



Neuromuscular Electrical Stimulation in the Treatment of Dysphagia

Clinical Highlights

Thank you for your interest in Ampcare's Effective Swallowing Protocol (ESP™). We are happy to share highlights on peer-reviewed research utilizing ESP.

1. Findings demonstrate that providing intensive dysphagia therapy in 30 minutes is possible within inpatient, outpatient and/or home health settings, resulting in significant and functional improvements in swallow safety and an increase in swallow-related quality of life.

- a. *Pownall et al 2012*
- b. *Sproson et al 2018*
- c. *Martindale et al 2019*

PDPM/PDGM Importance – supporting better/faster outcomes in 30-minutes also resulting in more cost-effective treatment sessions.

2. Findings demonstrate that patients reported clinically and statistically significant improvements in their swallow-related quality of life using SWAL-QoL (standardized patient outcome measure).

- a. *Pownall et al 2012*
- b. *Sproson et al 2018*
- c. *Martindale et al 2019*

PDPM/PDGM Importance – improving the quality of reporting outcomes by adding the patient's perspective.

3. Findings demonstrate that ESP is the only technology shown to facilitate the swallowing mechanism, strengthen the anterior neck musculature and speed up airway closure times and/or duration for the treatment of dysphagia.

- a. *Campbell et al 1998*
- b. *Safi et al 2010*
- c. *Watts 2013*
- d. *Matsumoto et al 2016*
- e. *Watts et al 2018*
- f. *Arslan et al 2018*
- g. *Ogura et al 2022*

PDPM/PDGM Importance – the ability to measure progress with standardized outcome methodologies.

* Campbell et al 1998 and Polansky et al 2008 were funded by Ampcare, LLC. Six of the eight published research studies after 2008 were completely independent of Ampcare, LLC. On the other two, Ampcare, LLC funding was less than 3%. Individual breakdowns can be found in the acknowledgments section in each publication.

A Summary of the Evidence on Ampcare's Effective Swallowing Protocol (ESP™)

Last updated October 28, 2022

Neuromuscular electrical stimulation (NMES) used as an adjunct modality in the treatment of dysphagia has received increased adoption by medical professionals since the clearance of Ampcare's Effective Swallowing Protocol (ESP) by the **Food and Drug Administration in 2013**. The Ampcare ES is the only hand-held device that offers the highest intensity with adjustable phase durations on the market with such clearance. Every aspect of this protocol (i.e. parameters, electrode size, placement and exercises) allows the clinician to enhance patient comfort with improved clinical outcomes.

ESP is a specialized NMES administered through two uniquely designed external pie shaped electrodes. The protocol includes a portable hand-held unit that uses a non-invasive electrical current to stimulate inactive nerves or atrophied swallowing muscles and a posture device to provide the ideal head and neck position. The postural support will also serve as part of Ampcare's resistive exercise program to strengthen the muscles necessary to rehabilitate a functional swallow.

NMES as used in the treatment of dysphagia involves the administration of small electrical impulses to swallowing muscles in the throat through electrodes attached to the skin overlying the musculature. The therapist determines which musculature would benefit from this facilitation through a standard evaluation procedure, which typically includes a cranial nerve assessment and some form of instrumental assessment. The data gathered from the assessments permit the therapist to recommend an electrode placement in order to facilitate the target nerve and muscle(s). Once the current intensity has been increased to a satisfactory level, the therapist commences with Ampcare's resistive exercise protocol with the patient. The patient exercises the swallowing muscles for up to 30 minutes while receiving concurrent electrical stimulation. The electrical stimulation when applied in this manner accelerates muscle strengthening, cortical reorganization (especially after stroke), and neurovascular coupling thereby increasing the effectiveness of the therapy.

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

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

The evidence base for the use of electrotherapy as practiced by PT's is robust and insurance generally covers its use. In a fee-for-service payment structure either CPT code 97032 (attended electrical stimulation; in 15 minutes increments) or CPT code G0283 (unattended electrical stimulation; untimed) can be used. As the evidence using this new philosophy becomes available,

and the clarification between the different uses of NMES in dysphagia is understood, Ampcare's plan is to push for a CPT code billable by experienced clinicians.

The use of electrotherapy to strengthen weak swallowing muscles in dysphagia is conceptually sound based on the experience in PT practice and its supporting evidence. It has however not yet received approval by the insurance industry due to a perceived lack of evidence supporting safety and efficacy of the use of electrotherapy in dysphagia.

The following reviews the evidence and highlights of some published and/or presented research that utilized Ampcare's ESP.

Safety

The use of Ampcare's ESP in the treatment of dysphagia has been demonstrated to be safe. The studies reviewed all tracked for the occurrence of adverse events and in over 12,100 treatment sessions none were reported, across all patient ages and diagnoses.

