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VitalStim® Plus

Scientific Studies Overview

DJO GLOBAL

Stroke

Brain injury

Head/Neck cancer

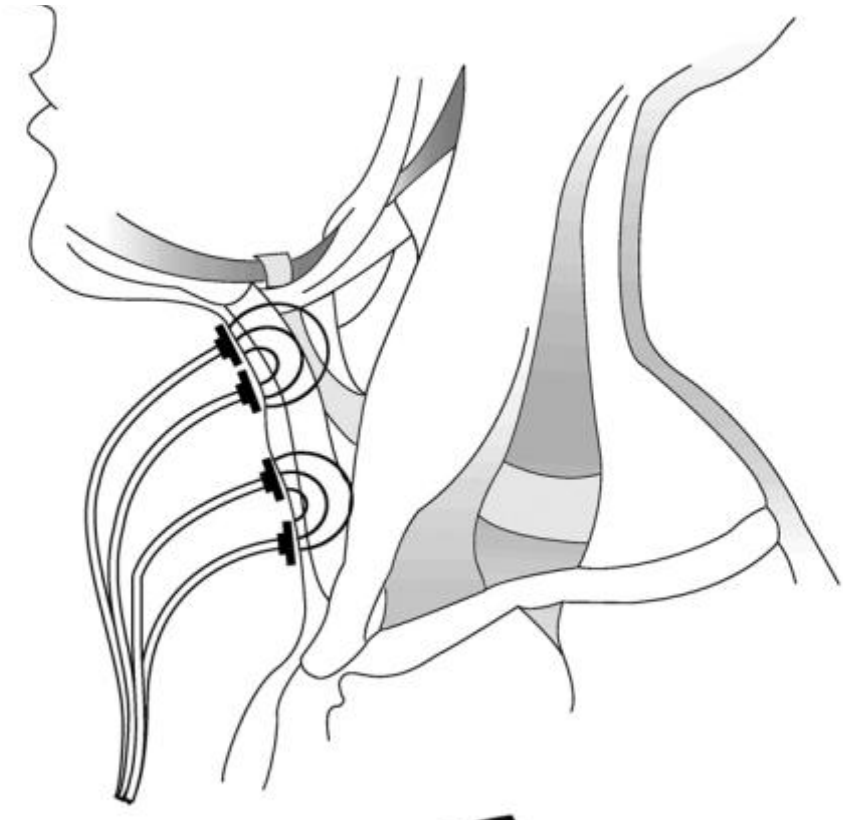
Various ethiologies

Tube fed patients

Cortical reorganisation

Dysphonia

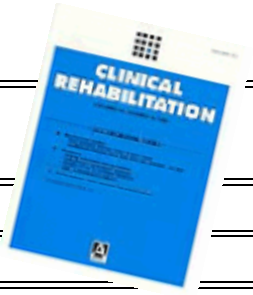
Kinematic analysis



VITALSTIM® THERAPY

DYSPHAGIA in STROKE PATIENTS (studies in chronological order)

Effects of neuromuscular electrical stimulation combined with effortful swallowing on post-stroke oropharyngeal dysphagia: a randomised controlled trial.	
Authors	Park JS, Oh DH, Hwang NK, Lee JH.
Published	J Oral Rehabil. 2016 Jun;43(6):426-34.
Date	Jun 2016
Place of origin	Inje University, Gimhae, Korea
Background	In recent years, NMES combined with traditional swallowing therapy has been used to improve functional recovery in patients with post-stroke dysphagia.
Objective	To investigate the effects of effortful swallowing combined with neuromuscular electrical stimulation on hyoid bone movement and swallowing function in stroke patients.
Tested products	VitalStim
Study design & methods	**Single-blind, randomised, controlled study.** *Subjects*: 50 stroke patients with mild dysphagia (onset duration >6 months) who were able to swallow against the resistance applied by using NMES and cooperate actively in training. *Methods*: • In the experimental group, two pairs of electrodes were placed horizontally in the infrahyoid region to depress the hyoid bone. The NMES intensity was increased gradually until the participants felt a grabbing sensation in their neck and performed an effortful swallow during the stimulation. • In the placebo group, the same procedure was followed except for the intensity, which was increased gradually until the participants felt an electrical sensation. • Electrode placement was in the infrahyoid region, one channel at the left side and the other channel at the right side, targeting the sternohyoid, sternothyroid and omohyoid muscles - with the aim of providing resistance to the upward hyoid movement during swallowing as a form of resistance training. All participants underwent this intervention for 30 min per session, 5 sessions per week, for 6 weeks. *Outcomes*: Videofluoroscopic swallowing studies (VFSS) were carried out before and after the intervention and kinematics of the hyoid bone and swallowing function were analysed based on the VFSS.
Results	• Before the intervention, there were no significant differences in VDS, movement of the hyoid bone and PAS score between the 2 groups. *Effects on kinematics of the hyoid bone* • The experimental group showed significant improvement in vertical and horizontal displacements of the hyoid bone, whereas the placebo group did not show any statistically significant improvement. *Effects on swallowing function* • The experimental group showed a statistically significant difference in the total score, the oral and pharyngeal phase of VDS, and on the PAS, whereas the placebo group showed a statistically significant difference only in the total score and the oral phase of the VDS.
Conclusion	Effortful swallowing combined with NMES produced a significant increase in anterior and superior hyoid bone movement and a significant improvement of swallowing function in the pharyngeal phase.
Key message	Effortful swallowing combined with NMES was confirmed to be effective in the pharyngeal phase of swallowing and in improving hyoid movement in stroke patients with dysphagia.
Pubmed ID	26969528

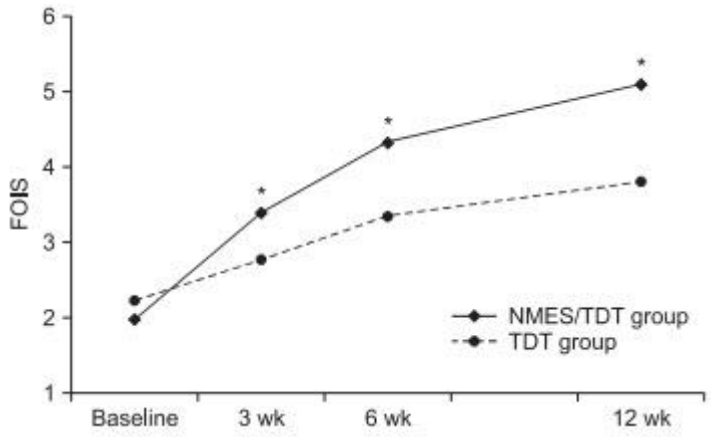


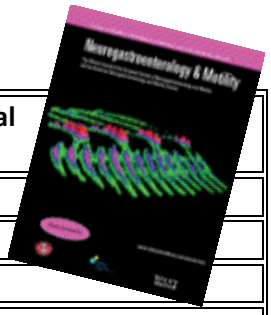
The effects of surface neuromuscular electrical stimulation on post-stroke dysphagia: A systemic review and meta-analysis.	
Authors	Chen YW, Chang KH, Chen HC, Liang WM, Wang YH, Lin YN
Published	Clin Rehabil. 2015 Feb 19. [Epub ahead of print]
Date	Feb 2015
Place of origin	Department of Physical Medicine and Rehabilitation, Wan Fang Hospital, Taipei Medical University, Taipai, Taiwan.
Objective	To evaluate whether swallow treatment with neuromuscular electrical stimulation is superior to that without neuromuscular electrical stimulation, and whether neuromuscular electrical stimulation alone is superior to swallow therapy.
Study design & methods	**Systematic review and meta-analysis.** *Studies*: randomized and quasi-randomized controlled trials that used neuromuscular electrical stimulation to treat post-stroke dysphagia. • 8 studies met the inclusion criteria *Methods*: the meta-analysis comprised two main comparisons: • swallow treatment with neuromuscular electrical stimulation vs. swallow treatment without neuromuscular electrical stimulation • neuromuscular electrical stimulation vs. traditional swallow therapy.
Results	*Swallow treatment with NMES vs. swallow treatment without NMES* • Significant standardized mean difference (SMD) of 1.27 (95% confidence interval (CI) = 0.51-2.02, P = 0.001) • Significant heterogeneity (I2 = 85%). • The SMD of 1.31 (P< 0.01) in the videofluoroscopic swallowing study subgroup analysis indicated that swallow treatment with NMES was more effective than that without NMES in improving the swallowing performance on videofluoroscopic swallowing study. *NMES alone vs. swallow therapy* • The meta-analysis demonstrated a non-significant SMD of 0.25 (95% CI = -0.16-0.65, P = 0.23) without significant heterogeneity (I2 = 16%).
Conclusion	• Swallow treatment with NMES seems to be more effective than that without NMES for post-stroke dysphagia in the short term considering the limited number of studies available. • Evidence was insufficient to indicate that neuromuscular electrical stimulation alone was superior to swallow therapy.
Key message	Adding NMES to swallow therapy significantly increases the effectiveness of the treatment.
Pubmed ID	25697453

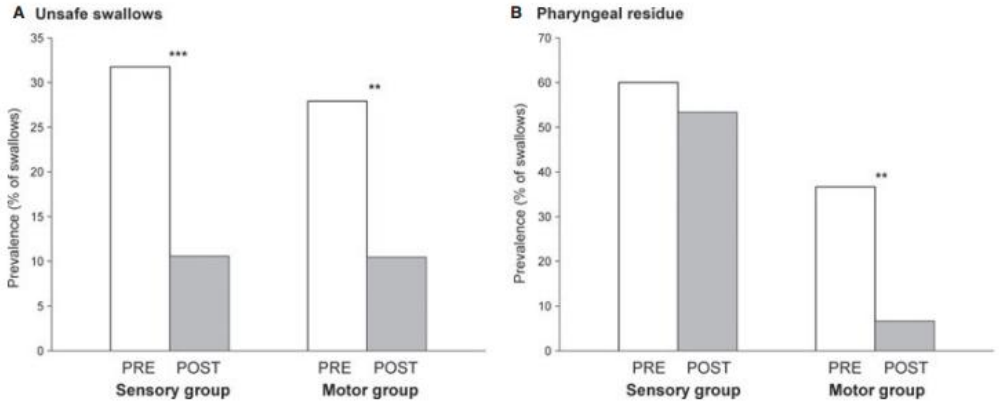
Effect of Low-Frequency rTMS and NMES on Subacute Unilateral Hemispheric Stroke With Dysphagia	
Authors	Lim KB, Lee HJ, Yoo J, Kwon YG
Published	Ann Rehabil Med. 2014 Oct;38(5):592-602.
Date	Oct 2014
Place of origin	Department of Physical Medicine and Rehabilitation, Inje University Ilsan Paik Hospital, Goyang, Korea.
Objective	To investigate the effect of low-frequency repetitive transcranial magnetic stimulation (rTMS) and neuromuscular electrical stimulation (NMES) on post-stroke dysphagia.
Tested products	VitalStim
Study design & methods	**Randomised comparative study.** *Subjects*: 60 patients with subacute (<3 months), unilateral hemispheric stroke and dysphagia, of which 47 completed the sudy. *Methods*: patients were randomly assigned to • Conventional dysphagia therapy (CDT), • rTMS group: rTMS was performed at 100% resting motor threshold with 1 Hz frequency for 20 minutes per session (5 days per week for 2 weeks). • NMES group: electrical stimulation was applied to the anterior neck for 30 minutes per session (5 days per week for 2 weeks). All three groups were given conventional dysphagia therapy for 4 weeks. *VitalStim protocol:* • Vitalstim electrode position 1: between the digastrics muscle and the hyoid bone and between the hyoid bone and the thyroid cartilage for channel 1, and between the thyroid cartilage and the cricoids cartilage and vertically under the cricoid cartilage for channel 2. • Intensity was between 7 and 9 mA (motor level) • Duration of a treatment session: 30 minutes • Duration of the treatment: 5days/week for 2 weeks • Total sessions: 10 *Outcomes*: • Functional dysphagia scale (FDS), • Pharyngeal transit time (PTT), • Penetration-aspiration scale (PAS), • American Speech-Language Hearing Association National Outcomes Measurement System (ASHA NOMS) swallowing scale. Patients were assessed at baseline, after 2 weeks, and after 4 weeks.
Results	• 47 patients completed the study; 15 in the CDT group, 14 in the rTMS group, and 18 in the NMES group. • Mean changes in FDS and PAS for liquid during first 2 weeks in the rTMS and NMES groups were significantly higher than those in the CDT group, but no significant differences were found between the rTMS and NMES group. • PTT showed a decreased pattern in all three groups. The rTMS and NMES groups showed a greater decrease than the CDT group in the PTT, but the difference among the groups was not significant. • No significant difference in mean changes of FDS and PAS for semi-solid, and ASHA NOMS was observed among the three groups.
Conclusion	Both rTMS and NMES induced the early recovery of the swallowing function for liquid in stroke patients, but no difference was observed between the two methods. Therefore, both low-frequency rTMS and NMES might be useful therapeutic options to recover swallowing function of dysphagic stroke patients.
Key message	Both low-frequency rTMS and NMES could induce **early recovery** from dysphagia; therefore, they both could be **useful therapeutic options** for dysphagic stroke patients.
Pubmed ID	25379488

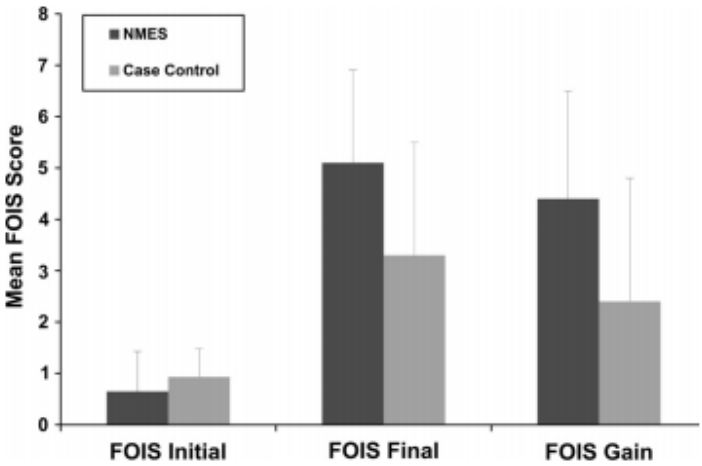
Functional Outcome in Acute Stroke Patients with Oropharyngeal Dysphagia after Swallowing Therapy.	
Authors	Huang KL, Liu TY, Huang Y, Leong CP, Lin WC, Pong YP.
Published	J Stroke Cerebrovasc Dis. 2014 Nov-Dec;23(10):2547-53.
Date	Sep 2014
Place of origin	Department of Otolaryngology-Head and Neck surgery, Chang Gung Memorial Hospital, Chiayi, Taiwan.
Background	Dysphagia after stroke is associated with mortality and increased pulmonary complications. Swallowing therapies may decrease pulmonary complications and improve patients' quality of life after stroke.
Objective	To assess the functional recovery of acute stroke patients with dysphagia after different swallowing therapies.
Tested products	Intelect VitalStim
Study design & methods	**Randomised comparative study.** *Subjects*: 29 acute (<3 month) stroke patients with dysphagia. *Methods*: patients were randomly divided into 3 therapy groups: • Traditional swallowing (TS), • Oropharyngeal NMES with VitalStim, • Combined NMES/TS. *VitalStim protocol:* • VitalStim electrode position 1: in one vertical line with channel 1 above the thyroid notch and channel 2 below the thyroid notch • Duration of a treatment session: 60 min • Treatment frequency: 3x/week • Total treatment: 10 sessions • The intensity was increased according to patient's comfort to motor level (muscle contraction). *Outcomes*: • Clinical functional oral intake scale (FOIS) • 8-point penetration-aspiration scale (PAS) • Functional dysphagia scale (FDS) of VFS Outcomes were compared before and after treatment.
Results	• There were no differences in the clinical parameters and swallowing results of the FOIS and VFS before swallowing treatment among the 3 groups (P > .05). • TS therapy and combined therapy both had significant swallowing improvement after therapy according to the FOIS and 8-point PAS (P < .05). • When comparing the results of the VFS among the 3 groups, the combined NMES/TS group had significantly better swallowing performance in FDS score than TS or NMES groups for eating cookies and thick liquid (P < .05).
Conclusion	• TS therapy and combined therapy both have therapeutic effects on improving the swallowing function based on the clinical FOIS and 8-point PAS during VFS in acute stroke patients with dysphagia. • However, among the 3 therapies, **the combined NMES with TS therapy may result in more positive effects**, because it showed a significant improvement in FDS when the patients were on a solid diet and thick liquid during VFS.
Key message	In acute stroke patients with dysphagia, combined NMES/TS therapy is the most effective swallowing therapy in taking solid diets and thick liquids.
Pubmed ID	25245482

Study of transcutaneous neuromuscular electrical stimulation (vitalstim) therapy for post-stroke dysphagia.	
Authors	Li L, Li Y, Huang R, Yin J, Shen Y, Shi J.
Published	Eur J Phys Rehabil Med. 2015 Feb;51(1):71-8.
Date	Jul 2014
Place of origin	Barrow Neurological Institute, St. Joseph's Hospital and Medical Center, Phoenix, USA
Background	Dysphagia is not uncommon after stroke. Dysphagia may delay the functional recovery and substantially affects the quality of life after stroke, mainly if left untreated. To detect and treat dysphagia as early as possible is critical for patients' recovery after stroke.
Objective	To investigate the effects of neuromuscular electrical stimulation (VitalStim) and traditional swallowing therapy on recovery of swallowing difficulties after stroke.
Tested products	VitalStim hand held device
Study design & methods	**Randomized controlled trial.** *Subjects*: 135 stroke patients (>3 months) who had a diagnosis of dysphagia (age 50--80). *Methods*: subjects were randomly divided into 3 groups receiving 4 weeks of therapy: • Traditional swallowing therapy (n=45), consisting of basic training and direct food intake training, • VitalStim therapy (n=45), • VitalStim therapy plus traditional swallowing therapy (n=45). *VitalStim protocol:* • VitalStim electrode position 1: top set of electrodes was placed in submental region between anterior belly of digastric muscle and hyoid bone, and hyoid bone and thyroid cartilage. The bottom set was placed between thyroid cartilage and cricoid cartilage, and below cricoid cartilage. • Intensity was increased to approx 7mA (motor level) • Duration of a treatment session: 1 hour • Treatment frequency: 5x/week • Total treatment: 20 sessions *Outcomes*: swallowing function was assessed at baseline and after 4 weeks of treatment by: • Surface electromyography (sEMG), • Standardized Swallowing Assessment (SSA), • Videofluoroscopic Swallowing Study (VFSS): Oral transit time (OTT), pharyngeal transit time (PTT) and lanyngeal closure duration (LCD). • Visual analog scale (VAS) for pain
Results	• 118 subjects completed the study, 40 in the traditional swallowing therapy group and VitalStim therapy group, 38 in the VitalStim + traditional swallowing therapy group. • Baseline VAS was highest in the VitalStim group indicating more severe condition in this group at baseline. • There were significant improvements in sEMG value, SSA and OTT and PTT scores in each group after the treatment (P<.001). • LCD scores did not change significantly. • The improvements is sEMG value , SSA value , OTT and PTT were significantly higher in the VitalStim + traditional swallowing therapy group than the other two groups (P<.001). • There were no significant differences in the improvements between the VitalStim and Traditional therapy groups.
Conclusion	• Both VitalStim and traditional therapy significantly improved swallowing function. The combination of both modalities produced significantly higher improvements that the single treatments. • The authors conclude VitalStim coupled with traditional therapy is the best treatment option for patients with post-stroke dysphagia. • They believe VitaStim is an important addition to the armamentarium of the swallowing therapist.
Key message	VitalStim therapy coupled with traditional swallowing therapy significantly improves swallowing function in post-stroke dysphagic patients.
Pubmed ID	25052012

