


## Appendix VII: Review of the evidence

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High level summary	Notes
 <ul style="list-style-type: none"><li>• &gt;100 peer-reviewed studies in print</li><li>• &gt;90% use VitalStim device and protocol</li><li>• Continued growth of evidence</li><li>• Key findings:<ul style="list-style-type: none"><li>• <b>Safety:</b> well established</li><li>• <b>Efficacy:</b> NMES contributes significantly to treatment outcome when added to swallowing exercise</li><li>• <b>User and patient satisfaction:</b> both therapists and patients report good outcomes and no adverse events</li></ul></li></ul>	

### Executive Summary

Electrical stimulation for therapeutic purposes is a widely used treatment tool in the treatment of dysphagia. The most common application is neuromuscular electrical stimulation (NMES) where the current is introduced to the body through surface electrodes attached to the skin.

This literature review lists publications on this subject. Many lower level studies such as case reports, user surveys and expert opinion papers have not been included.

**Safety** – No occurrences of adverse events have been reported by the manufacturer or regulatory bodies to date, nor have any been reported in the professional literature.

**Effect of electrical stimulation on voice** – Anecdotal evidence has been reported on the beneficial effect of NMES on voice function, mostly as a side effect of its use for dysphagia. The studies evaluating the effect of NMES on voice function are not included in this dysphagia focused review. The interested reader is referred to the following papers.

- Lagorio, 2010 – Behavioral voice therapy with adjunctive NMES reduced vocal fold bowing.
- Fowler, 2011 – An exploratory study of voice change associated with healthy speakers after transcutaneous electrical stimulation to laryngeal muscles.

- Guzman, 2014 – Significant improvement of voice function post stimulation.
- Byeon, 2015 – Dysphagia patients treated with NMES improved voice loudness and stabilized periodicity of vocal cord vibration (jitter, shimmer).
- Ko, 2016 – Patients with stroke and TBI treated for dysphagia symptoms also showed measurable improvement in phonation.
- Ras, 2016 - electrical stimulation-supported voice therapy in cases of vocal fold immobility improves voice parameters.
- Lagorio, 2008 – Case study demonstrating positive effect on voice of using NMES used for dysphagia.
- Perez, 2014 – Randomized controlled case series demonstrating positive effect on voice measures in 10 patients with recurrent laryngeal nerve paralysis of transdermal electrical stimulation over the larynx during the phase of maximal glottal occlusion.
- Ptok, 2008 – Randomized controlled study showing positive effect of NMES on acoustic measures in patients with unilateral vocal fold paralysis.

**Kinematics** – Several papers have evaluated the kinematic effect of applying electrical stimulation to the swallowing structures. Variables that have been studied include the current intensity or amplitude, electrode placement, age, functional activity during stimulation (swallowing or at rest), and functional status (dysphagic vs. healthy).

- Arslan, 2018 – Study evaluates effect of motor level stimulation to suprahyoid muscles only in healthy volunteers. Swallowing kinematics were not impacted by stimulation except for the starting point of the hyoid (more anterior).
- Barikroo, 2017 – Study comparing different amplitudes of stimulation in both older and younger healthy volunteers. Electrical stimulation in older volunteers benefitted pressure generation and speed of the swallow.
- Beom, 2015 – Compared motor level stimulation to brain injury patients with electrodes either placed suprahyoid only or supra- and infrahyoid. Outcomes were positive without significant difference between them.
- Berretin-Felix, 2014 – Electrical stimulation at different intensities was applied to older and younger healthy adults. Motor level stimulation increased propulsive force of the posterior tongue in older adults with motor level stimulation. Motor level stimulation produced a positive increase in hypopharyngeal pressures in both groups.
- Heck, 2012 – Healthy volunteers received submental stimulation synchronized to swallowing. Peak pressure decreased in the hypopharynx and at upper esophageal sphincter 5 and 30 minutes post stimulation. Across all assessment times, effortful swallows generated greater peak pharyngeal pressures and lower upper esophageal sphincter pressures. The effect lasted up to an hour in the hypopharynx.

- Humbert, 2006 – Healthy young volunteers showed depression of hyoid and decreased swallow safety during maximal motor stimulation.
- Jungheim, 2015 – Healthy volunteers received suprahyoid stimulation at motor and sensory (sham) levels. Motor level stimulation group showed decreased upper esophageal sphincter pressures and increased relaxation times as compared to sham stimulation.
- Jungheim, 2017 – Healthy volunteers received low and medium frequency stimulation to suprahyoid muscles. Maximum tongue base pressure increased following stimulation with medium frequency. Low frequency protocol did not produce any significant changes.
- Kim, 2015 – Study comparing effect of different electrode positions on movement of hyoid bone during swallowing and at rest. All placements resulted in hyoid bone displacement in anterior and inferior direction at rest but not at maximal excursion during swallowing, resulting in a greater maximal excursion during stimulation.
- Kim, 2017 – Post-stroke dysphagic patients received infrahyoid only stimulation to act as a resistor during swallowing. Maximal hyoid displacement pharyngeal constriction improved.
- Ludlow, 2007 – Chronic dysphagic patients received maximal intensity stimulation at rest, at sensory level stimulation and during maximal level stimulation. Sensory level stimulation improved swallow safety. Maximal level stimulation showed a surprising inverse relationship between intensity and swallow safety.
- Nam, 2013 – Study comparing supra- and infrahyoid electrode placement to suprahyoid only in dysphagic patients with acquired brain injury. Supra- and infrahyoid group showed improved hyoid protraction and laryngeal elevation. Suprahyoid group showed increase only in maximal anterior hyoid excursion distance and velocity.
- Park, 2009 – Study comparing sensory to motor level stimulation in post-stroke dysphagic patients. Hyolaryngeal excursion improved as result of electrical stimulation combined with effortful swallowing in motor group only.
- Park, 2014 – Study comparing sensory to motor level stimulation with electrodes placed below hyoid only to deliver resistance to hyolaryngeal excursion. Hyolaryngeal excursion improved as result of motor level electrical stimulation combined with effortful swallowing.
- Takahashi, 2017 – Electrical stimulation was delivered to hyolaryngeal area (infra- and suprahyoid) of 18 young, healthy adults. Tongue pressure during stimulation was significantly lower than before or after stimulation, but significantly greater after stimulation than at baseline. Suprahyoid activity was also greater after stimulation. Position of the hyoid at rest was descended during stimulation, but vertical movement was greater than before or after stimulation. After stimulation, maximal excursion of the hyoid at rest and at the maximum elevation were more superior than before stimulation.

**Sensory versus Motor level stimulation** – Traditional NMES is delivered at motor level current intensity where involuntary muscle contractions are evoked by the current flow. Since the current penetrates the skin on its way to the motor neuron there will also be a significant amount of stimulation of sensory neurons. How much of the therapeutic effect observed during the use of NMES can be attributed to the afferent input to the brainstem and cortex? Is there a therapeutic difference between using a motor and sensory only level of current intensity? The studies listed below explore these questions.

- Baijens 2013 – No effect noted of addition of electrical stimulation in Parkinson’s population; no difference between sensory and motor.
- Berretin-Felix, 2014 – Motor stimulation benefitted older versus younger healthy adults, especially oro- and hypopharyngeal pressures.
- Gallas, 2009 – Sensory stimulation benefits dysphagia rehabilitation post-stroke.
- Hara, 2020 – sensory stimulation utilizing interferential current in dementia patients with dysphagia reduced cough latency times.
- Heijnen, 2012 – Motor and sensory stimulation levels benefitted Parkinson’s patients equally.
- Jungheim, 2014 – Motor and sensory stimulation have favorable effect on upper esophageal sphincter dynamics; motor slightly better than sensory.
- Ludlow, 2007 – Sensory level stimulation improved swallow safety. Motor stimulation caused hyoid descent and, surprisingly, further improvement of swallow efficacy.
- Park, 2009 – Post-stroke patients in the motor level group showed significantly increased hyolaryngeal excursion as compared to the sensory level group.
- Park, 2012 – Post-stroke patients receiving motor level stimulation below the hyoid demonstrated a significantly better increase hyolaryngeal excursion and PES opening than patients in sensory level group.
- Rofes, 2013 – Sensory and motor stimulation both improved swallow safety. Only motor level stimulation improved swallow efficacy.
- Umay, 2017 – Sensory stimulation of the skin over bilateral Masseter muscles in acute stroke patients produces better outcomes than sham stimulation.
- Zhang, 2015 – Sensory and motor electrical stimulation with traditional therapy yielded better outcomes than no electrical stimulation in brainstem stroke patients. Sensory level electrical stimulation yielded better results than motor level stimulation in this population.

### **Use in Parkinson’s patients**

- Heijnen, 2012 – no effect noted of addition of electrical stimulation, either sensory or motor.

- Baijens, 2012 – no effect noted of addition of electrical stimulation, either sensory or motor.
- Baijens, 2013 – no effect noted of addition of electrical stimulation, either sensory or motor.
- Park, 2018 – Positive effect noted on hyoid superior and anterior excursion and better Penetration-Aspiration scale scores for NMES with concurrent effortful swallowing as compared to effortful swallowing alone.

### **Use in Head and Neck Cancer patients**

- Peng, 2016 – Suggests favorable effect of NMES to counter the genetic mutation occurring during radiation therapy.
- Bhatt, 2015 – Favors use of NMES.
- Langmore, 2015 – No significant effect found for use of NMES without concurrent exercise in chronic dysphagic patients status post radiation.
- Linkov, 2011 – Use of VitalStim in animal model directly over malignant tumor did not exacerbate tumor growth.
- Long, 2013 – VitalStim used as an adjunct to dilatation significantly increased swallow function in post-radiation patients.
- Pattani, 2010 – Use of NMES significantly improved xerostomia symptoms in post radiation patients.
- Ryu, 2008 – RCT on use of VitalStim in patients status post radiation. Electrical stimulation group showed significantly better outcomes.

### **Use in Stroke patients**

- Bülow, 2008 – sample size too small to detect effect of NMES.
- Chen, 2015 – Meta-analysis favoring use of NMES post stroke.
- Gallas, 2009 – Sensory level stimulation benefits chronic post-stroke patients.
- Huang, 2014 – NMES benefits acute stroke patients.
- Kushner, 2013 – NMES improves outcomes when added to traditional therapy in acute stroke.
- Lee, 2014 – NMES better than traditional dysphagia therapy in acute stroke; all electrodes infrahyoid.
- Li, 2015 – VitalStim with concurrent exercise significantly better than VitalStim alone or exercise alone in stroke patients.
- Lim, 2009 – NMES significantly better than thermotactile stimulation in stroke patient.
- Lim, 2014 – NMES and transcranial direct current stimulation both superior to traditional dysphagia therapy in subacute stroke patients.
- Park, 2009 – Motor level stimulation significantly benefits hyolaryngeal excursion post-stroke.
- Park, 2012 – Motor level stimulation significantly benefits hyolaryngeal excursion and PES opening post-stroke.

