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Electrical Stimulation and Swallowing: How Much Do We Know?

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Abstract

Consequences of dysphagia substantially reduce quality of life, increase the risk of medical complications and mortality, and pose a substantial cost to healthcare systems. As a result, it is no wonder that the clinical and scientific communities are showing interest in new avenues for dysphagia rehabilitation. Electrical stimulation (e-stim) for the treatment of swallowing impairments is among the most studied swallowing interventions in the published literature, yet many unanswered questions about its efficacy remain. In the meantime, many speech-language pathologists who treat dysphagia are attending educational and training sessions to obtain certifications to use this technique. Here, we review the values and limitations of the published literature on the topic of e-stim for swallowing to assist clinicians in decision making in their clinical practice. The discussion provides a review of swallowing anatomy and physiology, the fundamentals of e-stim, and information essential for the readers' independent critique of these studies—all of which are crucial for evaluating the possible effects of e-stim.

Keywords

Deglutition disorders; electrical stimulation

Effective swallowing is crucial for maintaining adequate nutrition, hydration, and quality of life. The simple act of swallowing saliva occurs approximately once every minute,¹ mostly involving no conscious thought. Yet, swallowing is a very complex neuromuscular task, requiring rapid and precise coordination of numerous cranial nerves and muscle pairs, with the patterned swallow response typically lasting no more than 1 second.² Impairments of swallowing have the potential to confound and even precede medical complications, and reduce quality of life in patients. This has intensified the call for successful, restorative management options for dysphagia.

Since the late 1980s there has been an increasing amount of discussion regarding the effects of electrical stimulation (e-stim) in individuals with dysphagia. Many of the early claims of success were not validated with scientific research and consequently, offer no more than testimonials and anecdotal reports. In 1996, Freed et al introduced and described a method of e-stim (also called neuromuscular e-stim) to the anterior neck muscles and face in humans as a means of improving swallowing.³ Following this publication, in 2002, the U.S. Food

and Drug Administration cleared VitalStim Therapy^{®4} (EMPI, Danbury, CT) to market external e-stim for dysphagia. Since then, numerous scientific reports by different research groups have been dedicated to understanding its effect on normal and disordered swallowing over both short- and long-term periods. Patient populations that have been studied with e-stim include post-stroke, traumatic brain injury, head and neck cancer, neuromuscular disease, progressive neurological disease, Sjogren's syndrome, de-conditioning, respiratory failure, and other chronic medical conditions.⁵

The company VitalStim reports widespread practice of the technique by clinicians specialized to treat dysphagia. Along with great interest in e-stim, great controversy has surrounded its use. Although, e-stim is commonly used in physical therapy and sports medicine, its fairly recent introduction to speech-language pathology and related fields has demanded continuing scientific investigations, updated reviews, and commentaries of the evidence to aid our understanding of its effects and to assist clinicians in providing the best evidence-based practice. Although, it has been broadly assumed that the effects of the treatment can be observed in various levels (physiology, neurophysiology, quality of life, and function of swallowing), much of the research so far has focused on understanding the physiological effects of surface e-stim. The goal of this review is to help clinicians to learn the value and limitations of estim, through an in-depth and updated review of the literature, so that they can apply that knowledge to their clinical practice.

OVERVIEW OF NORMAL AND DISORDERED SWALLOWING

Models of swallowing biomechanics are typically divided into phases, including oral, pharyngeal, and esophageal phases. These phases are physiologically interconnected, but distinguishing among them helps to explain the biomechanical and neural control mechanisms associated with the swallowing process as a whole. Although discussed as separate processes, the interdependence of the phases must be considered throughout. Before any clinical use of e-stim is initiated, it is imperative that clinicians have a solid understanding of normal swallowing anatomy and physiology.

The goal of the oral phase includes acceptance, preparation, and transport of the bolus into the pharynx. It is controlled largely by cortical areas and therefore represents the aspect of swallowing under voluntary control.^{6,7} The voluntary nature of this phase means that it is flexible in managing a variety of bolus textures and sizes. Thus, duration of preparation is highly variable according to bolus properties and individual inclinations. To transport the bolus into the pharyngeal cavity, the tongue sequentially squeezes the bolus toward the pharynx by contact from the front of the hard palate backward. This posterior bolus propulsion relays critical sensory information to brain areas responsible for evoking the patterned pharyngeal response. The pharyngeal phase of swallowing involves numerous biomechanical events in rapid succession, completed in less than 1 second including elevation of the velum, hyoid bone, and larynx; intrinsic laryngeal closure; pharyngeal squeeze; and opening of the upper esophageal sphincter.^{2,8} Because of the complexity of the pharyngeal phase, minimal deviations in spatial or temporal coordination can substantially disrupt its efficacy.

New treatments emerge with the hope of remedying the complexities of pharyngeal phase swallowing impairments. However, until robust evidence comes to light, the urgency to remedy dysphagia usually results in recommendations of management techniques. Many widely used management options have typically emerged into clinical practice ahead of supportive, empirical evidence.⁹⁻¹¹ Many techniques were designed to immediately minimize symptoms of dysphagia rather than restore physiologic deficits, therefore providing only compensatory, transient relief from the burden of this impairment. Despite

these limitations, research is underway and findings are beginning to answer questions related to treatment effects. Relevant to this review, research on e-stim as a rehabilitation method has garnered much attention for its potential to minimize dysphagic symptoms, especially for pharyngeal phase dysphagia.