The effect of early neuromuscular electrical stimulation therapy in acute/subacute ischemic stroke patients with Dysphagia.	
Authors	Lee KW, Kim SB, Lee JH, Lee SJ, Ri JW, Park JG.
Published	Ann Rehabil Med. 2014 Apr;38(2):153-9.
Date	Apr 2014
Place of origin	Dept. of Physical Medicine and Rehabilitation, Dong-A University College of Medicine, Busan; Regional Cardiocerebrovascular Center, Dong-A University Hospital, Busan, Korea.
Objective	To compare the outcome of an early application of neuromuscular electrical stimulation (NMES) combined with traditional dysphagia therapy (TDT) versus traditional dysphagia therapy only in acute/subacute ischemic stroke patients with moderate to severe dysphagia by videofluoroscopic swallowing study (VFSS).
Tested products	VitalStim
Study design & methods	**Prospective randomised comparative study.** *Subjects*: 57 dysphagic stroke patients were enrolled in a VFSS within 10 days after stroke onset. *Methods*: Patients were randomly assigned into two treatment groups. • 31 patients received NMES combined with TDT (NMES/TDT group) • 26 patients received TDT only (TDT group). *VitalStim protocol:* • Electrode placement: not clear from the study (confusing info in abstract versus methods) • Intensity: maximal tolerable intensity • Duration of treatment session: 30 minutes, • Treatment frequency: 5 days / week during 3 weeks • Total treatment: 15 sessions *Outcomes*: The swallowing function was evaluated at baseline and 3, 6, and 12 weeks after baseline. Outcomes of the VFSS were assessed using the Functional Oral Intake Scale (FOIS).
Results	• Both groups showed a significant improvement on the FOIS after treatment. • The FOIS score was significantly more improved at 3, 6 and 12 weeks after baseline in the NMES/TDT group than in the TDT group ($p<0.05$).  *Change in FOIS in both groups. FOIS is significantly increased in NMES/TDT group compared with TDT group at 3, 6 and 12 wks. *p<0.05* • NMES groups did not show any adverse effects until 12 weeks after stroke.
Conclusion	An early application of NMES combined with TDT showed a positive effect in acute/subacute ischemic stroke patients with dysphagia. These results indicated that the early application of NMES could be used as a supplementary treatment of TDT to help rehabilitate acute/subacute dysphagic stroke patients by improving their swallowing coordination.
Key message	Early VitalStim therapy applied to post-stroke dysphagia patients showed a significant improvement in their swallowing function at 3, 6, and 12 wks after onset of stroke compared with the traditional therapy only.
Pubmed ID	24855608



Effect of surface sensory and motor electrical stimulation on chronic post-stroke oropharyngeal dysfunction.	
Authors	Rofes L, Arreola V, López I, Martin A, Sebastián M, Ciurana A, Clavé P.
Published	Neurogastroenterol Motil. 2013 Nov;25(11):888-e701.
Date	Nov 2013
Place of origin	Centro de Investigación Biomédica en Red de enfermedades hepáticas y digestivas (CIBERehd), Instituto de Salud Carlos III, Barcelona, Spain.
Background	Chronic poststroke oropharyngeal dysfunction (OD) is a common condition, leading to severe complications, including death. Treatments for chronic poststroke OD are scarce.
Objective	To assess and compare the efficacy and safety of treatment with surface electrical stimulation (e-stim) at sensory and motor intensities in patients with chronic poststroke oropharyngeal dysfunction. Sensory e-stim is used in this study with the aim to stimulate the peripheral sensory system through thyrohyoid electrodes to increase afferent drive and promote cortical plasticity.
Tested products	Intelect VitalStim
Study design & methods	**Randomised double-blind parallel group study.** *Subjects*: 20 chronic poststroke patients with OD. Mean age was 75, mean days poststroke was 336.26. Each patient served as his/her own control. *Methods*: patients were randomly assigned to e-stim at sensory (n=10) or motor level (n=10). *Vitalstim protocol:* • sensory e-stim: treatment intensity: 75% of motor threshold, electrode placement thyrohyoid • motor e-stim: treatment intensity: motor threshold, electrode placement suprahyoid • Duration of treatment sessions: 1 hour • Frequency of treatment: 5 days / week • Total treatment: 10 sessions (10 days) *Outcomes*: videofluoroscopy was performed at the beginning and end of the study to assess signs of impaired efficacy and safety of swallow and timing of swallow response.
Results	• After sensory stimulation, the number of unsafe swallows was reduced by 66.7% ($p < 0.001$), the laryngeal vestibule closure time by 22.94% ($p = 0.027$) and maximal vertical hyoid extension time by 18.6% ($p = 0.036$). • After motor stimulation, the number of unsafe swallows was reduced by 62.5% ($p = 0.002$), the laryngeal vestibule closure time by 38.26% ($p = 0.009$) and maximal vertical hyoid extension time by 24.8% ($p = 0.008$). • Moreover, the motor stimulus reduced the pharyngeal residue by 66.7% ($p = 0.002$), the upper esophageal sphincter opening time by 39.39% ($p = 0.009$), and increased bolus propulsion force by 211.1% ($p = 0.008$).  • No serious adverse events were detected during the treatment.
Conclusion	Surface e-stim, both at sensory and motor intensities, is a safe and effective therapy for chronic poststroke dysphagic patients, with specific effects on the safety and efficacy of swallowing. **Both sensory and motor level stim improve safety of swallow, motor level stim additionally improves efficacy of swallow.**
Key message	VitalStim is a safe and effective treatment for chronic poststroke dysphagic patients.
Pubmed ID	23937476

Neuromuscular electrical stimulation efficacy in acute stroke feeding tube-dependent dysphagia during inpatient rehabilitation.	
Authors	Kushner DS, Peters K, Eroglu ST, Perless-Carroll M, Johnson-Greene D.
Published	Am J Phys Med Rehabil. 2013 Jun;92(6):486-95.
Date	Jun 2013
Place of origin	Department of Rehabilitation Medicine, University of Miami Miller School of Medicine, Miami, FL, USA.
Objective	To compare the efficacy of neuromuscular electrical stimulation (NMES) in addition to traditional dysphagia therapy (TDT) including progressive resistance training (PRT) with that of TDT/PRT alone during inpatient rehabilitation for treatment of feeding tube-dependent dysphagia in patients who have had an acute stroke.
Tested products	VitalStim
Study design & methods	**Case Control study.** *Subjects*: 92 patients who have had an acute stroke with initial Functional Oral Intake Scale (FOIS) scores of 3 or lower and profound to severe feeding tube-dependent dysphagia. • NMES group: 65 patients, received NMES with TDT/PRT • Case-control group: 27 patients, received only TDT/PRT. Initial FOIS score in the NMES group was significantly worse than in the case-control group. *VitalStim protocol*: • All patients received daily treatment session of 1 hour during a mean of 18 days. • Multiple standard electrode placements were used depending on clinical assessment. • Intensity was increased to submaximal motor contraction level. *Outcomes*: FOIS (Functional Oral Intake Scale) scores before and after intervention (clinical evaluation by speech language pathologist (SLP))
Results	• The mean ± SD FOIS score after NMES with TDT/PRT treatment was 5.1 ± 1.8 compared with 3.3 ± 2.2 in the case-control TDT/PRT group. • The mean gain for the NMES group 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 TDT/PRT group ($z = 3.64$; $P < 0.001$).  • 46% (30 of 65) of the patients within the NMES group had minimal or no swallowing restrictions (FOIS score of 5-7) after treatment, whereas 26% (7 of 27) of those in the case-control group improved to FOIS scores of 5-7, a statistically significant difference ($P = 0.01$).
Conclusion	This study suggests that NMES with TDT/PRT is significantly more effective than TDT/PRT alone during inpatient rehabilitation in reducing feeding tube-dependent dysphagia in patients who have had an acute stroke.
Key message	NMES added to traditional dysphagia therapy (TDT) is more effective than TDT alone and is safe and easy to implement through trained SLPs.
Pubmed	23478451

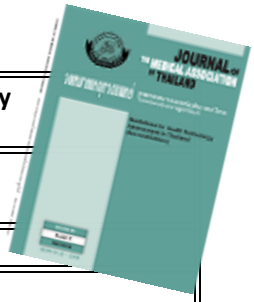
Combined Neuromuscular Electrical Stimulation (NMES) with Fiberoptic Endoscopic Evaluation of Swallowing (FEES) and Traditional Swallowing Rehabilitation in the Treatment of Stroke-Related Dysphagia.	
Authors	Sun SF, Hsu CW, Lin HS, Sun HP, Chang PH, Hsieh WL, Wang JL.
Published	Dysphagia. 2013 Dec;28(4):557-66.
Date	Apr 2013
Place of origin	Department of Physical Medicine and Rehabilitation, Kaohsiung Veterans General Hospital, Kaohsiung, Taiwan.
Background	Dysphagia is common after stroke. Neuromuscular electrical stimulation (NMES) and fiberoptic endoscopic evaluation of swallowing (FEES) for the treatment of dysphagia have gained in popularity, but the combined application of these promising modalities has rarely been studied.
Objective	To evaluate whether combined NMES, FEES, and traditional swallowing rehabilitation can improve swallowing functions in stroke patients with moderate to severe dysphagia.
Tested products	VitalStim
Study design & methods	**Prospective Case Series.** *Subjects*: 32 patients with moderate to severe dysphagia poststroke (≥3 weeks). 29 patients completed the study. *Methods*: • Patients received 12 sessions of NMES for a period of 2-3 weeks. • FEES was done before and after NMES for evaluation and to guide dysphagic therapy. • All patients subsequently received 12 sessions of traditional swallowing rehabilitation for 4 weeks (50 min/day, 3 days/week). *VitalStim protocol:* • VitalStim electrode position 3b: one pair placed horizontally in the submental region above the hyoid bone and the other pair over the thyroid cartilage on either side of the midline in the laryngeal region on the hyrohyoid muscles medial to sternocleidomastoid muscle. • Current intensity: motor level – max tolerable/comfortable intensity. • Duration of treatment session: 1 hour/day • Treatment frequency: 5 days / week • Total treatment: 12 sessions *Outcomes*: • Primary outcome measure was the Functional Oral Intake Scale (FOIS). • 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	• FOIS, 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 ($p < 0.001$, each compared with baseline). • Most patients reported considerable satisfaction with no serious adverse events. • 23 of the 29 (79.3 %) patients maintained oral diet with no pulmonary complications at 2-year follow-up.
Conclusion	This preliminary case series demonstrated that combined NMES, FEES, and traditional swallowing rehabilitation showed promise for improving swallowing functions in stroke patients with moderate-to-severe dysphagia. The benefits were maintained for up to 2 years. The results are promising enough to justify further studies.
Key message	The positive results from this case series, showing improved swallowing functions and patient satisfaction, provide support for introducing this promising combination treatment including VitalStim into clinical practice.
Pubmed	23584790

Effortful swallowing training combined with electrical stimulation in post-stroke Dysphagia: a randomized controlled study.	
Authors	Park JW, Kim Y, Oh JC, Lee HJ.
Published	Dysphagia. 2012 Dec;27(4):521-7.
Date	Dec 2012
Place of origin	Department of Physical Medicine and Rehabilitation, Dongguk University Ilsan Hospital, Republic of Korea.
Background	Upward and superior movement of the larynx is an important aspect of swallowing and is very closely related to airway protection, while decreased laryngeal elevation causes aspiration.
Objective	To test the effect of effortful swallow combined with surface electrical stimulation used as a form of resistance training in post-stroke patients with dysphagia.
Tested products	VitalStim
Study design & methods	**Double-blind, randomized, controlled study.** *Subjects*: 20 post-stroke (> 1 month) dysphagic patients. *Methods*: patients were randomly divided into two groups: • Effortful swallow with infrahyoid motor electrical stimulation (experimental group, n = 10). Electrical stimulation was applied to the skin above the infrahyoid muscle with the current adjusted until muscle contraction occurred and the hyoid bone was depressed. • Effortful swallow with infrahyoid sensory electrical stimulation (control group, n = 10). The stimulation intensity was applied just above the sensory threshold. *Vitalstim Protocol:* • All electrodes were placed infra-hyoid. • Duration of treatment session: 20 min • Treatment frequency: 3x / week • Total treatment: 12 sessions, 4 weeks • The patients in both groups were asked to swallow effortfully in order to elevate their hyolaryngeal complex when the stimulation began. *Outcomes*: • Hyolaryngeal excursion: max anterior hyoid displacement, max vertical hyoid displacement, max anterior laryngeal displacement, max vertical laryngeal displacement • Maximal width of the upper esophageal sphincter (UES) opening • Penetration-aspiration scale (PAS) Blinded biomechanical measurements before and after training were performed.
Results	• In the experimental group, the maximal vertical displacement of the larynx was increased significantly after the intervention ($p < 0.05$). • The maximal vertical displacement of the hyoid bone and the maximal width of the UES opening increased but the increase was not found to be significant ($p = 0.066$). • There was no increase on those parameters in the control group. • There were no significant changes in anterior movement and the PAS.
Conclusion	Effortful swallow training combined with electrical stimulation as a form of resistance training increased the extent of laryngeal excursion. This intervention can be used as a new treatment method in post-stroke patients with dysphagia.
Key message	Effortful swallow combined with VitalStim surface electrical stimulation increased the extent of laryngeal excursion in post-stroke patients with dysphagia.
Pubmed ID	22447240

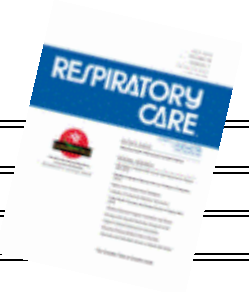
Treatment of post-stroke dysphagia by vitalstim therapy coupled with conventional swallowing training.	
Authors	Xia W, Zheng C, Lei Q, Tang Z, Hua Q, Zhang Y, Zhu S.
Published	J Huazhong Univ Sci Technolog Med Sci. 2011 Feb;31(1):73-6.
Date	Feb 2011
Place of origin	Department of Neurology, Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China.
Objective	To investigate the effects of VitalStim therapy coupled with conventional swallowing training on recovery of post-stroke dysphagia.
Tested products	VitalStim
Study design & methods	**Randomised controlled study.** *Subjects*: 120 patients with post-stroke dysphagia (duration +/- 9 days on average) *Methods*: patients were randomly and evenly divided into three groups: • conventional swallowing therapy group, • VitalStim therapy group, • VitalStim therapy plus conventional swallowing therapy group. *VitalStim protocol:* • Electrode placement and intensity: according to VFSS scores, patient's tolerance, and condition of patients. • Duration of treatment session: 30 min • Treatment frequency: 2x/day – 5 days/week • Total treatment: 4 weeks (40 sessions) *Outcomes*: swallowing function was evaluated before and after the treatment: • Surface electromyography (sEMG) of swallowing muscles • Standardized Swallowing Assessment (SSA) score • Videofluoroscopic Swallowing Study (VFSS) tests • Swallowing-related quality of life score (SWAL-QOL)
Results	• There were significant differences in sEMG value, SSA, VFSS, and SWAL-QOL scores in each group between prior to and after treatment. • After 4-week treatment, sEMG value, SSA, VFSS and SWAL-QOL scores were significantly greater in the VitalStim therapy plus conventional swallowing training group than in the conventional swallowing training group and VitalStim therapy group • There were no significant differences in the outcome measures after treatment between conventional swallowing therapy group and VitalStim therapy group.
Conclusion	VitalStim therapy coupled with conventional swallowing therapy can alleviate post-stroke dysphagia and thereby improve patients' quality of life.
Key message	Significantly better recovery of swallowing function when VitalStim is added to standard exercise therapy.
Pubmed ID	21336727

Sensory transcutaneous electrical stimulation improves post-stroke dysphagic patients.	
Authors	Gallas S, Marie JP, Leroi AM, Verin E.
Published	Dysphagia. 2010 Dec;25(4):291-7.
Date	Dec 2010
Place of origin	Service de physiologie digestive, urinaire, respiratoire et sportive, Rouen Cedex, France.
Background	Oropharyngeal dysphagia is frequent in stroke patients and increases mortality, mainly because of pulmonary complications.
Objective	To test the hypothesis that sensitive transcutaneous electrical stimulation applied submentally during swallowing could help rehabilitate post-stroke oropharyngeal dysphagia by improving cortical sensory motor circuits.
Tested products	
Study design & methods	**Outcomes study.** *Subjects*: 11 patients with stable chronic post-stroke dysphagia with pharyngeal residue and/or laryngeal aspiration diagnosed by videofluoroscopy. *Methods*: • Submental electrical stimulations were performed for 1 h every day for 5 days (electrical trains: 5 s every minute, 80 Hz, under motor threshold). During the electrical stimulations, the patients were asked to swallow one teaspoon of paste or liquid. • Electrodes were placed supra-hyoid, in front of the mylohyoid muscles. *Outcomes*: swallowing was evaluated before and after the week of stimulations using • Dysphagia handicap index questionnaire • Videofluoroscopy • Cortical mapping of pharyngeal muscles (pharyngeal motor evoked potentials were registered during transcranial pharyngeal cortical stimulations).
Results	• The results of the questionnaire showed that oropharyngeal dysphagia symptoms had improved ($p < 0.05$) • The videofluoroscopy measurements showed that laryngeal aspiration ($p < 0.05$) and pharyngeal residue ($p < 0.05$) had decreased and that swallowing reaction time ($p < 0.05$) had improved. • Oropharyngeal transit time, pharyngeal transit time, laryngeal closure duration had not changed. • Motor cortical excitability and cortical pharyngeal muscle mapping were not changed suggesting that high-frequency submental electrical stimulations improved swallowing function with no change in the motor cortex. This may be explained by a modification of the sensory cortex, but a direct brainstem effect cannot be ruled out.
Conclusion	These results indicated that sensory submental electrical stimulations during swallowing tasks could help to rehabilitate post-stroke swallowing dysphagia by improving swallowing coordination. Plasticity of the sensory swallowing cortex is suspected.
Key message	Sensory submental electrical stimulation improved oropharyngeal dysphagia symptoms: laryngeal aspiration and pharyngeal residue both decreased, and swallow reaction times improved.
Pubmed ID	19856025