- Permsirivanich, 2009 – sEMG triggered stimulation of thyrohyoid significantly benefits swallow safety and efficacy in post-stroke patients.
- Rofes, 2013 – Sensory and motor stimulation both improved swallow safety in post-stroke patients. Only motor level stimulation improved swallow efficacy.
- Sun, 2013 – NMES significantly benefits post-stroke patients with moderate to severe dysphagia.
- Tan, 2013 – Meta-analysis favoring use of NMES post stroke.
- Xia, 2011 – VitalStim with concurrent exercise significantly better than VitalStim or exercise alone in post-stroke patients.
- Zhang, 2015 – Sensory and motor stimulation both improved swallow safety and efficacy versus no stimulation in post-medullary stroke patients. Sensory stimulation improved better than motor stimulation in this population.

**Meta-analyses** – Five meta-analyses have been performed, all favoring the addition of NMES to an active exercise program.

- Alamer, 2020 – NMES for post-stroke dysphagia.
- Cheng, 2019 – NMES in treating adults with dysphagia.
- Carnaby-Mann, 2007 – NMES for dysphagia.
- Chen, 2015 – NMES for post-stroke dysphagia.
- Tan, 2013 – NMES for non-stroke dysphagia.

**Review articles and opinion papers** – Various literature review articles and opinion papers have been written on the use of transcutaneous electrical stimulation in the treatment of dysphagia. They are listed below in chronological order of publication. The reader is advised to consider the publication date and assess the scope of the review accordingly.

- Clark, 2009: Evidence-based systematic review: effects of neuromuscular electrical stimulation on swallowing and neural activation.
- Huckabee, 2007: Emerging modalities in dysphagia rehabilitation: neuromuscular electrical stimulation.
- Humbert, 2012: Electrical stimulation and swallowing: How much do we know?
- Miller, 2013: Electrical stimulation in treatment of pharyngolaryngeal dysfunctions.
- Crary, 2014: Adoption into clinical practice of two therapies to manage swallowing disorders: exercise based swallowing rehabilitation and electrical stimulation.
- Poorjavad, 2014: Surface electrical stimulation for treating swallowing disorders after stroke: A review of the stimulation intensity levels and the electrode placements.

- Barikroo, 2018: Follow up survey on the adoption into clinical practice of electrical stimulation in the treatment of dysphagia.

**Excluded papers** –The following is a list (not exhaustive) of publications that were not included in this review (mainly due to lower level design).

- Boswell, 1985 – Case study reporting positive effect of use of electrical stimulation on side effects of radiation.
- Bauer, 1984 – Case study reporting positive effect of use of electrical stimulation on xerostomia post-radiation.
- Cheung, 2010 – Case study reporting positive effects of use of NMES in dysphagic patient with Sjögren’s syndrome.
- Freed, 2001 – Publication on subset of patients studied as part of data collection for purposes of FDA 510(k) clearance.
- Kiger, 2006 – Study reporting no benefit on sEMG recordings of stimulated muscles post treatment.
- Lee, 2012 – Case study reporting positive effect of using NMES in patient with Wilson’s disease.
- Oh, 2007 – Case series suggesting positive impact of NMES on cortical re-organization.
- Rice, 2012 – Several case studies suggesting positive effect of adding NMES to treatment regime in early intervention population.
- Shaw, 2005 – Retrospective review of outcomes focused on healthcare economics measures.

## Literature review

The following is a complete list of papers on the subject of surface electrical stimulation for the treatment of dysphagia. (last update 01/16/2019)

*Arslan, 2018: Effect of submental NMES on swallowing kinematics.*

Design:	Prospective observational
Objective:	Evaluate effects of submental SES on hyo-laryngeal kinematics during swallowing
Subjects:	30 healthy adults
Method:	Subjects received submental SES while swallowing 50 times (using an error-based learning paradigm).
Outcome measures:	Hyoid and laryngeal kinematic measures (starting position, peak position).
Results:	Submental SES did not alter any hyo-laryngeal swallowing kinematic measures. However, submental SES significantly changed the starting position of the hyoid bone just prior to the swallow onset. On average, submental SES immediately prior to swallow onset can

position the hyoid approximately 20% closer to its peak swallowing point.

*Baijens, 2012: Surface ES in dysphagic Parkinson's patients.*

- Design:** Case Control Study
- Objective:** Describe the effects of a single session of surface electrical stimulation in different electrode positions in 10 patients with Parkinson's disease and oropharyngeal dysphagia.
- Subjects:** 10 mentally competent dysphagic patients with a diagnosis of Parkinson's disease and 10 healthy controls
- Method:** ES was delivered using 3 electrode placements while 12 total trials of 10cc of thin liquid barium were administered by syringe under videofluoroscopy.
- Outcome measures:** Temporal, spatial and visuoperceptual variables were scored by raters who were blinded to the group, electrode placement and current status.
- Results:** For most of the temporal, spatial and visuoperceptual variables tested using the ES, no statistically significant changes were found. Some temporal and spatial variables were found to be significant in both groups regardless of stimulation status.

*Baijens, 2013: Surface ES in dysphagic Parkinson's patients.*

- Design:** Randomized control study
- Objective:** Describe the effects of a series of treatment sessions session of surface electrical stimulation in different electrode positions in 10 patients with Parkinson's disease and oropharyngeal dysphagia.
- Subjects:** 90 mentally competent dysphagic patients randomly allocated to 3 groups: standard logopedic treatment with no added stimulation, standard logopedic treatment with added sensory stimulation or standard logopedic treatment with added motor level stimulation.
- Method:** ES was delivered 5x weekly for 3 weeks. Stimulation was delivered to the submental region (suprahyoid) only.
- Outcome measures:** Temporal, spatial and visuoperceptual variables were scored by raters who were blinded to the group, electrode placement and current status.
- Results:** Some of the temporal, spatial and visuoperceptual variables showed statistically significant improvement in



all groups. No significant difference was noted between the electrical stimulation groups and the no stimulation groups, suggesting the positive effect was attributable to the standard logopedic treatment techniques.

*Barikroo, 2017: Effect of NMES on swallow kinematics in young and older volunteers.*

- Design:** Randomized controlled double-blind study
- Objective:** To compare the effect of transcutaneous electrical stimulation amplitude on timing of lingual–palatal and pharyngeal peak pressures during swallowing in healthy younger and older adults.
- Subjects:** 34 healthy adults (20 younger and 14 older).
- Method:** Volunteers swallowed 10 ml of nectar-thick liquid under three stimulation conditions: no stimulation, low-amplitude stimulation and high-amplitude stimulation. Stimulation was delivered by surface electrodes on the anterior neck.
- Outcome measures:** Timing of pressure peaks for lingual–palatal contacts and pharyngeal pressures were measured under each condition.
- Results:** A significant age × stimulation amplitude interaction was identified for the base of tongue and the hypopharynx. At the base of tongue, low-amplitude electrical stimulation resulted in slower swallows in the younger adults compared with no electrical stimulation. In older adults, low-amplitude electrical stimulation resulted in faster swallows compared with high-amplitude electrical stimulation. At the hypopharynx, no significant differences were identified in pressure timing across the electrical stimulation amplitudes in both age groups. In each case, low-amplitude electrical stimulation resulted in faster swallows in older adults compared with younger adults.

*Barikroo, 2018: Impact of pulse duration and frequency on perceived comfort during NMES.*

- Design:** Descriptive physiology study
- Objective:** Compare the impact of varying levels of pulse duration and frequency on the maximum tolerated amplitude and discomfort in healthy older adults.
- Subjects:** 24 healthy older adults.

Method: Electrical stimulation was delivered to the submental region. Subjects were evaluated in multiple stimulation conditions: frequency of 30 Hz vs 80 Hz and pulse duration of 300  $\mu$ sec versus 700  $\mu$ sec.

Outcome measures: Maximum tolerated amplitude and perceived tolerance.

Results: Maximal amplitude tolerance and perceived discomfort were significantly improved with lower frequency and lower pulse duration.

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

Design: Prospective observational study without control arm

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.

*Beom, 2011: Prospective study of effects of ES on dysphagia after brain injury.*

Design: Prospective non-concurrent control comparative design.

Objective: To observe the effect of repetitive electrical stimulation of the suprahyoid muscles in dysphagic patients with brain injury.

Subjects: 28 acute brain injury patients with dysphagia (26 x stroke, 2 x TBI).

Method: Patients admitted between January '06 and March '07 (n=21) received conventional therapy only (CDM group). Patients admitted between April '07 and July '07 (n=7) received conventional swallowing exercise therapy with concurrent electrical stimulation (ESSM group). Electrical stimulation parameters were as follows: frequency = 60 pps, pulse duration = 500  $\mu$ sec; duty cycle = 1 sec ON/1 sec OFF. Treatments were delivered 2x per day for 30 minutes, 5 days per week x 4 weeks.

Outcome measures: VDS, ASHA-NOMS.

Results: Both groups improved but without significant differences between the study groups.

- Comments: 1) Electrical stimulation protocol used was a sensory protocol with a 1:1 duty cycle and intensity defined as “maximal tolerable”. Since tolerance differs between subjects, it is difficult to interpret these results.
- 2) Conventional treatment group was significantly larger than electrical stimulation group (21 vs. 7). Etiology between groups also differed significantly with 9 of 21 patients in the CDM group with lesions located in the brainstem, compared to 0 of 7 in the ESSM group. Chronicity of the lesion also differed.

*Beom, 2015: Effect of supra- vs. infrahyoid electrode placement in patients with brain injury.*

- Design: Randomized prospective non-concurrent control comparative design
- Objective: To compare the effect of repetitive electrical stimulation of suprahyoid muscles versus concurrent supra- and infrahyoid muscles in dysphagic patients with brain injury.
- Subjects: 132 brain injury patients with dysphagia. Diagnoses included CVA, TBI, tumor.
- Method: Patients were randomized to one of 2 groups: the SI group had 2 pairs of electrodes in supra- and infrahyoid placements; the SM group had 2 pairs of electrodes placed submentally, above the hyoid bone. The SI group received motor level stimulation with the VitalStim device and protocol (frequency: 80 pps; pulse duration: 700  $\mu$ sec; duty cycle: near continuous). The SM group received stimulation with a modified protocol (frequency: 50 pps, pulse duration: 500  $\mu$ sec; duty cycle: not specified. Patients received traditional swallowing exercise concurrently to the electrical stimulation. 10 to 15 sessions of 30 minutes were delivered over 2-3 weeks.
- Outcome measures: Functional Dysphagia Scale, penetration/aspiration as per videofluoroscopy.
- Results: Patients in both groups improved without significant differences between groups.
- Comments: 1) Since the kinematic effect on hyolaryngeal structures of the 2 placements is different, the absence of significant differences between groups suggest that sensory stimulation may have a significant effect on the therapeutic outcome, more so than the effect of the motor contraction.

