheses, such as “to improve swallowing,” or “to increase oral intake of food,” or “because nothing else worked, and we were desperate.”

The problem is that e-stim for swallowing should serve a specific purpose. For example, many patients aspirate on thin liquids because of delayed onset of the pharyngeal swallow response. When a clinician recommends replacing thin liquids with thickened liquids for such a patient, the expected outcome (reduced

aspiration) and rationale (thickened liquids move more slowly, thereby minimizing the negative effects of a delayed response to the bolus) are fairly well known and logical.

With respect to e-stim, let's consider this same patient's diagnosis: delayed onset of the pharyngeal swallow resulting in aspiration of thin liquids. Under what circumstances would you decide that e-stim is appropriate?

To answer, one first has to determine the physiological cause of the diagnosis. In other words, why is the patient's pharyngeal phase so delayed? The answer to this question is not completely understood by swallowing experts. So, when there is uncertainty about the cause of the diagnosis, why should a clinician apply electrical stimulation—an additional unknown entity—to the equation without first pursuing some logical thought process about its intended use and identifying a clear rationale for why it should be successful?

What is the marketed, intended use of VitalStim<sup>®</sup>, the most commonly used device for delivering e-stim in a clinical setting? The manufacturer's website claims the following: "Combining VitalStim<sup>®</sup> and traditional therapy allows clinicians to accelerate strengthening, restore function, and help the brain remap the swallow" (VitalStim<sup>®</sup> Dysphagia, 2011).

These strong claims give rise to many questions. What exactly is the power of e-stim? How does the brain "remap" a swallow? Though some studies have reported that e-stim is beneficial, others show that it is either not beneficial or produces outcomes no different from those produced by traditional swallowing treatment alone. Also, studies that report cortical mapping after e-stim involve highly technical methodologies—neural stimulation and imaging—after direct stimulation of the pharyngeal mucosa in patients (Jayasekeran et al., 2010). Conversely, Gallas, Marie, Leroi, and Verin (2010) found no differences in cortical mapping in patients after submental electrical stimulation.

## Lack of Evidence-Based Support

E-stim is widely used and accepted in the field of physical therapy. However, objective, scientific findings do not support e-stim's marketed outcomes for swallowing. To date, studies on the effects of e-stim on swallowing have been conducted in healthy individuals and individuals with dysphagia over short- and long-term periods. Short-term studies in healthy individuals and adults with dysphagia typically examine the immediate physiological effects of e-stim on the neck and/or the submental region. In summary, short-term physiological studies in healthy individuals and patients report hyolaryngeal descent when stimulation induces muscle contractions in the anterior neck.

Also, when swallowing with concurrent stimulation that causes a muscle contraction, healthy adults and patients had significantly reduced hyo-laryngeal elevation (Humbert et al., 2006; Ludlow et al., 2007). The clinician who does not understand why hyolaryngeal descent occurs needs to seek more information on the principles of surface e-stim and about swallowing anatomy and physiology. This finding directly contradicts the information in the VitalStim<sup>®</sup> training manual, which states that significant laryngeal elevation is expected in the first e-stim session in patients (Wijting & Freed, 2003).

The online, marketed information also lists benefits reported in long-term studies, including that e-stim is safe and effective for patients (Carnaby-Mann & Crary, 2007); accelerates the recovery time from a restricted diet (Blumenfeld, Hahn, Lepage, Leonard, & Belafsky, 2006); and helps patients achieve sustained improvement and long-term results, even when traditional treatment alone has not been effective.

However, other studies do not report the same benefits (Bulow, Speyer, Baijens, Woisard, & Ekberg, 2008; Freed, Freed, Chatburn, & Christian, 2001; Kiger, Brown, & Watkins, 2006). Many studies are limited by a small sample size (< 40 patients) and/or the presence of heterogeneous etiologies of dysphagia, lack of a control or comparison group, and a focus on functional measures as the primary outcome. In an evidence-based

systematic review of e-stim for swallowing, Clark, Lazarus, Arvedson, Schooling, and Frymark concluded that 10 of the 14 studies on this topic were exploratory, with significant methodological flaws, and that more high-quality studies are needed before firm conclusions can be made (Clark et al., 2009).

