

Neuromuscular Electrical Stimulation in the Treatment of Dysphagia

A Summary of the Evidence

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Executive summary

Neuromuscular electrical stimulation (NMES) used as an adjunct modality in the treatment of dysphagia has gained increasing adoption by medical professionals since the clearance by the Food and Drug Administration in 2002 of VitalStim Therapy, the only device on the market with such clearance.¹

NMES as used in the treatment of dysphagia involves the administration of small electrical impulses to swallowing muscles in the throat through electrodes attached to the skin overlying the musculature. The therapist determines which musculature would benefit from this facilitation through the standard evaluation procedure which typically includes some form of instrumental assessment. The data gathered from the assessment permit the therapist to recommend an electrode placement in order to facilitate the target musculature. Once the current intensity has been increased to a satisfactory level, the therapist commences traditional exercise therapy with the patient. The patient exercises the swallowing muscles for periods of up to 1 hour while receiving concurrent electrical stimulation. The electrical stimulation when applied in this manner accelerates muscle strengthening, accelerates cortical reorganization (especially after stroke), and increases the effectiveness of the exercise therapy.

The treatment of dysphagia in the USA falls primarily to Speech Language Pathology (SLP) professionals and to a lesser extent Occupational Therapists. Therapists treating dysphagia employ a variety of techniques and strategies to limit the risks of aspiration and to accelerate recovery. Strategies employed to limit the risks of aspiration may include compensatory swallowing maneuvers and diet modifications. Active treatment approaches include exercise therapy and behavioral techniques.

SLP's receive graduate level training in the evaluation and treatment of dysphagia but course work typically does not include training in the use of electrotherapy. The use of this modality is common in the practice of Physical Therapy (PT) where it is primarily used to decrease pain and increase muscle strength but also has other applications such as facilitating tissue healing.

The evidence base for the use of electrotherapy as practiced by PT's is robust and insurance generally covers its use. In a fee-for-service payment structure either CPT code 97032 (attended electrical stimulation; in 15 minutes increments) or CPT code 97014 (unattended electrical stimulation; untimed; Medicare requires CPT code G0283 to be used instead) is used.

The use of electrotherapy to strengthen weak swallowing muscles in dysphagia is conceptually sound based on the experience in PT practice and its supporting evidence. It has however not yet received approval by the insurance industry due to a perceived lack of evidence supporting safety and efficacy of the use of electrotherapy in dysphagia. However, the evidence base has continued to grow at a significant pace over the past years. In actual fact, available evidence supporting the use of NMES for dysphagia at

present exceeds the evidence supporting other reimbursable interventions used in the treatment of dysphagia.

The following reviews the evidence and highlights the strengths and weaknesses of published and/or presented research.

Safety

The use of NMES in the treatment of dysphagia has been demonstrated to be safe. The studies reviewed all tracked for the occurrence of adverse events and none were reported, across all patient ages and diagnoses. Freed and colleagues in their submission of treatment data to the FDA to obtain clearance for VitalStim Therapy² specifically tracked for changes in pulse oxymetry readings and cardiac function (heart rate, blood pressure). They reported data on 892 patients and reported no reports of laryngospasm, no reports of bradycardia and no reports of electromagnetic interference with cardiac pacemakers. 29 of the patients studied by Freed were pediatric patients. Christiaanse and colleagues³ also evaluated the use of VitalStim Therapy in the pediatric population and reported no adverse events in 30 patients.

Efficacy

Carnaby-Mann and Crary performed a meta-analysis of the published literature of the past 30 years.⁴ Their search identified 81 papers that studied the therapeutic use of surface electrical stimulation in the treatment of dysphagia. After applying strict inclusion criteria 7 studies remained with a total of 255 dysphagic patients treated with NMES on the throat area specifically to treat dysphagia. They confirmed that no adverse events were identified and attributed a statistically significant positive treatment effect favoring the use of NMES on the throat in the rehabilitation of dysphagia (Hedges $g = 0.66$). Bülow and colleagues recently completed a randomized controlled study comparing treatment outcomes of electrotherapy versus traditional treatment techniques in stroke patients with chronic dysphagia.⁵ Their study demonstrated that both treatment approaches yielded positive treatment outcomes even though the small patient numbers failed to identify a significant difference between them. A more recent study⁶ also compared the use of NMES (VitalStim) with traditional treatment techniques. They randomized 23 subacute stroke patients with severe dysphagia into a rehabilitation group receiving traditional interventions or an NMES group receiving NMES with swallowing exercise. They found that the NMES group made significantly greater gains in their swallow function.

User and patient satisfaction

Therapists in the USA are rapidly adopting the use of NMES in the treatment of dysphagia. Besides the growing empirical evidence base, this adoption is primarily as a result of widespread reports of good patient outcomes and good patient satisfaction. Crary and colleagues confirmed these outcomes in an independent user survey.⁷ The survey which was sent out to 2,000 practicing SLP's confirmed that the majority of users are reporting good outcomes, good therapist and patient satisfaction and no adverse events.

Diagnosis specific application of NMES for dysphagia

Head and Neck Cancer – Several studies have studied the effects of NMES in the cancer population. Several early papers demonstrate a trend toward a beneficial treatment effect on the sequelae of radiation therapy such as pain, xerostomia (dry mouth) and mucositis.⁸⁻¹⁰ More recent studies corroborate these findings.^{2, 11-13} All studies report improved functional swallowing as a result of the improvements in the outcome measures. Since signs and symptoms induced by radiation therapy are well known contributors to the onset of dysphagia, the use of NMES appears to be a promising preventative as well as curative treatment modality in this population. A recent presentation¹⁴ substantiates this potential. In this study the authors identify decreased severity of radiation induced fibrosis in patients receiving NMES and dysphagia therapy concurrently to receiving radiation. A publication by Lin et al.¹⁵ confirms improved swallowing as a result of electrical stimulation in chronic dysphagia after receiving radiation therapy for nasopharyngeal cancer over 1 year ago.