2) The study results must be interpreted with caution due to the heterogeneity of etiology and chronicity (5-1,095 days post injury). Also, different stimulation protocols were used for both groups, rendering comparison between groups less reliable.

*Berretin-Felix, 2014: Effect of motor and sensory level stimulation on swallow physiology.*

- Design:** Physiology study.
- Objective:** To investigate the effect of different intensity levels of transcutaneous electrical stimulation of supra- and infrahyoid musculature on intraoral and pharyngeal pressures during swallowing.
- Subjects:** 20 young (20-30 years old) and 14 elderly (60-79 years old) healthy subjects.
- Method:** 2 electrodes were placed horizontally above hyoid over suprahyoid musculature and 2 electrodes were placed horizontally between thyroid cartilage and hyoid bone over thyrohyoid muscles. Participants swallowed 3 different consistencies (thin liquid, thick liquid and pudding) in 3 conditions: with no stimulation, with sensory stimulation and with motor stimulation.
- Outcome measures:** Pressures between tongue and hard palate, at the base of the tongue and in the hyopharynx.
- Results:** Anterior tongue pressure was reduced in both groups during motor level stimulation. Posterior tongue pressure was increased for older adults with motor level stimulation. Motor level stimulation produced a positive increase in hypopharyngeal pressures in younger and older adults.

*Bhatt, 2011: NMES for dysphagia in patients with head and neck cancer.*

- Design:** Retrospective non-concurrent control comparative design
- Objective:** To investigate the role of transcutaneous neuromuscular electrical stimulation (TNMES) in maintaining swallowing function during chemoradiation for locally advanced head and neck cancer.
- Subjects:** 43 consecutive patients with locally advanced head and neck cancer were treated with TNMES. Outcomes were compared with 55 historical control patients.
- Method:** Records for patients receiving TNMES were evaluated and compared to historical records for patients who

received traditional therapy without TNMES. Validated swallowing scale scores were assigned.

- Outcome measures: Functional Oral Intake Scale score.
- Results: All patients swallowing scores declined post CT+RT. A difference in mean decline in scores for CG versus TG using Functional Oral Intake Scale was seen, favoring TNMES intervention. TNMES group showed better gains in swallowing ability than traditional therapy.

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

- Design: Retrospective case control study
- Objective: Compare effect of electrical stimulation 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 Thermal Stimulation.
- Outcome measures: Swallow ability on non-validated swallow scale.
- Results: Patients who had received electrical stimulation received fewer treatments and required shorter hospitalization. Swallow score improvement were superior for electrical stimulation group.

*Bogaardt, 2008: Use of NMES in the treatment of dysphagia in multiple sclerosis patients.*

- Design: Case series
- 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.

*Bülow, 2008: ES versus traditional therapy.*

- Design:** Multi-center randomized controlled study
- Objective:** Compare effect of use of electrical stimulation 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. Videofluoroscopy 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.

*Byeon, 2020: Effect of combined NMES with Mendelsohn maneuver on dysphagia.*

- Design:** Prospective case series
- Objective:** To assess and compare the effectiveness of using NMES combined with the Mendelsohn maneuver versus either intervention alone.
- Subjects:** 43 patients with dysphagia secondary to subacute CVA.
- Method:** Patients were assigned to the Mendelsohn group (n=15), the NMES group (n=13) or the combined NMES + Mendelsohn group (n=15).
- Outcome measures:** Functional Dysphagia Scale (FDS) and Swallowing Quality of Life questionnaire (SWAL-QOL).
- Results:** FDS and SWAL-QOL scores were highest for the combined group and lowest for the NMES alone group.

*Calabrò, 2016: NMES in chronic neurogenic dysphagia.*

- Design:** Prospective case study
- Objective:** To assess the effectiveness of the VitalStim device, and to investigate the neurophysiological mechanisms underlying functional recovery.
- Subjects:** A 34-year-old man with severe chronic dysphagia post TBI.

**Method:** Patient underwent two different intensive rehabilitation trainings, including either conventional rehabilitation alone or coupled to VitalStim training.

**Outcome measures:** Patient swallowing function was evaluated in two separate sessions (i.e. before and after the two trainings) by means of ad hoc swallowing function scales and electrophysiological parameters (rapid paired associative stimulation).

**Results:** The patient did not report any side effects either during or following both the intensive rehabilitation trainings. An important improvement in swallowing function was observed only after Vitalstim training with the patient eventually being able to safely eat solid food.

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

**Design:** Meta-analysis

**Objective:** Evaluate effect of use of electrical stimulation 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 electrical stimulation for dysphagia. A case series.*

**Design:** Prospective case series

**Objective:** Evaluate effect of use of electrical stimulation 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.

*Carnaby, 2019: MDTP versus MDTP+NMES versus Usual Care.*

Design: Double-blind placebo controlled randomized trial

Objective: Assess and compare an exercise-based intervention (MDTP) with MDTP + additional NMES versus ‘usual care’.

Subjects: 53 subacute stroke patients.

Method: Patients were randomized to an MDTP group, an MDTP with concurrent NMES group or a Usual Care group.

Outcome measures: Clinical swallowing ability, oral intake, weight, patient perception of swallow and occurrence of dysphagia related complications.

Results: Patients in the MDTP group showed the greatest improvement.

*Chen, 2015: NMES for dysphagia after stroke; a meta-analysis.*

Design: Meta-analysis

Objective: Assess whether swallow treatment with NMES is superior to that without NMES, and whether NMES alone is superior to swallow therapy.

Subjects: Pubmed and Scopus databases were searched for randomized or quasi-randomized English-language studies published before December 31, 2014. Subjects included in the study were adult stroke patients with



dysphagia that were treated with NMES. 8 studies were identified that met the inclusion criteria.

- Method:** The meta-analysis compared, (1) swallow treatment with NMES vs. swallow treatment without NMES, and (2) NMES vs. traditional swallow therapy. The eight studies included 329 patients with post-stroke dysphagia.
- Outcome measures:** Included studies used different outcome measures, including Functional Oral Intake Scale, Videofluoroscopy, Pen-Asp scale, and others. Change scores were extracted and a standardized mean difference (SMD) calculated.
- Results:** SMD was significant when comparing swallow treatment with NMES to swallow treatment without NMES. The comparison of NMES alone with swallow therapy demonstrated a non-significant SMD. Swallow treatment with NMES seems to be more effective than that without NMES for post-stroke dysphagia.

*Choi, 2016: NMES for oral/facial strengthening in post-stroke patients.*

- Design:** Descriptive physiology study
- Objective:** To determine the influence of NMES parameters on the excitability of corticobulbar projections to the submental musculature.
- Subjects:** Nine dysphagic subjects post-stroke.
- Method:** Patients received NMES (VitalStim device and protocol) to the paretic side of the face (over buccal branch). Electrical stimulation was applied at submaximal motor level (grabbing sensation, small visible contraction) for 30 minutes a day, 5 days a week, for 4 weeks.
- Outcome measures:** Maximal cheek strength (MCS) and maximal lip strength (MLS) as measured with IOPI (Iowa Oral Performance Instrument); VFSS assessment of swallow function; Videofluoroscopy Dysphagia Scale; 7 subtests of oral stage function were also analyzed: lip closure, bolus formation, mastication, apraxia, tongue to palate contact, premature bolus loss, and oral transit time.
- Results:** MCS and MLS improved following intervention from  $14.3 \pm 3.4$  to  $18.4 \pm 2.8$  kPa and from  $10.6 \pm 2.7$  to  $13.4 \pm 2.7$  kPa, respectively. The oral phase VDS score statistically significantly decreased from  $27.0 \pm 5.0$  to  $22.2 \pm 4.3$  points.

*Doeltgen, 2010: Frequency of electrical stimulation and submental muscle facilitation.*

Design: Descriptive physiology study

Objective: To determine the influence of NMES parameters on the excitability of corticobulbar projections to the submental musculature.

Subjects: 25 healthy volunteers subjects.

Method: Transcranial magnetic stimulation (TMS) was used in event-related protocols, triggered by either volitional contraction of the submental muscles or pharyngeal swallowing, to assess corticobulbar excitability prior to, immediately following, and 30, 60, and 90 minutes post-NMES. In the first 2 experiments, 4 stimulus frequencies (5, 20, 40, and 80 Hz) and 3 NMES dosages, manipulated through stimulus train durations or number of repetitions, were evaluated.

Outcome measures: MEP amplitude.

Results: 80Hz NMES increased motor-evoked potential (MEP) amplitude at 30 minutes and 60 minutes poststimulation after 60 repetitions of 4-s event-related NMES trains. Non-event-related and continuous NMES did not affect MEP amplitudes.

Comments: Findings are relevant to dysphagia therapists utilizing NMES as questions often arise about best frequency to use for different patients. A limitation of the present study is that it was performed in healthy volunteers, not dysphagic patients.

*Frost, 2018: Traditional therapy with or without NMES in chronic dysphagia.*

Design: Prospective case series

Objective: Evaluate effects of the addition of NMES to current rehabilitation programs in the United Kingdom.

Subjects: 10 adult patients with chronic dysphagia of neurological etiology.

Method: Patients received 5 weeks of traditional swallowing therapy followed by 5 weeks of traditional swallowing therapy combined with NMES. NMES was delivered with the VitalStim device. Treatment sessions were delivered 3x per week.

Outcome measures: FOIS, SWALQOL

Results: FOIS score improved in 9 out of 10 patients after receiving the NMES phase of treatment.

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

**Design:** Outcomes study

**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.

*Guillén-Solà, 2017: Respiratory muscle training with concurrent NMES in dysphagia.*

**Design:** Prospective, single-blind, randomized-controlled trial.

**Objective:** To evaluate the effectiveness of inspiratory/expiratory muscle training (IEMT) and neuromuscular electrical stimulation (NMES) to improve dysphagia in stroke.

**Subjects:** 62 patients with dysphagia were randomly assigned to standard swallow therapy (SST) (Group I, controls, n=21), SST + IEMT (Group II, n=21) or SST + sham IEMT + NMES (Group III, n=20).

**Method:** All patients followed a 3-week standard multidisciplinary rehabilitation program of SST and speech therapy. The SST + IEMT group's muscle training consisted of 5 sets/10 repetitions, twice-daily, 5 days/week. Group III's sham IEMT required no effort; NMES consisted of 40-minute sessions, 5 days/week, at 80Hz.