Efficacy

Ampcare has independently funded one pilot study in Texas and has joined with Devices for Dignity and Sheffield Teaching Hospital in the United Kingdom on a case study series (phase I) and pilot trial (phase II) for adult/geriatric patients. The findings to date of these studies have shown that individuals that receive Ampcare's ESP have a success rate range of 75-85% (patients improved to a point of a diet upgrade) along with the ability to improve swallow function. In some cases, patients were able to discontinue the need for tube feedings.

Literature review

The following is a list of articles and papers written on Ampcare's ESP for the treatment of dysphagia.

Campbell et al 1998: Educational Research: Promoting Laryngeal Elevation with E-Stim.

Design: Preliminary Report

Objective: Report on Ampcare's electrical stimulation parameters to measure laryngeal elevation using an accelerometer/Computerized Laryngeal Analyzer (CLA).

Subjects: 25 healthy normal subjects.

Method: Compared 3 dry swallows to 3 Ampcare parameter trials without assistance for 5 seconds using CLA for measurements.

Outcome measures: Observed 76% of mV from dry swallow with Ampcare parameters only.

Results: Ampcare was the 1st to prove you can move the hyoid and larynx in an anterior and superior direction with transcutaneous NMES alone. Next step is to test the hypothesis that NMES in the form of ESP combined with exercise can improve swallow function.

Full report: [Promoting-Laryngeal-Elevation-with-E-Stim-6-22-1998.pdf](#)

Polansky et al 2008: Pilot Trial: Treatment of patients with decreased hyolaryngeal excursion with Ampcare's electrical stimulation parameters and traditional exercise versus traditional exercise.

Design: Randomized Controlled Trial (RCT)

Objective: Evaluate benefit of Ampcare's electrical stimulation parameters combined with traditional exercise (ESwE) compared to traditional exercise (TE) alone on patients with reduced hyolaryngeal elevation as a result of their dysphagia diagnosed using Modified Barium Swallow Study (MBSS).

Subjects: 124 patients with diagnosis of CVA, Hypoxic Encephalopathy, Pneumonia, Parkinson's disease. Excluded patients with implanted electronic devices and head and neck cancer.

Method: 2:1 allocation ratio. ESWE delivered for 30 minutes QD or 15 minutes BID in conjunction with traditional exercise for a minimum of 20 treatments versus TE alone.

Outcome Measures: 74% of the ESWE arm and 11% of the TE arm displayed a diet upgrade on follow up MBSS.

Results: Patients with dysphagia due to diminished hyolaryngeal elevation who receive Ampcare's ESWE improved at a higher rate than those patients receiving TE.

Full report: [Hard-to-Swallow-May-2008.pdf](#)

Safi et al 2010 Howard University with NIH: Investigational Study: Evaluation of Submental Stimulation in Healthy Volunteers.

Design: Case Reports

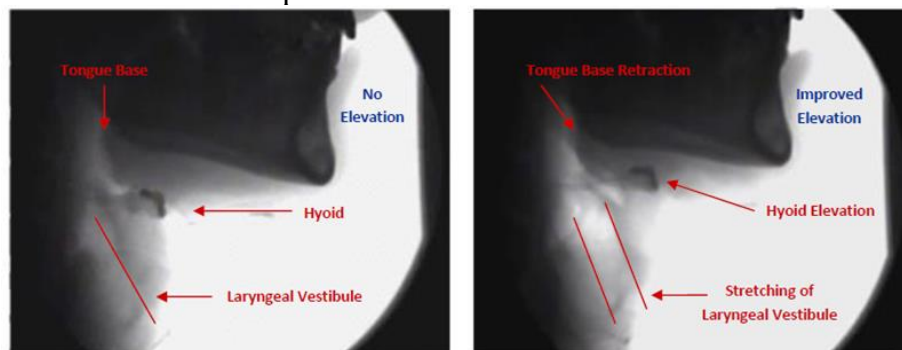
Objective: Determine if submental electrical stimulation (ES) using the Ampcare's parameters with E Series Electrodes could induce hyoid and laryngeal movement in healthy adults.

Subjects: 7 healthy normals.

Method: ES delivered for 3 seconds using video fluoroscopy (VF) recorded trials during stimulation at rest and swallowing, and during swallowing without stimulation were analyzed using Peak Motus and Matlab software to measure movement.

Outcome measures: During stimulation periods alone, the hyoid movement was 3.32 mm, the subglottic air column moved 1.37 mm and the vestibule was opened by 1.4 mm.

Results: Hyolaryngeal excursion was achieved with Ampcare's parameters and E Series Electrodes alone with a perturbation occurring in the laryngeal vestibule. This perturbation combined with swallowing exercises appears to provide an intrinsic resistance while moving the hyoid and larynx in the proper direction. Refer to VF pictures below.



