

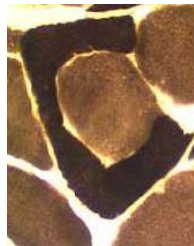
Dysphagia due to stroke

- Majority of dysphagic patients are cortical or brainstem stroke patients
- Dysphagia generally resolves in majority of cortical stroke patients within 6 months
- Brainstem stroke causes more severe and permanent dysphagia due to damage to cranial nerve nuclei
- Medical priority in treating dysphagia:
 - Prevent dehydration and malnutrition
 - Avoid development of aspiration pneumonia



Swallow dysfunctions in CVA

- Swallow system is impaired as a result of multiple contributing factors:
 - Decreased neural drive to swallowing musculature
 - Insufficient sensory feedback for efficient motor control
 - Muscle atrophy as a result of disuse
 - Myofascial restrictions as a result of disuse



Disuse atrophy

- Dysphagia is associated with disuse atrophy, especially of fast-twitch, type II muscle fibers
 - Patients elicit spontaneous swallows with less frequency than non-dysphagic counterparts
 - Individuals with compromised health and those of advanced age are most susceptible to disuse atrophy
- Significant atrophy is evident as soon as 72 hours post-stroke
- Atrophy is reversible with exercise

Burkhead LM, Sapienza CM, Rosenbek JC. Strength-training exercise in dysphagia rehabilitation: principles, procedures, and directions for future research. *Dysphagia*. Jul 2007;22(3):251-265.

Urso M, Clarkson M, Price T. Immobilization effects in young and older adults. *European Journal of Applied Physiology*. 2006;96:564-571.

Nicosia MA, Hind JA, Roecker EB, et al. Age effects on the temporal evolution of isometric and swallowing pressure. *J Gerontol A Biol Sci Med Sci*. Nov 2000;55(11):M634-640.



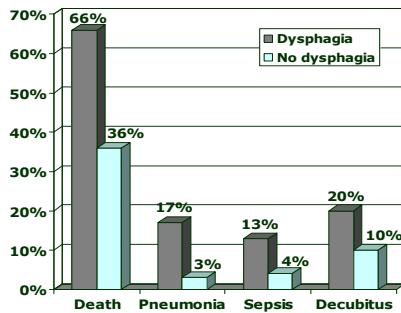
Swallow dysfunctions in CVA

- Management strategies often reinforce underlying impairments
 - Patients are often taught compensatory swallowing techniques (e.g., turning head or tucking chin when swallowing) to improve swallow safety but at the expense of normal swallow dynamics
 - Diets are often modified to a consistency requiring slower contractions
 - Diets are often limited to a quantity and consistency that limits aspiration but decreases oral intake



Burden of illness

Occurrence of complications 1 year post stroke in patients with severe dysphagia and a PEG compared to patients without dysphagia. (CMS data file analysis)



Covance. VitalStim Therapy economic model. 2005

Limited treatment options

Compensation (mainstay of current management)

- Head turn
- Chin tuck
- Modified diet
- Supraglottic swallow

Medical management

- PEG
- Medication – anti-reflux, botox, etc.
- Surgery – dilatation, myotomy, etc

Therapy

- Biofeedback (sEMG, pressure)
- Effortful swallow
- Oromotor exercise
- Thermotactile stim
- Mendelsohn, Masako, Shaker
- Electrotherapy (recent addition = VitalStim)



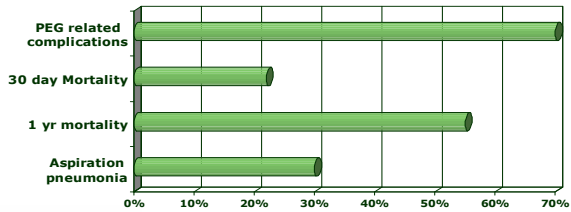
Conventional therapies

- Conventional treatment and management strategies have little supporting evidence
- Data demonstrate that:
 - Management strategies are effective at limiting aspiration but not at improving swallowing
 - Feeding tubes do not reduce aspiration nor occurrence of aspiration pneumonia
 - Feeding strategies (tubes, diet modifications, etc.) do not improve hydration



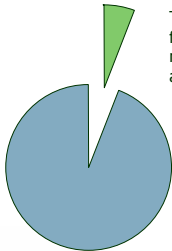
Langmore SE, Terpenning MS, Schork A, Chen Y, Murray JT, Lopatin D, Loesche WJ. Predictors of aspiration pneumonia: how important is dysphagia? *Dysphagia* 13 (2): 69-81, 1998
 Martin B, Corlew M, Wood H, Olson D, Golopoul L, Wingo M, Kirmani N. The Association of Swallowing Dysfunction and Aspiration Pneumonia. *Dysphagia* 9 (1): 1-6, 1994

Complications of PEG tubes



American Gastroenterological Association Technical Review on Tube Feeding for Enteral Nutrition. *Gastroenterol.* 1995; 108: 1282-1301

Cost of enteral tube feeding



Total annual cost to Medicare for enteral feeding supplies was more than \$670 million (6% of annual DME budget).