Stroke – CVA is the most common diagnosis of patients presenting with dysphagia. Consequently, the majority of dysphagia patients in the NMES literature are stroke patients (a total of 693 patients are included in the studies in this review). Even though dysphagia frequently resolves spontaneously in the first 6 months post stroke, the studies point to a definite treatment effect in both acute and chronic dysphagia.

The data submitted to the FDA² (n = 446 stroke patients) indicates NMES is a safe and effective treatment modality in this population. Subsequent publications confirm this finding.¹⁶⁻¹⁸

To control for the confounding variable of spontaneous recovery, Crary and colleagues only included chronic, treatment refractory dysphagic patients in a well designed prospective case series.¹⁹ They report equally positive treatment outcomes. The same chronic population was studied by Ludlow et al.²⁰ This study did not evaluate the treatment condition but rather the immediate effects of applying electrical current to the throat musculature as is the case during normal treatment conditions. They report a safer swallow as soon as the patients reported noticing the sensation of the current. At a maximal intensity level these patients demonstrated a descent of the hyolaryngeal complex but surprisingly this did not increase dysphagia signs.

Shaw et al. evaluated the use of VitalStim Therapy retrospectively in an inpatient environment (45% of their sample of 18 patients were stroke patients).²¹ They noted an improvement in swallowing ability, a decreased need for tube feeding and an improved diet level.

Oh and colleagues²² evaluated whether the positive treatment effects observed by clinicians and researchers in stroke patients would coincide with changes in cortical representation of the swallowing muscles. Using transcranial magnetic stimulation (TMS) and videofluoroscopic evaluation of swallowing, they were indeed able to establish a relationship between objective improvement of swallowing ability and a corresponding expansion of the cortical representation.

A more recent study⁶ compared the use of NMES (VitalStim) with traditional treatment techniques in 23 subacute stroke patients. They found that the NMES group made significantly greater gains in their swallow function.

Other – Several case reports have been published reporting positive treatment outcomes in a variety of diagnoses and indications. Baijens et al. report on successful resolution of dysphagia as a result of using electrotherapy in a patient with Opercular Syndrome.²³ Lagorio et al. report short and long term changes in laryngeal function in a patient with tongue base cancer as a result of using VitalStim Therapy.²⁴ These changes led not only to improved swallowing function but also in improved voice function. Recently a case series was presented for publication reporting on the effects of electrical stimulation in patients with multiple sclerosis. Significantly improved swallow safety and function was reported.²⁵ Another recent publication²⁶ reports on benefits of the addition of ES to a voice rehabilitation program.

VitalStim Therapy Protocol and Reimbursement

In most available studies the VitalStim Therapy device and electrodes were used to deliver the therapy. The VitalStim Therapy device is the only device on the US market specifically cleared by the FDA for the treatment of dysphagia with electrode placements on the anterior portion of the neck.¹ The equipment, the accompanying supplies and the mandatory competency training for treating therapists were specifically designed to satisfy safety and efficacy concerns of the FDA. The use of VitalStim Therapy, when applied as instructed and as intended, is therefore consistent with the FDA cleared protocol and supported by evidence. This is an important consideration from a reimbursement perspective since Medicare will not reimburse for therapy delivered using “off-label” (not cleared by the FDA) equipment and supplies; CMS considers these to be experimental and investigational and therefore not covered.²⁷ This point is highlighted by the findings of Doeltgen and colleagues presented at the Dysphagia Research Society in 2008.²⁸ They compared the effect of different frequencies of neuromuscular electrical stimulation on the facilitation levels of the stimulated muscle group, in this case the submental musculature. They found that the frequency used in VitalStim Therapy (80 Hz) is facilitatory but that lower frequencies are inhibitory, suggesting that therapists should not use these lower frequencies when treating the swallowing system.

Literature review

The following is a complete list of papers on the subject of surface electrical stimulation for the treatment of dysphagia.

Baijens, 2008: Case report: Treatment of patient with opercular syndrome. ²³

Design: Case study (Grade: D)
Objective: Report on treatment outcomes of patient with opercular syndrome treated with VitalStim Therapy.
Subjects: 76 year old man with severe dysphagia as a result of 2 consecutive strokes suffered 3 years earlier. Patient had failed prior traditional therapy.
Method: VitalStim Therapy delivered for 60 minutes over a period of 5 months.
Outcome measures: Swallowing score based on FEES and VFSS evaluation.
Results: Patient returned to full oral intake with minor diet modifications.

Bauer, 1983: Treatment of head and neck cancer pain with surface electrotherapy. ⁸

Design: Case reports (Grade: C)
Objective: Evaluate benefit of electrical stimulation (ES) for pain control in head and neck cancer.
Subjects: 3 patients status post surgery and radiation therapy (RT) for squamous cell carcinoma of the head/neck.
Method: ES delivered for 2 minutes to painful areas of the head and neck. Current applied with an alternating current stimulator.
Outcome measures: Pain rating on 1-10 visual analog scale before and after each ES treatment and amount of pain medication patients were taking.
Results: All patients had a significant decrease in pain after ES and no side effects were reported.