Neuromuscular electrical and thermal-tactile stimulation for dysphagia caused by stroke: a randomized controlled trial	
Authors	KB Lim, HJ Lee, SS Lim, YI Choi
Published	J Rehabil Med. 2009 Feb;41(3):174-8.
Date	2009
Place of origin	Korea (Inje University, Goyang - Howon University, Gunsan)
Background	The efficacy of NMES in treating dysphagia is currently under debate.
Objective	To assess the effectiveness of neuromuscular electrical stimulation (combined with thermal-tactile stimulation) in patients with dysphagia caused by stroke and compare this with thermal-tactile stimulation treatment (TTS) alone.
Tested products	VitalStim
Study design & methods	**Randomized controlled study.** *Subjects*: **28 patients** with diagnosed dysphagia after stroke completed the study. 22 patients had onset of stroke <6 months, 6 patients >6 months prior to the study. *Methods*: • Patients were assigned to either the experimental group (ES + TTS; n=16) or to the control group (TTS; n=12). *VitalStim protocol:* • Vitalstim electrode position 3b: the paired electrodes were placed above the hyoid bone and between the hyoid bone and thyroid cartilage to stimulate the supra-hyoid muscles. • Intensity : supra- and infrahyoid region were stimulated at an average level of 7mA • Duration of treatment session: 1 hour per day, • Treatment frequency: 5 days per week. • Duration of treatment varied from 2-30 days, depending on severity. *Outcome measures:* • score on functional swallowing scale (Freed; non-validated) • score on Penetration-Aspiration Scale (Rosenbek) • pharyngeal transit time measured on videofluoroscopic imaging • discomfort score during treatment on visual analog scale • satisfaction score on 10-point analog scale. Rater • analyzing the VFSS was blinded to the identity of the patients and • whether or not they were part of the study. • tube-feeding ratio in the 2 groups was assessed before and after the study Patients were assessed before and after 4 weeks of treatment. The assessing physiatrist was blinded to the study and the patient groups.
Results	• **Penetration-Aspiration 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. • **Satisfaction scores** were significantly better in the experimental group. • **Discomfort scores** did not significantly differ in both groups • 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.
Conclusion	The results suggest that neuromuscular electrical stimulation combined with thermal-tactile stimulation is a better treatment for patients with swallowing disorders after stroke than thermal-tactile stimulation alone.
Key message	Better results when VitalStim therapy is added to thermal-tactile stimulation treatment.
Pubmed	19229451



Comparing the Effects of Rehabilitation Swallowing Therapy vs. Neuromuscular Electrical Stimulation Therapy among Stroke Patients with Persistent Pharyngeal Dysphagia: A Randomized Controlled Study	
Authors	Permsirivanich W, Tipchatyotin S, Wongchai M, Leelamanit V, Setthawatcharawanich S, Sathirapanya P, Phabphal K, Juntawises U, Boonmeeprakob A.
Published	J Med Assoc Thai. 2009 Feb;92(2):259-65.
Date	2009
Place of origin	Prince of Songkla University, Songkhla, Thailand
Background	Dysphagia after stroke is associated with increased mortality, higher dependence, and longer hospitalization. Different therapeutic strategies have been introduced to improve swallowing impairment. There are no current studies that compare rehabilitation swallowing therapy (RST) and neuromuscular electrical stimulation therapy (NMES).
Objective	To compare treatment outcomes between traditional dysphagia rehabilitation therapy (RST) and NMES intervention in stroke patients with pharyngeal dysphagia.
Tested products	VitalStim
Study design & methods	**Prospective, randomized, single-blinded study** *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). • The traditional therapy group received a combination of compensatory maneuvers, swallowing exercises and thermotactile stimulation. • The NMES group received NMES (VitalStim) with swallowing exercises. Patients in both groups received treatment for 60 minutes, 5 days per week for 4 weeks or until they reached functional oral intake scale (FOIS) level 7. *Vitalstim protocol:* • Electrode position 1: the first electrode was placed midline 1 mm above the thyroid notch, the second electrode immediately superior to the first, the third electrode 1 mm below the thyroid notch, and the fourth electrode immediately inferior to the third. • Intensity was increased until patients felt a grabbing sensation (motor level). • Duration of treatment session: 1 hour • Treatment frequency: 5 days per week • Treatment duration: 4 weeks or until FOIS level 7 *Outcome measures:* • Change in functional oral intake score (FOIS). • Complications related to the treatment • Number of therapy sessions
Results	• At the end of treatment, the average numbers of therapy sessions per subject in the RST and NMES groups were 18.36 ± 3.23 and 17.25 ± 5.64, respectively, a non-significant difference. • Average changes in FOIS scores were 2.46 ± 1.04 for the RST group and 3.17 ± 1.27 for the NMES group, statistically significant at $p < 0.001$. • No complications were observed in either group.
Conclusion	While both RST and NMES therapy showed a positive effect in the treatment of persistent dysphagia in stroke patients, NMES was significantly superior.
Key message	Significantly greater improvement in Functional Oral Intake Scale with VitalStim therapy compared to traditional therapy
Pubmed	19253803



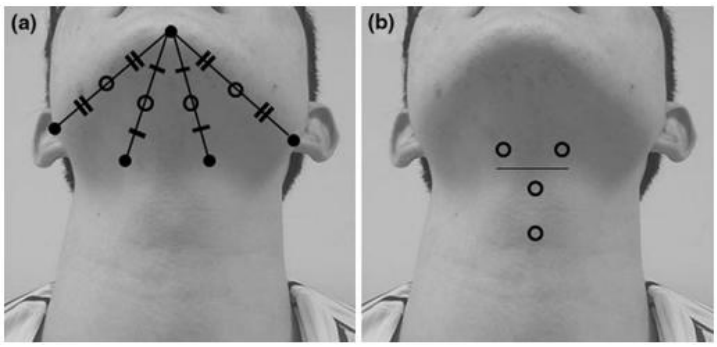
Electrical stimulation for swallowing disorders caused by stroke.	
Authors	Freed ML, Freed L, Chatburn RL, Christian M.
Published	Respir Care. 2001 May;46(5):466-74.
Date	2001
Place of origin	Respiratory Care Department, University Hospitals of Cleveland, Cleveland OH, USA.
Background	An estimated 15 million adults in the United States are affected by dysphagia (difficulty swallowing). Severe dysphagia predisposes to medical complications such as aspiration pneumonia, bronchospasm, dehydration, malnutrition, and asphyxia. These can cause death or increased health care costs from increased severity of illness and prolonged length of stay. Existing modalities for treating dysphagia are generally ineffective, and at best it may take weeks to months to show improvement. One common conventional therapy, application of cold stimulus to the base of the anterior faucial arch, has been reported to be somewhat effective.
Objective	Compare the effectiveness of ES treatment to thermal-tactile stimulation (TS) treatment in patients with dysphagia caused by stroke and assess the safety of the technique.
Tested products	VitalStim
Study design & methods	**Controlled outcomes study.** *Subjects*: 99 dysphagic stroke patients with evidence of aspiration. *Methods*: patients received one of 2 treatment conditions: • Electrical Stimulation (n=63): VitalStim, daily for 1 hour • Thermo-tactile Stimulation (n=36): touching the base of the anterior faucial arch with a metal probe chilled by immersion in ice, daily for 1 hour. *VitalStim protocol:* • Electrode placement was supra- and infra-hyoid for most patients, except for those who had undergone tracheotomy where the electrodes were place suprahyoid. • Stimulation intensity was increased within patient tolerance to motor level. • Duration of treatment session: 1 hour • Treatment frequency: daily *Outcomes*: Swallow function before and after the treatment regimen was assessed: • Swallow score (non-validated): from 0 (aspirates own saliva) to 6 (normal swallow) based on substances the patients could swallow during a modified barium swallow.
Results	• The treatment groups were of similar age and gender ($p > 0.27$), co-morbid conditions ($p = 0.0044$), and initial swallow score ($p = 0.74$). • Both treatment groups showed improvement in swallow score, but the final swallow scores were significantly higher in the ES group (4.52 versus 1.39; $p > 0.0001$). • 98% of ES patients showed some improvement compared to 42% of TS patients. • 27% of TS patients remained at initial swallow score and 11% got worse. • These results are based on similar numbers of treatments (average of 5.5 for ES and 6.0 for TS, $p = 0.36$). • Most patients retained their final swallow function for over 2 years (89% for ES and 67% for TS). • There were no reported complications.
Conclusion	98% of patients in ES group improved swallow compared to 42% of patients in the thermo-tactile group. ES appears to be a safe and effective treatment for dysphagia due to stroke and results in better swallow function than conventional TS treatment.
Key message	Significantly better improvement of swallow function with VitalStim compared to thermo-tactile stim.
Pubmed ID	11309186

DYSPHAGIA in BRAIN INJURY PATIENTS

A randomized controlled study of neuromuscular electrical stimulation in oropharyngeal dysphagia secondary to acquired brain injury.	
Authors	Terré R, Mearin F.
Published	Eur J Neurol. 2015 Apr;22(4):687-e44.
Date	Jan 2015
Place of origin	Functional Digestion Rehabilitation Unit, Institut Guttmann, Neurorehabilitation Hospital, Barcelona, Spain.
Objective	To evaluate the effectiveness of neuromuscular electrical stimulation (NMES) treatment in patients with oropharyngeal dysphagia secondary to acquired brain injury.
Tested products	Chattanooga VitalStim
Study design & methods	**Prospective randomised double-blinded controlled study.** *Subjects*: 20 patients with neurological oropharyngeal dysphagia (14 stroke and 6 severe traumatic brain injury - subacute stage <6m). *Methods*: patients were randomly allocated to one of 2 groups: • 10 patients underwent NMES and conventional swallowing therapy. • 10 patients underwent sham electrical stimulation (SES) and conventional swallowing therapy. Both groups completed 20 sessions (5/wk) of 45 min stimulation. *VitalStim protocol* • electrode placement 3b: the top set was placed horizontally in the submental region over the mylohyoid muscle above the hyoid, and the bottom set was placed on the skin over the thyroid cartilage on either side of the midline, over the region of the thyrohyoid muscle, medial to the sternocleidomastoid muscle. • intensity: motor level *Sham protocol:* • The top electrode was placed on the chin region of the lower jaw and the bottom electrode was placed on either side of the thyroid cartilage in the midline of the thyrohyoid region, internal to the sternocleidomastoid muscle. • No stimulation was applied in the lower electrode and an intensity of 2.5 mA was applied to the upper electrode (without contraction of muscular activity and with minimal patient sensation). *Outcomes:* • FOIS (functional oral intake scale) • Subjective patient satisfaction on a Likert scale (much worse, worse, somewhat worse, the same, somewhat better, better, much better). • Videofluoroscopic examination • Esophageal manometry Patients were assessed at baseline, at the end of treatment (1 month) and at 3-month follow-up.
Results	• Mean FOIS score before treatment was 1.9 for the NMES group and 2.1 for the SES group. • After treatment, the NMES group increased by 2.6 points (4.5 points) compared with only 1 point (3.1 points) for the SES group (P = 0.005). • At 3m of follow-up, mean scores were 5.3 and 4.6 respectively; thus, both groups improved similarly. • At that time point (3 months), tracheal aspiration persisted in six patients in each group. • However, a significant improvement in relation to the bolus viscosity at which aspiration appeared was found in the NMES group versus the SES group (P = 0.015). • Also, a significant increase (P = 0.04) in pharyngeal amplitude contraction was observed at the end of treatment (1 month) in the NMES group compared with the SES group. • At 1m there was a significant difference between groups in patient satisfaction: 6 patients in the NMES vs. 0 patients in the SES group felt 'much better'; 3 patients in the NMES group vs. 1 patient is the SES group felt 'better'. • At 3m the subjective scores were also better for the NMES group, but the difference was not significant.
Conclusion	The results of this study suggest that NMES shortens the recovery time and significantly improves swallowing function in patients with acute oropharyngeal dysphagia secondary to acquired brain injury. The technique is well tolerated and free of adverse effects.

Key message	NMES significantly accelerated swallowing function improvement in patients with oropharyngeal dysphagia secondary to acquired brain injury.
Pubmed ID	25573027

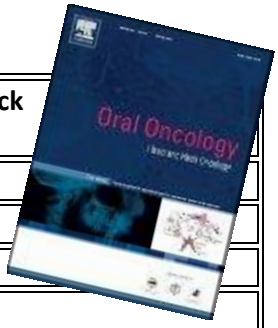
Effect of Electrical Stimulation of the Suprahyoid Muscles in Brain-Injured Patients with Dysphagia.	
Authors	Beom J, Oh BM, Choi KH, Kim W, Song YJ, You DS, Kim SJ, Han TR
Published	Dysphagia. 2015 Aug;30(4):423-9.
Date	Aug 2015
Place of origin	Department of Rehabilitation Medicine, Chungnam National University Hospital, Daejeon, Republic of Korea.
Background	
Objective	To determine whether neuromuscular electrical stimulation of the suprahyoid muscle is effective compared to that of the infrahyoid muscle in brain-injured patients with dysphagia.
Tested products	VitalStim
Study design & methods	**Randomised parallel group study.** *Subjects*: 132 patients with subacute stroke, traumatic brain injury, or brain tumor. *Methods*: patients were randomly allocated to: • NMES on the suprahyoid muscles (SM group, n = 66): 2 electrode pairs above the hyoid bone; StimPlus device, 60Hz; 500µsec. • NMES on the suprahyoid and infrahyoid muscles (SI group, n = 66): 1 electrode pair above and 1 pair below the hyoid bone; VitalStim device, 80Hz; 700µsec; electrode placement 2a. All patients had 10–15 sessions of electrical stimulation during the period of 2–3 weeks. The stimulation intensity was motor level, submaximal. *Outcomes*: the following measurements were done using VFS • Functional dysphagia scale (FDS) • Swallow function score (SFS) • Supraglottic penetration • Subglottic aspiration
Results	• **FDS scores** decreased from 42.0 ± 19.1 to 32.3 ± 17.8 in the SM group and from 44.8 ± 17.4 to 32.9 ± 18.8 in the SI group by per-protocol (PP) analysis, and those decreased from 41.2 ± 20.9 to 34.5 ± 20.3 in the SM group and from 44.3 ± 19.1 to 35.7 ± 20.5 in the SI group by intention-to-treat (ITT) analysis, after electrical stimulation ($p < 0.001$ for each). • **SFS scores** increased from 3.3 ± 1.8 to 4.2 ± 1.6 in the SM group and from 2.8 ± 1.8 to 4.0 ± 1.8 in the SI group by PP analysis, and those increased from 3.3 ± 1.6 to 3.9 ± 1.6 in the SM group and from 2.8 ± 1.9 to 3.6 ± 2.0 in the SI group by ITT analysis, after electrical stimulation ($p < 0.001$, respectively). • However, changes in FDS scores, SFSs were comparable between the SM and the SI groups. • The proportions of patients who revealed improvement in **penetration or aspiration** after NMES were 52.5 % in the SM group and 55.9 % in the SI group, which was not significantly different between the two groups.
Conclusion	The results suggest that both SM and SI therapies induced similar improvements in swallowing function in brain-injured patients.
Key message	NMES treatment significantly imporves swallowing function in brain-injured patients. There was no difference between suprahyoid only or supra+infrahyoid electrode placement.
Pubmed ID	25917017

Kinematic Effects of Hyolaryngeal Electrical Stimulation Therapy on Hyoid Excursion and Laryngeal Elevation.	
Authors	Nam HS, Beom J, Oh BM, Han TR.
Published	Dysphagia. 2013 Dec;28(4):548-56.
Date	Apr 2013
Place of origin	Department of Rehabilitation Medicine, Seoul National University College of Medicine , Seoul,Republic of Korea.
Objective	To assess the effect of repeated treatment sessions of electrical stimulation of the neck muscles on the amplitude of hyoid and laryngeal excursion in dysphagia patients with acquired brain injury.
Tested products	VitalStim
Study design & methods	**Case Control study.** *Subjects*: 50 dysphagia patients in a tertiary hospital with acquired brain injury. *Methods*: patients were randomly assigned into two different treatment groups. • One group received electrical stimulation on the suprahyoid muscles only (SM); • The other group received stimulation with one pair of electrodes on the suprahyoid muscles and the other pair on the infrahyoid muscles (SI).  • Duration of treatment session: 30 min • Treatment frequency: 5 days / week • Total treatment: all patients received 10-15 sessions of ES over 2-3 weeks. • Intensity was increased to max tolerable level, just below pain threshold. • Conventional swallowing therapies were conducted during the 30-min session simultaneously. VFSS (videofluoroscopic swallowing study) was carried out before and after the treatment. *Outcomes*: Temporal and spatial parameters of the hyoid excursion and laryngeal elevation during swallowing were analyzed by two-dimensional motion analysis.
Results	• The SM group (n = 25) revealed a significant increase in maximal anterior hyoid excursion distance and velocity , but there was no significant increase laryngeal elevation. • The SI group (n = 25), however, showed a significant increase in maximal superior excursion distance and maximal absolute excursion distance of laryngeal elevation, but no significant increase in hyoid excursion. • 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.
Conclusion	EST on the suprahyoid muscle 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. The results suggest that targeted electrical stimulation based on pathophysiology is necessary.
Key message	The increase in distances and velocities of hyoid excursion and laryngeal elevation were different according to the stimulation sites. The results favor the idea of targeted electrical stimulation therapy based on the pathophysiology of swallowing problems.
Pubmed ID	23605128