Patient at rest under VF

Patient receiving Ampcare's protocol

Carmichael et al 2011: Texas Speech-Language-Hearing Association Presentation - Educational Research: Effects of Neuromuscular Electrical Stimulation and Bolus Size on Hyolaryngeal Activity.

Design: Pilot Study

Objective: Investigate the effects of Ampcare's electrical stimulation (ES) parameters and E Series Electrodes on the suprahyoid musculature to assess laryngeal muscle activity during swallow of different bolus sizes.

Subjects: 20 healthy normals.

Method: ES delivered over the suprahyoids while sEMG measured the infrahyoids and VF monitored bolus.

Outcome measures: sEMG Muscle activity with ES swallows were increased when compared to swallows without ES. There were three penetration events with ES on and two events with no ES using Rosenbek's Penetration/Aspiration Scale.

Results: sEMG indicated a 3-fold increase in muscle activity with ES swallows versus non-ES swallows. No significant effect of bolus size (5cc vs. 20 cc) was found. Safest treatment is to perform ES swallows NPO/indirect with resistive exercise.

Enderby et al, 2011: Phase I Case Study Series.

Design: Feasibility Trial

Objective: Evaluate the effectiveness of the Ampcare ESP protocol for patients who had failed traditional interventions.

Subjects:

- 5 patients: 59-78 y/o Males, had completed traditional care but were still PEG dependent.
- 2 CVA, 2 Head/Neck Cancer and 1 Parkinson Disease/Osteomyelitis to the skull.

Method: Patients received 20 sessions of Ampcare's ESP (5 times/week for 4 weeks).

Outcome measures: Rosenbek Penetration/Aspiration Scale, Waxman Dysphagia Severity Scale, Functional Oral Intake Scale.

Results:

- 2 of the 5 patients weaned off the PEG tubes in 1 month. A 3rd patient was weaned off the PEG tube after 3 months of completing the protocol.
- All 5 patients showed improvements in their swallowing ability.

Pownall et al 2012: ESSD Poster Presentation: An Investigation into the Effects of Neuromuscular Electrical Stimulation of the Laryngeal Elevation Musculature on Swallowing Function in Patients Presenting with Persistent Dysphagia.

Design: Case Study

Objective: Investigate the effects of Ampcare's ESP in patients with persistent dysphagia.

Subjects: 5 patients with stable dysphagia (minimal period of 3 months with persistent dysphagia – feeding tube dependent) with decreased laryngeal elevation on VF. Excluded patients with: implanted electronic devices, severe aphasia, pregnancy, and active head and neck cancer.

Method: ESP was performed 5 days a week for 30-minute treatments for 4 weeks.

Swallowing abilities were re-assessed by VF, clinical assessment, and questionnaire.

Outcome measures: Rosenbek Penetration/Aspiration Scale (PAS), Functional Oral Intake Scale (FOIS), Questionnaire regarding the acceptability of the intervention.

- Results: Two patients returned to full diet having been on non-oral feedings for 5 months and over 24 months respectively and without pneumonia after 1-year follow-up. A 3rd patient was weaned off their PEG tube after 3 months of completing the protocol. The remaining patients introduced an increase in the amount and range of food consistencies to their oral intake. These results fostered a Phase II pilot study.

Full report: [ESSD-Barcelona2012.pdf](#)

Watts, Christopher, 2013: Measurement of Hyolaryngeal Muscle Activation Using Surface Electromyography for Comparison of Two Rehabilitative Dysphagia Exercises. Arch Phys Med Rehabil 94: 2542-2548.

Design: Within-subject, repeated-measures

Objective: Investigate the effects of a resistive-based chin-to-chest (CtC) exercise on measures of hyolaryngeal muscle activation compared with a head-lift exercise.

Subjects: 20 healthy normals.

Method: All participants performed an isometric jaw-opening exercise against resistance (CtC) using Ampcare's posture device and an isometric head-lift exercise, both targeting activation in the hyolaryngeal muscles.

Outcome measures: Microvolts as measured by sEMG sensors placed on the skin surface over the suprahyoid muscles. Dependent variables included the peak microvolts (mV) during 10 seconds of sustained contraction and the difference in mV from rest to peak contraction for each exercise.

Results: Activation in the hyolaryngeal musculature as measured via sEMG was significantly greater when participants performed the CtC exercise compared with the head-lift exercise. The difference measures in mV calculated between rest and contraction for each exercise revealed a 2-fold increase in hyolaryngeal muscular activation.

Conclusion: The isometric CtC exercise resulted in greater activation of the hyolaryngeal muscles compared to an isometric head-lift exercise.