**Outcome measures:** Dysphagia severity, assessed by Penetration-Aspiration Scale, and respiratory muscle strength (maximal inspiratory and expiratory pressures) at the end of intervention and 3-month follow-up.

**Results:** Maximal respiratory pressures were most improved in Group II. Swallowing security signs were improved in Groups II and III at the end of intervention. No differences in Penetration-Aspiration Scale or respiratory

complications were detected between the 3 groups at 3-month follow-up.

*Hamada, 2017: Sensory stimulation to prevent pneumonia in acute stroke.*

- Design: Prospective observational study.
- Objective: Investigate the effects of adding sensory level surface electrical stimulation on the risk of developing aspiration pneumonia post-stroke.
- Subjects: 53 dysphagic acute post-stroke patients.
- Method: Subjects received sensory electrical stimulation in addition to usual care.
- Outcome measures: Occurrence of aspiration pneumonia.
- Results: Risk of pulmonary infection was significantly decreased in the general dysphagia/surface e-stim combination therapy group.

*Hara, 2020: Interferential current sensory stimulation in dysphagic nursing home patients with dementia.*

- Design: Prospective study
- Objective: Determine the efficacy of interferential current transcutaneous electrical sensory stimulation (IFC-TESS) in patients with dementia who were being treated for dysphagia in nursing homes under normal living condition.
- Subjects: 54 dysphagic nursing home patients with dysphagia.
- Method: Subjects received sensory level electrical stimulation utilizing interferential current for 2 sessions per day, 5 days per week, for 3 weeks.
- Outcome measures: Primary outcome measure was change in cough latency time. Secondary outcome measures were cough frequency, functional oral intake scale (FOIS) score and oral calorie intake.
- Results: The cough latency times before and after the 3-week intervention were 15.8 (7.0–60.0) and 6.7 (3.6–30.7) s/min, respectively. IFC-TESS improved the cough reflex and oral calorie intake in older nursing home residents with dementia.

*Heck, 2012: Effect of submental NMES on pharyngeal pressure generation.*

- Design: Descriptive physiology study

**Objective:** Investigate the immediate and late effects of submental event-related NMES on pharyngeal pressure generation during non-effortful and effortful saliva swallows.

**Subjects:** 20 healthy volunteers (10 male, 10 female)

**Method:** Subjects received 80Hz NMES of 4 second duration to submental area. Stimulation was timed to 60 volitional saliva swallows at intervals of 1 swallow per every 30 seconds.

**Outcome measures:** Manometric measures of peak pressures and duration of pressure events in the oropharynx, hypopharynx, and the upper esophageal sphincter were taken during non-effortful and effortful saliva swallows. Measures were taken at baseline, during stimulation, and at 5, 30 and 60 minutes post-stimulation.

**Results:** Baseline pharyngeal and upper esophageal sphincter pressures did not differ between stimulated and non-stimulated swallows. At 5 and 30 minutes post stimulation, peak pressure decreased at the hypopharyngeal and at the upper esophageal sphincter sensor during non-effortful swallows. Across all assessment times, effortful swallows consistently generated greater peak pharyngeal pressures and lower upper esophageal sphincter pressures than non-effortful swallows. The effect lasted up to an hour only in the hypopharynx. No changes in duration of pressure events were noted.

*Heijnen, 2012: NMES vs traditional therapy in dysphagic patients with Parkinson's disease.*

**Design:** 3 arm randomized comparative effect study

**Objective:** To compare the effects of traditional logopedic dysphagia treatment with those of neuromuscular electrical stimulation (NMES) as adjunct to therapy on the quality of life in patients with Parkinson's disease and oropharyngeal dysphagia.

**Subjects:** 88 patients were randomized to 3 treatment groups: traditional treatment (TT) alone, TT + sensory level stimulation (NMES-S), and TT + motor level stimulation (NMES-M).

**Method:** TT group received a combination of traditional dysphagia treatment interventions (oral motor exercise, airway protection maneuvers, postural compensation); NMES-S and NMES-M had 2 electrodes placed submentally with intensity set to sensory level and motor level respectively.

Outcome measures: SWAL-QOL, MD Anderson Dysphagia Inventory (MDADI), Dysphagia Severity Scale, Functional Oral Intake Scale. Measurements were taken pre-treatment, post-treatment and at 3 months follow up. Data were also captured using FEES and MBS evaluations.

Results: All groups improved on quality of life measures but not on functional scores. No significant changes between groups were noted.

*Huang, 2014: Functional outcomes of NMES for dysphagia in acute stroke.*

Design: Prospective randomized controlled trial.

Objective: To evaluate the functional recovery of stroke patients comparing swallowing therapy with and without the addition of NMES.

Subjects: 29 patients with oropharyngeal dysphagia as a result of recent hemispheric stroke (less than 3 months ago), randomly assigned to one of 3 treatment groups: traditional swallowing therapy (TS), oropharyngeal neuromuscular electrical stimulation (NMES) or combined NMES/TS.

Method: All patients received a total 10 therapy sessions of 60 minutes each, 3 x per week. Patients in the TS group received oral exercise, compensatory techniques (e.g., chin tuck, head tilt, and head rotation), faucial thermal-tactile stimulation, and swallowing therapeutic maneuvers (e.g., supraglottic swallowing, effortful swallowing, and the Mendelsohn maneuver); patient in the NMES group received electrical stimulation at a submaximal motor level intensity (patient felt a contraction) with electrodes in midline arrangement above and below the thyroid notch; patients in the NMES/TS group received the interventions of the TS group while also receiving NMES at the same time.

Outcome measures: Functional oral intake scale score, Penetration-Aspiration Scale, Functional Dysphagia Scale.

Results: Patients in all groups improved. Patients in the NMES/TS groups showed significantly greater improvements in Functional Dysphagia Scale scores than patients in the other groups.

*Huh, 2020: Optimal electrode placement for NMES in post-stroke dysphagia.*

Design: Prospective randomized study

Objective: Determine the optimal placement of electrodes for neuromuscular electrical stimulation (NMES) for post-stroke dysphagia therapy.

- Subjects:** 31 post-stroke patients with dysphagia randomized to 3 groups according to electrode placement. In Group A (n = 10), two pairs of electrodes were attached horizontally on the suprahyoid and infrahyoid muscles. In Group B (n = 11), one pair of electrodes was attached horizontally on the suprahyoid muscles while the other was attached vertically on the infrahyoid muscles. In Group C (n = 10), the electrodes were attached vertically, with one pair above the hyoid bone and the other above the cricoid cartilage.
- Method:** All patients received rehabilitation treatment via NMES combined with effortful swallowing training five times weekly for four weeks.
- Outcome measures:** Functional Dysphagia Scale (FDS) and Dysphagia Outcome and Severity Scale (DOSS) scores.
- Results:** Group A showed significantly greater improvement than Group B in overall FDS ( $p = 0.009$ ) and pharyngeal-phase FDS (FDS-P;  $p = 0.005$ ) scores. Group A also showed significant improvement when compared with Group C in overall FDS ( $p = 0.001$ ) and FDS-P ( $p = 0.001$ ) scores.

*Humbert, 2006: Effect of electrical stimulation on movement and safety in healthy volunteers.*

- Design:** Descriptive physiology study
- Objective:** To evaluate the influence of different electrode placements on movement of hyoid and larynx and effect on swallow safety.
- Subjects:** 29 healthy 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.

Comments: Results of the study are difficult to relate to the VitalStim treatment condition. The study does not evaluate the VitalStim Therapy treatment condition, but 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. It also did not test the effect for the duration of a typical treatment session nor repeat it for multiple session.

*Humbert, 2013: NMES used as perturbation training.*

Design: Descriptive physiology study

Objective: To evaluate whether adaptive motor learning occurs as a result of using NMES during swallowing as a means to introduce perturbation.

Subjects: 9 healthy volunteers

Method: Single channel electrical stimulation was delivered to the infrahyoid musculature. Stimulation was delivered at sensory (control) and motor levels.

Outcome measures: Peak hyoid and laryngeal movement.

Results: The excursion of both hyoid and larynx showed clear adaptation after introduction of electrical stimulation. This effect was evident during stimulation after first few swallows and immediately after stimulation was removed.

*Jungheim, 2015: Effect of NMES on upper esophageal sphincter relaxation time.*

Design: Prospective randomized experimental trial.

Objective: To evaluate the influence of NMES on opening and closing dynamics of the upper esophageal sphincter.

Subjects: 26 healthy adult volunteers were recruited for the study (9 male, 17 female).

Method: Volunteers were asked to swallow 2 mL of water under 3 different conditions: during sham stimulation (0 mA), during motor stimulation (20 mA) and during submotor stimulation (10 mA). Stimulation consisted of a single biphasic pulse (pulse duration of 5 ms) applied bilaterally through 2 active electrodes fixed to the anterior neck on either side of the larynx and one neutral electrode fixed to the posterior neck. Intraluminal pressures were recorded and compared to reference values taken during swallowing without any stimulation.

Outcome measures: Manometric pressure values at level of upper esophageal sphincter as measured from intraluminal catheter.



**Results:** Swallows during stimulation at both intensity levels showed decreased upper esophageal sphincter pressures and increased relaxation times as compared to sham stimulation. Comparison of the stimulation levels (10 and 20 mA) showed a trend favoring the motor level stimulation.

*Jungheim, 2017: Influence of submandibular NMES on pharyngeal kinematics.*

**Design:** Prospective kinematic study.

**Objective:** To evaluate the influence of two different NMES protocols on intraluminal pressure generation and dynamics of the upper esophageal sphincter.

**Subjects:** 29 healthy adult volunteers.

**Method:** Volunteers were asked to swallow water swallows after receiving continuous NMES for 10 min in the submandibular region using one of two different stimulation protocols: low-frequency stimulation and mid-frequency stimulation.

**Outcome measures:** Manometric pressure values in the pharynx and at level of upper esophageal sphincter as measured from intraluminal catheter with high-resolution manometry.

**Results:** Maximum tongue base pressure increased by 8.4% following stimulation with the medium frequency protocol. Changes in UES function were not found. The low frequency protocol did not produce any significant changes in the parameters examined.

*Kim, 2015: Impact of NMES on movement of hyolaryngeal structures.*

**Design:** Prospective case control study

**Objective:** Assess movements of hyolaryngeal structures during surface electrical stimulation utilizing 3 different electrode placements: supra- and infrahyoid, infrahyoid only and midline.

**Subjects:** 20 healthy volunteers.

**Method:** Movements of the hyolaryngeal structures during swallow of 5 ml of diluted barium liquid were compared to movements that occurred during electrical stimulation of the musculature at maximal motor level.

**Outcome measures:** Kinematic measurements of the hoid bone using videofluoroscopy.

**Results:** Hyoid bone was initially displaced inferiorly and anteriorly by the electrical stimulation, however it

reached the same end position as during no stimulation. Results were the same for all 3 electrode positions.