DYSPHAGIA in HEAD/NECK CANCER PATIENTS

Impact of Transcutaneous Neuromuscular Electrical Stimulation on dysphagia in head and neck cancer patients treated with definitive chemoradiation.	
Authors	Bhatt AD, Goodwin N, Cash E, Bhatt G, Silverman CL, Spanos WJ, Bumpous JM, Potts K, Redman R, Allison WA, Dunlap NE.
Published	Head Neck. 2015 Jul;37(7):1051-6.
Date	Apr 2014
Place of origin	Department of Radiation Oncology, Massachusetts General Hospital, Boston, MA, USA.
Background	Dysphagia or dysfunctional swallowing is one of the most detrimental side effects of radiation therapy for head and neck cancer.
Objective	To investigate the role of Transcutaneous NMES therapy in maintaining swallowing function during chemoradiation for locally advanced head and neck cancer.
Tested products	VitalStim (hand-held)
Study design & methods	**Retrospective study** (of a prospectively maintained database of 1141 H&N Cancer patients treated at the institution from January 2006 to March 2011). *Subjects*: 98 patients with locally advanced head and neck cancer. *Methods*: 43 consecutive patients treated with TNMES (treatment group - TG) were compared to 55 control patients (CG). • TG received ≥ 10 VitalStim treatments, mean number of treatments = 14 (range 1-38). • CG received ≤ 9 VitalStim treatments, mean number of treatments = 0 (range 0-9) *Vitalstim protocol:* • VitalStim electrode positions 3a and 3b: supra- and infra-hyoid • Intensity was increased to ≥ 5mA (motor level) • Duration of treatment session: 45-60 min • Treatment frequency: 3x / week beginning at the 1st week of the chemoradiotherapy. *Outcomes*: 3 validated swallowing scores: • Functional Oral Intake Scale (FOIS) - the higher the FOIS (1-7), the better the swallowing function. • 8-point Penetration/Aspiration Scale (PAS) - the higher the PAS (1-8), the worse the swallowing funtion. • Swallowing Performance Status Scale (SPSS) - the higher the SPSS (1-7), the worse the swallowing funtion. The average time between completion of XRT and follow-up data collection, including formal swallow evaluation was 4.5 months.
Results	• Both groups showed worsening swallowing function post chemoradiotherapy when compared to pre-treatment with a decline seen in all 3 swallowing scores. • FOIS score was significantly more declined in the CG versus the TG (23% vs 7%, p=0.015, significant). • *8-point PAS* score was more increased in the CG versus the TG (41% vs 5%, p=0.121, n.s.). • *SPSS* score was more increased in the CG versus the TG (45% vs 18%, p=0.393, n.s.). • Age, race, >10 pack years smoking, diabetes, stage, nodal disease, accelerated fractionation, weight loss, dietary modification, no TNMES and RT dose were identified as significant for poorer scores on the swallowing scales.
Conclusion	• This study found a **significant benefit of VitalStim therapy** using FOIS swallowing scoring scales with trends using SPSS and the 8 point PAS scale. • TNMES can be an **effective adjunctive therapy** in addition to traditional swallowing exercises and could be considered in **both reduction and prevention of dysphagia** in locally advanced head and neck cancer patients.
Key message	Early intervention with VitalStim therapy may successfully reduce swallowing morbidity after chemoradiotherapy for locally advanced head and neck cancers.
Pubmed	24710791

Effects of functional electrical stimulation on dysphagia caused by radiation therapy in patients with nasopharyngeal carcinoma	
Authors	Lin PH, Hsiao TY, YC, Ting LL, Chen WS, Chen SC, Wang TG
Published	Support Care Cancer. 2011 Jan;19(1):91-9.
Date	Nov 2009
Place of origin	Taipei, Taiwan, Republic of China
Background	The prevalence of dysphagia following radiotherapy ranges from 27 to 80% of nasopharyngeal carcinoma patients depending on assessment methods, definition of swallowing impairment, radiation dosage, duration of post-RT.
Objective	To assess the effectiveness of functional electrical stimulation on the swallowing function of irradiated nasopharyngeal carcinoma patients with dysphagia.
Tested products	VitalStim
Study design & methods	**Randomised controlled case series.** *Subjects:* 20 nasopharyngeal carcinoma subjects with dysphagia *Methods*: patients were divided into • **Functional electrical stimulation (FES) group**: received FES (VitalStim) of the supra-hyoid muscles. • **Home rehabilitation program (HRP) group**: performed self-swallowing exercises at home. *VitalStim protocol:* • VitalStim electrode position 3a: the paired electrodes were placed above the hyoid bone and between the hyoid bone and thyroid cartilage to stimulate the supra-hyoid muscles • Intensity was adjusted to each subject's maximum tolerance. • Duration of treatment session: 60 min • Treatment frequency: 1-3 times / week • Total treatment: 15 sessions *Outcomes*: videofluoroscopic study was done before and after the therapy. • penetration–aspiration scale (PAS), • oral transit time (OTT), pharyngeal transit time (PTT), pharyngeal delay time (PDT) • discplacement (anterior & superior) of the hyoid bone (from resting to highest position), + duration and velocity of displacement • the bolus stasis areas in the valleculae and pyriform sinus. • quality of life questionnaire scores
Results	*1) Comparison of FES group results pre- and post-treatment* **Most swallowing outcomes of the FES group improved after FES**. The following outcomes improved significantly (p=<0,05): • Quality of life score (p=0.003) >> IMPROVED QUALITY OF LIFE • Displacement duration of hyoid bone during thin barium swallowing (p=0.01) • Displacement velocity of hyoid bone during thin barium (0.001) and paste barium (p=0.028) swallowing >> MORE EFFECTIVELY PROTECT THE AIRWAY AND REDUCE ASPIRATION • The pyriform sinus stasis area of the paste barium (p=0.026) group >> GREATER EASE OF SWALLOWING *2) Comparison of HRP group results pre- and post-treatment* **Most swallowing outcomes did not improve in the HRP group**. *3) Comparison of changes after therapy in FES vs. HRP group* The degree of improvement in the movement speed of the hyoid bone in the thin barium (p=0.018) and the PAS of the paste barium (p=0.016) were statistically significantly greater in the FES group than in the HRP group.
Conclusion	FES may improve swallowing function by increasing the velocity of hyoid bone movement and reducing the pyriform sinus stasis, and also brings out a better quality of life.
Key message	VitalStim therapy can improve swallowing function and quality of life and reduce aspiration in NPC patients with post-radiotherapy dysphagia.
Pubmed	20091057

The effect of electrical stimulation therapy on dysphagia following treatment for head and neck cancer	
Authors	Ryu JS, Kang JY, Park JY, Nam SY, Choi SH, Roh JL, Kim SY, Choi KH.
Published	Oral Oncol. 2009 Aug;45(8):665-8.
Date	2008
Place of origin	University of Ulsan College of Medicine, Seoul, Republic of Korea
Background	Dysphagia is a common complication following treatment of head and neck cancer, with aspiration being the most common manifestation.
Objective	To evaluate the effect of neuromuscular electrical stimulation (NMES) in patients suffering from dysphagia following treatment for head and neck cancer.
Tested products	VitalStim (hand-held)
Study design & methods	**Prospective, double blinded, randomized case control study.** *Subjects:* 26 patients with dysphagia after carcinoma treated with surgery and/or radiation therapy. *Method:* Patients were randomized to either the experimental group who received ES with traditional swallowing exercise (n=14) or the control group who received sham-ES with traditional swallowing exercise (n=12). • Patients in the ES group received VitalStim electrical stimulation at motor level • Patients in the sham-ES group received the TENS therapy (sensory stimulation, with a TENS device) *VitalStim protocol:* • Electrode placement: one pair horizontal immediately above and the other pair below the thyroid notch. • Intensity: motor level • Duration of treatment session: 30 min • Treatment frequency: 5 days / week • Total treatment: 10 sessions – 2 weeks Patients in the sham-ES group received the same treatment protocol except for the ES. In all patients the 30 minutes stimulation were followed by 30 min traditional dysphagia therapy. *Outcome measures:* • Functional Dysphagia Scale, FDS (numerical scale derived from VFSS), • Clinical Dysphagia Scale, CDS (numerical scale derived from bedside evaluation), • American speech-language-hearing association national outcome measurement system (ASHA NOMS), • MD Anderson Dysphagia Inventory (MADI).
Results	• Pretreatment evaluation showed no significant differences between the two groups for all parameters. • Average changes of FDS score were significantly (P=0.039) higher for the experimental group (11.4±8.1) than for the control group (3.3±14.0). • Changes in CDS, ASHA NOMS and MADI were greater in the experimental group, but the differences were not significant (P>0.05).
Conclusion	NMES combined with traditional swallowing training is superior to traditional swallowing training alone in patients suffering from dysphagia following treatment for head and neck cancer.
Key message	Better results when Vitalstim therapy is added to traditional swallowing training in dysphagia patients following head/neck cancer treatment.
Pubmed	19095492

Transcutaneous electrical stimulation versus traditional dysphagia therapy: A nonconcurrent cohort study	
Authors	Blumenfeld L, Hahn Y, Lepage A, Leonard R, Belafsky PC.
Published	Otolaryngol Head Neck Surg. 2006 Nov;135(5):754-7.
Date	2006
Place of origin	Center for Voice and Swallowing, University of California at Davis, Sacramento, and Scripps Center for Voice and Swallowing, La Jolla - California
Background	Swallowing difficulties (dysphagia) affect nearly 15 million adults in the United States. There have been very few innovations in the treatment of swallowing disorders in recent years. The mainstay of nonsurgical therapy continues to be dietary restriction, swallowing maneuvers, and swallowing exercise. The treatment efficacy of these modalities is generally poor.
Objective	To critically evaluate the efficacy of electrical stimulation (ES) in treating persons with dysphagia and aspiration.
Tested products	VitalStim (Chattanooga)
Study design & methods	**Retrospective** nonconcurrent cohort study. *Subjects*: 80 chronic dysphagia patients. The etiology of dysphagia was respiratory failure (60/80 or 75%), stroke (4/80 or5%), sepsis (3/80 or 4%), and other chronic conditions. *Methods*: the charts of **40** consecutive individuals undergoing **ES** and **40** consecutive persons undergoing **traditional dysphagia therapy** (TDT) were reviewed. • ***Patients in the traditional dysphagia therapy*** (TDT) cohort received interventions that focused on a combination of therapeutic exercise, compensatory maneuvers, and diet texture modifications. • ***Patients in the electrical stimulation*** (ES) cohort were treated solely with the ***VitalStim*** electrical stimulation. *VitalStim protocol:* • Electrodes were placed in a horizontal montage just above the thyroid notch. • Intensity: motor level • Duration of treatment sessions: 30 minutes • Total treatment: average 10 sessions *Outcome*: Swallow severity score (Freed 2001) All patients underwent pre- and post-treatment swallowing assessment. Assessments were completed by an interdisciplinary team consisting of a speech language pathologist, otolaryngologist, and technician utilizing both **videofluoroscopy** and fiberoptic **endoscopic** evaluation of swallowing.
Results	• The **swallow severity scale** improved from 0.50 to 1.48 in the TDT group ($P < 0.05$) and from 0.28 to 3.23 in the ES group ($P < 0.001$). After adjusting for potential confounding factors, **persons receiving ES did significantly better** in regard to improvement in their swallowing function than persons receiving TDT ($P = 0.003$). • The **mean number of treatments** was 13 (±7) in the TDT group and 10 (±5) in the ES group ($P = 0.014$). • The **mean length of stay** was 87 (±156) days for the TDT group and 51 (±33) days for the ES group ($P = 0.154$). • There were **no complications** related to ES therapy in this study and all patients tolerated the treatments without event.
Conclusion	The results of this retrospective case control study suggest that dysphagia **therapy with transcutaneous electrical stimulation is superior** to traditional dysphagia therapy alone in individuals in a long-term acute care facility. Individuals receiving ES therapy required **fewer treatment sessions** and displayed a trend toward a **shorter length of hospitalization** than persons receiving traditional dysphagia therapy.
Key message	Significantly better improvement in swallowing function, less treatment sessions needed and shorter hospital stay with Vitalstim treatment.
Pubmed	17071307

DYSPHAGIA in TUBE FED PATIENTS

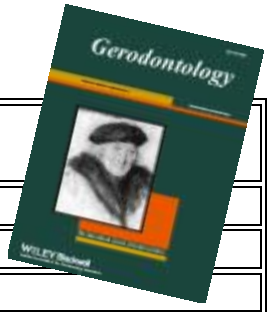
Neuromuscular Electrical Stimulation for Treatment-Refractory Chronic Dysphagia in Tube-Fed Patients: A Prospective Case Series.	
Authors	Scarponi L, Mozzanica F, De Cristofaro V, Ginocchio D, Pizzorni N, Bottero A, Schindler A
Published	Folia Phoniatr Logop. 2016 May 5;67(6):308-314.
Date	May 2016
Place of origin	University of Milan, Milan, Italy.
Background	
Objective	The aim of this study was to evaluate the role of neuromuscular electrical stimulation (NMES) in tube-fed patients with severe and chronic dysphagia refractory to traditional swallowing therapy (TT).
Tested products	VitalStim
Study design & methods	**Case series.** *Subjects*: 11 consecutive dysphagic patients with tube-dependent nutrition and who had not responded to 6 months of traditional therapy (TT). *Methods*: 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. *Outcomes*:: in order to evaluate the swallowing impairment, each patient underwent a fiberoptic endoscopic examination (FEES) of swallowing immediately before the beginning of the treatment, after 2 weeks and after 4 weeks.
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.
Conclusion	6 of 11 of the enrolled patients, in fact, passed to a total oral diet with single or multiple consistencies despite specific food limitations or special preparation or compensation. NMES as adjunctive treatment to TT may offer a new possibility for the management of tube-fed patients who are refractory to TT.
Key message	6 of 11 patients became tube independent following VitalStim treatment.
Pubmed ID	27160206

Examining the Evidence on Neuromuscular Electrical Stimulation for Swallowing: A Meta-analysis	
Authors	Carnaby-Mann GD, Crary MA.
Published	Arch Otolaryngol Head Neck Surg. 2007 Jun;133(6):564-71.
Date	2007
Place of origin	University of Florida Health Science Center, Gainesville, Forida
Background	Recently, NMES has been proposed for the treatment of swallowing disorders (dysphagia).
Objective	To examine the evidence on the effect of NMES in improving clinical swallowing ability.

Study design & methods	**Systematic review with Meta-Analysis**
	Methods:
	• *Data Sources:* MEDLINE, PubMed, CINAHL, NML, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, doc online, Google, and EMBASE were searched for studies using NMES to treat dysphagia between January 1966 and August 2006.
	• *Study Selection:* Included were published or unpublished, English-language, clinical trials with a quantifiable dependent variable.
	• A total of 81 studies were reviewed. **7 studies were accepted for analysis** including a **total of 255 patients** with dysphagia due to multiple etiologies.
	  ○ 2 of the trials were **controlled clinical studies**, with 103 subjects in the treatment group and 76 subjects in the control group.
	  ○ the 5 other trials used a **before-after design**, with 76 subjects receiving treatment.
	Outcomes:
	• ***Clinical swallowing score*** was the only variable used as an outcome measure across all studies. It is among the most commonly used measures in studies examining the effectiveness of behavioral swallowing interventions and NMES for swallowing. Despite being influenced by a clinician's perception, these scores do provide a widely accepted measure of a patient's swallowing performance over time.
	• *Qualitative anylisis of the studies* was done using *"Best-evidence" synthesis:* studies are categorized into (1) strong, (2) moderate, (3) limited, (4) indicative, or (5) insufficient evidence
	• *Effect sizes* were calculated to compare results across studies.
	• *Standardized mean difference* (Hedges g) was also determined for each study by calculating the difference between mean changes in experimental and control groups and dividing by the average population standard deviation.

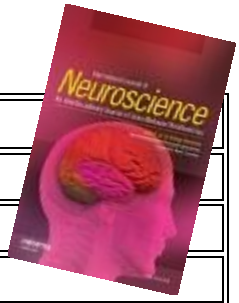
Results	• The meta-anysis showed a **statistically significant summary effect size** supporting the use of NMES in the rehabilitation of swallowing disorders. • The Controlled Clinical Trials and the before-after trials demonstrated **positive overall effects**. • **Mean improvement of 20%** in swallowing performance following treatment across all the studies. • Using NMES can produce **sustained improvements** in swallowing even after the stimulator is turned off (therapeutic effect). • The **qualitative "best-evidence"** synthesis provided indicative findings to support this form of treatment for swallowing rehabilitation, with 3 of the 7 included studies recording **"high" quality** ratings on this scale.
Conclusion	This preliminary meta-analysis revealed a small but significant summary effect size for transcutaneous NMES for swallowing.
Key message	This meta-analysis supports the use of NMES for the treatment of swallowing disorders with mean improvement of 20% in swallowing performance following treatment across all the studies.
Pubmed ID	17576907

SENSORY VERSUS MOTOR LEVEL STIM – PHYSIOLOGY STUDY



Immediate effects of transcutaneous electrical stimulation on physiological swallowing effort in older versus young adults.	
Authors	Berretin-Felix G, Sia I, Barikroo A, Carnaby GD, Crary MA.
Published	Gerodontology. 2014 Nov 12. [Epub ahead of print]
Date	Nov 2014
Place of origin	Speech Pathology/Audiology Department, Bauru Dental School, University of São Paulo, São Paulo, Brazil.
Background	Swallowing physiology changes with age. Reduced physiological swallowing effort in older adults including lower lingua-palatal and pharyngeal pressures may increase risk for swallowing dysfunction. Transcutaneous electrical stimulation (TES) has been advocated as an adjunctive modality to enhance outcomes in exercise-based therapy for individuals with dysphagia. However, significant variation in how TES is applied during therapy remains and the physiological swallowing response to TES is poorly studied, especially in older adults.
Objective	This study compared the immediate impact of different transcutaneous electrical stimulation (TES) amplitudes on physiological swallowing effort in healthy older adults versus young adults.
Tested products	VitalStim
Study design & methods	**Physiology study.** *Subjects*: 20 healthy young (20-30y) and 14 healthy older (60-79y) adults. *Methods*: participants swallowed materials of three consistencies (thin liquid, thick liquid and pudding) in three volumes (5 ml, 10 ml and 20 ml) and in three conditions: • *Sensory stimulation*: 2 mA below the initial motor response amplitude • *Motor stimulation:* 2 mA below the identified maximum tolerance amplitude • *No stimulation:* with electrodes in place without any electrical stimulation applied. These three conditions were presented to each participant in random order. Three-minute rest periods of no stimulation were provided between each condition. *VitalStim protocol:* • *Electrode placement*: channel 1 electrodes were aligned horizontally above the hyoid bone (targeting suprahyoid muscle groups) and channel 2 electrodes were aligned horizontally between the hyoid bone and the thyroid cartilage, inferior and medial to the posterior horns of the hyoid bone (targeting infrahyoid muscle groups) • *Stimulation amplitudes* for sensory and motor stimulation conditions were determined individually for each participant. Initial motor response amplitude was identified as the lowest stimulation amplitude at which participants reported a pulling or grabbing sensation. Maximum tolerance amplitude was defined as the highest TES amplitude that participants could tolerate without pain. *Outcomes*: physiological swallowing effort was assessed through: • Lingua-palatal pressure • Pharyngeal manometric pressures: base of tongue pressure and hypopharyngeal pressure.
Results	Multivariate analyses identified interactions between age and stimulation amplitude on lingual and pharyngeal functions. • Motor stimulation reduced anterior tongue pressure in both age groups ($p < 0.04$) • Motor stimulation reduced posterior lingua-palatal pressures in young adults only ($p < 0.07$) • Motor stimulation increased hypopharyngeal pressures in both groups ($p < 0.002$) • Sensory stimulation increased base of tongue (BOT) pressures in older adults ($p < 0.06$) • Sensory stimulation decreased BOT pressures in young adults ($p < 0.06$)
Conclusion	• A one-size-fit-all approach to TES in dysphagia rehabilitation may be misdirected. • Age and stimulation amplitude interact in determining immediate physiological responses on swallow performance. • These results may support the need to modify the clinical application of TES in dysphagia rehabilitation from patient to patient. • Older (and perhaps weaker) patients might respond differentially depending on sensory or motor stim. • Furthermore, different aspects of swallowing impairment (e.g. lingual vs. hypopharyngeal) may respond differently to sensory versus motor stim.
Key message	Varying stimulation amplitude (sensory vs. motor level) may have specific and differential effects, depending on location and participant age.
Pubmed ID	25393704