Belafsky, 2004: Prospective study of effects of ES on dysphagia. ²⁹

Design: Prospective observational study without control arm (Grade: C)
Objective: Evaluate effect of use of ES on swallow function.
Subjects: 22 patients with dysphagia. Etiology: Stroke (10/22), Respiratory failure (4/20), Cricopharyngeal dysfunction (2/20), H/N cancer (3/20), Steroid myopathy (1/20).
Method: Non-randomized, non-blinded. Patients received an average of 10 ES treatments.

Outcome measures: Non-validated swallow function scale.
Results: Well tolerated with no complications. Swallow score improved 2.1 – 4.9 after therapy.

*Blumenfeld, 2006: ES in chronic, severe dysphagia.*³⁰

Design: Retrospective case control study (Grade: B)
Objective: Compare effect of ES to Thermal Stimulation (TS) on dysphagia.
Subjects: 80 patients with dysphagia, mostly due to respiratory failure.
Method: 40 patients had received ES, 40 other patients had received TS.
Outcome measures: Swallow ability on non-validated swallow scale.
Results: Patients who had received ES received fewer treatments and required shorter hospitalization. Swallow score improvement were superior for ES group.

*Bogaardt, 2008: Use of NMES in the treatment of dysphagia in MS patients.*²⁵

Design: Case series (Grade: C)
Objective: Evaluate NMES as a method to treat dysphagia in multiple sclerosis
Subjects: 25 patients with multiple sclerosis and swallowing problems. 16 male, 9 female, average age 53.1 years.
Method: Patients received 6 treatments sessions over 3 weeks (2 sessions per week). Patients were instructed to swallow as soon as they felt the electricity, which surged in and out at set intervals for 20 minutes. The suprahyoid (submandibular) and thyrohyoid muscles were stimulated to facilitate hyolaryngeal excursion.
Outcome measures: Results on a timed swallowing task (speed of swallowing different consistencies); score on Penetration-Aspiration scale and on Dysphagia Severity Scale as measured with FEES; Quality of Life score.
Results: Patients demonstrated a significant decrease in piriform pooling, significantly less aspiration of thin liquids and improved self-reported swallowing ability and quality of life.

*Boswell, 1985: Treatment of radiation side-effects with surface electrotherapy.*¹⁰

Design: Case control study (Grade: B)
Objective: Evaluate ES as a method to treat radiation side effects of mucositis, pain, dryness, and dysphagia
Subjects: 10 patients undergoing radiation therapy (RT) for oropharyngeal cancer compared to a randomly selected, retrospective, control

group of 13 patients with oropharyngeal cancer who had previously completed RT.

- Method: ES group received ES within 4 hours after receiving RT. ES treatments were varied and individually tailored per patient tolerance. Treatment sessions continued until symptoms were nil or minimal.
- Outcome measures: RT interruptions from mucositis and subjective reports of symptoms on symptom report.
- Results: ES group had no RT interruptions from mucositis as compared to 9/13 patients in the control group with RT interruptions because of symptoms. All ES patients had symptoms minimized or eliminated during RT and benefit remained up to 1 year post-treatment unless recurrence of disease occurred. No side effects were reported.

*Boswell, 1989: Treatment of radiation side-effects with surface electrotherapy.*⁹

- Design: Single case study (Grade: C)
- Objective: Investigate effect of ES on RT side effects (irreversible xerostomia, temporary dysgeusia, throat pain, and possible mucositis and radiation dermatitis) immediately following RT
- Subjects: Single patient receiving RT for carcinoma of the right tonsillar area.
- Method: ES provided to radiated area up to 30 minutes immediately following each radiation session.
- Outcome measures: Patient rated dryness on a 5-level non-validated scale prior to and immediately following each ES treatment. RT side effects were monitored.
- Results: Decrease in xerostomia: saliva flow was normal by the termination of RT. Patient exhibited no mucositis, radiation dermatitis, dysgeusia, or throat pain.

*Bülow, 2008: ES versus traditional therapy.*⁵

- Design: Randomized study (Grade: B)
- Objective: Compare effect of use of ES to use of traditional treatment techniques in stroke patients with chronic dysphagia.
- Subjects: A total of 25 patients were randomized into one of 2 groups, one group receiving electrotherapy without any additional therapy or maneuver, the other group receiving a combination of traditional therapy techniques.

Method: Patients received 15 1-hour treatment sessions over a 3 week period. VFS and self-rating of swallowing ability was analyzed before and after therapy.

Results: Both groups showed significant improvement in swallowing ability and safety. The sample size was too small to detect a difference between the treatment groups.

*Carnaby-Mann, 2007: Meta-analysis of treatment literature on use of ES for dysphagia.*⁴

Design: Meta-analysis (Grade: B)

Objective: Evaluate effect of use of ES swallowing rehabilitation.

Subjects: A total of 255 patients were studied in 7 of 81 research papers evaluated to determine effect size of the use of ES.

Method: Accepted studies were evaluated for quality. Data was analyzed individually and then pooled.

Results: The analysis shows a significant effect size for ES in the treatment of swallowing disorders indicating support for the use of ES.

*Carnaby-Mann, 2008: Effect of ES for dysphagia. A case series.*¹⁹

Design: Prospective case series (Grade: B)

Objective: Evaluate effect of use of ES with concurrent standardized exercise regimen on swallow function in chronic dysphagia patients.

Subjects: 6 adult patients with treatment refractory chronic pharyngeal dysphagia were treated via a standardized protocol of swallowing-based exercise with adjunctive NMES. Patient diagnoses included stroke (n=3), cancer (n=2), traumatic brain injury (n=1).