ELECTRICAL STIMULATION: WHAT IS IT?

One of the common goals for administering estim in other disciplines apart from swallowing rehabilitation has been to improve or restore muscle use. In patients, e-stim can be used to augment weak muscle contractions and thereby improve purposeful movement of structures that are controlled by those muscles. This can be achieved either transcutaneously (surface e-stim) or percutaneously (intramuscular, intrinsic, epimysial). In either case, electrical current flows from a source (an external device) that can alter current intensity (amplitude), then through electrodes that are in direct contact with the body. Commonly, the goal for rehabilitative use is to allow electrical current to create a contraction by depolarizing the nerves that are responsible for motor innervation to a particular muscle or to particular muscle fibers. Clinicians usually instruct patients to attempt to volitionally activate the target muscle(s) with concurrent e-stim or to remain at rest and allow stimulation to cause a contraction by electrical current alone.

Compared with percutaneous e-stim, surface e-stim is most commonly used in both clinical and research environments due to its noninvasive nature. Surface e-stim is applied with two bipolar electrodes (positive and negative charges) that are adhered to the skin surface overlying the muscles of interest; if the motor point is stimulated (the point where the nerve enters the muscle) then larger contractions can be elicited with the least amount of electrical current. The current that is flowing between the two electrodes is the electrical field. If the intensity of the stimulation is increased, then the electrical field can stimulate deeper structures in the body. Following this principle, surface stimulation activates from surface to deeper areas, such that tissues closest to the surface electrodes receive stronger current, while deeper structures receive weaker current. This means that tissues within the field of the electrical current will be stimulated to various degrees depending on the intensity of the electrical field and, as such, surface e-stim does not offer specificity for stimulating muscles. This lack of specificity does not pose considerable concern for larger muscles that are relatively isolated or for muscle groups that have similar functions. However, this issue creates more limitations when stimulating muscles in the neck and face because they are small, short, in close proximity to one another or superimposed upon one another, and may have different functions. In other words, when stimulating muscles on the neck, clinicians must be aware that they could be stimulating many different muscles because the electrical current is likely larger than any single superficial muscle in the neck.

Percutaneous (intramuscular, intrinsic, epimysial) e-stim delivers stimulation via hooked wire electrodes to nerve endings in close proximity to the target muscles in which they are inserted. This eliminates several constraints apparent with surface stimulation. As the implanted electrodes bypass the skin, there is less concern about impedance to stimulation (adipose tissue underlying the skin) or activation of superficially located pain receptors. Because electrode placement is more focal, specificity of muscle stimulation is enhanced, especially in the case of smaller, deeper, and harder to reach muscles such as those of the head and neck. Although percutaneous stimulation can selectively stimulate target muscles, it is invasive, expensive, and requires expertise for injecting the electrodes into the muscles.

Percutaneous stimulation of laryngeal and other muscles involved in swallowing has been investigated largely for the applicability of estim for voice rehabilitation,¹² and assisting airway function.^{13–15} The investigation of percutaneous e-stim on swallowing function is

limited to a small number of studies.^{16,17} Despite this paucity of the literature on percutaneous stimulation, information from these two studies can be considered in conjunction with studies utilizing surface electrode placements for greater insight into the effects of this technique. The majority of empirical evidence of the VitalStim Therapy System for dysphagia is based on surface electrode placements, which utilizes surface electrodes, in response to the limitations of using percutaneous electrodes in many clinical settings.

CONSIDERATIONS FOR SURFACE ELECTRICAL STIMULATION ON THE ANTERIOR NECK

Many muscles of the anterior neck are extrinsic laryngeal muscles that are meant to alter the position of the larynx and hyoid bone. These structures move up and forward primarily with contraction of the mylohyoid, geniohyoid, and anterior belly of the digastrics (suprahyoid muscles that move the hyoid bone) and the thyrohyoid (approximates the larynx and hyoid). Other extrinsic laryngeal muscles pull the hyoid bone and larynx down and overlie the thyrohyoid muscle. These are infrahyoid muscles and include the sternohyoid, sternothyroid, and omohyoid. All supra- and infrahyoid muscles are deep to a broad, thin, superficial muscle called the platysma that depresses and wrinkles the skin of the lower face and neck for facial expressions. Concurrent stimulation of the supra- and infrahyoid muscles could result in cancellation of positive effects (elevation in the case of swallowing), or even induce negative effects on hyolaryngeal excursion.¹⁸

While this discussion will focus largely on surface e-stim, the reader is encouraged to be mindful of the aforementioned limitations posed by this method of stimulation. The unavoidable stimulation of all muscles within the electrical field might not pose a limitation if all muscles in the field serve the same function. For example, the suprahyoid muscles (anterior belly of digastric, mylohyoid, and geniohyoid) pull the hyoid bone up and forward, which is beneficial for swallowing. Based on the knowledge of anatomy and physiology alone, it suggests that surface stimulation to this region could elevate the hyoid or move it anteriorly when the mandible is anchored. Percutaneous bilateral stimulation of the mylohyoid muscle at rest induces displacement of the larynx of ~50% of that seen for swallowing.¹⁶ However, surface stimulation of this region does not appear to facilitate hyoid bone displacement in a similar manner.¹⁸ Regardless of the underlying mechanism responsible for any observed changes, the evidence suggests that surface stimulation impacts on swallowing biomechanics differently than percutaneous stimulation, most likely due to differences in specificity of the stimulation.