Full Report: [Watts-Study-of-Chin-to-Chest-Exercise2013.pdf](#)

Pownall et al, 2015: Dysphagia Research Society International Poster Award Winner – (Chicago, IL): Combined electrical stimulation and exercise for swallow rehabilitation post-stroke: A Randomized Controlled Trial (RCT) (Accepted for Publication in the International Journal of Language & Communication Disorders 2018).

Design: RCT

Objective: This pilot builds on the successful feasibility study (Pownall & Enderby, 2011) using the Ampcare ESP program.

Subjects: 30 patients with post stroke dysphagia of >1-month duration.

Method: Compare the control group (usual care) to the intervention group (4 weeks of treatment – 5 days per week for 30 minutes using the Ampcare Effective Swallowing Protocol (ESP).

Outcome measures:

- MASA (Mann Assessment of Swallowing Ability)
- FOIS (Functional Oral Intake Scale)
- Rosenbek Penetration/Aspiration Scale during VF
- SWAL-QoL (Quality of Life in Swallowing disorders)

Results:

- FOIS (End of treatment)
 - Usual Care- 50% Improved
 - Intervention (Ampcare)- 62% Improved
- FOIS (1 month Follow Up)
 - Usual Care- 57% Improved
 - Intervention (Ampcare)- 75% Improved
- Rosenbek Penetration/Aspiration Scale (Diet):
 - Usual Care- 17% Improved
 - Intervention (Ampcare)- 58% Improved
- Rosenbek Penetration/Aspiration Scale (Liquids)
 - Usual Care- 50% Improved
 - Intervention (Ampcare)- 58% Improved

- SWAL-QoL (End of Treatment)
 - Usual Care- 38% Improved
 - Intervention (Ampcare)- 83% Improved
- SWAL-QoL (1 month Follow Up)
 - Usual Care- 42% Improved
 - Intervention (Ampcare)- 100% Improved

Full Report: [DRS-Chicago2015.pdf](#)

Matsumoto S & Shimodozono M., 2016: *Advanced Medical Treatment Series 47-Latest Topics on Rehabilitation for Clinicians and Co-medical staff*, 190-193.

Figure 5 is a representation of the data published by Dr. Shuji Matsumoto in Japan, and the text that follows is from Dr. Matsumoto’s published report that supports our claims that ESP at rest can move the hyo-laryngeal complex and that the anatomical inference that ensues can be visualized.

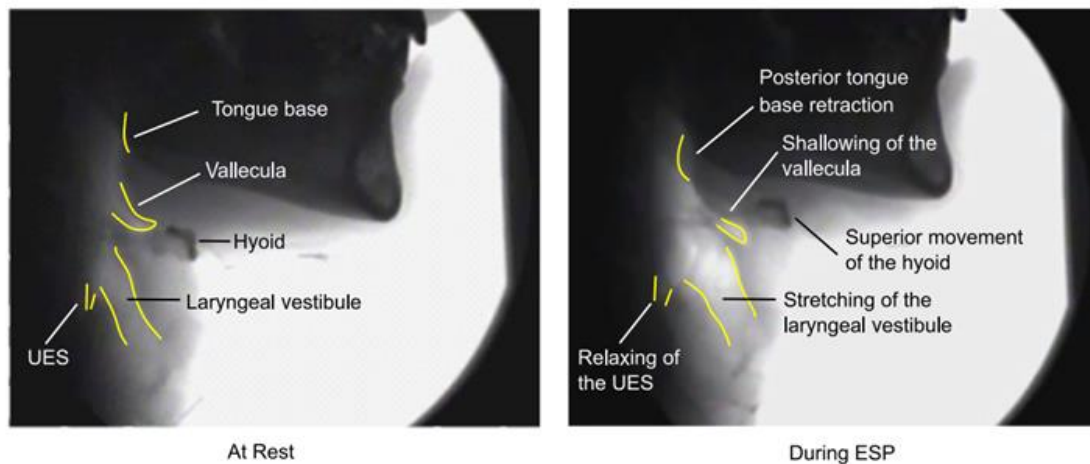


Fig.5 Effect of Ampcare ESP™

“We have independently obtained the device (Ampcare’s system) and applied ESP (to a healthy subject), the posterior tongue base retraction, retroversion of the epiglottis, shallowing of the vallecular and the pyriform sinus, and the relaxing of the upper esophageal sphincter was observed (see above). This (ESP system) seems to have the effect that no other NMES (device) has.” – printed in the *Advanced Medical Treatment Series 47-Latest Topics on Rehabilitation for Clinicians and Co-medical staff*, Pages 190-193.

Sproson, L., Pownall, S., Enderby, P., and Freeman, J., 2018: *Combined electrical stimulation and exercise for swallow rehabilitation post-stroke: A pilot randomized control trial. International Journal of Language & Communication Disorders*, 53(2), 405-417.