Method: Subjects received treatment for one hour per day, five days per week, for three weeks. Patients underwent clinical and instrumental baseline, post treatment, and six month follow up evaluations.

Outcome measures: Clinical swallowing ability, functional oral intake, and change in body weight; change in hyoid and laryngeal elevation during swallowing measured from videofluoroscopic swallowing examinations; and patient perception of swallowing ability and descriptive changes on instrumental swallowing examinations.

Results: 80% of patients demonstrated significant improvement in clinical swallowing ability, functional oral intake, weight gain, and patient perception of swallowing ability. Hyoid elevation during swallowing demonstrated a non-significant decrease following therapy but laryngeal elevation increased, indicating improved hyolaryngeal approximation, especially when swallowing thick consistencies. All patients significantly increased the range and

amount of materials they consumed safely. No patient experienced a treatment-related or swallowing-related complication. Four of five patients who were followed out to six months post treatment maintained functional gains.

*Chaudhuri, 2006: ES for acute dysphagia after stroke.*¹⁸

Design: Prospective randomized study (Grade: B)

Objective: To compare the effectiveness of electric stimulation with traditional dysphagia treatment following an acute stroke.

Subjects: 11 acute stroke patients (<6wk) with dysphagia.

Method: Patients divided into 2 groups: ES group (n=6) and group 2 receiving traditional dysphagia treatment (n=5). ES patients received ES in addition to swallowing exercises at same frequency as patients in group 2 received traditional therapy.

Outcome measures: National Outcome Measurement System (NOMS) swallowing level was assigned to each patient based on diet and supervision level as determined by pre- and post-treatment videofluoroscopic swallow studies.

Results: Progress made for swallowing level for group 1 was statistically significant but not for group 2.

*Cheung, 2010: Use of neuromuscular electrical stimulation in patient with Sjögren's Syndrome.*³¹

Design: Case report (Grade: C)

Objective: Report on the effectiveness of the use of NMES in a patient with Sjögren's Syndrome after traditional treatment alone failed.

Subjects: 54 year old female with severe pharyngeal dysphagia characterized by delayed pharyngeal transit time, pooling in the valleculae, penetration, and absence of laryngeal elevation.

Method: Patient was treated with NMES 1hour, 3x/week in conjunction with a swallowing rehabilitation program.

Outcome measures: After 10 treatment sessions, swallow functioning was assessed in real time with NMES using VFSS which showed immediate improvement in tongue retraction, clearing of the valleculae, increase in laryngeal elevation, and shortening of pharyngeal transit time. A final VFSS follow-up test was conducted prior to discharge.

Results: After 46 sessions with NMES, oral and pharyngeal phases of swallowing were normal, and her diet level was maintained at 1 year follow-up.

*Christiaanse, 2003: Use of electrical stimulation in the pediatric population.*³

Design: Case series (Grade: C)

Objective: Report on the effectiveness of the use of ES in the pediatric population.

Subjects: 30 consecutive pediatric patients referred for ES after failing traditional dysphagia therapy. Patients had multiple etiologies: congenital anomaly (n=17), acquired CNS lesion (n=7), or unknown (n=6).

Method: Patients received ES to the anterior neck for an average of 22 sessions of 1 hour each, until the swallow had improved or until no further improvement was noted.

Outcome measures: Swallow score on non-validated scale. Videofluoroscopy evaluation.

Results: 17/30 patients improved with 5/30 achieving a normal swallow. No adverse events were reported.

*Clark, 2009: Systematic review of literature on use of NMES in swallowing rehabilitation.*³²

Design: Evidence based systematic review (Grade: B)

Objective: To systematically review the literature examining the effects of NMES on swallowing and neural activation.

Subjects: 14 articles were identified that met the criteria for inclusion in the systematic review. These English language articles were peer reviewed, were published between 1996 and 2007, and addressed one or more of 5 clinical questions about the effectiveness of NMES in swallowing rehabilitation.

Outcome measures: Accepted studies were evaluated for methodological quality based on the ASHA Levels of Evidence Scheme. Papers were analyzed individually and synthesized where possible. Magnitude of effect size was calculated wherever possible.

Results: Promising results are reported in the reviewed literature on the use of surface NMES as a motor facilitation tool (VitalStim). The use of NMES as a sensory facilitation tool is also reported as a promising modality. Studies on both these application methods generally have methodological limitations, making it difficult to estimate effect size.

*Crary, 2007: User and patient satisfaction surveys with use of ES.*⁷

Design:	User survey (Grade: D)
Objective:	To evaluate practice patterns and experience of therapists using ES as a treatment modality for dysphagia.
Subjects:	Survey sent to 2,000 therapists; 840 respondents.
Outcome measures:	Perceptions of use of electrotherapy. Practice patterns of users. Reported outcomes.
Results:	Most common etiology treated with ES is stroke (>70%). Majority of users (>70%) treat for 1-hour sessions, 3-5 x per week. Majority of respondents use other treatment techniques (>90%) in conjunction with ES. Majority of users report good outcomes in >50% of patients: advanced oral diet and reduced aspiration. Majority (>50%) report no complications of ES. Overall satisfaction with ES was high for patients (80%) and therapists (78%).