STUDIES OF IMMEDIATE AND LONG-TERM EFFECTS IN NORMAL AND PATIENT GROUPS

Studies of the effects of e-stim on swallowing can be separated by the length of the study (immediate vs. long-term) and the population being studied (healthy vs. patient population). Often, the goal of immediate-effects e-stim studies is to answer questions about changes to physiology with muscle stimulation. These physiological studies are beneficial because they provide conclusive evidence about the impact of surface stimulation and lead to better research questions for long-term studies in patients. Long-term studies in healthy and unhealthy populations answer questions about possible system changes that have rehabilitative potential, carry-over effects, and the duration of any observed therapeutic benefit. Taken together, immediate and long-term studies can answer important, larger questions about the effects of e-stim on swallowing.

IMMEDIATE EFFECTS OF ELECTRICAL STIMULATION (SINGLE APPLICATIONS)

The immediate physiological effects of e-stim have been studied at rest, during swallowing, and at sensory and sensory + motor levels. Muscle stimulation at rest can reveal the impact of the stimulation alone, unconfounded by volitional movement, which implies which muscles in a muscle group are being targeted by stimulation with a particular electrode position. Muscle stimulation combined with a task can show how stimulation impacts a particular movement. Stimulation at the sensory level occurs when only the cutaneous afferents (sensory receptors in the skin) are being stimulated by the surface electrodes. Sensory + motor stimulation occurs when the stimulation intensity is increased to activate both cutaneous afferents and motor nerves for a muscle contraction (Table 1).

The immediate physiological effects of surface e-stim to the submental muscles and anterior neck was examined in 29 healthy adults.^{18,19} Using the VitalStim device, participants were administered e-stim at rest and during swallowing at the sensory + motor level. The stimulation at rest trials were tested with 10 different electrode placements; some with electrodes positioned: (a) only above the hyoid bone; (b) only below the hyoid bone, and: (c) both above and below the hyoid bone. The amplitude of the electrical current delivered was determined by gradually increasing intensity until the participant reported a grabbing sensation and was at the maximum tolerance level. As indicated above, the significance of the hyoid bone as a marker for placement separation is that suprahyoid muscles are functionally antagonistic to infrahyoid muscles. Testing them in various placements that account for this antagonistic relationship helps to separate the effect of stimulation on physiology more meaningfully.

The results of this study showed that placements with electrodes only below the hyoid (overlying infrahyoid muscles only) and placements above and below the hyoid (overlying supra and infrahyoid muscles) depressed the hyolaryngeal complex to varying degrees. The most descent was observed with a placement that targeted both supra- and infrahyoid muscles. Depression of the hyoid bone and larynx likely occurred with this placement because the infrahyoid muscles are larger, more superficial and easier to stimulate than suprahyoid muscles. Those electrode placements that were only above the hyoid bone (overlying suprahyoids) either caused nonsignificant or minimal anterior or superior hyoid movement among participants.

The effects of stimulation on swallowing 5 mL of liquid barium were tested in the same participants using the supra- and infrahyoid electrode position that caused the most significant hyolaryngeal descent. Results showed that these healthy participants had significantly reduced hyolaryngeal range of motion (peak elevation) with concurrent stimulation, but no change in bolus pharyngeal transit time. Stimulated swallows also had significantly more penetration of liquid barium into the laryngeal vestibule compared with nonstimulated swallows.

In addition to elevation and anterior movement of the hyolaryngeal complex during swallowing, intrinsic laryngeal closure is also an important aspect of deglutition. Closure of the vocal folds was examined with e-stim using the same 10 electrode placements as in the study described above, also at the sensory + motor level. Nasolaryngoscopy was used to image true vocal fold movement with concurrent surface estim at rest. Results indicated that minimal vocal fold angle change was achieved with stimulation (ranging from 2.4 to 2.8 degrees), suggesting that surface e-stim to the submental and neck regions does not produce immediate true vocal fold adduction adequate for airway protection during swallowing.

Ludlow et al tested the immediate physiological effects of e-stim in a group of poststroke patients with chronic pharyngeal dysphagia.²⁰ The stimulation levels during at rest trials were sensory + motor as in the healthy study described above, while the swallowing trials included both sensory and sensory + motor stimulation. In this patient study, at rest trials also caused significant hyoid and laryngeal descent. However, swallowing trials with concurrent sensory-only stimulation (not sensory + motor) reduced instances of penetration or aspiration in this patient group. These data suggest that sensory surface e-stim during swallowing in patients might alter the motor pattern similarly to what is thought to occur with other sensory-based treatments such as thermal-tactile, taste, or vibrotactile treatments.²¹

LONG-TERM EFFECTS OF THERAPEUTIC REGIMES OF E-STIM: HEALTHY AND PATIENT POPULATION

Long-term studies of the effects of e-stim on swallowing are becoming increasingly prevalent in the literature and have the potential to directly contribute to clinical settings in ways that studies of immediate effects cannot.^{22–30} For instance they provide useful information about the duration and intensity of the successful interventions as well as the immediate, and sometimes long-term, follow-up effects. On the other hand, it is challenging to draw strong conclusions from a small number of long-term studies that have focused on heterogenous patient populations³¹ or have used outcome measures that are not directly comparable to one another (Table 2).