CORTICAL REORGANISATION



Recovery of swallowing function is accompanied by the expansion of the cortical map.	
Authors	Oh BM, Kim DY, Paik NJ.
Published	Int J Neurosci. 2007 Sep;117(9):1215-27.
Date	2007
Place of origin	Department of Rehabilitation Medicine, Gangwon-Do Rehabilitation Hospital, Chuncheon, Republic of Korea
Background	Recent studies reported electrical stimulation (ES) of the neck muscles to be a promising therapeutic modality for dysphagia. However, the mechanism by which this therapy improves swallowing function requires further determination.
Objective	The purpose of the present study was to reaffirm whether multiple sessions of ES applied to the neck muscles improve swallowing function, and determine whether this improvement is accompanied by longterm cortical reorganization in patients with dysphagia.
Tested products	Portable battery-powered electrical stimulator (E707 EMS, Essential Care Products Ltd.)
Study design & methods	**Prospective Case series.** *Subjects:* **8 adult dysphagic patients** were treated via a standardized protocol of electrotherapy. Patient diagnoses included cortical stroke (n=4) and lower motor neuron lesion (n=4). *Method:* • Subjects received electrotherapy treatment for 1 hour per day, 5 days per week, for 2 weeks (total 10 session). • Pulse frequency was fixed at 70 Hz and pulse duration was adjusted to 300μs with a duty cycle of 20-s on and 10-s off. • Stimulation intensity was adjusted to a level that elicited muscle contraction and was increased as tolerated by the patient. • Electrodes were placed on the anterior belly of the digastric and thyrohyoid muscles *Outcomes:* patients received VFSS (videofluoroscopic swallowing study) and TMS (transcranial magnetic stimulation) evaluations before start of treatment and 12 hours after last treatment session. • clinical swallowing ability, • swallowing function: Videofluoroscopic Functional Dysphagia Scale (VFDS), and Dysphagia Outcome and Severity Scale (DOSS) • cortical representation and cortical excitability.
Results	• Patients demonstrated **significant improvement in swallowing ability** as confirmed clinically and by VFSS. • Average DOSS grade was significantly improved from 2.9 to 4.3 after ES (p=.042), and average VFDS also showed a significant decrease from 45.9 to 19.3 (p=.035) • This change was found to **correlate with cortical reorganization**: it was observed that the cortical map was expanded after ES in patients who showed swallowing functional improvements, thus indicating a therapy-induced recruitment of new cortical areas, whereas the cortical map did not change in the patient without an improved swallowing function. • In the study this plastic change lasted at least 12 h, which suggests a **long-term change** which may be functionally relevant because the presence of this plastic change was accompanied by the improvement of swallowing in the present study.
Conclusion	The findings in this study suggest that **multiple sessions of ES** on the neck muscles might help **improve swallowing function**, and that this improvement might be related to the **long-term cortical reorganization**
Key message	Motor level electrical stimulation improved swallowing function which was correlated with increased cortical representation suggesting a causal relationship between cortical reorganization and swallow function improvement.
Pubmed ID	17654088

Differential effects of neuromuscular electrical stimulation parameters on submental motor-evoked potentials.	
Authors	Doeltgen SH, Dalrymple-Alford J, Ridding MC, Huckabee ML
Published	Neurorehabil Neural Repair. 2010 Jul-Aug;24(6):519-27.
Date	2010
Place of origin	University of Canterbury, Christchurch, New Zealand.
Background	Previous research showed that NMES of the muscles underlying the pharynx and faucial pillars affects the excitability of corticobulbar projections in a frequency- and duration-specific manner. Based on these previous findings, it is likely that different muscles, or groups of muscles, involved in swallowing will have specific optimal stimulation parameters. The anterior hyomandibular (submental) muscles are primary targets for the clinical application of NMES to improve disordered swallowing, but the optimal NMES parameters for this application are unknown. Furthermore, NMES administered during execution of a purposeful motor task (event-related NMES) may be superior to NMES administered when the target muscle is at rest (non-eventrelated NMES).
Objective	To determine the influence of NMES parameters on the excitability of corticobulbar projections to the submental musculature.
Study design & methods	**Experimental laboratory study** on healthy human volunteers. *Subjects*: 25 healthy young adults. 10 subjects participated in experiment 1-2; 15 subjects partcipated in experiment 3-4. *Methods*: 4 experimental protocols were applied. Stimulation electrodes were placed bilaterally on the submental muscles. sEMG triggered stimulation was triggered by volitional contraction of the left thyrohyoid muscle. • *Experiment 1* compared 4 different stimulation frequencies 5Hz - 20Hz - 40Hz - 80Hz during sEMG triggered stimulation. • *Experiment 2* compared 3 different stimulation doses at a fixed frequency of 80Hz (identified as optimal frequency in exp. 1): 60x4s stimulus train - 60x1s stimulus train - 20x4s stimulus train • *Experiment 3* replicated the sEMG triggered 60x4s stimulus train at 80Hz protocol in a different participant cohort to test reproducibility of the results across different populations. • *Experiment 4* compared the sEMG triggered stimulation (60x4s stimulus train at 80Hz) with non-sEMG triggered stimulation (triggered automatically and independently from volitional thyrohyoid contraction; 60x4s stimulus train at 80Hz) and continuous stimulation (80Hz). *Outcome assessment*: Transcranial magnetic stimulation (TMS) was used to assess corticobulbar excitability prior to, immediately following, and 30, 60, and 90 minutes post-NMES. MEP (motor evoked potential) amplitude of the submental muscles was measured in each of the experimental conditions and compared to baseline (prestimulation).
Results	• 80 Hz was identified as the optimal frequency producing the largest effect on MEP amplitude. • sEMG triggered 60x4s stimulus train was identified as the optimal dose producing the largest effect on MEP amplitude. • sEMG triggered (event-related) stimulation was superior to non-triggered (non-event-related) NMES • Continuous NMES was superior to NMES applied in 60x4s trains (non-event-related).
Conclusion	Changes in corticobulbar excitability induced by NMES of the submental muscle group are frequency and dose dependent and only occur after NMES triggered by volitional swallowing.
Key message	NMES at 80Hz frequency, applied in a functional context - i.e. sEMG triggered by volitional swallow - has the greatest effect on corticobulbar excitability.
Pubmed ID	20228230

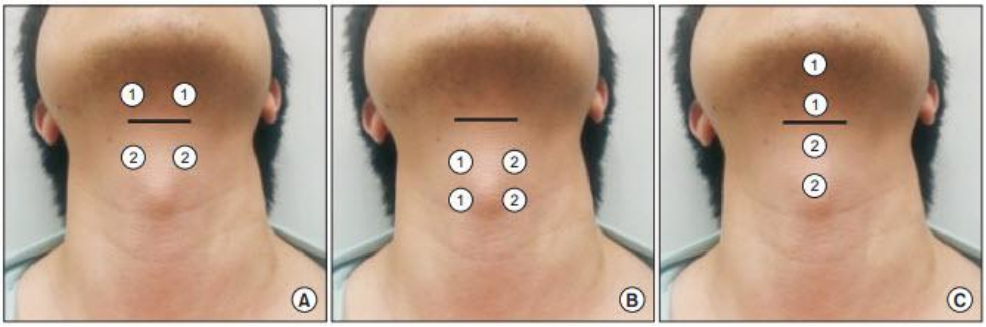
Effect of submental sensitive transcutaneous electrical stimulation on virtual lesions of the oropharyngeal cortex.	
Authors	Cugy E, Leroi AM, Kerouac-Laplante J, Dehail P, Joseph PA, Gerardin E, Marie JP, Verin É.
Published	Ann Phys Rehabil Med. 2015 Dec 21. [Epub ahead of print]
Date	Dec 2015
Place of origin	université de Bordeaux, Bordeaux, France.
Background	
Objective	To assess the effect of submental sensitive transcutaneous electrical stimulation (SSTES) on pharyngeal cortical representation after the creation of an oropharyngeal cortical virtual lesion in healthy subjects.
Study design & methods	**Experimental study.** *Subjects*: 9 healthy individuals *Methods & outcomes:* • Motor-evoked potential amplitude of the mylohyoid muscles was measured with transcranial magnetic stimulation (TMS) • The oropharyngeal cortex was mapped by cartography • Videofluoroscopic parameters of swallowing function were measured before and after SSTES (at the end of SSTES [0min] and at 30 and 60min), after the creation of a cortical virtual lesion (repetitive TMS, 1Hz, 20min on the dominant swallowing hemisphere - the rTMS causes a temporary inhibition of the cortical areas due to hyperpolarisation).
Results	• Swallow reaction time increased and MEP amplitude decreased after repetitive TMS (virtual lesion), as seen on videofluoroscopy. • Electrical stimulation reversed these effects: swallow reaction time decreased (significant after 30 min) and MEP amplitude of the mylohyoid muscle increased immediately with SSTES. • rTMS immediately affects motor cortical excitability - on cortical mapping the number of points eliciting a cortical response after rTMS decreased. • With electrical stimulation the number of points with a cortical response increased in the dominant lesioned hemisphere ($P<0.05$) on 0, 30 and 60 min, remaining constant at 60min ($P<0.05$).
Conclusion	This study of healthy subjects with a virtual oropharyngeal cortical lesion demonstrated that SSTES stimulation allowed for reversing the cortical inhibition obtained with rTMS and increased the cortical excitability of the oropharyngeal motor cortex. It also reversed the increase in observed swallow response time. These findings suggest that this technique might be able to reverse poststroke oropharyngeal dysphagia.
Key message	SSTES may be effective for producing cortical plasticity for mylohyoid muscles and reverses oropharyngeal cortical inhibition in healthy subjects. It could be a simple non-invasive way to treat post-stroke dysphagia.
Pubmed ID	26717886

DYSPHONIA - IMPROVE VOICE QUALITY

Neuromuscular electrical stimulation of the cricothyroid muscle in patients with suspected superior laryngeal nerve weakness.	
Authors	Guzman M, Rubin A, Cox P, Landini F, Jackson-Menaldi C
Published	J Voice. 2014 Mar;28(2):216-25.
Date	Mar 2014
Place of origin	Lakeshore Professional Voice Center, Lakeshore Ear, Nose and Throat Center, St. Clair Shores, Michigan; School of Communication Sciences, University of Chile, Santiago, Chile.
Background	Injury to the superior laryngeal nerve (SLN) can result in dysphonia, and in particular, loss of vocal range. It can be a particularly difficult problem to address either with VT or surgical intervention.
Objective	To demonstrate the clinical effectiveness of NMES in combination with traditional voice therapy (VT) for rehabilitating dysphonia secondary to suspected superior laryngeal nerve (SLN) weakness in two female subjects.
Tested products	VitalStim
Study design & methods	**Retrospective case study.** *Subjects*: • *Case 1*: A 48-year-old music teacher and classically trained soprano presented with a 2-year history of dysphonia after an upper respiratory infection. • *Case 2*: A 63-year-old amateur soprano presented with dysphonia after 10 months of thyroid surgery for multinodular goiter. *Methods*: • Surface electrodes were placed in two different places: (1) first, in a horizontal configuration along the cricothyroid space and then (2) in a vertical configuration along the posterior part of the thyroid notch. • Case 1 received 17 VitalStim sessions in total. • Case 2 received 8 VitalStim sessions in total. *Outcomes*: • Acoustic parameters. • Videolaryngoscopy observations.
Results	• Both acoustic analysis and endoscopic evaluation demonstrated important improvements after treatment. • In the first patient, the major change was obtained within the primo passaggio region; specifically, a decrease in voice breaks was demonstrated. • In the second patient, an improvement in voice quality (less breathiness) and vocal range were the most important findings. • Additionally, each patient reported a significant improvement in their voice complaints.
Conclusion	Neuromuscular laryngeal electrical stimulation in combination with traditional vocal exercises may be useful to improve both speaking and singing voice quality in patients with SLN weakness.
Key message	VitalStim therapy in combination with vocal exercises might be a useful tool to improve voice quality in patients with SLN injury.
Pubmed	24315659

Cross-system effects of dysphagia treatment on dysphonia: a case report	
Authors	Lagorio LA, Carnaby-Mann GD, Crary MA.
Published	Cases J. 2008 Jul 30;1(1):67.
Date	2008
Place of origin	College of Public Health and Health Professions, University of Florida, Gainesville, FL
Background	Traditionally, treatment of dysphagia and dysphonia has followed a specificity approach whereby treatment plans have focused on each dysfunction individually. Recently however, a therapeutic cross-system effect has been proposed between these two dysfunctions.
Objective	Investigate the potential impact on voice function of utilizing NMES for dysphagia therapy.
Tested products	VitalStim
Study design & methods	**Case study.** *Subject*: a 74 year old patient with dysphagia after receiving radiation for tongue base cancer. Methods: • Patient was treated for his dysphagia for **15 treatment sessions**. • After changes in voice quality were noted on treatment 5, voice measurements were taken before, during and after each therapy session beginning on treatment day 6. • Objective and validated voice parameters were tracked during 10 treatment series and at 1 week, 1 month and 6 months follow up. *Outcome measures:* • **Acoustic measurements** of maximum phonation time (MPT), pitch range (highest and lowest attainable pitch), and habitual pitch while reading were obtained using the VisiPitch IV (KayPentax: Lincoln Park, NJ). • **Swallowing function** was evaluated pre- and post-therapy and at 6 months follow-up via standardized clinical, endoscopic, and videofluoroscopic evaluations including completion of the Mann Assessment of Swallowing Ability (MASA) and the Functional Oral Intake Scale (FOIS) [7], as well as self perception of swallow function measured via bisection of a 100 mm visual analog scale (VAS).
Results	• Significant **improvement of voice parameters**: instrumental measurements, endoscopic measurements and perceptual voice function. Improvements were **maintained at 6 months follow-up**, except for the highest pitch level. • The patient demonstrated **improvement in all swallowing measures** immediately after completion of the therapy program. These improvements were not maintained through the 6-month follow-up due to post-radiation changes, specifically radionecrosis of his mandible and complications affecting his esophagus. • The cross-improvement of both the vocal and swallowing function can be explained by an **improved laryngeal muscle function** through the dysphagia NMES treatment program.
Conclusion	This case-report documented improvement in MPT and highest attainable pitch in one individual who completed a dysphagia therapy program. Although phonation and swallowing represent two different laryngeal functions, the improvements seen in this case report support recent evidence that treating deficits in one function may result in cross-system effects on the function not being actively rehabilitated.
Key message	The dysphagia VitalStim NMES treatment program showed a concomitant improvement of vocal function.
Pubmed ID	18667069

KINEMATIC ANALYSIS

Different Movement of Hyolaryngeal Structures by Various Application of Electrical Stimulation in Normal Individuals.	
Authors	Kim SH, Oh BM, Han TR, Jeong HJ, Sim YJ.
Published	Ann Rehabil Med. 2015 Aug;39(4):535-44.
Date	Aug 2015
Place of origin	Kosin University College of Medicine, Busan, Korea. Seoul National University College of Medicine, Seoul, Korea.
Objective	To identify the differences in the movement of the hyoid bone and the vocal cord with and without electrical stimulation in normal subjects and with different electrode placements.
Tested products	VitalStim
Study design & methods	**Experimental prospective study on healthy subjects.** *Subjects*: 20 healthy volunteers *Methods*: all subjects were tested during swallowing, first without electrical stimulation, followed by electrical stimulation at maximal tolerated motor level in 3 electrode placement conditions (with 10 min rest in between conditions). *The 3 different electrode placements were:* • A: Channel 1 supra- and channel 2 infrahydoid - horizontal position (3b): targeting the suprahyoid and infrahyoid muscles • B: Infrahyoid only, channel one at left side , channel 2 at right side of thyroid notch: targeting the thyrohyoid and sternohyoid muscles • C: Channel 1 supra- and channel 2 infrahydoid - vertical position.  *Outcomes*: • Two-dimensional motion analysis using a videofluoroscopic swallowing study with and without electrical stimulation was performed. • Kinematic analysis of the hyoid and larynx movement according to temporal change.
Results	• The main outcomes of this study demonstrated an initial downward displacement as well as different movements of the hyoid bone with the three electrode placements used for electrical stimulation. • The initial positions of the hyoid bone with the placements in A and B resulted in an inferior and anterior displaced position. • During swallowing, the hyoid bone moved in a more superior and less anterior direction, resulting in almost the same peak position compared with no electrical stimulation. *Electrode placement A:* • Compared to swallowing without NMES, the hyoid bone showed greater initial vertical downward and greater intial horizontal anterior displacement; however vertical and horizontal peak point reached almost the same position in both conditions. • The vocal cord vertical movement showed no differences with versus without NMES; while both the initial and peak anterior horizontal diplacement was greater with NMES. *Electrode placement B:* • Compared to swallowing without NMES, the hyoid bone showed greater initial vertical downward and

	• Greater intial horizontal anterior displacement; however vertical and horizontal peak point reached almost the same position in both conditions. • The vocal cord vertical movement showed no differences with versus without NMES; while the initial anterior horizontal diplacement was greater with NMES. *Electrode placement C:* • Except for greater initial anterior displacement and horizontal disctance of the vocal cord, there were no important differences between swallowing with versus without NMES.
Conclusion	• Electrical stimulation caused an initial depression of the hyoid bone, which reached nearly the same peak position during swallowing in healthy volunteers. • The elevation of the hyoid bone was not dependent on the position of the electrode on the neck, such as on the infrahyoid only or on both the supra and infrahyoid muscles. The only electrode position that did not have a significant effect on the movement of the hyoid bone was the vertical electrode. • Contrary to the results of previous studies, the motion analysis showed **significant elevation of the hyoid bone during swallowing**. • Therefore, when used as resistance training, electrical stimulation during swallowing can be **effective for producing a motor learning effect.**
Key message	Initial hyoid bone depression with NMES was compensated by significant elevation during swallowing, resulting in the same peak postion as in swallowing without NMES.
Pubmed ID	26361589

sEMG

&

sEMG BIOFEEDBACK

in

EVALUATION AND TREATMENT OF DYSPHAGIA

sEMG for SCREENING and EVALUATION of swallowing function

Vaiman et al. established normative sEMG data for adults and children in multiple publications, as well as a standardized protocol for screening – published between 2004 and 2009.