*Doeltgen, 2008: Frequency of electrical stimulation and submental muscle facilitation.*²⁸

Design:	Physiology study on normal subjects (Grade: C)
Objective:	Compare the effects of electrical stimulation at different frequencies (5 Hz, 20 Hz, 40 Hz and 80 Hz) on the excitability of the submental muscles.
Subjects:	Normal subjects.
Method:	Subjects received electrical stimulation following a voluntary swallow effort. Maximum evoked potentials (MEP) were recorded in the submental muscles by means of transcranial magnetic stimulation (TMS).
Outcome measures:	MEP amplitude.
Results:	5, 20 and 40 Hz stimulation inhibited MEP amplitude whereas 80 Hz (as used in VitalStim Therapy) facilitated MEP amplitude. Findings suggest a positive treatment effect of electrical stimulation at 80 Hz.

*Fowler, 2009: Use of surface electrical stimulation for voice*³³

Design:	Prospective repeated-measures design (Grade: C)
Objective:	To determine if voice characteristics could be modulated in healthy speakers by using VitalStim.
Subjects:	20 healthy volunteers (10 male, 10 female).
Method:	Subjects received 1 hour of ES as per typical dysphagia treatment protocol (VitalStim), i.e., with concurrent exercise therapy.

Outcome measures: Voice recordings were collected prior and immediately following the treatment session. Measured parameters consisted of a sustained vowel task and reading of the Rainbow Passage.

Results: Measurable changes were recorded for both voice parameters but these were variable in amplitude and direction and were not statistically significant. Further research with larger sample size is needed to quantify the effect of ES on voice production.

*Freed, 1998: FDA data*²

Design: Outcomes study (Grade: B)

Objective: Compare effects on dysphagia of three different treatment conditions: electrical stimulation at sensory intensity level (E1), electrical stimulation at motor level stimulation (E2) and thermal stimulation (T).

Subjects: 892 dysphagic patients (both hospitalized and ambulatory patients) of multiple etiologies: stroke (n=446), neurodegenerative diseases (n=136), respiratory disorders (n=156), cancer (n=61), other (n=64), iatrogenic (n=17), myasthenia gravis (n=2), myopathy (n=8), post-polio syndrome (n=2). 58% of patients (n=516) had severe dysphagia.

Method: The first 157 patients were randomly assigned to one of 2 treatment conditions: T or E1. The following 735 patients were assigned to either E1 or E2 group. Patients were treated until normal swallowing ability was achieved or when no further improvement was obtained. Follow up evaluations were performed after 3 years.

Outcome measures: Score on swallow scale (non-validated).

Results: ES (E1 and E2 combined) had a success rate of 98.4% compared with 32.7% for T. For patients with severe dysphagia, ES had a success rate of 97.5% of restoring swallowing past the point of requiring a PEG. Functional swallow gains were retained at 3-year follow up. No reported complications, electromagnetic interference with cardiac pacemakers, no occurrences of laryngospasm or bradycardia.

*Freed, 2001: Electrical stimulation vs thermal stimulation for dysphagia after stroke.*¹⁶

Design: Outcomes study (Grade: B)

Objective: Compare effects of electrical stimulation (ES) to thermal stimulation (TS) on dysphagia.

Subjects: 99 dysphagic stroke patients with evidence of aspiration.

Method: Patients received one of 2 treatment conditions: Electrical Stimulation (n=63) or Thermal Stimulation (n=36). Outcome measures: Score on swallow scale (non-validated), ability to regain oral food intake while in hospital and changes on fluoroscopic swallow exam.

Results: 98% (62/63) of patients in ES group improved swallow compared to 42% (15/36) of patients in TS group with improved swallow. No reported complications.

*Gallas, 2009: Sensory stimulation improves swallowing after stroke.*³⁴

Design: Outcomes study (Grade: B)

Objective: Evaluate effects of sensory level electrical stimulation on dysphagia in chronic post-stroke patients.

Subjects: 11 post-stroke patients with chronic dysphagia.

Method: Patients received electrical stimulation to the submental area every day for one week. Electrical stimulation was delivered at sensory level (below motor recruitment threshold). Patients received 80 Hz pulse trains for 5 seconds once per minute for a total of one hour per session. Patients were evaluated before and after the treatment week with a standardized videofluoroscopy procedure. Bolus transit times, pharyngeal stasis and penetration/aspiration were evaluated and a dysphagia score was assigned.

Results: Oropharyngeal dysphagia symptoms improved, laryngeal aspiration and pharyngeal residue both decreased, and swallow reaction times improved.

*Humbert, 2006: Effect of ES on movement and safety in normals.*³⁵

Design: Physiology study on normal subjects (Grade: C)

Objective: To evaluate the influence of different electrode placements on movement of hyoid and larynx and effect on swallow safety.

Subjects: 29 normal volunteers

Method: 10 different electrode placements were applied to the anterior neck. Placements were chosen based on recommended VitalStim Therapy protocol. Electricity was applied at maximum tolerated intensity.

Outcome measures: Movement of the hyoid and larynx. Safety of the swallow as measured on a new swallowing scale (NIH-SSS). All measures were recorded at rest and during swallowing while receiving maximal electrical stimulation and compared to non-stimulated swallows.

Results: The hyoid and larynx showed a downward movement during maximal stimulation at rest and a decreased elevation during swallowing. The stimulated swallows were also judged less safe than non-stimulated swallows. It should be noted that the study does not evaluate the VitalStim Therapy treatment condition. It tests the effect of electrical current applied at a maximal intensity, which is significantly higher than that used during VitalStim Therapy, and does so on normal individuals.

*Kiger, 2006: Comparison of VitalStim to traditional therapy.*³⁶

Design: Retrospective case control study (Grade: B)

Objective: To compare treatment outcomes of traditional dysphagia therapy with treatment outcomes obtained with the addition of VitalStim Therapy.