One of the earliest controlled studies examined the long-term effects of surface e-stim in stroke patients delivered as a therapeutic regime assigned to one of two treatment groups: surface e-stim or thermal-tactile stimulation³² (Table 2). The purpose of this study was to compare the effects of e-stim to thermal-tactile stimulation and to assess the safety of surface e-stim. Measurements were obtained using fluoroscopic images of swallows of various consistencies. A speech-language pathologist assigned a “swallow function score” from 0 to 6. The methodology of the study included different durations and frequencies of treatment blocks to patients, while patients were recruited with a variable level of dysphagia severity and length of dysphagia symptoms. A total of 99 patients completed this study and both groups ended with a higher swallow function score, but after 2 years, 89% of e-stim patients retained the improved swallow function score, while only 67% of thermal-tactile patients retained their improved status. The authors concluded that surface e-stim was a safe and effective treatment modality for dysphagia caused by stroke and that surface e-stim resulted in better swallowing outcomes than thermal-tactile stimulation to the posterior oral cavity (faucial pillars). These findings are confounded with limitations, however, since in some patients the data were collected during the time of spontaneous recovery (acute phase), which might have accounted for some of the improvement. Also, the authors did not report randomization of patients to treatment groups and blinded scoring.

Table 2 summarizes the results of studies investigating the long-term effects of blocks of e-stim as a therapeutic regime. All but one of the patient studies included functional changes as an outcome measure. Fewer included physiological measures, and only two studies have reported either quality of life or neurophysiological outcomes. Gallas et al examined the neurophysiological effects of submental transcutaneous e-stim, showing no significant change in measurements of excitability of the activation of cortical areas involved in swallowing.³³ Apart from the Freed et al (2001) study, the remainder were performed with a small number of patients (varying from 6 to 25 patients in the studies), minimizing robust conclusions about the effects of e-stim.

Only two studies have investigated longer term effects of e-stim on a healthy population. Park et al studied the effects of effortful swallowing with concurrent e-stim below the hyoid bone (causing hyolaryngeal descent) in healthy adults.²⁵ They reported that 20 minutes of e-stim for 2 weeks caused greater hyoid elevation, but no change in forward hyoid excursion was evident. However, results faded within 2 weeks posttreatment. Both Park et al and Suiter et al found no significant difference in electromyography signal between the control group and the e-stim group after e-stim treatment in healthy adults.³⁴

Most long-term studies included the stroke population or mixed etiologies, but only two studies included samples of over 40 patients. The most frequently used treatment for the control group was traditional dysphagia therapy (i.e., application of the behavioral and compensatory techniques). Blindedness of the patients and the investigators continues to be an important issue in this group of studies, as is the various electrode placements and durations of therapeutic regimes (i.e., Bülow et al: 15 therapeutic sessions; Ryu et al: 20 therapeutic sessions, etc.).^{35,36}

In summary, there are many limitations to the current treatment studies. Studies using different electrode placements limit a clear consensus on whether swallowing is enhanced, unaffected, or negatively influenced by combined supra- and infrahyoid electrode placements. Also, interpreting functional outcome measures that do not objectively quantify changes in swallowing biomechanics must be done with caution. Very few patient studies have objectively quantified specific outcome measures such as the degree of hyolaryngeal excursion or changes in muscle activation as a result of surface e-stim. Findings from treatment studies could be combined, yielding stronger overall conclusions about e-stim if they included: (a) an appropriate control group; (b) a randomized process for the treatment group assignment; (c) a stable population (i.e., chronic dysphagia) or a very homogeneous population in both treatment groups; and (d) explicit reporting that all analyses or clinical decisions were done while blinded to the treatment group.

DISCUSSION: CLINICAL IMPLICATIONS FOR USING ELECTRICAL STIMULATION

Successful rehabilitation of pharyngeal phase impairments presents a unique challenge for clinicians, and will continue to do so without a more thorough understanding of how the nervous system initiates and completes this phenomenon. More challenges ensue since pharyngeal swallowing is not readily seen without imaging technology (i.e., videofluoroscopy, fiberoptic endoscopic evaluation of swallowing).

Perhaps the greatest challenge for clinicians and researchers is to determine the parameters for judging the utility of a given treatment methodology. Efficacy studies are challenging, costly and time intensive due to the need for a robust control group, a strict randomization process, researcher and patient blinding, and a large, homogeneous sample of patients.

We need to improve our understanding of the effects of e-stim in specific types of disorders and specific levels of severity before we can widely apply the treatment to the general dysphagic population. The three important principles that guide evidence-based practice are client and patient values, clinical expertise, and current best evidence. The Clark et al review⁵ concludes that surface e-stim to the neck for muscle strengthening has been most often studied, yielding the most promising outcomes, but controlled trials are needed for evidence of efficacy.

In the meantime, clinicians must take the necessary time to determine the effectiveness of a given treatment as an individualized approach, always keeping the clinical goal for the

patient in mind. If surface e-stim is a treatment consideration, its physiological effects must be assessed with imaging, similarly to other compensatory mechanisms (i.e., chin tuck) or per-oral trials of various consistencies. This will provide an objective baseline from which change can be measured against.