Comments:

1) The study confirms that maximal motor level stimulation of the infrahyoid musculature in healthy adults causes a descent of the hyoid bone.

2) The fact that the hyoid bone still reaches the same end point suggests that the muscles moving the hyoid up and forward end up producing more work to move the hyoid bone over the greater distance and against resistance.

*Kim, 2017: Use of NMES as a resistor in post-stroke dysphagia.*

Design: Randomized controlled single-blinded study

Objective: Evaluate the effect of effortful swallow combined with surface electrical stimulation as a form of resistance training on pharyngeal constriction function in post-stroke patients with dysphagia.

Subjects: 19 post-stroke patients with dysphagia.

Method: Patients received 20 min effortful swallow training with resistive electrical stimulation for 5 days per week for 4 weeks. Electrical stimulation was applied on the infrahyoid area as resistance against hyoid elevation. Stimulation intensity was adjusted daily up to the maximum tolerable level of the participant.

Outcome measures: Blinded biomechanical measurements of the extent of hyoid elevation were taken and the pharyngeal constriction ratio (PCR) determined after training. The change of the PCR and the relationship between hyoid elevation and the PCR were evaluated.

Results: Post-training PCR was significantly decreased compared to pre-training PCR. There was a high inverse correlation between the hyoid elevation and the PCR suggesting that resistive electrical stimulation training increases pharyngeal constriction.

*Ko, 2016: Effect of NMES on dysphonia in stroke and TBI patients.*

Design: Controlled pilot study

Objective: To investigate the effect of laryngopharyngeal neuromuscular electrical stimulation (NMES) on dysphonia in patients with dysphagia caused by stroke or traumatic brain injury (TBI).

Subjects: 18 patients with stroke (n=16) or TBI (n=2).

**Method:** subjects were divided into conventional swallowing training only (CST, n=6) and CTS + NMES (n=12) groups. Patients received 5 60-minute sessions per week for 4 weeks. Patients in the NMES group received NMES using the VitalStim equipment with electrodes placed on either side of the thyroid notch and at the level of the hyoid bone.

**Outcome measures:** Perceptual, acoustic and aerodynamic analyses. The correlation between dysphonia and swallowing function was also investigated utilizing the functional dysphagia scale.

**Results:** Significant differences in the GRBAS (grade, roughness, breathiness, asthenia and strain scale) total score and sound pressure level (SPL) between the two groups over time. The improvement of the total GRBAS scores at 2 weeks was positively correlated with the improved pharyngeal phase scores on the functional dysphagia scale at 2 weeks.

*Kushner, 2013: NMES for dysphagia in acute stroke patients in inpatient rehab.*

**Design:** Case control study

**Objective:** Compare the efficacy of neuromuscular electrical stimulation in addition to traditional dysphagia therapy including progressive resistance training with that of traditional dysphagia therapy/progressive resistance training alone during inpatient rehabilitation for treatment of feeding tube-dependent dysphagia in patients who have had an acute stroke.

**Subjects:** 92 dysphagic acute stroke patients. Initial Functional Oral Intake Scale scores of 3 or lower and profound to severe feeding tube-dependent.

**Method:** 65 patients, the NMES group, received NMES with traditional dysphagia therapy/progressive resistance training; 27 patients, the case-control group, received only traditional dysphagia therapy/progressive resistance training. Treatment occurred in hourly sessions daily. Initial Functional Oral Intake Scale score in the NMES group was significantly worse than in the case-control group.

**Outcome measures:** Functional Oral Intake Scale scores before and after intervention.

**Results:** Mean gain for the NMES group with traditional dysphagia therapy/progressive resistance training was 4.4

points; and for the case-control group, 2.4 points. Significant improvement in swallowing performance was found for the NMES group compared with the control group. Within the NMES group, 46% (30 of 65) of the patients had minimal or no swallowing restrictions (Functional Oral Intake Scale score of 5-7) after treatment, whereas 26% (7 of 27) of those in the case-control group improved to Functional Oral Intake Scale scores of 5-7, a statistically significant difference.

*Kushner, 2019: Traditional Dysphagia Therapy (TDT) versus TDT + NMES.*

- Design:** Retrospective case control study
- Objective:** Compare swallowing outcomes and discharge destinations in acute stroke patients treated in an inpatient rehabilitation (IR) setting with traditional dysphagia therapy or NMES.
- Subjects:** 359 patient charts were reviewed. Patients had dysphagia secondary to acute stroke and had a FOIS score of 3 or lower (feeding tube dependent). Patients received either usual care (n=169) or traditional therapy + NMES (n=190).
- Method:** Outcome measures were compared retrospectively. Treatment occurred in hourly sessions, 5 days per week.
- Outcome measures:** FOIS score and discharge destination.
- Results:** NMES with TDT was associated with better discharge swallowing outcomes and FOIS scores than TDT alone during IR in treating acute-stroke feeding-tube-dependent dysphagia; and was associated with more discharges to community and less transfers back to acute-care.

*Langmore, 2015: ES for dysphagia in head and neck cancer patients.*

- Design:** Randomized controlled trial
- Objective:** Evaluate effect of use of ES on swallow function in head and neck cancer patients with chronic dysphagia post radiation.
- Subjects:** 170 adult, chronic dysphagic head and neck cancer patients, 2 years post radiation therapy.
- Method:** Subjects were randomized to one of two groups: electrotherapy (4 sec ON, 12 sec OFF) to submental musculature with concurrent swallowing exercise for 60 swallows per session or sham NMES with same swallowing exercise routine.

Outcome measures: Count of occurrence of penetration and aspiration on video fluoroscopy. Self-perception of Quality Of Life (Head and Neck Cancer Inventory). Diet type (Performance Status Scale).

Results: The addition of NMES did not produce any added benefit to exercise alone. Neither group benefitted significantly.

Comments: Authors used a duty cycle to deliver the current (4/12), as opposed to the more widely adopted protocol of continuous stimulation (VitalStim). The deeply established mechanical restrictions in range of motion due to radiation were probably contributory to the lack of effect of either NMES or exercise.

*Lee, 2014: Early NMES for dysphagia in acute stroke patients.*

Design: Prospective randomized controlled

Objective: To compare the outcome of an early application of neuromuscular electrical stimulation (NMES) combined with traditional dysphagia therapy versus traditional dysphagia therapy only in acute/subacute ischemic stroke patients with moderate to severe dysphagia.

Subjects: 57 dysphagic stroke patient within 10 days after stroke onset.

Method: Patient were randomly assigned into two treatment groups. 31 patients received NMES and traditional dysphagia therapy combined, 26 patients received traditional dysphagia therapy only. NMES was delivered for 30 minutes at max tolerable intensity to infrahyoid musculature targeting the sternohyoid.

Outcome measures: Videofluoroscopy at baseline and 3, 6 and 12 weeks after baseline.

Results: NMES group showed statistically significant improvements better than the traditional dysphagia therapy group at all measurement intervals.

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

Design: Prospective case series

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. Stimulation was delivered for 4 seconds every time it was triggered. Duration of treatment varied from 2-30 days, depending on severity of the condition.

**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.

*Li, 2015: Electrical stimulation and thermo-tactile stimulation after stroke.*

**Design:** Randomized controlled study

**Objective:** To evaluate the effects of electrical stimulation combined with traditional therapy in patients with dysphagia after cortical stroke.

**Subjects:** 45 patients with diagnosed dysphagia after stroke were randomized into one of 3 groups: traditional therapy, VitalStim or VitalStim with traditional therapy.

**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:** Surface EMG (sEMG), standard Swallowing Assessment (SSA), score on Penetration-Aspiration Scale (PAS) via videofluoroscopy, visual analog scale (VAS) of comfort during treatment and satisfaction score on 10-point analog scale.

**Results:** All outcome measures improved significantly more in the VitalStim + traditional therapy group than in the other groups.

*Li, 2019: NMES for dysphagia in Wilson's disease.*

**Design:** Randomized controlled study

**Objective:** To evaluate and compare the effects of NMES vs exercise therapy for dysphagia in patients with Wilson's disease.

**Subjects:** 60 patients with dysphagia secondary to Wilson's disease were randomized to either a swallow exercise group (n=30) or an NMES group (n=30).

**Method:** Patients received treatment for 8 weeks.

Outcome measures: Water swallow test and standardized swallow assessment.  
Results: Swallow improvement was significantly better in the treatment group.

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

Design: Randomized controlled study  
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, pharyngeal transit time measured on videofluoroscopy, comfort during treatment on visual analog scale and satisfaction score on 10-point analog scale. Rater analyzing the videofluoroscopy 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.

*Lim, 2014: Transcranial magnetic stimulation vs NMES in subacute post stroke patients.*

Design: Randomized controlled study  
Objective: To compare the effects of electrical stimulation (VitalStim) and transcranial magnetic stimulation on swallowing function.

- Subjects:** 47 subacute stroke patients (onset <3 months) with diagnosed dysphagia. Patients were randomly assigned to a conventional dysphagia treatment group (CDT), a CDT + repetitive transcranial magnetic stimulation group (rTMS) or to a CDT + neuromuscular electrical stimulation group (NMES).
- Method:** Patients in all groups received CDT (oropharyngeal muscle strengthening, ROM exercises, thermal-tactile stimulation, Mendelssohn maneuver, bolus trials) for 4 weeks (1 session per day, 5 sessions per week). In addition to the CDT, patients in the rTMS group received rTMS for 20 minutes per day, 5 days per week for the first 2 weeks. Patients in the NMES group received daily sessions of NMES (VitalStim device and protocol) in addition to CDT for 30 minutes, 5 days per week for the first 2 weeks.
- Outcome measures:** Functional Dysphagia Scale, pharyngeal transit time (PTT), Penetration-Aspiration Scale (PAS), ASHA National Outcomes Measurement System (NOMS).
- Results:** NMES and rTMS groups showed statistically significant improvements compared to the CDT group on the Functional Dysphagia Scale and PAS outcomes. Differences were not significant for PTT and ASHA-NOMS.

*Lin, 2011: Electrical stimulation in patients with dysphagia post-nasopharyngeal carcinoma.*

- Design:** Randomized controlled trial
- Objective:** Study aimed to assess the effectiveness of functional electrical stimulation on the swallowing function of irradiated nasopharyngeal carcinoma patients with dysphagia.
- Subjects:** 20 patients status post radiation due to nasopharyngeal carcinoma.
- Method:** Patients received either NMES to suprahyoid muscles with active swallowing exercise or received a home exercise program.
- Outcome measures:** Quality of life questionnaire; penetration-aspiration score (PAS), hyoid movement, bolus transit times and pyriform stasis from videofluoroscopy.
- Results:** NMES group did significantly better on all outcome measures.