Design: RCT

Objective: This pilot builds on the successful feasibility study (Pownall & Enderby, 2011) using the Ampcare ESP program.

Subjects: 30 patients with post stroke dysphagia of >1-month duration.

Method: Compare the control group (usual care) to the intervention group (4 weeks of treatment – 5 days per week for 30 minutes using the Ampcare Effective Swallowing Protocol (ESP)).

Outcome measures:

- FOIS (Functional Oral Intake Scale)
- Rosenbek Penetration/Aspiration Scale (PAS) during VF
- SWAL-QoL (Quality of Life in Swallowing disorders)

Results: Thirty patients were recruited; 15 were randomized to the Ampcare ESP intervention arm and 15 to usual care. A greater proportion (75%, or 9/12) of patients receiving Ampcare ESP improved compared with 57% (or 8/14) of the usual-care group. Patients receiving Ampcare ESP also made clinically meaningful change (a comparative benefit of 1.5 on the FOIS, and on the PAS: 1.35 for diet and 0.3 for fluids) compared with usual care. The intervention group also reported much better outcome satisfaction.

Conclusions: The pilot demonstrated successful recruitment, treatment safety and tolerability and clinically meaningful outcome improvements, justifying progression to a fully powered study. It also showed clinically meaningful treatment trends for the Ampcare ESP intervention.

Full Report: [Sproson et al2018-IJLCD.pdf](#)

Safi et al 2017: Effect of surface neuromuscular electrical stimulation on labial and lingual muscles in healthy volunteers. International Journal of Rehabilitation Research. 40(2):119-126.

Design: Non-Randomized Controlled Study

Objective: The aim of this study was to determine what effect(s) submental and labial NMES would have on lingual and labial muscle strength in healthy participants.

Subjects: Fourteen healthy adults; (27–49 years old) 6 in control group and 8 in treatment group.

Methods: The treatment group performed a structured oral motor exercise (OME) program targeting specific labial, buccal, and lingual muscles in conjunction with the NMES. The control group performed the same OME program without NMES. All participants received three sessions per week over 4 weeks. A pre-treatment and post-treatment test with the Iowa Oral Performance Instrument was used to measure the strength of labial and lingual muscles in both groups.

Results: On comparing the total change in labial and lingual strength between the two groups, an increase in total labial strength was found in the treatment group compared with the control group.

However, the control group showed an increase in total lingual strength compared with the treatment group. Results for all measurements were not statistically significant.

Conclusions: This study concluded that NMES may be a promising modality to combine with labial and buccal exercises for improvement of muscle strength.

Report: Copyright ©2017 Wolters Kluwer Health, Inc. All rights reserved.

Watts CR., Dumican MJ., 2018: The effect of transcutaneous neuromuscular electrical stimulation on laryngeal vestibule closure timing in swallowing. BMC Ear, Nose and Throat Disorders. 18:5.

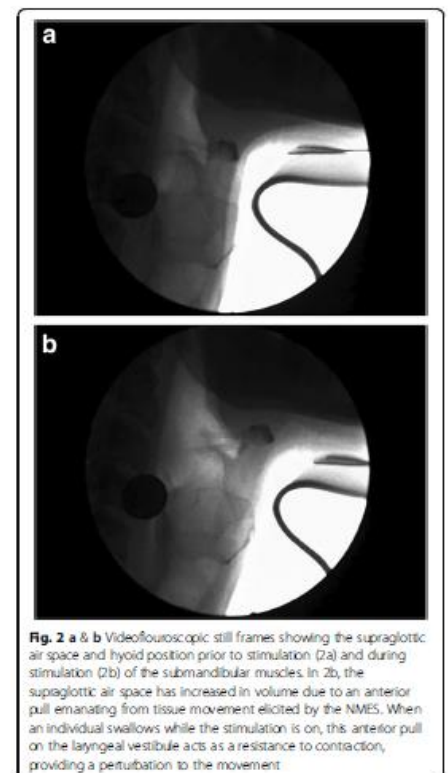
Design: Within-subject, repeated-measures

Objective: To investigate the effect of Ampcare's ESP on the timing of laryngeal vestibule closure during the pharyngeal stage of swallowing.

Subjects: Nine healthy adults.

Method: All participants performed 16 swallows (3 pre-stimulation, 10 during stimulation, 3 post-stimulation). The ten consecutive stimulations were applied to the submandibular hyolaryngeal muscles while performing a dry swallow. Laryngeal vestibule closure reaction time (LVCrt – time for complete closure) and the laryngeal vestibule closure duration (LVCd – length of time closure time) were measured from videofluoroscopic imaging pre-stimulation and post-stimulation.