Surface electromyographic studies of swallowing in normal subjects: a review of 440 adults.	
Report 1. Quantitative data: timing measures. **Report 2. Quantitative data: amplitude measures.** **Report 3. Qualitative data.**	
Authors	Vaiman M, Eviatar E, Segal S.
Published	Report 1: Otolaryngol Head Neck Surg. 2004 Oct;131(4):548-55. Report 2: Otolaryngol Head Neck Surg. 2004 Nov;131(5):773-80. Report 3: Otolaryngol Head Neck Surg. 2004 Dec;131(6):977-85.
Date	2004
Place of origin	Department of Otolaryngology, Assaf Harofeh Medical Center, Sackler Faculty of Medicine, Tel Aviv University, Israel.
Objective	To **establish normative data** for the **duration** (Report 1) and **amplitude** (Report 2) of muscle activity and regarding the **shape** of the sEMG record (Report 3) during swallowing and drinking, clinically useful for ENT department. The authors more specifically investigated whether there were differences in sEMG activity related to age or bolus type. The reflex part of the swallow was evaluated, i.e., duration of oral final stage, pharyngeal stage, initial esophageal stage period. This entire period starts with the onset of masseter and submental muscle group EMG activity and ends with termination of submental and infrahyoid activity.
Study design & methods	**Prospective observational study.** *Subjects*: 440 healthy adults (230 women and 210 men, ranging in age from 18 to 78 years). *Methods*: *Subjects were separated into age groups as follows:* • 18-30y / 31-40y / 41-50y / 51-60y / 61-70y / 70+y *sEMG activity of 4 muscle groups, all covered by the platysma, was evaluated:* • orbicularis oris superior and inferior muscles • masseter muscle • the submental muscle group including the anterior belly of digastric, mylohyoid, and geniohyoid muscles • the infrahyoid muscle group These muscles were selected because they are superficial and they are involved in the oral and pharingeal phases of the swallow. *Five tests were examined including* • voluntary swallow of saliva ("dry" swallow), • voluntary single water swallows as normal (variable volume of a bolus, 'wet' swallow), • voluntary single swallows of fixed amount of water (20 mL 'excessive' swallow or 'stress test'), • continuous drinking of 100 mL of water. • monitoring of spontaneous swallowing of saliva during 1 hour period (Report 1 only). *Outcomes*: • Report 1 measured the duration (sec) of oral, pharyngeal, and initial esophageal stages of swallowing for the different age groups. • Report 2 measured the amplitude mean and range (µV) of electric activity during swallowing for the different age groups. Range of electric muscle activity is the difference between the minimal and maximal sEMG value of the muscle group. • Report 3 evaluated the graphic records (shape) during swallowing and drinking for the different age groups.
Results	• The mean **resting potential** was between 2.5 and 2.8 µV for the 4 muscle groups with no significant difference between the 4 age groups. • In the 3 swallow tests,sEMG **activity of the submental group was higher** than sEMG activity of the masseter and infrahyoid muscle group: 30-55% higher compared to masseter activity (mean & range); 40-65% higher

	compared to infrahyoid group (range). • Report 3 showed **several types of normal swallows** as seen at the surface EMG records. The authors defined 3 main types of normal swallow: single-share, double-share, and triple-share swallows. *Gender effect* • There is **no statistically significant difference** for the duration and amplitude of muscle activity and the shapes of the sEMG recordings **between male and female** adults during single swallowing and continuous drinking in all age groups. *Effect of age* • The **elderly subjects** showed **increased duration** of swallows and prolonged drinking time, and **decreased amplitude** range of the submental and infrahyoid muscle groups. • Report 3 showed that in **elderly** (70+) subjects, the swallow is usually **wider** (longer, see Report 1) and shows **lack of good coordination** between activities of different muscles involved in deglutition. *Effect of bolus type* • The main population (ages 18-70) **adapt to larger bolus volume by increasing the swallow duration** (sEMG sec). • **70+ subjects adapt to larger bolus volume through increased muscle activity** (sEMG μV)
Conclusion	sEMG of swallowing is a simple and reliable method for evaluation of swallowing with a low level of discomfort during the examination. The method can be easily used in outpatient ENT departments for quick evaluation of patients. The normative amplitude data can be used for comparison purposes in preoperative and postoperative stages and in EMG monitoring during ENT treatment.
Key message	sEMG of swallowing is a **simple** and **reliable** method for evaluation of swallowing. The **normative sEMG data** presented in this article can be used as a reference in swallowing evaluation.
Pubmed ID	Report 1: 15467634 - Report 2: 15523465 - Report 3: 15577801

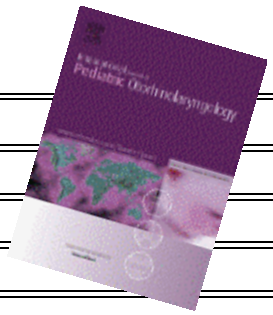
Quick reference simplified set of normative data for electric activity obtained by surface EMG for the masseter, submental group (SUB) and laryngeal strap muscles (INF) during various tests, in μV. [age range: normal range of voltage values]

	Age groups (y)		
Saliva swallow	18–70: **1.0–5.44**		70+: **1.44–6.24**
Normal swallow	18–70: **1.0–5.74**		70+: **2.3–6.7**
20 cc swallow	18–70: **1.8–6.2**		70+: **1.8–8.13**
One swallow while drinking	18–70: **0.56–2.56**		70+: **0.55–3.0**
100 cc drinking	18–60: **6.2–15.4**	61–70: **5.4–21.4**	70+: **7.1–28.3**
# swallows while drinking	18–40: **4–9**	41–70: **4–12**	70+: **4–16**

Quick reference simplified set of normative data for electric activity obtained by surface EMG for the masseter, submental group (SUB) and laryngeal strap muscles (INF) during various tests, in μV. [age range: normal range of voltage values]

	Age groups (y)		
Saliva swallow			
Masseter range	18–30: **4.5 – 15.9**	31–70: **5.54 – 12.1**	70+: **2.94–22.42**
SUB range	18–30: **13.4–59.72**	31–70: **9.52 – 49.5**	70+: **10.2–42.32**
INF range	18–40: **2.0–4.5**	41–70: **2.5–4.3**	70+: **4.3–7.25**
Normal swallow			
Masseter range	18–60: **2.2–31.0**	61–70: **1.97 – 27.69**	70+: **3.77–20.0**
SUB range	18–30: **11.4–63.41**	31–50: **12.58–51.6**	51–70+: **7.4 – 44.8**
INF range	18–40: **2.85–6.3**	41–70: **3.8–5.6**	70+: **4.33–8.0**
Excessive swallow			
Masseter range	18–40:**1.5–37.0**	41–70: **1.2 – 29.4**	70+: **4.65–21.13**
SUB range	18–30: **19.28–50.80**	31–70+: **12.1 – 47.44**	
INF range	18–40: **3.8–6.55**	41–70: **3.9–6.23**	70+: **4.5–9.3**
100 cc drinking			
Masseter mean (real)*	18–70: **0.8 – 6.2**		70+: **1.0 – 7.84**
SUB mean (real)	18–60: **3.5 – 11.5**	61 – 70+: **4.25 – 16.25**	
INF mean (real)	18–70: **1.4–2.8**		70+: **1.0–3.85**

*Raw mean = computer-calculated mean, while Real mean = raw mean minus the mean resting potential of an actual muscle covered by skin (2.808 μV = for the m. submental and m. infrahyoid, 2.495 μV = for the m. masseter, and 4.542 = for the m. orbicularis oris).



Surface electromyographic studies of swallowing in normal <u>children</u>, age 4-12 years.	
Authors	Vaiman M, Segal S, Eviatar E.
Published	Int J Pediatr Otorhinolaryngol. 2004 Jan;68(1):65-73.
Date	2004
Place of origin	Tel Aviv University, Tel Aviv, Israel.
Objective	To establish normative database for duration and amplitude of sEMG recordings of muscle activity during swallowing and continuous drinking in healthy children.
Study design & methods	**Prospective observational study.** *<u>Subjects</u>*: 100 healthy children age 4-12y. *<u>Methods</u>*: Subjects were separated into 2 age groups: • 4-8y / 9-12y • A group of 40 healthy adults, age 18-30 years, was taken as a control group. sEMG activity of 4 muscle groups, all covered by the platysma, was evaluated: • orbicularis oris superior and inferior muscles • masseter muscle • the submental muscle group including the anterior belly of digastric, mylohyoid, and geniohyoid muscles • the infrahyoid muscle group Four tests were examined including • voluntary swallow of saliva ("dry" swallow), • voluntary single water swallows as normal (variable volume of a bolus, 'wet' swallow), • voluntary single swallows of fixed amount of water (15 mL 'excessive' swallow or 'stress test'), • continuous drinking of 50 mL of water. *<u>Outcomes</u>*: For each group of muscles, amplitude (mean and range) and duration of electric activity during swallowing was measured for the two age groups.
Results	• Normative data for duration and amplitude of muscle activity during single swallowing and continuous drinking are established for healthy children. (tables 1-4 of this article). • The duration of muscle activity during swallows and drinking in all tests showed decrease with the age, and this tendency is statistically significant • There was no statistically significant difference in amplitude (range) measurements between children and adults (P=0.05). • There was no statistically significant difference between male and female children duration of muscle activity during single swallowing and continuous drinking in all age groups (P>/=0.05).
Conclusion	Surface EMG of swallowing is a simple and reliable noninvasive method for screening evaluation of swallowing with low level of discomfort of the examination. The normative timing of events data can be used for evaluation of complaints and symptoms, as well as for comparison purposes in pre- and postoperative stages and in electromyography (EMG) monitoring during ENT or neurological treatment. These parameters represent normal deglutition, and can be used to identify abnormalities in pediatric patients, and provide a basis for comparison of swallowing performance, both within and between patients.
Key message	sEMG is a reliable screening tool for swallow evaluation in children.
Pubmed ID	14687689

Table 1 The duration of muscle activity (mean ± S.D.) in different single swallow tests, in s, as recorded by the surface EMG

Tests	Age groups (years)		
	Adult control	9–12	4–8
Saliva swallow	3.06 ± 1.4	4.1 ± 1.7	4.8 ± 1.9
Normal swallow	3.37 ± 1.27	4.5 ± 1.8	4.9 ± 1.9
Excessive swallow	3.74 ± 1.2	4.9 ± 2.0	5.2 ± 2.3

Table 2 Continuous drinking of 50 cm^3 of water—duration of muscle activity excluding the initial oral stage (mean ± S.D.)

	Age groups (years)		
	Adult control	9–12	4–8
Total duration (s)	10.2 ± 2.78	13.6 ± 4.2	17.9 ± 5.32
Number of swallows	6.9 ± 1.8	8.4 ± 2.5	10.7 ± 2.90
Duration of one swallow (s)	1.51 ± 0.4	1.64 ± 0.5	1.75 ± 0.6
ml per swallow	12.7 ± 2.55	7.2 ± 2.6	4.8 ± 1.73
ml per swallow (%)	100	56	37.8

The control group of adults consumed 100 cm^3 of water, the duration was then divided into two.

Table 3 Range (amplitude) of electric activity of m. orbicularis oris (OO), masseter (MS), submental (SUB) and laryngeal strap muscles (infrahyoid) (LSM) in different swallow tests, in μV (mean ± S.D.)

Tests	Age groups (years)		
	Adult control	9–12	4–8
OO: swallow of saliva	54.493 ± 21.272	49.862 ± 28.364	49.343 ± 19.961
OO: normal swallow	56.752 ± 18.031	55.354 ± 18.652	57.113 ± 29.743
OO: excessive swallow	62.234 ± 29.072	57.367 ± 17.345	59.338 ± 23.092
MS: swallow of saliva	10.218 ± 2.564	13.684 ± 5.754	8.986 ± 1.943
MS: normal swallow	17.124 ± 7.548	11.875 ± 4.183	15.966 ± 6.984
MS: excessive swallow	17.236 ± 10.043	14.892 ± 4.193	16.317 ± 7.033
SUB: swallow of saliva	33.473 ± 11.043	26.875 ± 8.325	28.342 ± 9.983
SUB: normal swallow	36.750 ± 10.032	26.754 ± 9.025	27.403 ± 9.743
SUB: excessive swallow	34.044 ± 9.972	30.908 ± 6.222	29.318 ± 9.045
LSM: swallow of saliva	10.027 ± 2.236	8.655 ± 2.877	8.276 ± 1.294
LSM: normal swallow	16.183 ± 6.954	12.875 ± 3.545	14.284 ± 5.804
LSM: excessive swallow	16.744 ± 7.034	12.095 ± 3.158	13.297 ± 5.789

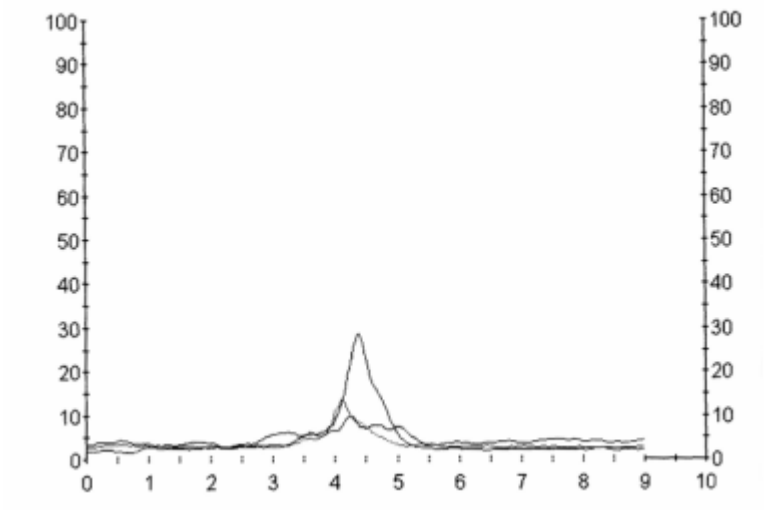
Table 4 Mean of electric activity of masseter (MS), submental (SUB) and laryngeal strap (infrahyoid) muscles (LSM) during different swallow tests (μV) (mean ± S.D.)

Tests	Age groups (years)		
	Adult control	9–12	4–8
MS: swallow of saliva	3.950 ± 1.384	3.367 ± 1.782	3.975 ± 1.392
MS: normal swallow	6.147 ± 2.365	6.192 ± 2.052	5.985 ± 1.674
MS: 20 cm^3 swallow	6.257 ± 2.496	6.108 ± 2.795	6.302 ± 2.635
SUB: swallow of saliva	9.476 ± 2.564	8.972 ± 2.025	9.134 ± 2.204
SUB: normal swallow	10.392 ± 3.05	9.696 ± 2.302	9.563 ± 2.483
SUB: 20 cm^3 swallow	9.467 ± 2.396	10.164 ± 2.567	9.708 ± 2.855
LSM: swallow of saliva	3.350 ± 1.381	3.307 ± 1.263	3.575 ± 1.332
LSM: normal swallow	6.107 ± 2.363	6.032 ± 2.011	5.785 ± 1.674
LSM: 20 cm^3 swallow	6.217 ± 2.495	6.004 ± 2.373	6.102 ± 2.231

Results of the above studies have been combined and summarized in the following publication:

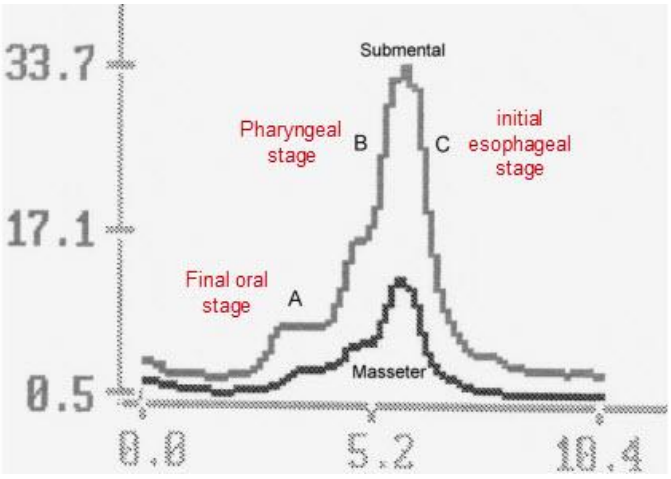
Standardization of surface electromyography utilized to evaluate patients with dysphagia.	
Authors	Vaiman M.
Published	Head Face Med. 2007 Jun 6;3:26.
Date	2007
Place of origin	Department of Otolaryngology, Assaf Harofe Medical Center, Affiliated to the Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel.
Background	Patients suspected of having swallowing disorders, could highly benefit from simple diagnostic screening before being referred to specialist evaluations.
Objective	To introduce sEMG as a rapid screening method for patients with complaints suggestive of dysphagia or odynophagia that need to be differentiated and localized in oral, laryngeal and esophageal causes, and to suggest steps for standardization of sEMG assessment of normal and abnormal deglutition, as had been done for electrocardiograms one hundred years ago.
Study design & methods	Specifics steps for establishing standards for applying the technique for screening purposes (e.g., evaluation of specific muscles), the requirements for diagnostic sEMG equipment, the sEMG technique itself, and defining the tests suitable for assessing deglutition (e.g., saliva, normal, and excessive swallows and uninterrupted drinking of water) are presented in detail. A previously described normative database for single swallowing and drinking and standard approach to analysis was compared to data on the duration and electric activity of muscles involved in deglutition and with sEMG recordings in order to estimate stages of a swallow.
Results	See above publications
Conclusion	SEMG of swallowing is a simple and reliable method for screening and preliminary differentiation among dysphagia and odynophagia of various origins. This noninvasive radiation-free examination has a low level of discomfort, and is simple, timesaving and inexpensive to perform. With standardization of the technique and an established normative database, sEMG can serve as a reliable screening method for optimal patient management.
Key message	SEMG of swallowing is a simple, reliable, non-invasive and inexpensive method for dysphagia screening.
Pubmed ID	17553152

Stages of the normal swallow (reflex part).