*Linkov, 2011: Electrical stimulation over squamous cell carcinoma in mice.*



Design: Murine model

Objective: Test the effects of transcutaneous ES on malignant tumor growth.

Subjects: 6 athymic nude mice.

Method: 6 mice were injected with cutaneous squamous cell carcinoma (SCC7) cells to form a solid tumor. The mice were randomized into treatment and control groups. The treatment group received ES directly to the tumor site for 8 days.

Outcome measures: Tumor volumes were measured before, during and after treatment.

Results: ES did not promote the growth of the underlying tumor in the murine model.

Comments: VitalStim device and protocol were used. Absence of harmful effect is potentially very relevant to rehabilitation professionals treating head and neck cancer patients. More research is needed.

*Long, 2013: NMES and dilatation in radiation-induced dysphagia.*

Design: Randomized controlled trial

Objective: Evaluate effect of combination of NMES and balloon dilatation with traditional therapy as compared to traditional therapy alone on swallow safety and efficacy.

Subjects: 60 patients with radiation induced dysphagia status post nasopharyngeal cancer treatment.

Method: Patients were randomly assigned to receive traditional therapy (control group) or traditional therapy plus NMES and dilatation for 4 months.

Outcome measures: Water swallow test (WST) and videofluoroscopic swallowing study were administered before and after treatment. Videofluoroscopy yielded measures for oral transit time, swallow reaction time, pharyngeal transit time and laryngeal closure duration.

Results: The study group showed statistically significantly greater gains in swallow safety and efficacy than the control group. All timing measures showed significantly greater gains in the study group.

*Ludlow, 2007: Use of NMES in chronic dysphagia.*

Design: Case series

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 stimulation with Penetration-Aspiration Scale (PAS) and NIH Swallow Safety Scale (NIH-SSS; scale developed for this study).
Results:	Hyoid bone demonstrated descent during max motor stimulation at rest. PAS scores were not impacted by sensory nor max motor stimulation during swallowing. NIH- SSS scores improved with sensory stim, but not max motor stimulation during swallows. Individual PAS scores improvement was noted in some with a surprising inverse relationship to the degree of hyoid descent during stimulation at rest.
Comments:	<p>1) The study did not test the VitalStim treatment environment (multiple sessions of 30-60 mins each); it observed for movements and swallow safety in various conditions.</p> <p>2) The authors hypothesize that the surprising inverse relationship between PAS scores and hyoid descent in some patients could be attributed to a resistance effect produced by the infrahyoid muscles.</p> <p>3) Several later papers have further evaluated the influence of electrode position on kinematics and swallow safety and efficacy. See Park, 2012; Kim, 2015; Beom, 2015.</p>
	<i>Maeda, 2017: Interferential current sensory stimulation in post-stroke dysphagia.</i>
Design:	Double-blind randomized controlled study
Objective:	Evaluate effect of delivering sensory level interferential current stimulation to the anterior neck on outcomes of dysphagia rehabilitation.

**Subjects:** 43 in-hospital patients with post-stroke dysphagia.

**Method:** Patients were randomly allocated to receive sensory stimulation (SS) or sham stimulation. Electrodes were placed on the neck – the anterior electrodes at the edge of the thyroid cartilage and the posterior electrodes placed 4.0 cm from the ipsilateral electrode – along the mandible. The 15-min SS or sham interventions were undertaken twice per day (am and pm), 5 days per week for 2 weeks. The intensities of the SS and sham interventions were set at 3.0 mA (insufficient to produce muscle contractions) and 0.1 mA, respectively. These procedures were not carried out during meal times or when other therapeutic interventions, such as dysphagia rehabilitation, physical training, and nursing care, were being performed. Participants in both groups received the usual treatment in addition to SS/sham stimulation.

**Outcome measures:** Penetration-Aspiration Scale (PAS) using videofluoroscopy; cough latency times; oral nutritional intake; Functional Oral Intake Scale (FOIS).

**Results:** WST, RSST, and DOSS improved significantly in all groups. Both NMES groups showed significantly greater gains in all measures as compared to control group. A comparison between groups A and B showed no significant difference for the different electrode placements.

*Meng, 2018: NMES in post-stroke dysphagia.*

**Design:** Randomized controlled study

**Objective:** Evaluate effect of addition of NMES to traditional dysphagia therapy in post stroke dysphagia and compare the effect of different electrode placements.

**Subjects:** 30 patients with post-stroke dysphagia.

**Method:** Patients were randomly allocated into treatment group A (TGA), treatment group B (TGB) and control group according to a random number table. The three groups of patients all received traditional dysphagia therapy (TDT). Besides this, NMES treatment was applied on different sites of patients' neck in group A (suprahyoid only) and B (supra- and infrahyoid) separately.

**Outcome measures:** Water swallow test (WST), repetitive saliva swallowing test (RSST) and dysphagia outcome, severity scale (DOSS), and superior/anterior displacement of the

hyolaryngeal complex while swallowing semi-liquid diet as per videofluoroscopy pre-treatment and 2 weeks post-treatment.

**Results:** WST, RSST, and DOSS improved significantly in all groups. Both NMES groups showed significantly greater gains in all measures as compared to control group. A comparison between groups A and B showed no significant difference for the different electrode placements.

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

**Design:** Randomized controlled double-blind study

**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 oral intake 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 intake (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.

*Moon, 2013: Effect of NMES on functional dysphagia scale scores.*

**Design:** Cohort study

**Objective:** To determine the effect of using neuromuscular electrical stimulation in the elderly population.

**Subjects:** 18 elderly (> 70 years of age) healthy adults and 10 healthy younger (< 30 years of age) adults (control group).

**Method:** Subjects received 2 weeks of neuromuscular electrical stimulation, 60 minutes per session, 1 session per day, 5 days per week.

**Outcome measures:** Functional Dysphagia Scale (FDS), Pharyngeal transit Time (PTT)

**Results:** Quality of the swallow improved in the elderly trial group to the point of matching the average Functional Dysphagia Scale score of the younger control group. Specifically, bolus formation, oral residue, timing of the swallow, vallecular and pyriform residuals, and pharyngeal wall coating were all observed to be improved.

*Nam, 2013: Kinematic effects of electrical stimulation on hyolaryngeal excursion.*

**Design:** Case control study

**Objective:** Assess the effect of repeated treatment sessions of electrical stimulation of the neck muscles on the amplitude of hyoid and laryngeal excursion.

**Subjects:** 50 dysphagic patients in a tertiary hospital with acquired brain injury.

**Method:** Patients were randomly assigned into two different treatment groups. One group received electrical stimulation on the suprahyoid muscles only with a modified VitalStim protocol (frequency = 60 Hz, pulse duration = 500  $\mu$ sec); the other group received stimulation according to the VitalStim protocol (frequency = 80 Hz, pulse duration = 700  $\mu$ sec) with one pair of electrodes on the suprahyoid muscles and the other pair on the infrahyoid muscles. All patients received 10-15 sessions of ES over 2-3 weeks. Videofluoroscopy was carried out before and after the treatment.

**Outcome measures:** Temporal and spatial parameters of the hyoid excursion and laryngeal elevation during swallowing were analyzed by two-dimensional motion analysis.

**Results:** The suprahyoid group (n = 25) revealed a significant increase in maximal anterior hyoid excursion distance and velocity, but there was no significant increase laryngeal elevation. The supra/infrahyoid group group (n = 25), showed a significant increase in maximal superior excursion distance and maximal absolute excursion distance of laryngeal elevation. There were no significant differences between the two groups with

respect to changes in maximal anterior hyoid excursion distance and velocity, and maximal distance of superior laryngeal elevation. Electrical stimulation on the suprahyoid musculature induced an increase in anterior hyoid excursion, and infrahyoid stimulation caused an increase in superior laryngeal elevation. Hyolaryngeal structural movements were increased in different aspects according to the stimulation sites.

Comments: Results suggest that targeted electrical stimulation based on pathophysiology is essential.

*Oh, 2011: Effect of NMES on swallow function in healthy older adults.*

Design: Prospective within subject design

Objective: Evaluate effect of use of NMES on swallow function in healthy elderly adults.

Subjects: 18 elderly (>70 yo) healthy subjects, 10 young (<30 yo) healthy adults. Young adult swallow function was used as a comparative norm to compare swallow function of the elderly adult subjects. Elderly adult subjects were treated via a standardized protocol of electrotherapy.

Method: Subjects received treatment for one hour per day, five days per week, for two weeks. Patients received videofluoroscopy evaluation before the start of the experiment and after completion of the last NMES session.

Outcome measures: Pharyngeal transit time as per videofluoroscopy and Functional Dysphagia Scale as per investigator observation.

Results: Elderly patients had significantly higher pharyngeal transit times (slower transit) than younger adults. The pharyngeal transit time improved significantly (faster transit) after receiving NMES. The elderly subjects also demonstrated significant improvement in swallowing ability.

*Oh, 2019: Supra- versus infrahyoid electrode placements.*

Design: Prospective, randomized trial

Objective: To compare the effect of NMES on dysphagia using different electrode placements.

Subjects: 26 patients with dysphagia secondary to stroke.

Method: Patients were randomized to either a suprahyoid or infrahyoid electrode placement group. motor level or

sensory level NMES group. NMES was delivered for 30 minutes, 5 days per week for 4 weeks.

Outcome measures: Videofluoroscopy: Functional Dysphagia Scale (FDS) and Penetration-Aspiration Scale (Pen-Asp).

Results: Both groups showed significant improvement. No significant differences were noted between groups.

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

Design: Prospective, randomized case series

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, 2012: Effortful swallowing and concurrent NMES.*

Design: Randomized Controlled Trial

Objective: Test the effect of surface electrical stimulation as a form of resistance training in post-stroke patients with dysphagia.

Subjects: 20 post stroke dysphagic patients.

Method: The patients were randomly assigned to either a control or experimental group. Both groups had all electrodes placed below the hyoid. The experimental group performed effortful swallowing with motor level stimulation; the control group performed effortful swallowing with sensory level stimulation. Patients received 12 sessions of 20 minutes for 4 weeks.

Outcome measures: Videofluoroscopy was performed to analyze hyolaryngeal movement, upper esophageal sphincter

opening and the Penetration-Aspiration scale before and after treatment.

**Results:** The experimental group demonstrated a significant increase in vertical movement of the larynx. In addition, the hyoid demonstrated an increase in vertical movement and the upper esophageal sphincter demonstrated greater opening, though these effects were not significant.

*Park, 2014: Predictive value of pharyngeal residue on likelihood of improvement with treatment.*

**Design:** Retrospective study.

**Objective:** To determine the cutoff value of the pharyngeal residue for predicting reduction of aspiration, by measuring the residue of valleculae and pyriform sinuses through videofluoroscopy after treatment with NMES (VitalStim) in stroke patients with dysphagia.