Outcome measures: Measurements were calculated in milliseconds (ms) and obtained from the pre-stimulation and post-stimulation swallows. LVCrt and LVCd were averaged across the 3 swallows for each participant. Two separate Wilcoxon Signed Ranks tests were applied to the LVCrt and LVCd data, respectively, representing a comparison of



repeated pre-stimulation measurements to post-stimulation measurements.

Results: Indicated a significant effect with Ampcare's ESP on LVCrt but not LVCd. LVCrt was significantly reduced (timing was 39% faster) during swallows immediately after stimulation compared to pre-stimulation.

Conclusions: Findings from this study support the supposition that laryngeal muscles respond to perturbations via adaptation learning, which might be used for rehabilitation of neuromuscular swallowing impairment.

Full Report: [Watts-LVC-Article_BMC-ENT2018.pdf](#)

Arslan SS., Azola A., Sunday K., Vose A., Plowman E., Tabor L., Singer M., Robison R., and Humbert IA., 2018: Effects of Submental Surface Electrical Stimulation on Swallowing Kinematics in Healthy Adults: An Error-Based Learning Paradigm. AJSLP. Vol. 27, 1375–1384.

Design: Clinical Study

Objective: Hyoid bone and laryngeal approximation aid airway protection (laryngeal vestibule closure) while moving toward their peak superior and anterior positions during swallowing.

Submental surface electrical stimulation (SES) is a therapeutic technique that targets the muscles that move the hyoid bone during swallowing. It is unknown whether submental SES only increases peak hyoid bone swallowing positions but not peak laryngeal swallowing positions, which could require faster or greater laryngeal movement to achieve adequate laryngeal vestibule closure.

Subjects: 30 healthy adults (21 females, 9 males).

Method: Examined the effects of submental SES on hyo-laryngeal kinematics in 30 healthy adults who swallowed 50 times using an error-based learning paradigm.

Results: Submental SES did not alter any hyo-laryngeal swallowing kinematic. However, submental SES significantly changed the starting position of the hyoid bone just prior to the swallow onset (more anterior; $p = .003$). On average, submental SES immediately prior to swallow onset can position the hyoid approximately 20% closer to its peak swallowing point even with low intensity levels of this study.

Conclusions: These findings indicate that electrical stimulation of the agonists for hyoid movement might not alter swallowing outcomes tested in this study on healthy subjects. However, submental SES could have clinical utility by minimizing swallowing impairments related to reduced hyoid swallowing range of motion in individuals with dysphagia.

Full Report: [Arslan et al-2018-AJSLP-Submental-SES-on-Swallowing-Kinematics.pdf](#)

Martindale N., Stephenson J., and Pownall S., 2019: Neuromuscular Electrical Stimulation Plus Rehabilitative Exercise as a Treatment for Dysphagia in Stroke and Non-Stroke Patients in an NHS Setting: Feasibility and Outcomes. Geriatrics. 4, 53; doi:10.3390.

Design: Feasibility Study – A Single-Arm Trial

Objective: To determine if it is feasible to provide an intensive therapy program combining neuromuscular electrical stimulation (NMES) with exercise against resistance in the treatment of dysphagia in a public healthcare setting. Before conducting the necessary RCTs to address these important questions, however, it would be prudent to ensure that time intensive NMES therapy programs can be offered widely within the constraints of NHS in the UK.

Subjects: 31 patients (17 stroke, 14 non-stroke). After checking the data sets for comparability, it was deemed appropriate for the outcome data from these patients to be combined with that of the 12 stroke patients previously reported (Spruson et al 2018) to enable statistical analysis on a larger data set ($n=43$).

Method: Examined the effects of an NMES therapy program (Ampcare ESP) on patients (20 sessions over a 6-week period) having reduced laryngeal elevation determined during video fluoroscopy (VF).

Outcome measures:

- FOIS (Functional Oral Intake Scale)
- Rosenbek Penetration/Aspiration Scale (PAS) during VF
- SWAL-QoL (Quality of Life in Swallowing disorders)

Results: Indicated a statistically significant increase in the amount and variety of food a patient was able to take orally (FOIS) following completion of treatment ($p < 0.001$). There was also a significant improvement in secondary outcome measures of swallow safety with fluids (PAS) ($p < 0.001$) and swallow-related quality of life (SWAL-QoL) ($p < 0.001$).

Conclusions: These findings demonstrated that the provision of intensive dysphagia therapy is possible within an NHS setting, particularly for the stroke population who are recommended to have 45 minutes therapy per day in national guidelines. It has shown that Ampcare's ESP resulted in significant and functional improvements in swallow safety and an increase in swallow-related quality of life in a subset of patients with dysphagia resulting from both stroke and non-stroke etiologies. Benefits of the intervention were observed in some patients who received the therapy less intensively, increasing the feasibility of providing it for non-stroke patients in a clinical setting.