Functional measures—such as oral intake and weight gain—are important indicators of success. However, they cannot be tied directly to e-stim as the cause of such changes, unless physiological measures are considered alongside functional gains. After all, physiology is responsible for bolus flow.

For instance, a study that compares two treatments one week and eight weeks post-stroke might show that at one week, all patients are on a restricted diet or NPO (*nil per os*; nothing by mouth). This outcome is functional (diet). If, after eight weeks of treatment, one patient group has a diet that is significantly improved and the other's has not changed much, then one might conclude that the treatment with the most significant improvement in oral intake is superior. But, suppose the physiological changes between the two groups are identical, meaning that neither treatment affected the disordered physiology?

What explains this change in oral intake? Because rehabilitative swallowing treatments, such as e-stim, are expected to improve swallowing physiology and thus improve bolus flow, the physiological effects must be measured before one can claim strong benefits have been achieved. In addition, diet changes are subjective measures and, therefore, difficult to standardize. Therefore, researchers should be cautious in drawing conclusions of improvement based on their e-stim studies, unless those studies include an appropriate control group, an objective physiological measure that can explain the more subjective outcome measures such as oral intake, and explicitly stated means for minimizing investigator biases.

## Physiology Training

The training and education for SLPs who want to focus on swallowing and swallowing disorders as part of a medical model may not be uniformly ideal, even though it is within the scope of the SLP's practice. There is some content on the sensory-motor based systems, although it might not be taught strictly from a medical perspective. Furthermore, the required neurophysiology and anatomy and physiology courses—some at the undergraduate level—focus on speech, language, and hearing systems and seldom delve much into swallowing physiology.

Recently, ASHA recommended dysphagia content for the graduate curriculum (ASHA, 2007). However, this recommendation does not affect SLPs who have been practicing for many years—our most seasoned clinicians. ASHA's 2011 SLP Health Care Survey reported that SLPs in health care facilities spent about 42% of their time providing adult services in the area of swallowing (ASHA, 2011).

The anatomy of the neck is complex, and the swallowing sensorimotor system—particularly its neurophysiology—is not thoroughly understood by the research community. Muscles in the neck and face are small, in close proximity to one another or superimposed upon one another, and interdigitated, and may serve different functions depending on the task. Surface e-stim activates all tissues that can be stimulated by its electrical current and thus lacks specificity. Before any clinical use of e-stim is initiated, it is imperative that clinicians have a solid understanding of normal swallowing anatomy and physiology and how the patient's condition may affect this complex system.

Disparate training in swallowing can be a potential constraint, even for accepted swallowing treatments or compensatory mechanisms. For instance, the clinician must understand the structural changes in the upper-aerodigestive tract caused by a head turn to the right or left before choosing this technique. Studies show that a sour bolus and biofeedback can change swallowing kinematics (Ding, Logemann, Larson, & Rademaker,

2003) and are also associated with different cortical patterns of activity during swallowing (Humbert & Joel, 2011).

There are abundant continuing education opportunities for clinicians interested in increasing their knowledge of swallowing physiology, neurophysiology, and electrical stimulation. However, much of what has been published does not answer the critical questions about e-stim for swallowing. Therefore, given the disparate professional training on swallowing, clinicians' limited understanding of the principles of e-stim, and limited scientific evidence about e-stim's physiological outcomes in patients, widespread liberal use of e-stim in a clinical setting is contraindicated.

Clinicians are cautioned against accepting the marketing of e-stim's benefits in isolation. Take into account all sides of this debate and make an educated decision about whether to include it in your clinical practice.

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