Of course, the importance of having a solid knowledge of swallowing anatomy and physiology cannot be overstated for any swallowing clinician—whether e-stim is being used or not. As research advances, it is each clinician's duty to stay current with new findings in the use of surface e-stim and to be vigilant in critiquing experimental designs and the analysis of data. Together, the future of swallowing research and clinical practice has enormous potential for developing effective management strategies for dysphagia. This can be achieved with progressive partnerships among highly skilled clinicians and experienced researchers to ascertain the full potential and limitations of e-stim as well as other swallowing management options that are both known and not yet discovered.

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Table 1
Published Studies of the Immediate Physiological Effects of Surface Electrical Stimulation in a Healthy and Patient Population

Immediate effects of e-stim in a healthy population (Single application)							
References	Study Type	Subjects/etiology	Evaluation techniques	Treatment groups	Authors conclusion	Outcome measures	
Humbert et al., 2008	prospective	27 subjects (mean age: 39.2yrs, range: 23–57yrs)	<p>a. Vocal fold position - FEES</p>	<p>Pseudorandomised for 4 different placement of VitalStim® with additional submental placements NMES fixed 80 Hz, pulse duration 700 µs in Groups with randomised placements (ABC OR CBA):</p> <p>A. placements 1, 1 superior, 2, 2 superior, 2 inferior B. 3B, 3B superior C. 3A, 3A right, submental</p>	<p>a. placement 3BS significant reduction in vocal fold angle (p=0.031) by 2.8 degrees</p> <p>b. no correlation of change in vocal fold angle and changes in motion of hyolaryngeal complex from data by Humbert et al., 2006</p>	Physiological	Immediate results
Humbert et al., 2006	prospective pseudo- randomised	29 subjects (mean age: 39.5yrs, range: 20–60yrs)	<p>a. Movement of Hyolaryngeal complex at rest and swallowing (VFS)</p> <p>b. NIH-Swallowing Safety Scale</p>	<p>Pseudorandomised for 4 different placement of VitalStim® with additional submental placements NMES fixed 80 Hz, pulse duration 700 µs ‘ON’ state in random order :</p> <p>a. rest b. during swallows (5ml bolus)</p>	<p>i. REST: Significant Descent of laryngeal and hyoid bone (placement 3B) (p<0.0001) significant differences between placements 3B and 3B superior and placement 2 superior and 2 inferior (p<0.0001, respectively)</p> <p>ii. STIM during swallows:</p>	Physiological	Immediate results

Immediate effects of e-stim in a healthy population (Single application)						
References	Study Type	Subjects/etiology	Evaluation techniques	Treatment groups	Authors conclusion	Outcome measures
					Significant reduction of peak laryngeal elevation (p=0.012) and hyoid bone (p<0.0005), sig. less safe than the non-stimulated (p=0.0275) iii. stimulated swallows significant less safe than the non-stimulated (p=0.0275)	

Immediate effects of e-stim in patients (Single application)						
References	Study Type	Subjects/etiology	Evaluation techniques	Treatment groups	Authors conclusion	Outcome measures
Ludlow et al, 2007	Cohort-Case series	8/11 patients (mixed aetiology); 6 months stable pharyngeal dysphagia (stroke patients); rest patients: 2 years persistent dysphagia	<p>a. NIHSS Swallowing Safety Scale</p> <p>b. Penetration/aspiration scale</p> <p>c. Hyoid bone movement (x,y) on VFS</p>	<p>Intensities used:</p> <p>a. No stimulation</p> <p>b. maximum tolerated level stimulation</p> <p>c. sensory threshold stimulation</p> <p>'ON' state in random order:</p> <p>i. before swallows</p> <p>ii. during swallows</p> <p>iii. after swallows</p>	<p>a. active NMES at rest lowered hyoid bone (y axis) (p=0.016)</p> <p>b. lower threshold NMES during swallowing changed NIHSS significantly (p=0.025)</p> <p>c. no significant change for maximum tolerated level during swallowing</p> <p>d. no significant correlation between severity of dysphagia and changes in swallowing</p>	Physiological Immediate results

Immediate effects of e-stim in patients (Single application)							
References	Study Type	Subjects/etiology	Evaluation techniques	Treatment groups	Authors conclusion	Outcome measures	Follow-up post intervention
					with stimulation correlation of NIHSSS improvement and degree of hyoid bone depression during motor stimulation at rest($p=0.006$) e. f. active stimulation descends hyoid, opposite to movement for swallowing		

Table 2

Published Studies of Long-term Effects of Surface Electrical Stimulation Using a Therapeutic Regime in Patient and Healthy Populations