**Subjects:** 59 subacute post-stroke patients (<60 days post onset) with dysphagia.

**Method:** The patients were evaluated with videofluoroscopy at the beginning and end of treatment to quantify swallow safety and levels of pharyngeal residuals. Treatment consisted of NMES (VitalStim) and swallowing exercises. Patients that were deemed to have improved enough to progress their diet were compared to those that had not. The level of pharyngeal residuals prior to onset of treatment was correlated to the likelihood of improvement.

**Outcome measures:** Videofluoroscopy.

**Results:** Less pharyngeal residuals prior to onset of treatment was significantly correlated with greater likelihood of positive response to treatment.

*Park, 2016: Predictive value of pharyngeal residue on likelihood of improvement with treatment.*

**Design:** Randomized Controlled Trial

**Objective:** Determine effects of effortful swallowing combined with neuromuscular electrical stimulation on hyoid bone movement and swallowing function in stroke patients.

**Subjects:** 50 post stroke patients with mild dysphagia.

**Method:** The patients were randomly assigned to either a control or experimental group. Two electrodes (one pair) were placed below the hyoid to purposefully depress the hyoid. The experimental group performed effortful swallowing



with motor level stimulation; the control group performed effortful swallowing with sensory level stimulation. Patients received 5 30-minute sessions for 6 weeks.

- Outcome measures: Videofluoroscopy was performed to assess swallow safety and analyze hyoid kinematics.
- Results: Experimental group revealed a significant increase in anterior and superior hyoid bone movement and the pharyngeal phase of the swallowing function.

*Park, 2018: NMES in dysphagic Parkinson's patients.*

- Design: Randomized, single-blind, placebo-controlled trial
- Objective: Evaluate effects of effortful swallowing combined with neuromuscular electrical stimulation on hyoid bone movement and swallowing function in Parkinson's patients.
- Subjects: 18 patients with Parkinson's disease and dysphagia.
- Method: The patients were randomly assigned to either a control or experimental group. The experimental group performed effortful swallowing with motor level stimulation; the control group performed effortful swallowing with sham stimulation. Patients received 5 30-minute sessions for 4 weeks.
- Outcome measures: Videofluoroscopic Dysphagia Scale (VDS), Penetration-Aspiration Scale, anterior and superior hyoid movement.
- Results: Experimental group experienced a significant increase in anterior and superior hyoid bone movement and improved Penetration-Aspiration Scale scale. There was no difference between the groups in the VDS scores for oral and pharyngeal phases of the swallow.

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

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

**Method:** Prior to initiation of electrical stimulation and one to two months after electrical stimulation, saliva samples were collected and patients were asked to answer a Dysphagia and Xerostomia Index Questionnaire. All patients received electrical stimulation two to four months after completing XRT. Patients received three electrical stimulation 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.

*Peng, 2016: Influence of NMES on radiation induced fibrosis.*

**Design:** Randomized controlled study.

**Objective:** To analyze the expression of TGF- $\beta$ 1 and MyoD in cervical muscles during radiation therapy (RT) and their role in inducing muscle fibrosis, and evaluate the influence of the use of swallowing therapy with concurrent NMES on TGF- $\beta$ 1/MyoD homeostasis in patients undergoing radiation therapy.

**Subjects:** 30 patients with head and neck cancer were enrolled: 10 patients (control group) who underwent surgery for benign lesions, 20 patients (study group) underwent resection and post-operative radiation therapy.

**Method:** Patients in study group were randomized to receive post-operative radiation therapy alone or post-operative radiation therapy with dysphagia therapy and concurrent NMES. Intraoperative biopsies were obtained in all 30 patients. In the study groups, biopsies were repeated 4 weeks after completion of RT. TGF- $\beta$ 1 and MyoD expression were evaluated by immunohistochemistry and Western Blot.

**Outcome measures:** Histopathology, immunohistochemistry, Western Blot.

**Results:** Following RT, patients in study radiation only group (Group 1) had high expression of TGF- $\beta$ 1 and low levels of MyoD, a pattern consistent with development of fibrosis. Group II patients demonstrated TGF- $\beta$ 1 levels more consistent with that of non-irradiated tissue.

*Permsirivanich, 2009: ES versus Traditional Therapy.*

**Design:** Prospective, randomized, single-blinded

**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.

**Results:** Patients in both groups improved their functional swallowing but the NMES group showed a significantly greater change in their Functional Oral Intake Scale score.

*Rofes, 2013: Comparison of effects of sensory and motor level electrical stimulation on swallow efficacy and safety in chronic post-stroke dysphagia.*

**Design:** Quasi-experimental, randomized controlled pre-post treatment study

**Objective:** To assess and compare the efficacy and safety of electrical stimulation (VitalStim) at sensory and motor intensity levels in patients with chronic post-stroke oropharyngeal dysphagia.

**Subjects:** 20 adult patients with chronic dysphagia after stroke (>3 months post).

**Method:** Patients were randomized to receive either electrical stimulation at sensory level intensity (75% of motor threshold) or at motor level intensity (motor threshold). Patients received treatment for 1 hour per day, 5 days per week, for 2 weeks. Stimulation was received by the patients at rest (no concurrent swallowing exercises) with electrodes placed over thyrohyoid in the sensory group and suprahyoid in the motor group. Videofluoroscopy was performed and outcome measures were collected before and after the treatment series.

**Outcome measures:** Patients completed EAT-10 and Sydney Swallow Questionnaire self-rating instruments. Videofluoroscopy was analyzed for presence of oral, vallecular and pyriform sinus residues; laryngeal penetration and tracheobronchial penetration. Scores were assigned on

Penetration Aspiration Scale. Temporal analysis of the swallow was performed by measuring timing of opening and closing of the glossopalatal junction, velopharyngeal junction, laryngeal vestibule and upper esophageal sphincter. Bolus kinematics were analyzed by computing bolus velocity and bolus propulsion force.

**Results:** Sensory and motor stimulation reduced the number of unsafe swallows, and accelerated laryngeal vestibule closure time and maximal vertical hyoid extension time. Patients in both groups reduced the number of unsafe swallows by >60%. Motor group showed greater gains in swallow questionnaires. Motor stimulation also reduced pharyngeal residue and upper esophageal sphincter opening time, and increased bolus propulsion force. The amount of hyoid excursion did not change in either group but speed of movement increased in both (motor > sensory). Bolus velocity and propulsion force increased significantly in the motor group but not in the sensory group.

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

**Design:** Prospective, double-blind, randomized case control study

**Objective:** To evaluate effectiveness of electrical stimulation (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 videofluoroscopy), Clinical Dysphagia Scale (numerical scale derived from bedside evaluation), ASHA NOMS, MD Anderson Dysphagia Inventory.

**Results:** Patients in the electrical stimulation group showed a significantly better improvement in Functional Dysphagia

Scale scores (from videofluoroscopy) than patients in the sham group.

*Scarponi, 2016: NMES for treatment refractory dysphagia.*

- Design:** Prospective case series
- Objective:** Evaluate the role of neuromuscular electrical stimulation (NMES) in tube-fed patients with severe and chronic dysphagia refractory to traditional swallowing therapy (TT).
- Subjects:** 11 consecutive dysphagic patients with tube-dependent nutrition and who had not responded to 6 months of traditional therapy (TT).
- Method:** Each patient received NMES for 30 min and TT for 30 min, twice a day, 5 days per week for 4 weeks. VitalStim settings: two electrodes were placed just above the hyoid bone and two electrodes were placed over the thyrohyoid muscle at the level of the thyroid notch. Intensity was increased up to motor level (grabbing sensation). During stimulation, the patients were prompted to swallow saliva repeatedly and to perform swallowing exercises, including oral motor exercises, supraglottic and effortful swallow. TT consisted of Shaker exercise, Masako exercise, and Mendelsohn maneuver.
- Outcome measures:** Signs and symptoms of dysphagia per fiberoptic endoscopic examination.
- Results:** All enrolled patients managed to complete the swallowing treatment protocol for at least 2 weeks. After the 4-week treatment, 6 of 11 enrolled patients passed to a total oral diet with single or multiple consistencies despite specific food limitations or special preparation or compensation. Five patients, all affected by the most severe form of dysphagia, maintained tube-dependent nutrition.

*Sproson, 2018: Impact of NMES combined with resistive exercise in post-stroke dysphagia*

- Design:** Randomized controlled pilot study
- Objective:** To compare traditional therapy to NMES combined with resistive exercise in post-stroke dysphagia.
- Subjects:** Thirty patients with post-stroke dysphagia.
- Method:** Patients were randomized into either (1) usual speech and language therapy dysphagia care; or (2) NMES combined

with resistive exercise (Ampcare ESP protocol). Patients received treatment 5 days/week for 4 weeks.

**Outcome measures:** Functional Oral Intake Scale (FOIS), Penetration-Aspiration Scale (PAS) and Swallow Related Quality of Life (SWAL-QOL).

**Results:** Patients in the NMES group showed significantly greater improvement than patients in the usual-care group in all measures.

*Sun, 2013: NMES, FEES and traditional therapy in dysphagic stroke patients.*

**Design:** Prospective case series

**Objective:** Evaluate whether combined NMES, FEES, and traditional swallowing rehabilitation can improve swallowing functions in stroke patients with moderate to severe dysphagia.

**Subjects:** Thirty-two patients with moderate to severe dysphagia post-stroke ( $\geq 3$  weeks).

**Method:** Patients received 12 sessions of NMES for 1 h/day, 5 days/week within a period of 2-3 weeks. Fiberoptic evaluation of swallowing (FEES) was performed before and after NMES for evaluation and to guide dysphagia therapy. All patients subsequently received 12 sessions of traditional swallowing rehabilitation (50 min/day, 3 days/week) for 4 weeks.

**Outcome measures:** Primary outcome measure was the Functional Oral Intake Scale score. Secondary outcome measures included clinical degree of dysphagia, the patient's self-perception of swallowing ability, and the patient's global satisfaction with therapy. Patients were assessed at baseline, after NMES, at 6-month follow-up, and at 2-year follow-up.

**Results:** Twenty-nine patients completed the study. Functional Oral Intake Scale score, degree of dysphagia, and patient's self-perception of swallowing improved significantly after NMES, at the 6-month follow-up, and at the 2-year follow-up. Most patients reported considerable satisfaction with no serious adverse events. Twenty-three of the 29 (79.3 %) patients maintained oral diet with no pulmonary complications at 2-year follow-up.

*Takahashi, 2017: Effect of NMES on tongue pressure and hyoid movement.*

**Design:** Kinematic study

**Objective:** To evaluate the influence of electrical stimulation to the laryngeal musculature on tongue pressure generation and hyoid movement during swallowing.