Some other highlights of the research:

- Demonstrates that Ampcare's NMES parameters when paired with exercise provides clinically superior results for both Stroke and Non-Stroke patient types compared to traditional exercises.
- 42% of patients improved from full artificial nutrition to a sufficient recovery that enabled them to meet their nutritional needs 100% orally.

Full Report: [Martindale-Geriatrics2019.pdf](#)

Martindale et al 2020: ESSD Poster Presentation: Is There a Role for Neuromuscular Electrical Stimulation Therapy Programs (e.g. the Ampcare Effective Swallowing Protocol) in the Treatment of Post COVID-19 Dysphagia?

Design: Case Study

Objective: Investigate the effects of Ampcare's ESP in patients with persistent dysphagia following survival of COVID-19 who exhibit reduced laryngeal elevation.

Subjects: 4 patients with persistent dysphagia (a period of 47-77 days with persistent dysphagia – feeding tube dependent) with decreased laryngeal elevation on VF.

Method: ESP was performed for 30-minute treatment sessions for 20 treatments.

Swallowing abilities were re-assessed by VF and clinical assessment.

Outcome measures: Rosenbek Penetration and Aspiration Score (PAS), Functional oral intake scale (FOIS), International Dysphagia Diet Standardisation Initiative (IDDSI) and Waxman Dysphagia Severity Score.

Results: All 4 patients tolerated the therapy well and were able to reliably generate swallows in synch with stimulation.

Conclusion: This cohort of post critical care COVID-19 patients tolerated and were motivated to engage with this therapy. Their dysphagia was severe in presentation but improved sufficiently post therapy to allow the introduction of trials of a IDDSI level 5 diet. One patient was able to further increase oral intake after a period of level 5 diet trials suggesting that ESP may have “kick started” the swallow and that further progress may be made for these patients longer term. Further analysis of VF data is ongoing to allow more detailed analysis of the swallow impairment and improvement post therapy. These patients will be followed up longer term.

Full report: [ESSD Ampcare COVID-19 Data](#)

Martindale et al 2020: ESSD Poster Presentation: Neuromuscular Electrical Stimulation Plus Intensive Exercise Against Resistance (Ampcare ESP) in the Treatment of Post-Stroke Dysphagia: Further Evidence for Positive Outcomes.

Design: Case Reports from NICE Audit Tool (IP490)

Objective: Investigate the effects of Ampcare's ESP in patients with dysphagia post-stroke.

Subjects: 22 stroke patients from 5 NHS Trusts with pharyngeal dysphagia including decreased laryngeal elevation.

Method: ESP was performed for 30-minute treatment sessions up to 22 treatments.

Swallowing abilities were re-assessed by VF and/or clinical assessment.

Outcome measures: Functional oral intake scale (FOIS).

Results: 19 (86%) were able to safely increase the amount / variety of food they were eating.

10 of 11 patients who were NPO at the start of therapy were able to introduce some oral intake.

9 of 20 patients who were tube dependent were able to meet their needs orally after therapy.

Conclusion: Speech and Language Therapists in NHS services across the UK are using Ampcare ESP in the treatment of post-stroke dysphagia. Outcome data continues to demonstrate that many of these patients can eat a more varied diet following completion of the therapy program. A large proportion of these patients were able to meet their needs orally after completing the program.

Full report: [ESSD Ampcare Stroke Data 2020](#)

Ogura et al 2022: Immediate Effects of Electrical Stimulation on Oropharyngeal Structure and Laryngeal Vestibular Closure: A Pilot Study in Healthy Subjects. Progress in Rehabilitation Medicine. Vol. 7, 20220033.

Design: Pilot Study

Objective: This study examined the immediate effects of neuromuscular electrical stimulation (NMES) on the dynamics of oropharyngeal structure and laryngeal vestibular closure (LVC) in healthy subjects.

Subjects: Ten healthy male volunteers

Method: The study was conducted in four phases (each performed twice): (1) saliva swallow (SS) before evaluation (BEFORE), (2) NMES while at rest with no SS (NMES AT REST), (3) SS during NMES (DURING NMES), and (4) SS to examine the aftereffects of NMES (AFTER). What was measured - via Swallowtail Ver.1 - were the distances that the oropharyngeal structures moved in the NMES AT REST phase; also analyzed were the kinematics of saliva swallowing primarily in the BEFORE and AFTER phases.

Results: Four changes in the morphology of the oropharyngeal structure caused by NMES AT REST were statistically significant: anterior-upward (superior) displacement of the hyoid bone and larynx, and stretching the laryngeal vestibule and posterior ridge of the tongue root. Regarding the kinematics measured during SS, LVC duration in the AFTER phase was significantly longer than BEFORE. Regarding maximal displacement of the hyoid bone, there was significantly greater movement AFTER than BEFORE.