Long-term results of e-stim following a therapeutic regime in patients							
References	Study Type	Subjects/etiology	Evaluation techniques	Treatment groups	Authors conclusion	Outcome measures	Follow-up post intervention
Bogaardt et al, 2009	retrospective case series	25 patients with Multiple sclerosis (MS) (mean age: 53.1±9.8yrs) mean time since MS onset: 16.5±10.2 yrs	17/25 patients had FEES a. Dysphagia Severity Scale b. Quality of life questionnaire c. Penetration – Aspiration Scale (VFS) (Rosenbek, Robbins et al. 1996) d. Residue in valleculae and pyriform sinuses	EG: NMES at 30Hz, phase duration 200 µs, Placement 1 (Vital Stim®) 20 minutes for 6 sessions (2 sessions/week) 20 swallows; 60 swallows/session	a. significant statistical improvement in Dysphagia Severity Scale p<0.01 b. significant improvement in PA scores in EG for liquid (p<0.01) c. significant Change in pooling in pyriform sinuses post treatment. (p<0.01) d. significant change in quality of life swallowing score (p=0.01)	Functional Physiological	Immediate evaluation: 3 weeks post inclusion
Gallas et al, 2010	prospective case studies	11 dysphagic stroke patients (5 fem. 68 ± 11 yrs old > 8 weeks post stroke)	a. VFS b. Mapping with Pharyngeal Motor Evoked Potentials (TMS measurements) c. Dysphagia Handicap Index (French)	TES on submental area 5 sessions, 1h/day, 5s every minute, 80 Hz below motor threshold +Swallowing	a. significant decrease of SRT for liquid and paste (p<0.05) b. significant reduction of residue and A/P scores (p<0.05) c. no change in TMS measurements	Physiological Neurophysiological Quality of life	Immediately 1 week later post-treatment
Lim et al, 2009	randomised controlled Trial	36 stroke patients Inclusion criteria: a. confirmed stroke with MRI or CT imaging b. VFS-confirmed dysphagia c. score of 21 in Mini-Mental State Examination (MMSE) d. able to consent	a. Swallow Function Scale (Freed, Freed et al. 2001) b. Penetration – Aspiration Scale (VFS) (Rosenbek, Robbins et al. 1996) c. Pharyngeal Transit times (PTT) (10ml semi-solid and liquid both) d. VAS for discomfort and satisfaction during treatment	EG: 16 patients NMES (mean age: 67.8 yrs old) (1hr, 5days/wk, low intensity: 7 mA, 80Hz, Placement 3) +Thermal Stimulation (5trials/week, 4 wks) CG: 12 patients (60.8 yrs old) Thermal Stimulation (5 trials/week, 4 wks)	a. significant increase in the swallowing function scale in the EG. b. significant change in PA scores in EG for liquid and semi-solids c. Change in PTT was greater for EG post treatment. d. no significant change in discomfort scales. EG satisfactory scores	Functional Physiological	Immediately: 4 weeks post inclusion

Long-term results of e-stim following a therapeutic regime in patients							
References	Study Type	Subjects/etiology	Evaluation techniques	Treatment groups	Authors conclusion	Outcome measures	Follow-up post intervention
			e. Tube feeding ratio		e. increased significantly compared to CG. 6/12 of EG progressed to oral feeding. 1/7 in CG		
Permsirvanich et al, 2009	randomised controlled Trial	23 stroke patients Recruited 2 weeks after lesion With "pharyngeal dysphagia with safe swallowing"	a. FOJS b. Number of therapy sessions c. Complications during therapy	EG: 12 patients (mean age: 64.5 years old) NMES+ Oral motor exercises+ diet modification NMES: Placement 1, 80Hz, 700 pulse duration) CG: 11 patients (mean age: 64.7 yrs old) Traditional Therapy (therapeutic maneuvers and techniques) 20 sessions over 4 weeks (60 mins on 5 days/week)	a. non-significant difference between EG and CG for the number of therapy sessions b. significant change on FOJS for the EG compared to CG (p<0.001) No comment on complications during treatment	Functional	1 week before and 1 week post treatment
Ryu et al, 2009	randomised controlled Trial	26 Mixed aetiology all types head/neck cancer a. with surgical or radiation treatment for head and neck cancer b. dysphagia as a treatment complication c. with VFS confirmed dysphagia d. on restricted diet, with stable vital signs e. 'ability to participate'	a. Functional dysphagia scale (FDS) b. Clinical dysphagia scale (CDS) c. ASHA NOMS d. M.D. Anderson dysphagia Inventory (MADI)	EG: 14 patients (mean age: 63.4yrs) : NMES (30 mins, 80 Hz, 700 ms pulse duration, placement 3B) plus Traditional therapy (30 mins, therapeutic maneuvers) CG: 12 patients (mean age: 60.8 yrs old) Sham TENS low Intensity plus Traditional Therapy (therapeutic maneuvers and techniques) 10 sessions of 30 mins for 5 days/week over 2 weeks	a. statistical significant change observed in FDS for EG compared to CG (p=0.04)	Functional	Immediate evaluation: 2 weeks post inclusion
Bulow et al, 2008	randomised controlled Trial	25 stroke patients Inclusion criteria: 1 50-80 years old 2 one or more hemispheric CVA, no brainstem involvement, more than 3 months post lesion 3 no NG tube-fed, PEG-fed included	a. Videofluoroscopy (VFS); 5 ml thin and thick boli, temporal and misdirection measurements b. Nutritional status scale (non-standardised) c. Oral motor function test (non-standardised)	EG: 12 patients NMES (mean age: 70 years old) (Placement 3B, mean 13 mA). CG: 13 patients (mean age: 71 years old) Traditional Therapy (therapeutic maneuvers and techniques) 15 therapy sessions of 60 mins over 3 weeks (5 days/week)	b) no statistical difference between CG and EG. b) low correlation between measurements c) low correlation between objective evaluation and patient experience of improvement	Functional Physiological	Immediate evaluation: 3 weeks post inclusion