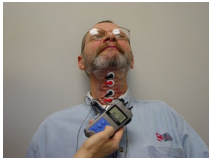
Estimated cost of providing 1 year of feeding via PEG is \$31,832. Main components of this cost include the initial PEG procedure, enteral formula and hospital charges for major complications.



Callahan CM, Buchanan NN, Stump TE. Healthcare costs associated with percutaneous endoscopic gastrostomy among older adults in a defined community. *J Am Geriatr Soc* 2001; 49(11):1525-1529

What is VitalStim Therapy?

- Use of Neuromuscular Electrical Stimulation (NMES) to reeducate swallow
- Device and method cleared by the FDA in 2001 as safe and efficacious in treatment of dysphagia



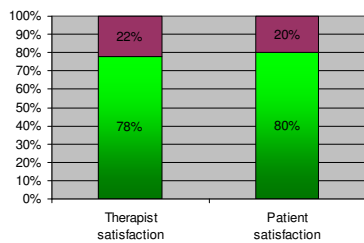
Therapy adoption



CIAO Seminars data 2003-2007. www.ciaoseminars.com

User & patient satisfaction

Survey of SLP's (users & non-users, n=2,000) shows that majority of users and patients report good satisfaction.



Crary M, Carnaby-Mann G, Faunce A. Electrical stimulation therapy for dysphagia: Descriptive results of two surveys. *Dysphagia*. 22 February 2007

Typical treatment session

- Prepare skin, attach electrodes
- Stimulation remains on or 1 hour or as per patient tolerance
- During stimulation patient actively practices swallowing
- Progress patient with different foods/liquids as per tolerance



Typical treatment session

- Progression to therapeutic intensity
 - "Tingling"
 - "Vibration"
 - "Warm "
 - "Grabbing"

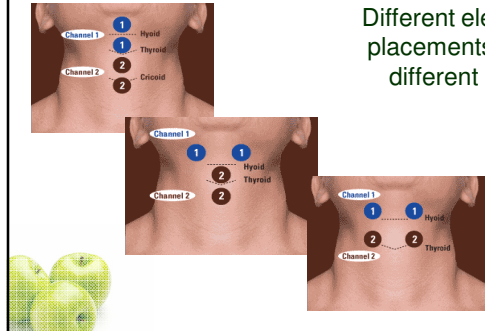


Limitations

- Denervated muscle does not respond to NMES
- Inability to elicit voluntary or reflexive swallow limits efficacy
- Structural abnormalities are not affected by NMES



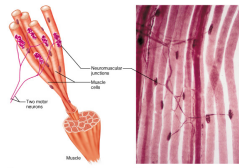
Sample electrode placement



Different electrode placements target different muscle groups

Effects of NMES on muscle

- NMES + concurrent exercise has been shown to produce:
 - Increase in contractile proteins
 - Increase in aerobic enzymes
 - Increase in mitochondrial size and number
 - Increase in capillary density



Preferential type II recruitment

- Fast-twitch fibers (type II) abundant in swallowing muscles
- Type II more prone to disuse atrophy than slow twitch (type I)
- Normal recruitment order is reversed during NMES (type II first, then type I) facilitating swallow specific strengthening therapy



Facilitation of cortical plasticity

- Brain plasticity enables recovery of swallow function after CVA and occurs spontaneously
 - Since complications of dysphagia represent major health risk, acceleration of recovery is medical priority
- NMES facilitates cortical reorganization
 - Induces repetitive swallows
 - Produces sensory stimulation
 - Provides movement feedback
 - Promotes functional, task-specific use