Subjects: Non-homogenous group of 22 dysphagic patients of mixed etiology; 11 patients in experimental group, 11 in control group. Patients in the experimental group were significantly more chronic than patients in the control group.

Method: 11 dysphagic patients treated with VitalStim Therapy during a 4-months period were compared to 11 dysphagic patients treated without VitalStim during a preceding period (when staff was not yet VitalStim trained).

Outcome measures: Non-validated swallow scales were used. Non-validated evaluation procedure and inconsistently applied; some patients received a FEES evaluation, others a VFSS.

Results: Patients in the control group had slightly better swallowing scores than patients in the experimental group. Because of the difference in chronicity and non-validated outcome tools used, no meaningful conclusions can be drawn.

*LaGorio, 2008: Benefit of ES for voice rehab.*²⁴

Design: Case study (Grade: D)

Objective: Investigate the potential impact on voice function of utilizing NMES for dysphagia therapy.

Subjects: Single 74 year old patient with dysphagia after receiving radiation for tongue base cancer.

Method: Patient was treated for his dysphagia for 15 treatment sessions. After changes in voice quality were noted on treatment 6, voice measurements were taken before, during and after each therapy session. Objective and validated voice parameters were tracked during the treatment series and at 3 and 6 months follow up.

Outcome measures: Instrumental pitch recordings, perceptual voice changes and functional use of voice.

Results: Patient showed a significant and lasting improvement of perceptual and functional voice function which was accompanied with objective improvements in phonation.

*Langmore, 2006: ES for dysphagia in head and neck cancer patients.*¹²

Design: Prospective case series (Grade: B)

Objective: Evaluate effect of use of ES on swallow function in dysphagia patients and evaluate whether swallow changes are accompanied by cortical reorganization.

Subjects: 7 adult, chronic dysphagic head and neck cancer patients, 2 years post radiation therapy.

Method: Subjects received electrotherapy to submental musculature for 20 minutes per day followed by exercises for 10 minutes. Patients took the unit home and performed self-treatment at home 3 x per day, 6 days per week for 3 months.

Outcome measures: Count of occurrence of penetration and aspiration on VFSS. Selfperception of Quality Of Life (QOL). Diet type.

Results: Aspiration was reduced from 50% to 14%; aspiration of liquids was reduced from 85% to 71%; residuals were reduced from 90% to 70%; oral diet levels were improved across the board; PEG tube dependence was reduced from 58% to 42%.

*Leelamanit, 2002: sEMG triggered stimulation of the thyrohyoid muscles.*¹⁷

Design: Prospective case series (Grade: B)

Objective: Test the hypothesis that synchronous contraction of the thyrohyoid muscle by ES during swallowing would improve dysphagia resulting from reduced laryngeal elevation.

Subjects: 23 patients with moderate to severe dysphagia of multiple etiologies: aging (n=10), CVA (n=4), other (n=9).

Method: Patients received sEMG triggered ES to the thyrohyoid muscle, up to 4 hours daily until improvement. Duration of treatment varied from 2-30 days, depending on severity.

Outcome measures: Laryngeal elevation (in cm's) on videofluoroscopy evaluation, treatment outcome according to patient self-reporting, and ability to eat regular food without aspiration.

Results: 20/23 patients improved, 6/20 relapsed and improved with subsequent treatment. No reported complications.

*Lim, 2009: Electrical stimulation and thermo-tactile stimulation after stroke.*³⁷

- Design:** Randomized controlled study (Grade: A)
- Objective:** To evaluate the effects of electrical stimulation combined with thermotactile stimulation (ES + TTS) with thermotactile stimulation alone (TTS) in patients with dysphagia after cortical stroke.
- Subjects:** 28 patients with diagnosed dysphagia after stroke completed the study. Patients were assigned to either the experimental group (ES + TTS; n=16) or to the control group (TTS; n=12).
- Method:** Patients received ES in the supra- and infrahyoid region at an average level of 7mA for 1 hour per day, 5 days per week. Duration of treatment varied from 2-30 days, depending on severity.
- Outcome measures:** Score on functional swallowing scale (Freed; non-validated), score on Penetration-Aspiration Scale (Rosenbek), pharyngeal transit time measured on VFSS, comfort during treatment on visual analog scale and satisfaction score on 10-point analog scale. Rater analyzing the VFSS was blinded to the identity of the patients and whether or not they were part of the study.
- Results:** Pen-Asp scores and pharyngeal transit times improved significantly in the experimental group but not in the control group. Swallow function improved in both but only the experimental group improvement was significant. Discomfort and satisfaction scores were significantly better in the experimental group. 6 out of 12 patients (50%) in the experimental group versus 1 out of 7 patients (14%) in the control group progressed to the point of having their tube removed after treatment.

*Lin, 2009: Electrical stimulation of dysphagic patients after radiation for nasopharyngeal cancer.*¹⁵

- Design:** Randomized controlled study (Grade: A)
- Objective:** To compare the effects of electrical stimulation (VitalStim) with a home based rehabilitation program in patients with dysphagia after radiation therapy.
- Subjects:** 20 patients with diagnosed dysphagia, > 1 year after receiving radiation therapy for nasopharyngeal cancer. Patients were randomly assigned to either the experimental group (FES) or to a home rehabilitation program (HRP).
- Method:** Patients received 15 sessions of ES (60 minutes) in the supra- and infrahyoid region with the electrodes placed over the suprahyoid and thyrohyoid musculature to facilitate hyolaryngeal excursion.

Patients in the HRP group were instructed to perform 2x daily strengthening exercises for the duration of the study.