Long-term results of e-stim following a therapeutic regime in patients							
References	Study Type	Subjects/etiology	Evaluation techniques	Treatment groups	Authors conclusion	Outcome measures	Follow-up post intervention
		<p>4 ability to elicit pharyngeal swallow, anterior hyoid bone and constrictor activity previously observed in VFS</p> <p>5 communication ability</p>	<p>d. VAS self-evaluation of complaints</p>				
Carnaby et al, 2008	prospective case studies	<p>6 stroke patients (mean: 63.6 yrs old, 5.1 yrs post stroke) Inclusion criteria:</p> <p>a. ability to participate in an NMES-based treatment program</p> <p>b. MMSE score of 23 or greater</p> <p>c. FOIS score of 5 or less</p> <p>d. pharyngeal dysphagia on VFS</p> <p>e. failure to respond previous swallowing therapy</p>	<p>a. FOIS (clinical improvement of 2 points)</p> <p>b. MASA (clinical improvement of 10 or more points)</p> <p>c. Hyoid and laryngeal kinematics (VFS thin, nectar thick, pudding of 5ml and 10ml)</p> <p>d. Bodyweight</p> <p>e. patients' perceptual evaluation</p>	<p>EG: NMES Placement 1), 80 Hz, 700 μs PLUS standardised across patients Traditional Therapy 15 sessions NMES, 1 hour/day or until level 6 on FOIS</p>	<p>a. significant change on clinical swallowing ability (MASA) (p<0.042)</p> <p>b. significant improvement in FOIS scale (p<0.02)</p> <p>c. significant weight increase (p<0.026)</p> <p>d. significant change of patients' perception (p<0.043)</p> <p>e. no significant change between post-treatment and 6 months clinical outcome measurements</p>	<p>Functional Physiological Quality of life</p>	<p>immediately post-treatment and 6 months follow-up</p>
Oh et al, 2007	uncontrolled prospective case series	<p>8 dysphagic stroke patients, mean age: 57yrs (4 fem, 57 yrs old, 4 hemispheric) Inclusion criteria:</p> <p>a. food residues occupying more than 50% of valleculae or pyriform sinuses post swallowing</p> <p>b. subglottic aspiration</p> <p>c. pharyngeal time >2s</p> <p>d. impaired UES</p>	<p>a. DOSS</p> <p>b. TMS topographic maps of cricothyroid muscle (Centre of Gravity) after 12 hours.</p> <p>c. VFS Functional Severity Scale</p>	<p>EG: NMES 10 sessions of 1h/day for 2 weeks Placement as Freed et al, 2001 NMES: at varying intensities, 70 Hz, 300μs</p>	<p>a. significant Increase in DOSS (p=0.042)</p> <p>b. significant Increase in VFS Functional Scale (p=0.035)</p> <p>c. no change in TMS measures, but CoG moved anteriorly</p>	<p>Functional Neurophysiological</p>	<p>Immediately post-treatment</p>
Shaw et al, 2007	retrospective case series	<p>18 patients mixed aetiologies (mean age: 59.3 yrs, range: 42 to 82 yrs) 10/18 consumed all food consistencies prior to therapy</p>	<p>a. Diet modification</p> <p>b. Laryngeal elevation</p> <p>c. Penetration/aspiration</p> <p>d. Swallow delay</p>	<p>EG: Hour NMES for sessions ranging from 7 to 28 NMES : 4 different electrode placements</p>	<p>a. 50% patients improved dysphagia severity score (p<.05)</p> <p>b. "entire" group statistical significant</p>	<p>Functional Physiological</p>	<p>immediate post treatment and telephone screen range of survey time: 1 to 21 months post treatment</p>

Long-term results of e-stim following a therapeutic regime in patients							
References	Study Type	Subjects/etiology	Evaluation techniques	Treatment groups	Authors conclusion	Outcome measures	Follow-up post intervention
			<p>e. Overall dysphagia severity score</p> <p>f. Residue severity</p>		<p>improvement $p < .05$ in diet intake, penetration/aspiration, residue, overall severity score</p> <p>c. 7/11 telephone screened patients reported improvement in swallowing (range of survey time: 1 to 21 months post treatment)</p>		
Blumenfeld et al, 2006	nonconcurrent cohort study	80 patients (mixed aetiologies) (mean age: 72±11 yrs)	<p>a. Functional dysphagia scale (FDS)</p> <p>b. Number of therapy sessions</p> <p>c. Length of hospital stay</p>	<p>EG: 40 patients 30 minutes of NMES therapy</p> <p>NMES: Placement 2 superior, 80 Hz, 700µs pulse duration</p> <p>CG: 40 patients (mean age: 30 minutes of traditional therapy</p> <p>Traditional Therapy (therapeutic maneuvers and techniques)</p>	<p>a. mean improvement with NMES compared to CG ($p=0.002$)</p> <p>b. less treatment sessions with NMES ($p=0.014$)</p> <p>c. change in PTT was greater for EG post treatment.</p> <p>d. no significant change in LOHS</p>	Functional	NA
Kiger et al, 2006	non-randomised controlled trial	22 mixed aetiologies (mean age: 67.5 yrs old) Inclusion criteria:	<p>a. Swallowing severity scale oral and pharyngeal (VFS or FEES)</p> <p>b. Diet consistency change</p>	<p>EG: 11 patients (mean age: 63.4 yrs old)</p> <p>NMES: Placement 1, 80 Hz, 700µs pulse duration</p> <p>CG: 11 patients (mean age: 71.5 yrs)</p> <p>Traditional Therapy (therapeutic maneuvers and techniques)</p>	<p>a. CG more improved in the oral phase than EG ($p > 1.00$, χ^2 test)</p> <p>b. no statistical significant difference for pharyngeal phase between EG and CG</p> <p>c. no statistical significant difference for diet advancement between EG and CG</p> <p>d. mean number of sessions for EG: 8.72, for CG: 3.36</p>	Functional Physiological	Immediately post treatment (varying sessions)
Leclamanit et al 2002	non-controlled prospective case series	20/23 mixed aetiologies (age range 35–87 yrs, mean age: 65yrs) Inclusion criteria:	a. Increased ability to swallow more than 3ml water without aspiration or coughing	EG: NMES (synchronised electrical stimulation)	a. 6 patients relapsed 2 to 9 months after initial success (treated with a second course)	Functional	Monthly follow-up (range 3–33 months)