**Subjects:** 18 healthy young adults.

**Method:** Electrical stimulation (phase duration = 200  $\mu$ s duration, frequency = 80 Hz, intensity = 80% of each participant's maximal tolerance) of the laryngeal region was applied. Each subject swallowed 5 ml of barium sulfate liquid 36 times at 10 s intervals. During the middle 2 min, electrical stimulation was delivered.

**Outcome measures:** Tongue pressure, electromyographic activity of the suprahyoid and infrahyoid muscles, and hyoid position per videofluorography.

**Results:** Tongue pressure during stimulation was significantly lower than before or after stimulation. Tongue pressure was significantly greater after stimulation than at baseline. Suprahyoid activity after stimulation was larger than at baseline, while infrahyoid muscle activity did not change. During stimulation, the position of the hyoid at rest was descended, the highest hyoid position was significantly inferior, and the vertical movement was greater than before or after stimulation. After stimulation, the positions of the hyoid at rest and at the maximum elevation were more superior than before stimulation. The deviation of the highest positions of the hyoid before and after stimulation corresponded to the differences in tongue pressures at those times. The results suggest that surface electrical stimulation applied to the laryngeal region during swallowing may facilitate subsequent hyoid movement and tongue pressure generation after stimulation.

*Tan, 2013: NMES vs traditional therapy for dysphagia. A meta-analysis.*

**Design:** Meta-analysis

**Objective:** Assess the overall efficacy of NMES in the treatment of dysphagia by comparing it to traditional dysphagia therapy.

**Subjects:** Published medical studies in the English language were obtained by comprehensive searches of the Medline, Cochrane and EMBASE databases from January 1966 to December 2011.

**Method:** Studies that compared the efficacy of treatment and clinical outcomes of NMES versus TT in dysphagia

rehabilitation were assessed. Two reviewers independently performed data extraction. Seven studies were eligible for inclusion, including 291 patients, 175 of whom received NMES and 116 of whom received TT. Of the seven studies, there were two randomised controlled trials, one multicentre randomised controlled trial and four clinical controlled trials.

**Outcome measures:** Data assessing swallowing function improvement were extracted as scores on the Swallowing Function Scale as the change from baseline (change scores).

**Results:** The change scores on the Swallowing Function Scale of patients with dysphagia treated with NMES were significantly higher compared with patients treated with TT. However, subgroup analysis according to aetiology showed that there were no differences between NMES and TT in dysphagia post-stroke. No studies reported complications of NMES.

*Tang, 2017: NMES and sEMG versus traditional treatment in Alzheimer's patients.*

**Design:** Retrospective trial.

**Objective:** Assess the efficacy of NMES and sEMG versus traditional therapy alone in patients with Alzheimer's disease.

**Subjects:** 103 patients diagnosed with Alzheimer's disease (AD) and dysphagia.

**Method:** Patients were retrospectively assigned to the control group (traditional therapy, n=50) or the treatment group (receiving sEMG and NMES in addition to traditional swallowing exercise, n=53). Exercises during sEMG consisted of Mendelsohn manoeuvre.

**Outcome measures:** Nutritional status, water swallow test, frequency and duration of aspiration pneumonia. Measures were taken at baseline and 12 weeks after completion of treatment.

**Results:** The treatment group (NMES and sEMG biofeedback + traditional therapy) did significantly better at the conclusion of treatment and at 3 month follow up.

*Terré, 2015: NMES versus sham-NMES in acquired brain injury.*

**Design:** Prospective randomized trial, double blind.

**Objective:** Assess the efficacy of NMES in the treatment of dysphagia in patients with acquired brain injury.



**Subjects:** 20 patients with dysphagia secondary to acquired brain injury: 14 stroke, 6 severe traumatic brain injury.

**Method:** Patients were randomly assigned to one of two groups: NMES + conventional therapy or sham-NMES + conventional therapy. Patients received 20 sessions (45 minutes, 5x per week).

**Outcome measures:** Functional Oral Intake Scale score, videofluoroscopic measures, esophageal manometric measures. Measures were taken at baseline, at end of treatment and at 3-month follow up.

**Results:** The NMES group did significantly better at the conclusion of treatment. At 3-month follow up the improvement in functional oral intake scale score was similar for both groups but manometric and videofluoroscopic measures were better for the NMES group.

*Toyama, 2014: NMES + traditional therapy for dysphagia after brain injury.*

**Design:** Prospective observer-blinded open-label controlled

**Objective:** To investigate the effect of using NMES with High Volt waveform combined with traditional dysphagia exercise in patients with dysphagia after brain injury.

**Subjects:** 26 dysphagic patients admitted in inpatient rehabilitation centre after brain injury without brainstem involvement.

**Method:** Patients were non-randomly assigned to experimental and control group. Experimental group received NMES followed by traditional exercise. NMES was delivered using the High Volt waveform, monopolar technique, to the Geniohyoid, Mylohyoid, anterior belly of the Digastric and Thyrohyoid. Control group only received traditional exercise. Both groups received treatment sessions of 40 mins, 5x per week for 8 weeks.

**Outcome measures:** Functional Oral Intake Scale score, anterior and superior displacement of hyoid and larynx, and videofluoroscopy dysphagia scale (VDS).

**Results:** The experimental group showed significantly greater improvement, especially in hyolaryngeal excursion and VDS.

*Umay. 2017: Sensory level stimulation of the Masseter.*

**Design:** Randomized controlled study.

**Objective:** Evaluate the effect of sensory level transcutaneous electrical stimulation over bilateral Masseter muscles on dysphagia in stroke patients.

**Subjects:** 98 stroke patients (45-75 yo) with dysphagia within 1 month post-stroke were randomly assigned to a sham or live electrical stimulation group. Both groups received traditional dysphagia therapy.

**Method:** Patients in the electrical stimulation group received sensory level stimulation of the skin overlying bilateral Masseter muscles. Treatment sessions lasted 60 minutes session and were delivered 5x per week for 4 weeks (20 sessions).

**Outcome measures:** MASA, FEES evaluation of penetration and aspiration, Neurological Examination Dysphagia Score (NEDS), Bedside Dysphagia Score (BDS).

**Results:** The electrical stimulation group showed a significant improvement in all outcome measures. No improvement was noted in the sham stimulation group.

*Watts, 2018: Effect of NMES on timing of laryngeal vestibule closure.*

**Design:** Descriptive physiology study

**Objective:** Evaluate whether the delivery of NMES to the submandibular musculature during swallowing facilitates neuromuscular pathways as a result of adaptation to the perturbation to the swallowing movements.

**Subjects:** 9 healthy volunteers.

**Method:** Subjects received electrical stimulation (Ampcare) to submandibular musculature while performing a series of dry swallows. The stimulator delivered symmetrical biphasic pulses (frequency = 30 pps, duty cycle = 5:15) at motor level intensity.

**Outcome measures:** Laryngeal vestibule closure reaction time (LVCrt) and duration (LVCd). Measurements were taken before during and after stimulation.

**Results:** Laryngeal vestibule closure reaction times were shorter (faster) after stimulation, suggesting a facilitative effect of NMES when applied during swallowing tasks.

*Xia, 2011: VitalStim with swallowing exercise post-stroke.*

**Design:** Randomized controlled study

**Objective:** Evaluate the effect of the use of VitalStim Therapy with concurrent conventional dysphagia therapy on muscle

activation and swallow function in dysphagic post-stroke patients.

- Subjects:** 120 acute stroke patients with dysphagia, 40-80 yo. Randomly assigned to Conventional Dysphagia Therapy Only group, to VitalStim Therapy Only group, or to VitalStim Therapy with concurrent Conventional Dysphagia Therapy group.
- Method:** Patients receiving VitalStim Therapy received 2 treatment sessions of 30 minutes per day for 5 days per week x 4 weeks.
- Outcome measures:** sEMG recording of hyolaryngeal muscle activity, Standardized Swallowing Assessment (SSA), videofluoroscopy and quality of life (SWAL-QOL).
- Results:** The VitalStim with concurrent exercise therapy group improved significantly more than the other groups in all outcome measures. Both the exercise alone and VitalStim alone groups improved in all measures as well, but there was no significant difference between them.

*Zhang, 2015: VitalStim with swallowing exercise post-stroke.*

- Design:** Prospective randomized controlled study
- Objective:** Evaluate and compare the effects of neuromuscular electrical stimulation (NMES) at sensory or motor level stimulation in patients with dysphagia due to medullary infarction.
- Subjects:** 82 medullary stroke patients with dysphagia were randomized into 3 groups: conventional dysphagia therapy only, conventional dysphagia therapy plus sensory level electrical stimulation, or conventional dysphagia therapy plus motor level electrical stimulation.
- Method:** Patients receiving electrical stimulation received 2 x 20 minutes treatment sessions per day, 5 days per week for 4 weeks.
- Outcome measures:** Water Swallow Test, Standardized Swallowing Assessment (SSA), Functional Oral Intake Scale, Swallowing-Related Quality of Life (SWAL-QOL).
- Results:** Both electrical stimulation groups showed better outcomes on all measures than the traditional dysphagia therapy group (no electrical stimulation). The sensory stimulation group did better than the motor stimulation group.

*Zhang, 2019: rTMS in combination with NMES for post-stroke dysphagia.*

Design:	Prospective randomized controlled study
Objective:	Determine whether repetitive transcranial magnetic stimulation (rTMS) combined with neuromuscular electrical stimulation (NMES) improves dysphagia and how rTMS protocols (bilateral vs. unilateral) combined with NMES can be optimized.
Subjects:	64 stroke patients with dysphagia were randomized into 4 groups: sham rTMS plus NMES (Sham-rTMS/NMES), ipsilesional 10-Hz rTMS plus NMES (Ipsi-rTMS/NMES), contralesional 1-Hz rTMS plus NMES (Contra-rTMS/NMES), and bilateral rTMS plus NMES (Bi-rTMS/NMES) groups.
Method:	Patients received NMES for 30 minutes: 2 channels with electrodes applied paramedian above and below the hyoid. rTMS was delivered concurrently to NMES for total of 10 sessions during a 2-week period (5 days/week).
Outcome measures:	Cortical excitability as measured by the amplitude of the motor evoked potential at the mylohyoid muscle cortical representative area, swallowing function as measured by the Standardized Swallowing Assessment, and the degree of dysphagia were evaluated at baseline, after the stimulation course, and at the 1-month follow-up.
Results:	Bi-rTMS/NMES produced higher cortical excitability and better swallowing function recovery. Compared with NMES alone, unilateral rTMS plus NMES had additional effects on cortical excitability and rehabilitation of dysphagia, but there were no differences between the Contra-rTMS/NMES and Ipsi-rTMS/NMES groups. No adverse events occurred.