Horizontal mark 3 – water intake, 3.5–4 – final oral stage, 4–4.5 – pharyngeal stage, 4.5–5.5 – initial esophageal stage.
Upper peak – submental location, middle peak – masseter location, lower peak – infrahyoid muscles location.
Total electric activity duration after water intake: 2.5 sec.

Surface electromyography as a screening method for evaluation of dysphagia and odynophagia.	
Authors	Vaiman M, Eviatar E
Published	Head Face Med. 2009 Feb 20;5:9.
Date	2009
Place of origin	Tel Aviv University, Israel.
Background	Current methods for evaluation of swallowing pathophysiology are associated with disadvantages such as: x-irradiation, need for specialized equipment, facility & personnel, expensive,... VFSS is the most commonly used tool but does not always identify neuromuscular abnormalities in pharyngeal or laryngeal physiology, and can hardly be used for a rapid screening process. Patients suspected of having swallowing disorders, could highly benefit from simple diagnostic screening before being referred to specialist evaluations. The aim of a screening procedure is to separate patients into groups with normal and abnormal deglutition. Screening so far is a filter to decide whether further clinical diagnostics or treatment is necessary. Swallowing is a muscular process involving 26 muscles and 5 cranial nerves. This fact suggests that surface electromyography (SEMG) might be a valuable method to be used for screening purposes and early diagnostics of dysphagia and odynophagia complaints. The authors have established a normative database for sEMG assessment of deglutition in previous publications, and the next step might be establishment of standards for this diagnostic procedure, i.e. a protocol.
Objective	The article analyzes various instrumental methods of dysphagia assessment, introduces surface electromyography (sEMG) to carry out rapid assessment of such patients, and debates proposed suggestions for sEMG **screening protocol** in order to identify abnormal deglutition.
Results	*sEMG as a screening method* • Different diseases have specific sEMG patterns, both in timing and amplitude of the record. The graphic record itself has visible peculiarities specific for each disease. *Protocol equipment* • The authors describe some technical requirements for an sEMG device to be used as a screening tool. VitalStim Plus meets most of the requirements. *sEMG technique* *4 muscle groups are to be examined* • for oral phase: the orbicularis oris superior and inferior (OO), • for oral phase: the masseter (MS), • for pharyngeal phase: the submental muscle group (SUB) which includes the anterior belly of the digastric, mylohyoid, and geniohyoid, all covered by the platysma, • for pharyngeal and initial oesophageal phases: (INF), the infrahyoid group, thyrohyoid, and the laryngeal strap muscles also covered by the platysma. *Protocol electrode positions:* • OO-location: 2 electrodes are to be applied at the right or left angle of mouth, one electrode above the upper lip, and another electrode below the lower lip • MS-location: 2 electrodes are to be placed parallel to the masseter muscle fibers on the left or right side of the face, preferably on the opposite side from the OO-location • SUB-location: 2 electrodes are to be attached to the skin beneath the chin on the right or left side of midline to record SUB myoelectrical activity over the platysma • INF-location: 2 electrodes are to be placed on the left or right side of the thyroid cartilage to record from the laryngeal strap and infrahyoid muscles *Protocol tests* *A set of 4 tests might be suggested:* • voluntary single swallows of saliva ("dry" swallow) - instruction to the patient:"Swallow your saliva" • voluntary single water swallows from an open cup ("normal", volume calculated per age group) - instruction to the patient:"Swallow this water in one gulp" • voluntary single swallows of an excessive amount of water (20 ml, "stress test") - instruction to the patient:"Swallow this water in one gulp" • continuous drinking of 100 cc of tap water from an open cup - instruction to the patient:"Drink this water as normal"

	Protocol analysis *includes assessment of:* • duration (in sec) • amplitude of electric activity (mean, in μV) • graphic patterns • number of swallows (in continuous drinking). The sEMG record of a normal swallow of a healthy person presents as a normal wave with upward deflections and a sharp apex when recorded from the MS, SUB and, to lesser extent, from INF locations.  Table 3 of this article presents a quick reference simplified set of sEMG data for screening purposes, with Combined analysis of timing, amplitude and a shape of the graphic record based on data from numerous studies. *Some remarks:* • Oral stage should be interpreted with caution because partially (initially) under voluntary control. • There is no visible difference between the shapes of SEMG recordings of swallows based on gender. • Elderly patients (age 70+) showed age-induced peculiarities in the recorded swallows: muscle activity is usually longer in duration, and suggests a lack of coordination between activities of different muscles during swallows and drinking. • For children, the duration of muscle activity during swallows and drinking significantly decreases with the age, while there is no statistically significant difference in electric amplitude measurements between children and adults. • Zenker's diverticulum, recurrent tonsillitis and TMJ disorders presents a typical sEMG pattern. • Dysphagia due to neurologic problems, however, might present difficulties when investigated by surface EMG, because sEMG recording can be contaminated by other muscles with random or associated activity during swallowing. Despite that, screening might still be successful in neurological cases if the record shows abnormal timing (prolongation), abnormal voltage (decreased) and abnormal shape of a signal (no peak).
Conclusion	• According to the published data, SEMG of swallowing is a simple and reliable method for screening and preliminary differentiation among dysphagia and odynophagia of various origins. This noninvasive radiation-free examination has a low level of discomfort, and is simple, time-saving and inexpensive to perform. The major weakness of the method seems to be inability for precise diagnostic of neurologically induced dysphagia. • With standardization of the technique and an established normative database, sEMG might serve as a reliable screening method for optimal patient management but cannot serve for proper investigation of neurogenic dysphagia.
Key message	sEMG is a reliable screening tool to detect abnormal swallowing based on shape of the sEMG graph, and duration and amplitude of the signal.
Pubmed	19232090

Quick reference simplified set of SEMG data for screening purposes. Vaiman et al. 2009										
Disorder	sEMG locations									
	Masseter			Submental			Infrahyoid			Additional peculiarity
	Duration	Amplitude	Shape	Duration	Amplitude	Shape	Duration	Amplitude	Shape	
Neurological	↑	↓	Abn	↑	↓	Abn	↑	N	N	Disorganized Peaks*
ENT	N	N	N	N	↓	Abn	N	↑	N	Multiple Peaks**
Maxillofacial (Oral)* **	↑	↓	Abn	↑	N	N	↑	N	N	
Gastroenterological	N	N	N	↑	N	Abn	↑	↑		Abn Regurgitation Peaks
Psychogenic** **	N	N	N	N	N	N	N	N	N	Shoulder tension

Shape: shape of the graphic record

N: normal, Abn: abnormal, ↑: higher than normal, ↓: lower than normal.

* Appearance of MS, SUB and INF peaks is not coordinated

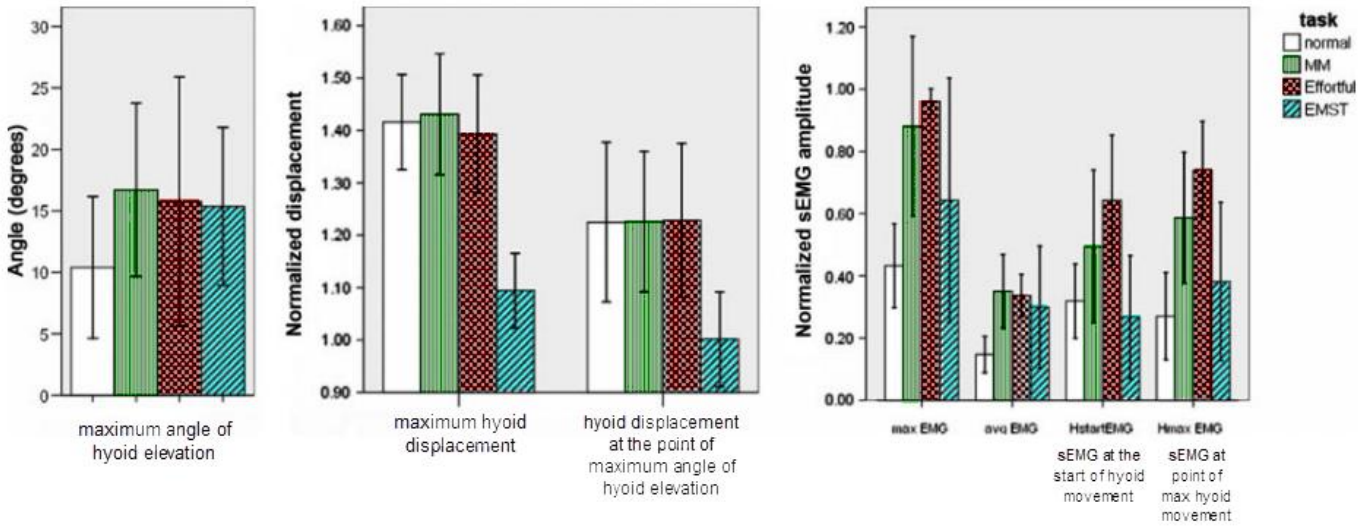
** One bolus can be swallowed in several shares

*** Including salivary gland diseases

**** Excluding malingering

Submental sEMG and hyoid movement during Mendelsohn maneuver, effortful swallow, and expiratory muscle strength training. 	
Authors	Wheeler-Hegland KM, Rosenbek JC, Sapienza CM.
Published	J Speech Lang Hear Res. 2008 Oct;51(5):1072-87.
Date	2008
Place of origin	Arizona State University, Tucson, Tempe, USA
Background	In rebilitation exercises, the principle of task specifity and overload are important. The principle of specificity holds that the best way to train a certain function is to do exercises that are similar to, or identical to, that function. The principle of overload holds that in order to increase the force-generating ability of a muscle, that muscle must be taxed beyond its current capacity to respond. That is, it must be exposed to a load greater than what it is typically exposed to on a daily basis.
Objective	This study investigated the concurrent biomechanical and electromyographic properties of 2 swallow-specific tasks (effortful swallow and Mendelsohn maneuver) and 1 swallow-nonspecific (expiratory muscle strength training [EMST]) swallow therapy task in order to examine the differential effects of each on hyoid motion and associated submental activation in healthy adults, with the overall goal of characterizing task-specific and overload properties of each task.
Study design & methods	**Prospective experimental study.** *Subjects*: 25 healthy male and female adults. *Methods*: each participant completed • normal swallow, • Mendelsohn maneuver swallow, • effortful swallow, and • EMST task (expiratory muscle strength training) in random order during concurrent videofluoroscopy and surface electromyography recording. *Outcomes*: *sEMG measures:* • Duration of the sEMG amplitude (from sEMG onset to offset) • Peak and mean amplitude, • Amplitude at the point of max hyoid elevation • Duration between sEMG onset and peak amplitude *VFS measures:* • Hyoid bone displacement: trajectory and elevation angle, referenced to the third cervical vertebra (C3)
Results	Results revealed significant differences in the trajectory of hyoid motion as measured by overall displacement and angle of elevation of the hyoid bone. As well, timing of hyoid movement and amplitude differences existed between tasks with regard to the activation of the submental musculature. • The maximum angle of hyoid elevation was significantly lower for the normal swallow task than for the Mendelsohn maneuver • The **3 tasks that included an actual swallow** (e.g., normal swallow task, effortful swallow, and Mendelsohn maneuver) had **greater hyoid displacement** values than the EMST task. • sEMG measures were generally highest for the Mendelsohn maneuver and effortful swallows, with the **effortful swallow achieving the highest sEMG values**, particularly at the point of hyoid maximum displacement. • The **normal swallow task had the lowest maximum and average sEMG measure**. • The relations between the times of maximum sEMG amplitude (TMax EMG), maximum hyoid displacement (T1), and maximum hyoid angle of elevation (T2) were also different between the swallow tasks, with effortful swallow patterns being similar to those produced in the normal swallow condition, indicating that with regard to task specificity, the **effortful swallow is the most task specific**. EMST appeared to be the least task specific exercise.

Conclusion	Study results demonstrated differential effects of the 3 experimental tasks on the principles of task specificity and overload. These principles are important in the development of effective rehabilitative programs.
Key message	Discrete differences were found between the different swallowing tasks for the trajectory of hyoid movement, submental sEMG measures, and relation between hyoid movement and submental sEMG, when measured concurrently.
Pubmed ID	18728114

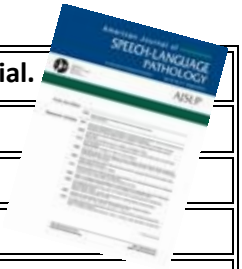


Identification of swallowing events from sEMG Signals Obtained from Healthy Adults.	
Authors	Crary MA, Carnaby Mann GD, Groher ME.
Published	Dysphagia. 2007 Apr;22(2):94-9.
Date	2007
Place of origin	Department of Communicative Disorders, University of Florida Health Science Center, Gainesville, Florida, USA.
Background	Surface electromyography (sEMG) is being used with increasing frequency to identify the occurrence of swallowing, to describe swallow physiology, and to treat impaired swallowing function in dysphagic patients. Despite this increased utilization, limited information is available regarding the validity and reliability of investigators and clinicians to interpret sEMG data in reference to swallowing.
Objective	• To examine the validity and interjudge reliability of swallow identification using sEMG records obtained from healthy adults. • Validity and reliability estimates were compared between experienced and naïve judges in the identification of swallows from graphic sEMG records.
Study design & methods	**Experimental study on healthy subjects.** *Subjects*: 44 healthy adults. *Methods*: Videofluoroscopic images and sEMG graphic information were acquired from the subjects swallowing 5 ml of standard barium sulfate liquid contrast. Graphic traces of sEMG activity depicting swallows and nonswallow movements were presented to each judge.
Results	• Multiple validity estimates were high, indicating a **strong degree of accuracy** in identification of swallows versus nonswallow movements from sEMG traces. • Experienced judges were more accurate than naïve judges (classification accuracy: experienced = 90% vs. naïve = 81%; p = 0.006). • Judges in both groups were more likely to classify swallows as nonswallow movements (false negatives) than to classify nonswallow movements as swallows (false positives). • Interjudge reliability estimates indicated a high degree of agreement among judges in the identification of swallows versus nonswallow movements from the sEMG signal, with higher agreement among experienced judges.
Conclusion	These results suggest that the **sEMG graphic record is a valid and reliable tool for identifying normal swallows** and that experience with this technique results in better identification and interjudge agreement.
Key message	The sEMG graphic record is a reliable assessment tool for identifying normal versus abnormal swallowing.
Pubmed	17294299

Biomechanical correlates of surface electromyography signals obtained during swallowing by healthy adults. 	
Authors	Crary MA, Carnaby Mann GD, Groher ME
Published	J Speech Lang Hear Res. 2006 Feb;49(1):186-93.
Date	2006
Place of origin	University of Florida Health Science Center, Gainesville, FL, USA.
Objective	The purpose of this study was to describe biomechanical correlates of the surface electromyographic signal obtained during swallowing by healthy adult volunteers.
Study design & methods	**Laboratory study** on healthy subjects. *Subjects*: 17 healthy adults. *Methods*: subjects were evaluated with simultaneous videofluoroscopy and surface electromyography (sEMG) while swallowing 5 mL of liquid barium sulfate. • 3 biomechanical swallowing events were analyzed: hyoid elevation, pharyngeal constriction, and opening-closing of the pharyngoesophageal segment. • For each biomechanical event and from the sEMG signal, the authors identified onset, peak, and offset time points. • From these points, duration measures were calculated. • Means and 95% confidence intervals were calculated for each measure. • Subsequently, correlations were evaluated between timing aspects of the sEMG traces and each biomechanical event.
Results	• Swallow onset in the sEMG signal preceded the onset of all biomechanical events. • All biomechanical events demonstrated a strong correspondence to the sEMG signal. • The strongest relationship was between hyoid elevation-anterior displacement and the sEMG signal.
Conclusion	These results suggest that the sEMG signal is a useful indicator of major biomechanical events in the swallow. Future studies should address the impact of age and disease processes, as well as bolus characteristics, on the biomechanical correlates of sEMG signals obtained during swallowing.
Key message	The sEMG signal is strongly correlated with the major biomechanical events of swallowing and is therefore a useful tool to evaluate swallowing patterns.
Pubmed	16533083

Surface electromyographic characteristics of swallowing in dysphagia secondary to brainstem stroke.	
Authors	Crary MA, Baldwin BO.
Published	Dysphagia. 1997 Fall;12(4):180-7.
Date	1997
Place of origin	Department of Communicative Disorders, University of Florida Health Science Center, Gainesville, USA.
Background	Surface electromyography (SEMG) provides an noninvasive avenue for evaluating swallowing physiology.
Objective	To describe SEMG characteristics associated with swallow attempts in 6 dysphagic patients who had suffered brainstem stroke compared with 6 age and gender-matched controls.
Study design & methods	**Case control series.** *Subjects*: 12 adults: 6 patients with dysphagia secondary to brainstem stroke and 6 healthy controls. *Methods*: • Myoelectric activity was monitored from three surface electrode placement sites: perioral, masseter, and infrahyoid. The unimpaired side of the face was used for perioral and masseter placements. • SEMG signals were amplified, filtered (wide band: 100-1 kHz), rectified, and integrated for 20 msec. The integrated signal was digitized with a sampling rate of 10 Hz and stored in an interactive software program for subsequent analysis. A 4-sec sampling window was used to evaluate each swallowing attempt. • SEMG data were obtained in each of the following conditions: (1) two trials of a resting baseline (mouth empty); (2–3) two trials each of an ‘‘active baseline’’ (holding 5 or 10 ml of water in the mouth without swallowing); (4) five no bolus (saliva) swallows; (5) five attempts to swallow 5 ml of water; and (6) five attempts to swallow 10 ml of water. Outcomes: Microvolt and time values for each condition were monitored.
Results	• Dysphagic subjects demonstrated significantly higher baseline activity than the control subjects in all three bolus conditions (p=0.002). • Dysphagia subjects demonstrated greater peak sEMG activity than the control group. • Dysphagia subjects demonstrated greater average sEMG activity than the control group. • Swallow durations in the dysphagic patients were shorter than those obtained from the control subjects. • The latency between the onset of the swallow and the peak microvolt value within the swallow event was lower in the dysphagic patients than in the controls for the perioral (p=0.001) and the masseter (p=0.002). • The dysphagic patient group coordination scores were significantly lower than the control group scores in both the no bolus ($p < 0.0001$) and 5 ml ($p < 0.0001$) conditions.
Conclusion	The results of this study indicate that patients with dysphagia secondary to brainstem stroke differed in both amplitude and timing aspects of swallowing attempts from asymptomatic age- and gender-matched controls. Specifically, the results indicated that during swallow attempts, dysphagic patients produced more muscle activity over a shorter duration and with less coordination than controls.
Key message	The noninvasive techniques of surface electromyography offer the possibility of studying swallowing physiology at a different level of description than radiographic imaging techniques or more invasive intramuscular electromyography.
Pubmed	Pubmed link