Long-term results of e-stim following a therapeutic regime in patients							
References	Study Type	Subjects/etiology	Evaluation techniques	Treatment groups	Authors conclusion	Outcome measures	Follow-up post intervention
		<p>Dysphagia resulting from reduced laryngeal elevation following the criteria:</p> <ul style="list-style-type: none"> a. history of dysphagia and aspiration b. wet phonation and/or aspiration during wet swallows c. laryngeal penetration/aspiration, reduced Laryngeal elevation, narrow pharyngo-esophageal segment on VFS d. palpation showing reduced laryngeal elevation <p>Exclusion criteria: paralysis of superior +recurrent laryngeal nerve or glosso-pharyngeal nerve</p>	<ul style="list-style-type: none"> b. Adequate oral intake and body weight gain c. VFS for i)laryngeal penetration, measured with maximum volume of water without aspiration, ii)laryngeal elevation in 2 swallows iii) PE segment width 	<p>NMES: 60Hz, 4 hours daily until 'improved swallowing': 'successful treatment' During NMES encouraged to continue Oral feeding</p>	<ul style="list-style-type: none"> b. Kaplan-Meier analysis of duration of initial of treatment revealed significant effects of initial severity and age 		
Freed et al, 2001	non-randomised controlled trial	<p>99/125 Stroke patients already treated with swallowing treatment with confirmed swallowing disorders in VFS</p> <p>Exclusion criteria:</p> <ul style="list-style-type: none"> a. inability to complete at least 2 consecutive days of therapy b. behavioral disorder c. substantial reflux from feeding tube d. dysphagia from drug toxicity 	<ul style="list-style-type: none"> a. Swallowing Function Scoring System b. Descriptive characteristics c. Treatment stopped when the patients were able to swallow thin liquids 	<p>EG: NMES (n=63 patients, mean age: 75.7 yrs) Inpatients: 1 hour and 10 minutes of challenge/assessment. Outpatients: 3 times/week for 1 hour. (varying intensity, 80 Hz, at 300µs, pause every minute, electrodes preferable to the right) CG: Thermal Tactile stimulation (n=36 patients, mean age: 78.1yrs) (3 of 20 minutes interval)Attempts to dry swallow challenged with thickened liquids (20 minutes, 3 times/day)</p>	<ul style="list-style-type: none"> a. similar number of treatments (average for EG: 5.5 and CG: 6.0) b. improvement in final swallows scores bigger for EG 	Functional	Medical records for 3 years

Long-term results of e-stim following a therapeutic regime in a healthy population							
References	Study Type	Subjects/etiology	Evaluation techniques	Treatment groups	Authors conclusion	Outcome measures	Follow-up post intervention
Park et al, 2009	experimental and control groups	16 healthy participants (mean age: 26.3 ± 2.4 yrs)	<ul style="list-style-type: none"> a. Submental muscle electrical activity (surface EMG) 	<p>EG: 8 healthy NMES Motor threshold (Placement 3A, 35Hz phase duration 200 µs, intensity: 4.38 ± 1.3)</p>	<ul style="list-style-type: none"> a. no significant change for sEMG pre and post-treatment 	Physiological	2 and 4 weeks post treatment

Long-term results of e-stim following a therapeutic regime in a healthy population							
References	Study Type	Subjects/etiology	Evaluation techniques	Treatment groups	Authors conclusion	Outcome measures	Follow-up post intervention
Sutier et al, 2006	crossover design ABBA	8 subjects (male: mean age: 27 ± 5.3yrs; female: 25 ± 0.5yrs)	<p>b. Hyoid excursion by VFS</p> <p>a. sEMG of 5 ml water swallowing at 2 and 4 weeks post intervention</p>	<p>CG: 8 healthy NMES at Sensory threshold (Placement 3A, 35Hz phase duration 200 μs, intensity: 2.00 \pm 0) 20 minutes session (2x10 minutes) for 2 weeks 2ml water every 10 s during 'ON' state</p> <p>EG: condition B: 10 sessions of 1hr NMES over 2 weeks NMES fixed 80 Hz, pulse duration 700 ms CG: condition A: no treatment</p>	<p>b. increased hyoid elevation only in EG, but no forward hyoid movement. Result faded within 2 weeks</p> <p>c no significant difference between Condition A and B</p>	Physiological	Immediate results post 2 weeks intervention

EG, experimental group; CG, control group.