Outcome measures: Score on quality of life questionnaire (MD Anderson Dysphagia Inventory), score on Penetration-Aspiration Scale (Rosenbek), oral and pharyngeal transit times, amplitude and velocity of anterior and superior hyoid bone displacement.

Results: Hyoid bone displacement did not change in either group but displacement velocity increased significantly in the experimental group. PAS and MDADI scores also improved significantly better in the experimental group.

*Ludlow, 2007: Use of ES in chronic dysphagia.*²⁰

Design: Case series (Grade: C)

Objective: Evaluate effect of use of ES on physiological movement of swallowing structures and swallowing safety and efficacy.

Subjects: 11 patients with chronic dysphagia (6 months to 5 years duration) following neurologic deficit (stroke (mixed), TBI, craniotomy for brainstem tumor, PD).

Method: Patients were randomly assigned to receive ES at sensory level (tingle) or motor level (tugging, max tolerance). Treatment conditions were controlled with no-stim condition. Simultaneous fluoroscopy was performed during swallows of 5ml or 10 ml of liquid barium

Outcome measures: Movement of hyoid and larynx during maximum stim at rest. Judgment of swallowing safety during stim with Penetration-Aspiration Scale and NIH Swallow Safety Scale (NIH-SSS; promising scale specially designed for this study).

Results: Hyoid bone demonstrated descent during max stim condition while larynx stayed in place, resulting in increased hyolaryngeal approximation. PEN-ASP scores not impacted by sensory nor max stim during swallows. NIH-SS scores improved with sensory stim, but not max stim during swallows.

*McDuffie, 2005: ES for xerostomia.*¹¹

Design: Retrospective review of patient questionnaires (Grade: C)

Objective: Evaluate effect of use of ES on xerostomia (dry mouth).

Subjects: 12 patients who had received post-operative RT.

Method: Non-randomized, non-blinded. Patients received an average of 10 ES treatments.

Outcome measures: Patient symptom report.

Results: All patients identified significant change post treatment. 67% increased saliva production and reported needing less water intake with meals. All patients reported sleeping longer and having moister lips.

*Mitchell, 2010: Use of VitalStim in neonates*³⁸

Design: Randomized controlled double-blind study (Grade: A).
Objective: To determine the effect of using NMES (VitalStim) in the neonatal population.
Subjects: 18 medically compromised premature infants with significant decrease in medical stability during PO attempts. Patients were randomly assigned to a live or sham stimulation group. Therapists were blinded to the group assignment. After 2 weeks, patients were offered a cross-over phase of 2 weeks during which they received known live stimulation.
Method: Subjects received 2 weeks of therapy.
Outcome measures: Swallow safety was assessed by clinical evaluation and radiographic swallow study by blinded evaluator on study entry, at 2 week mark and at study exit.
Results: The experimental group demonstrated a significantly higher percentage return to full oral PO (64% for experimental group vs. 29% for control group) and a significantly lower number needing a feeding tube after 2 weeks of stimulation. 8/9 patients in the control group crossed over into live stimulation after 2 weeks and all but one demonstrated significant improvement to avoid feeding tube placement,

*Oh, 2007: Effect of ES for dysphagia on cortical reorganization.*²²

Design: Prospective case series (Grade: B)
Objective: Evaluate effect of use of ES on swallow function in dysphagia patients and evaluate whether swallow changes are accompanied by cortical reorganization.
Subjects: 8 adult dysphagic patients were treated via a standardized protocol of electrotherapy. Patient diagnoses included cortical stroke (n=4) and lower motor neuron lesion (n=4).
Method: Subjects received treatment for one hour per day, five days per week, for two weeks. Patients received VFSS and TMS (transcranial magnetic stimulation) evaluations before start of treatment and 12 hours after last treatment session.
Outcome measures: Clinical swallowing ability, swallowing quality according to VFSS, cortical representation and cortical excitability.

Results: Patients demonstrated significant improvement in swallowing ability as confirmed clinically and by VFSS. Cortical representation and excitability increased significantly. This increase was correlated with improved swallow function suggesting a causal relationship between cortical reorganization and swallow function improvement.

*Park, 2009: Motor level ES with effortful swallow in post-stroke patients.*³⁹

Design: Prospective, randomized case series (Grade: B)

Objective: To evaluate the impact of motor level electrical stimulation combined with effortful swallows applied to infrahyoid musculature as a form of resistance exercise for suprahyoid muscles.

Subjects: 10 patients with dysphagia secondary to stroke.

Method: Patients were randomized to either a motor level or sensory level NMES group. Patients in both groups received active exercise therapy (effortful swallow) during the electrotherapy session for 20 minutes, 3 days per week for 4 weeks (total of 12 sessions).

Outcome measures: Extent of hyolaryngeal excursion and upper esophageal sphincter opening. Raters were blinded to the identity and group assignments of the patients.

Results: Patients in the motor level electrotherapy group showed significantly increased hyolaryngeal excursion as compared to the sensory level group.

*Park, 2009: Motor level ES with effortful swallow in normals.*⁴⁰

Design: Prospective, randomized case series (Grade: B)

Objective: To evaluate the impact on residual hyoid elevation of motor level electrical stimulation applied to infrahyoid musculature, combined with effortful swallows.

Subjects: 16 healthy volunteers.

Method: Patients were randomized to either a motor level or sensory level NMES group. Current intensity in the motor level group was increased until a noticeable hyoid depression occurred. Patients in both groups received ten (10) 20-minute treatments over 2 weeks.