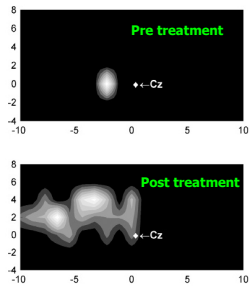


Hamdy et al. Gut feelings about recovery after stroke: the organization and reorganization of human swallowing motor cortex. *Trends Neurosci.* Jul 1998;21(7):278-282
Oh et al. Recovery of swallowing function is accompanied by the expansion of the cortical map. *Int J Neurosci.* Sep 2007;117(9):1215-1227

Oh (2007): Cortical reorganization

- 8 dysphagic patients
 - 46-69 yo
 - 4 x CVA, 4 x brainstem CVA or cranial nerve lesion
- 10 NMES treatments using VS placements
- Outcome measures
 - Swallow function per MBS
 - Cortical mapping of swallow muscles per TMS
- Significant expansion of cortical map post-tx

TMS mapping before and after treatment



Oh B-M, Kim D-Y, Paik N-J. Recovery of swallowing function is accompanied by expansion of the cortical map. *Int J Neurosci.* Sept 2007;117:1215-1227.

Indications for VitalStim

- A patient is indicated for dysphagia therapy when they:

Show signs of, or are at risk for aspiration

and/or

Have difficulty managing their diet



Possible signs of dysphagia

- Coughing/clearing of throat after swallow
- Abnormal volitional cough
- Decreased voice quality (wet, hoarse, weak)
- Recurring chest infections
- Requires multiple swallows or special maneuvers to clear throat
- Difficulty completing a meal
- Feeling of food being stuck in the throat
- Requires diet to be modified (e.g., thickening, pureed food, soft solids)
- Difficulty initiating a swallow
- Spillage of food/liquid from lips and/or drooling



Precautions, Contraindications

- Contraindicated
 - Directly over active neoplasm or infection
 - Directly over carotid sinus
- Caution
 - Implanted electronics (cardiac demand pacemakers, ICDs, VNS)
 - Uncontrolled seizure disorder





NMES in dysphagia treatment

Current state of research

Studies to date

- 11 positive studies and 1 meta-analysis in print corroborate positive findings reported in the field
 - Use of NMES for dysphagia is safe
 - Improvement in swallow scores is directly associated with use of electrical stimulation
 - Use of NMES is finding widespread adoption among dysphagia therapists
 - Both therapists and patients are very satisfied with outcomes
 - NMES in conjunction with swallowing exercise is more effective than traditional treatment techniques alone
 - Use of NMES tends to decrease inpatient length of stay as a result of improved swallow function



Safety

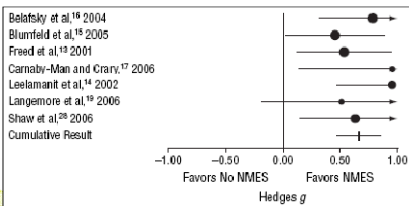
- All studies tracked for the occurrence of adverse events and none were reported across all patient ages and diagnoses
 - No changes in pulse oxymetry readings, heart rate, or blood pressure (n=892)
 - No reports of laryngospasm, bradycardia or electromagnetic interference with cardiac pacemakers
 - No adverse events in the pediatric population



Freed M. Use of electric stimulation to restore swallow function. *FDA trial data*, 1998
 Christiaanse M, Glynn J, Bradshaw J. Experience with transcutaneous electrical stimulation: A new treatment option for the management of pediatric dysphagia. *NCSHA*. Charleston; 2003

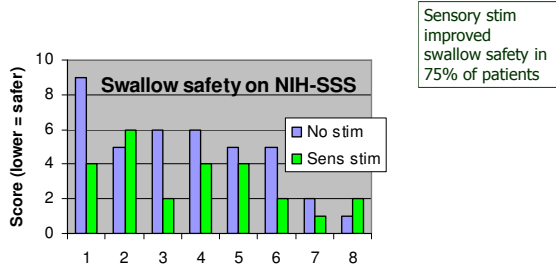
Efficacy

Meta-analysis of current data (total n=255) demonstrates significant treatment effect of ES added to standard treatment interventions



Carnaby-Mann GD, Crary MA. Examining the evidence on neuromuscular electrical stimulation for swallowing: a meta-analysis. *Arch Otolaryngol Head Neck Surg*. Jun 2007;133(6):564-571

NMES in chronic dysphagia



Sensory stim improved swallow safety in 75% of patients

Ludlow CL, Humbert I, Saxon K, Poletto C, Sonies B, Crujido L. Effects of surface electrical stimulation both at rest and during swallowing in chronic pharyngeal Dysphagia. *Dysphagia*. Jan 2007;22(1):1-10.