USE OF sEMG BIOFEEDBACK IN DYSPHAGIA TREATMENT



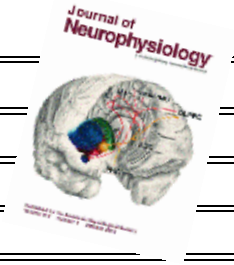
<u>Basic concepts</u> of surface electromyographic biofeedback in the treatment of dysphagia: a tutorial.	
Authors	Crary MA, Groher ME
Published	Am J Speech-Lang Pathol. May 2000;9:116-125.
Date	2000
Place of origin	College of Health Professions, University of Florida Health Science Center, Gainesville.
Background	Surface electromyographic (sEMG) biofeedback has been used to enhance behavioral treatment interventions in a variety of movement disorders involving the head and neck musculature. Despite the potential for widespread application of sEMG biofeedback-assisted treatments in motor disorders of the head and neck musculature, speech-language pathologists generally are not aware of these techniques or of their potential application to speech, voice, or swallowing disorders.
Objective	The intent of this tutorial is to provide a general introduction to surface electromyographic biofeedback techniques as they may apply to the rehabilitation of dysphagia in adults. Specific examples are provided based on clinical management of patients with dysphagia following brainstem stroke.
Study design & methods	This tutorial focuses on the author's experience using sEMG techniques with patients who have dysphagia following brainstem stroke. • First, the authors detail the basics of the methods and procedures for application of sEMG biofeedback in dysphagia treatment. • Second, the authors provide a detailed example of use of this technology in the treatment of chronic dysphagia in patients with brainstem stroke.
Results	*Videofluoroscopy and also Ultrasound imaging performed at the same time of sEMG during swallowing movements showed that the sEMG signal corresponds very well to what is seen on VFS and US, and is indeed a reliable measure for the quality of swallowing.* • Peak sEMG signal corresponds to peak hyolaryngeal elevation • Duration of the sEMG signal corresponds to duration of the squeezing aspect of swallowing • VFS and US confirmed that the submental and infrahyoid electrode placement sites are locations providing correspondance to both pharyngeal contraction and laryngeal elevation *sEMG Biofeedback is of special utility to promote or regain acquisition of volitional control of physiological processes that are automatic in healthy individuals.* • Swallowing activity is such a automatic physiological process - in absence oral swallowing activity in neurogenic dysphagia such as stroke, patients become unfamiliar with the movement patterns that underlie functional swallowing. • With sEMG those patients may improve control over swallow physiology leading to improved functional swallowing. *Appropriate patient selection is important because the interactive nature of the modality* • adequate auditory and visual sensory abilities • sufficient congnitive abilities *Electrode placement and skin preparation - electrodes should be placed in function of the goal of the treatment* • If the goal is to increase lip closure, electrode placement would be in the perioral region (mouth corner) • If the goal is to provide feedback on pharyngeal activity during swallow, submental and infrahyoid placement are appropriate. • Poorly placed or loosely connected electrodes may result in erroneous information being obtained from sEMG units. *Normal and abnormal sEMG swallowing characteristics can be represented/visualized on a trace graph* • sEMG microvolt activity is plotted against time • The graph of a swallowing event can be compared to a the graph representing a normal swallowing event in order to identify deviations. • The graph of a swallowing event can be used to check whether certain maneuvers (e.g. Mendelsohn) are performed properly

	Patient evaluation using sEMG Biofeedback • *Resting baseline* activity from head and neck musculature is estimated to be in the range from 0 to 4 mV, with an average of 2 mV. • *Active baseline* is obtained with the patient holding a bolus within the mouth - in normal subjects active baseline from infrahyoid site is does not show increased sEMG activity - certain patients show increased active baseline activity and may need relaxation therapy before exercise. • *Swallowing assessment*: sEMG swallowing evaluations are completed with a range of materials determined from the instrumental exam. *Treatment of dysphagia using sEMG Biofeedback* • sEMG is extremely useful in improving and sustaining pharyngeal contraction and laryngeal elevation during the swallow and in facilitating lip closure and tongue mobility. • Progress can be monitored: change in average or peak amplitude; percent success of surpassing threshold; percent success in maintaining contraction above threshold (or relaxation below threshold). • sEMG biofeedback supplementation encourages patients to swallow with more effort, with improved swallowing coordination, and can focus on sustained contractions during swallow attempts and relaxation of the throat musculature prior to swallow attempts. *Outcome data of clinical studies* • Collectively, the published reports suggest that sEMG-assisted treatment for dysphagia has the potential to facilitate improved swallow physiology in a short time frame. • Furthermore, functional outcomes from this approach are reported to be maintained for up to a 2-year period. • Even patients with chronic dysphagia requiring long-term gastrostomy feedings are able to return to oral food ingestion using sEMG biofeedback-assisted treatment.
Conclusion	sEMG biofeedback can facilitate enhanced rehabilitation of swallowing patterns and this improvement is maintained over time. It is is a useful adjunct to intensive swallowing treatment, specifically to facilitate enhanced learning of novel or difficult-to-monitor swallowing movements.
Key message	sEMG biofeedback is a useful adjunct in swallowing therapy to identify abnormal swallowing patterns and to facilitate enhanced functional rehabilitation of swallowing.

Functional benefits of dysphagia therapy using adjunctive sEMG biofeedback.	
Authors	Crary MA, Carnaby Mann GD, Groher ME, Helseth E.
Published	Dysphagia. 2004 Summer;19(3):160-4.
Date	2004
Place of origin	Department of Communicative Disorders, University of Florida Health Science Center, Gainesville, Florida, USA.
Background	Therapeutic approaches facilitating faster learning of specific swallowing movements would be valuable adjuncts to behavioral therapy programs. sEMG biofeedback has been advocated as an adjunct to swallowing therapy with prior reports of rapid progress in patients treated with this approach, even chronic patients; however these studies had methodological limitations.
Objective	To retrospectively evaluate the effect of a structured swallowing therapy program supplemented by sEMG biofeedback on swallowing function.
Study design & methods	**Retrospective study.** *Subjects*: 45 dysphagia patients: 25 patients post-stroke and 20 patients post treatment for head/neck cancer. • All patients enrolled in this program demonstrated pharyngeal dysphagia on videofluorographic examination characterized by reduced hyolaryngeal elevation during swallowing, reduced pharyngoesophageal segment opening, and postswallow residue. • 68% of stroke patients and 20% of head/neck cancer patients had undergone prior dysphagia therapy. *Methods*: all patients completed a systematic therapy program supplemented with sEMG biofeedback

	exercises(daily therapy sessions with a SLT + 2 biofeedback session per day at home). • Biofeedback was used during swallow attempts to assist the patient in maintaining the requested duration of each swallow attempt and to provide immediate information on the degree of effort associated with each swallow. • Electrodes were placed on the anterior neck of each individual between the hyoid bone and superior border ofthe thyroid cartilage. The ground electrode was placed over the thyroid notch area with each active electrode to right and left of the ground electrode. Outcomes: • Change in functional oral intake of food and liquid (FOIS) • Number of therapy sessions to discharge • Estimated cost per unit of functional change
Results	*Functional improvement:* • 87% (39/45) of all patients increased their functional oral intake of food/liquid including 92% of stroke patients and 80% of head/neck cancer patients. • Patients with dysphagia following stroke demonstrated greater improvement than those in the head/neck cancer group: average change in FOIS scores was 2.96 for the stroke group and 1.58 for the head/neck cancer group (p=0.079). • Prior to therapy, 71% of patients were reliant on nonoral sources ofnutrition (FOIS levels 1, 2, or 3), including 80% of stroke patients and 60% of head /neck cancer patients. Subsequent to therapy, 55% of stroke patients and 25% of the head/neck cancer patients initially reliant on nonoral feeding progressed to total oral feeding (p = 0.013). *Cost-effectiveness:* • Average total cost of therapy in the stroke group was $949 (average of 12.32 sessions · $76.99). In the head/neck cancer group, average total cost was $716 (average of 9.3 sessions · $76.99). • To estimate cost per unit of functional change, the total cost of therapy was divided by the change in the FOIS score. • Average cost per unit of functional change (average total cost/ FOIS change) in the stroke group was $321 ($949/2.96). In the head/neck cancer group, average cost per unit off unctional change was $453 ($716/1.58). • Patients in the stroke group completed more therapy sessions thus increasing the total cost of therapy, but they made more functional progress resulting in lower costs per unit of functional change than patients in the head/neck cancer group.
Conclusion	The results of this study indicate that sEMG biofeedback applied to a structured behavioral therapy program facilitates increased functional oral intake within a limited time frame in patients who demonstrate dysphagia following stroke or treatment for head/neck cancer. Stroke patients demonstrated more functional gains than head/neck cancer patients.
Key message	A dysphagia therapy program supplemented with sEMG biofeedback improved functional swallowing status in the majority of stroke and head/neck cancer patients who had not improved with previous standard therapy programs.
Pubmed ID	15383945

The use of biofeedback in the treatment of chronic dysphagia in stroke patients.	
Authors	Bogaardt HC, Grolman W, Fokkens WJ.
Published	Folia Phoniatr Logop. 2009;61(4):200-5.
Date	2009
Place of origin	Department of Otorhinolaryngology-Head and Neck Surgery, Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands.
Objective	To evaluate the efficacy of the use of surface electromyographic feedback in the treatment of stroke patients with chronic dysphagia.
Study design & methods	**Retrospective study.** *Methods*: • Data of 11 consecutive patients with chronic dysphagia after stroke (average time after onset was 31.1 months) were analyzed. • All patients had been previously treated by speech therapists without success. • Patients were treated for dysphagia with surface electromyography biofeedback as adjunct to normal exercises. • The treatment consisted of maintaining a swallow for 8–10s (i.e. modified Mendelsohn's maneuver) every 30s for a period of 20 min per treatment session. The swallowing activity was visualized by the use of sEMG of the submental muscles. *Outcome*: • Functional swallowing was estimated using the Functional Oral Intake Scale (FOIS).
Results	• At the start of the treatment 8 patients were tube dependent (FOIS < or = 4). 3 patients were on an oral diet, but with restrictions (FOIS > or = 5). • The patients were treated on average 7 times. The time between the first and last treatment session was on average 76.1 days. • Before treatment the average FOIS was 2.6 (SD +/-2.3) and after treatment 5.6 (SD +/-1.6). The median scores improved from 1 to 6, showing a significant and clinically relevant improvement ($p < 0.01$) in swallowing function. • In 6 of initially 8 patients with percutaneous enteral gastrostomy tubes, the feeding tube could be removed after treatment.
Conclusion	The data suggest that the use of surface electromyography as biofeedback in the treatment of chronic dysphagia after stroke could be an effective adjunct to standard therapy for swallowing disorders.
Key message	The use of sEMG as biofeedback in the treatment of chronic dysphagia after stroke produced significant improvement of swallowing function and tube removal in 6 of 8 tube dependant patients.
Pubmed ID	19590219



Self-Triggered Functional Electrical Stimulation During Swallowing	
Authors	Burnett TA, Mann EA, Stoklosa JB, Ludlow CL.
Published	J Neurophysiol. 2005 Dec;94(6):4011-8.
Date	2005
Place of origin	Laryngeal and Speech Section, Medical Neurology Branch, National Institute of Neurological Disorders and Stroke, National Institutes of Health, Bethesda, USA.
Background	• Hyolaryngeal elevation is essential for airway protection during swallowing and is mainly a reflexive response to oropharyngeal sensory stimulation. • Targeted intramuscular electrical stimulation can elevate the resting larynx and, if applied during swallowing, may improve airway protection in dysphagic patients with inadequate hyolaryngeal motion. • To be beneficial, patients must synchronize functional electrical stimulation (FES) with their reflexive swallowing and not adapt to FES by reducing the amplitude or duration of their own muscle activity. • Sensations of swallowing most likely come from afferents in the oropharyngeal mucosa that sense bolus movement and increased pressures due to tongue retraction and pharyngeal constriction. Individuals could either predict or react to such sensations when trying to synchronize FES with swallowing. • Assuming that synchronization of FES and swallowing is possible, it needs to be determined whether or not there is motor adaptation to its facilitative effects.
Objective	To evaluate the ability of healthy adults to manually synchronize FES with hyolaryngeal muscle activity during discrete swallows and to test for motor adaptation. • To test the hypothesis that healthy adults could trigger intramuscular mylo- and thyrohyoid stimulation in synchrony with volitional swallows of 2 ml water. • To evaluate whether or not volitionally triggered hyolaryngeal stimulation in the short-term altered the amplitude, duration, and relative timing of mylohyoid and thyrohyoid activity during swallowing.
Study design & methods	**Experimental laboratory study** on healthy subjects. *Subjects*: 3 healthy adults. *Methods*: • Hooked-wire electrodes were placed into the mylo- and thyrohyoid muscles to record electromyographic activity from one side of the neck and deliver monopolar FES for hyolaryngeal elevation to the other side. • After performing baseline swallows, volunteers were instructed to trigger FES with a thumb switch in synchrony with their swallows for a series of trials. • An experimenter surreptitiously disabled the thumb switch during the final attempt, creating a foil.
Results	• In baseline swallows, mylohyoid activity onset preceded laryngeal elevation by an average of 345 ms, whereas thyro-hyoid onset preceded laryngeal elevation by an average of 52 ms. • The onset and offset of thyrohyoid activity mirrored the rise and fall of the larynx • These baseline measures indicate that laryngeal movement during swallowing is more closely associated in time with thyrohyoid than with mylohyoid activity. • From the outset, volunteers synchronized FES with the onset of swallow-related thyrohyoid activity (approximately 225 ms after mylohyoid activity onset), preserving the normal sequence of muscle activation. They were immediately able to press the thumb switch so that there was no significant difference between their onset of thyrohyoid activity for swallowing and the onset of FES stimulation of the mylo- and thyrohyoid muscles on the opposite side of the neck. • A comparison between average baseline and foil swallows failed to show significant adaptive changes in the amplitude, duration, or relative timing of activity for either muscle, indicating that the central pattern generator for hyolaryngeal elevation is invariable with short term stimulation that augments laryngeal elevation during the reflexive, pharyngeal phase of swallowing.
Conclusion	The results demonstrate that normal volunteers can quickly synchronize a manual trigger with the pharyngeal phase of swallowing and that their muscle activation patterns do not quickly adapt to the augmentation effects of muscle stimulation.
Key message	Based on the results of this study, we may expect that a manually triggered hyolaryngeal FES system will be of greatest benefit to chronically dysphagic individuals with inadequate hyolaryngeal elevation but with adequate oral sensory, limb motor, and cognitive function.
Pubmed ID	16107520

A direct intervention program for chronic neurogenic dysphagia secondary to brainstem stroke.	
Authors	Crary MA.
Published	Dysphagia. 1995 Winter;10(1):6-18.
Date	1995
Place of origin	Department of Communicative Disorders, University of Florida Health Science Center, Gainesville, USA.
Background	Little objective documentation is available regarding the efficacy of therapies for oropharyngeal dysphagia. Information specifying efficacy of treatment for chronic dysphagic conditions is almost nonexistent.
Objective	To describe the therapy program (including sEMG biofeedback) and to present immediate and long-term outcome data from 6 patients presenting with chronic dysphagia secondary to brainstem stroke.
Study design & methods	**Case series.** *Subjects*: 6 consecutive adult patients between the ages of 61 and 72 y. Time post-onset ranged from 5 to 54m. • All patients demonstrated an "incomplete" swallow pattern identified by fluorographic swallow examination. • All patients were receiving total nutrition and hydration via gastrostomy feeding tubes and none could swallow their own saliva at the onset of therapy. • Each patient had received swallowing therapy during their initial rehabilitation period and 2 patients had received surgical myotomies, but no patient reported any improvement from the earlier treatments. *Methods*: • The therapy program incorporated swallowing instruction supplemented by surface electromyographic (SEMG) biofeedback to strengthen the pharyngeal response. • Swallowing instruction focused on developing a coordinated delivery of the bolus to the pharynx with sustained oral and pharyngeal postures. • The biofeedback component of the therapy program was designed to (1) provide the patient with information on movement patterns that were otherwise difficult to monitor, specifically, the pharyngeal component of swallowing including laryngeal elevation, pharyngeal contraction, and sustained pharyngeal contraction; and (2) increase the strength of the pharyngeal component of swallowing. • A target threshold of SEMG activity was identified during a pretherapy evaluation. This threshold represented a myoelectric activity level that the patient had to surpass to receive anditory/visual SEMG feedback. Each patient's task was to swallow with sufficient effort to obtain feedback and to maintain maximum contraction in the pharynx for 2 or more sec. As each patient achieved an 80% success level on these tasks, the threshold level was increased. • SEMG activity was measured from the anterior neck (throat) area using a series of three electrodes placed horizontally between the hyoid bone and the thyroid cartilage. • In addition to daily therapy sessions in the clinic, each patient was requested to complete 3 therapy sessions at home each day. *Outcomes*: • Immediate clinical outcome defined by each patient's ability to increase oral intake and reduce or eliminate tube feedings • Changes in swallowing physiology measured by independent, multichannel sEMG assessment of swallowing function completed before and after therapy. 4 measures of swallow function were generated: swallowing coordination, swallow duration, peak sEMG values, avarage sEMG activity. • Long-term outcome determined by questionnaire completed by patients 18-24 months following therapy.
Results	• Following completion of all therapies, 5 of the 6 patients returned to total oral feeding and were able to have their feeding gastrostomies removed. • Posttherapy swallow attempts demonstrated improved coordination, longer duration, and increased effort (peak and average myoelectric activity). • Positive results were maintained for up to 2 years posttherapy by all patients who succeeded (5/6).
Conclusion	• This report suggests that patients with chronic and total dysphagia secondary to brainstem stroke can recover the ability to tolerate a total oral diet following short-term, direct intervention including sEMG biofeedback. • sEMG techniques were instrumental in this program for both documenting change in swallowing patterns and providing patients with valuable information during therapy.
Key message	Immediate and long-term functional improvement of dysphagia in brain stem stroke patients following a therapy program that incorporated sEMG biofeedback.
Pubmed	7859537

Questions?

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