Outcome measures: EMG activity of suprahyoid musculature and extent of hyoid vertical excursion during swallowing. Measures were taken before, immediately following and 2 weeks post intervention.

Results: Patients in the motor level electrotherapy group showed significantly increased hyoid excursion immediately post intervention. This change was not maintained 2 weeks after the

intervention. There was no change in the sensory level group. The results confirm that electrical stimulation as applied in the study facilitates suprahyoid muscle recruitment resulting in improved hyoid elevation.

*Pattani, 2010: ES to improve xerostomia post-irradiation.*¹³

Design: Prospective trial

Objective: Determine if improvements of dysphagia in patients with head and neck cancer who received NMES was a result of decreased complaints of xerostomia and increased saliva production resulting from the e-stim.

Subjects: Five patients that received either postoperative radiation therapy or concomitant chemoradiotherapy and had been treated with e-stim.

Method: Prior to initiation of e-stim and one to two months after e-stim, saliva samples were collected and patients were asked to answer a Dysphagia and Xerostomia Index Questionnaire. All patients received e-stim two to four months after completing XRT. Patients received three e-stim treatments per week for a total of one to two months.

Results: All five patients noticed a significant improvement in dysphagia. Five out of five patients noticed a definite increase in saliva production with symptoms of decreased water intake during meals, sleeping longer hours at night, and increased moistness of lips.

*Permsirivanich, 2009: ES versus Traditional Therapy.*⁶

Design: Prospective, randomized, single-blinded (Grade: A)

Objective: To compare the effectiveness of the use of NMES with traditional dysphagia therapy.

Subjects: 23 patients with post-acute (>2 weeks) pharyngeal dysphagia secondary to stroke.

Method: Patients were randomized to either an NMES group (n=12) or a traditional therapy group (n=11). Patients in both groups received treatment for 60 minutes, 5 days per week for 4 weeks. The traditional therapy group received a combination of compensatory maneuvers, swallowing exercises and thermotactile stimulation. The NMES group received NMES (VitalStim) with swallowing exercises.

Outcome measures: Functional oral intake according the FOIS.

Results: Patients in both groups improved their functional swallowing but the NMES group showed a significantly greater change in their FOIS level.

Ptok, 2008: Effect of ES on voice quality. ²⁶

Design: Prospective, randomized (Grade: A)

Objective: To evaluate effectiveness of ES on voice quality in vocal fold paresis.

Subjects: 69 patients with unilateral recurrent laryngeal nerve paresis. Most patients had paresis as a result of recent surgery.

Method: Patients were randomized to either an ES group or an exercise group. Patients in the ES group received electrical stimulation for up to 10 minutes per treatment session. Patients in the exercise group received a standard exercise therapy program.

Outcome measures: Vocal fold vibration irregularity index (CFx) and maximum phonation time (MPT)

Results: Patients in the ES group showed a significantly better improvement in the CFx.

Ryu, 2008: Effect of ES on dysphagia in head and neck cancer. ⁴¹

Design: Prospective, double-blind, randomized case control study (Grade: A)

Objective: To evaluate effectiveness of ES (VitalStim) on dysphagia in head neck cancer patients status post surgery and/or radiation.

Subjects: 26 patients with dysphagia after carcinoma treated with surgery and/or radiation therapy.

Method: Patients were randomized to either an ES with traditional swallowing exercise group (experimental group, n=14) or a sham-ES with traditional swallowing exercise group (control group, n=12). Patients in the ES group received electrical stimulation for 30 minutes followed by 30 minutes of traditional dysphagia therapy. Patients in the sham-ES group received the same intervention except for the ES, where traditional TENS therapy (sensory stimulation only) replaced the motor level stimulation delivered to the experimental group.

Outcome measures: Functional Dysphagia Scale (numerical scale derived from VFSS), Clinical Dysphagia Scale (numerical scale derived from bedside evaluation), ASHA NOMS, MD Anderson Dysphagia Inventory.

Results: Patients in the ES group showed a significantly better improvement in FDS scores (from VFSS) than patients in the sham-ES group.

Shaw, 2007: Effect of ES in dysphagia. ²¹

Design: Retrospective case series (Grade: C)

Objective: To evaluate effectiveness of ES in dysphagia.

Subjects: 18 patients with dysphagia as a result of CVA (n=8), vagal nerve neuropathy (n=6), other (n=4). 12/18 patients were using a feeding tube before treatment.

Method: Patients had all received ES with a standardized treatment protocol and electrode placement for 1 hour per treatment session.

Outcome measures: Diet level, laryngeal elevation, presence of penetration or aspiration, residue severity, swallow delay and overall severity of dysphagia.

Results: 61% of patients experienced improvement in their swallow function, half of which no longer required a feeding tube. Results were more significant for patients with mild to moderate dysphagia.

Suiter, 2006: Effect of ES on normal muscle function. ⁴²

Design: Case control study (Grade: C)

Objective: Evaluate effect of use of ES on muscle activation in healthy adults.

Subjects: 10 healthy adults (2 withdrew from study). Randomly assigned to AB or BA group (A = patients received no treatment, B = patients received ES for 1 hr).

Method: Patients received both conditions A and B for a period of 2 weeks. ES sessions were given passively, without concurrent exercise, for 1 hour x 5 consecutive days per week.

Outcome measures: sEMG recording of submental muscle activity during a 5 ml water swallow, both pre- and post-treatment.

Results: No significant difference in peak myoelectric muscle activity between pre- and post-treatment assessments.

Comments: sEMG recording is not a reliable outcome measure for strength nor function.

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