Conclusions: Longer duration of LVC might be caused by adaptive learning with NMES-induced structural changes in the oropharynx. Further clinical studies are warranted to determine whether this approach improves dysphagia.

Full Report: [Ogura-ProgressinRehabilitationMedicine2022.pdf](#)

Dumican MJ., Harper, K., 2022: ASHA Poster Presentation: Swallowing Outcomes in Clinically Based Patients Using Neuromuscular Electrical Stimulation (NMES).

Design: Within-subject, repeated-measures

Objective: To examine the effects of Ampcare's ESP on mechanistic changes to swallow function in:

1. Absolute hyoid movement distance
2. Laryngeal kinematic timings
3. Swallow safety outcomes

Subjects: 16 post-stroke patients (13 male, 3 female).

Method: A comparison of baseline and final VFSS of clinical patients all with post-stroke after a range of 3-5 days a week and a minimum of 30 total days of treatment to obtain:

1. Hyoid Kinematics (anterior, superior, excursion)
2. Time-To-Laryngeal Vestibule Closure (LVC) & LVC Duration
3. Penetration-Aspiration Scale (PAS) scores

All measurements were obtained using TIMS-DICOM software for VFSS review. All patients in this study received Ampcare's ESP as a treatment protocol for dysphagia rehabilitation as their primary treatment, in various clinical settings. NMES was implemented with suprahyoid placement, frequency of 30 Hz, phase duration of 50 μ s and variable intensity in mA dependent on patient tolerance and progression.

Outcome measures: A one-way repeated measures ANOVA (RM-MANOVA) was performed to examine within-subjects changes of hyoid kinematics and laryngeal vestibule timings pre- and post-treatment. Crosstabulations were performed to examine pre- and post-treatment associations with penetration and/or aspiration.

Results: Crosstabulations displayed a significant association of lower PAS scores post-treatment ($\chi^2= 60.16, p< 0.001$). Pre-treatment PAS scores indicating penetration or aspiration (PAS scores ≥ 3) occurred on 47% of all swallows (figure 1), yet similar scores post-treatment occurred on only 11% of swallows (figure 2).

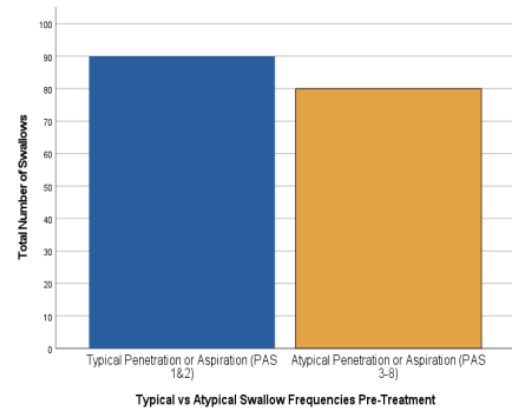
RM-MANOVA results indicated a significant effect of treatment on hyoid excursion ($F= 9.32, p= 0.008$) and time-to-LVC ($F=54.74, p< 0.001$) (figure 3).

Effect size calculations of partial eta-squared (η^2_p) indicated that both hyoid excursion ($\eta^2_p= .37$) and time-to-LVC ($\eta^2_p= .77$) demonstrated large effects.

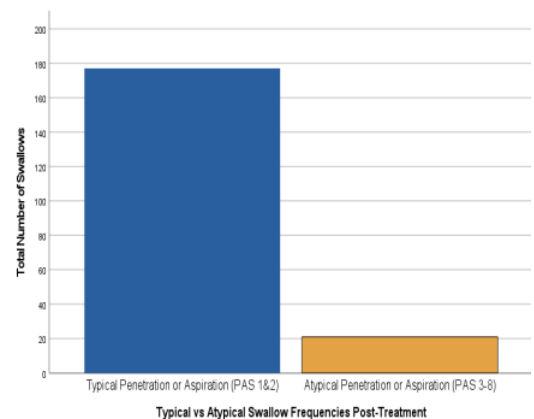
Conclusions: The results from this project support that NMES may be a viable treatment option for patients experiencing post-stroke dysphagia, in agreement with findings from Speyer et al. (2022), and particularly in dysphagia characterized by reduced laryngeal elevation and events of penetration and/or aspiration (Martindale et al., 2019). In this small, clinically based cohort of patients with post-stroke dysphagia, NMES with suprahyoid placement and parameters based on muscle and swallow physiology significantly improved hyoid excursion, decreased time-to-LVC, and decreased occurrences of penetration and/or aspiration.

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Pre-Treatment Typical and Atypical Swallow Safety (Figure 1)



Post-Treatment Typical and Atypical Swallow Safety (Figure 2)



Time-to-LVC Pre-Treatment vs Post-Treatment (Figure 3)

