Evidence-based systematic review: Effect of neuromuscular electrical stimulation on swallowing and neural activation

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Purpose: To systematically review the literature examining the effects of neuromuscular electrical stimulation (NMES) on swallowing and neural activation. The review was conducted as part of a series examining the effects of oral motor exercises (OMEs) on speech, swallowing, and neural activation.
Method: A systematic search was conducted to identify relevant studies published in peer-reviewed journals from 1960 to 2007. All studies meeting the exclusion/inclusion criteria were appraised for quality and categorized as efficacy or exploratory research based on predetermined criteria.
Results: Out of 899 citations initially identified for the broad review of OMEs, 14 articles relating to NMES qualified for inclusion. Most of the studies (10/14) were considered exploratory research, and many had significant methodological limitations.
Conclusions: This systematic review reveals that surface NMES to the neck has been most extensively studied with promising findings, yet high-quality controlled trials are needed to provide evidence of efficacy. Surface NMES to the palate, faucial pillars, and pharynx has been explored in Phase I research, but no evidence of efficacy is currently available. Intramuscular NMES has been investigated in a single Phase I exploratory study. Additional research is needed to document the effects of such protocols on swallowing performance.

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ARTICLE

Dysphagia, experienced by up to 22% of individuals over age 55 (Howden, 2004), may lead to an increased risk of malnutrition, dehydration, and aspiration pneumonia (Marik & Kaplan, 2003; Palmer, Drennan, & Baba, 2000). Quality of life may also be affected when individuals are unable to eat foods or drink beverages they previously enjoyed, and avoid social situations due to the embarrassment of choking (Lovell, Wong, Loh, Ngo, & Wilson, 2005). Oropharyngeal dysphagia is common to a number of acquired neurogenic conditions, including stroke (Mann, Hankey, & Cameron, 2000), degenerative neuromuscular disease (Kidney, Alexander, Corr, O'Toole, & Hardiman, 2004; Volonte, Porta, & Comi, 2002), and Alzheimer's disease (Chouinard, 2000). Speech-language pathologists (SLPs) seek to alleviate dysphagia and mitigate the negative impact of dysphagia through a variety of behavioral treatments as well as environmental and diet modifications (Crary & Groher, 2003; Logemann, 1998). One specific intervention, neuromuscular electrical stimulation (NMES), has recently been received with great interest by SLPs working with adults and children with swallowing disorders.

This relatively new approach to dysphagia management involves the application of an electrical current to peripheral tissue targets. Such stimulation aims to improve function by strengthening the swallowing musculature or by stimulating the sensory pathways relevant to swallowing, or both. To facilitate strengthening, muscle contractions are elicited by stimulating the motoneuron or the muscle fibers (see Clark, 2003, for review). The contractions elicited via NMES generally recruit larger and more motor units than voluntary contractions, causing metabolic responses within the muscle tissue that ultimately lead to increased strength (Mysiw & Jackson, 1996). NMES may be applied to resting muscles or superimposed on voluntary muscle contractions. The latter strategy is thought to be most appropriate for movement retraining (Mysiw & Jackson, 1996) and has been adopted by many of the dysphagia treatment protocols incorporating NMES (e.g., Freed, Freed, Chatburn, & Christian, 2001).

NMES for muscle strengthening is most typically administered transcutaneously or intramuscularly. Transcutaneous (surface) stimulation is applied via surface electrodes. Current travels through cutaneous tissues to the motoneurons. Intramuscular (IM) stimulation is typically applied via hook wire electrodes inserted directly into a muscle, or electrodes can be permanently implanted into the muscle (Hardin et al., 2007). IM stimulation can evoke a more localized response compared with that elicited via surface stimulation (Mysiw & Jackson, 1996). Clinical applications of NMES to the swallowing musculature typically utilize surface stimulation, whereas IM NMES is generally limited to research contexts.

NMES targeting sensory pathways typically utilizes surface stimulation. Because sensory receptors are nearer the skin surface than are motoneurons or muscle fibers, the threshold for sensory stimulation is lower than for muscle contraction and thus utilizes currents of relatively low amplitude (Ludlow et al., 2007). Sensory NMES is thought to enhance swallowing function by augmenting the sensory signals contributing to the elicitation and modulation of the swallowing response.

The fairly recent use of NMES in dysphagia management has garnered a great deal of interest from SLPs. In a 2005 Knowledge-Attitudes-Practices Survey, SLPs were asked to identify a clinical topic about which they wanted a better understanding of the current evidence (Mullen, 2005).NMES was the most frequently cited clinical topic from that survey. Therefore, the aim of this project is to examine the current state of the evidence for NMES in dysphagia management.

This evidence-based systematic review (EBSR) was conducted as part of a broader review examining the impact of oral motor exercises (OMEs) on speech and swallowing impairments. For these reviews, OMEs were operationally defined as nonspeech and nonswallowing activities that involve sensory stimulation to or actions of the lips, jaw, tongue, soft palate, larynx, and respiratory muscles, which are intended to influence the physiological underpinnings of the oropharyngeal mechanism and thus improve its functions. Subsequent reviews focusing on other non-NMES oral motor activities and their impact on speech and swallowing will be reported in separate EBSRs. Five clinical questions were targeted in this review:

1. What is the effectiveness of NMES on swallowing physiology (e.g., timing, pressures, and aspiration)?

2. What is the effectiveness of NMES on pulmonary health (e.g., aspiration pneumonia)?

3. What is the effectiveness of NMES on functional swallowing outcomes (e.g., oral intake, weight gain, and quality of life)?

4. What is the effectiveness of NMES on drooling/secretion management?

5. What is the effectiveness of NMES on neural activation during swallowing?

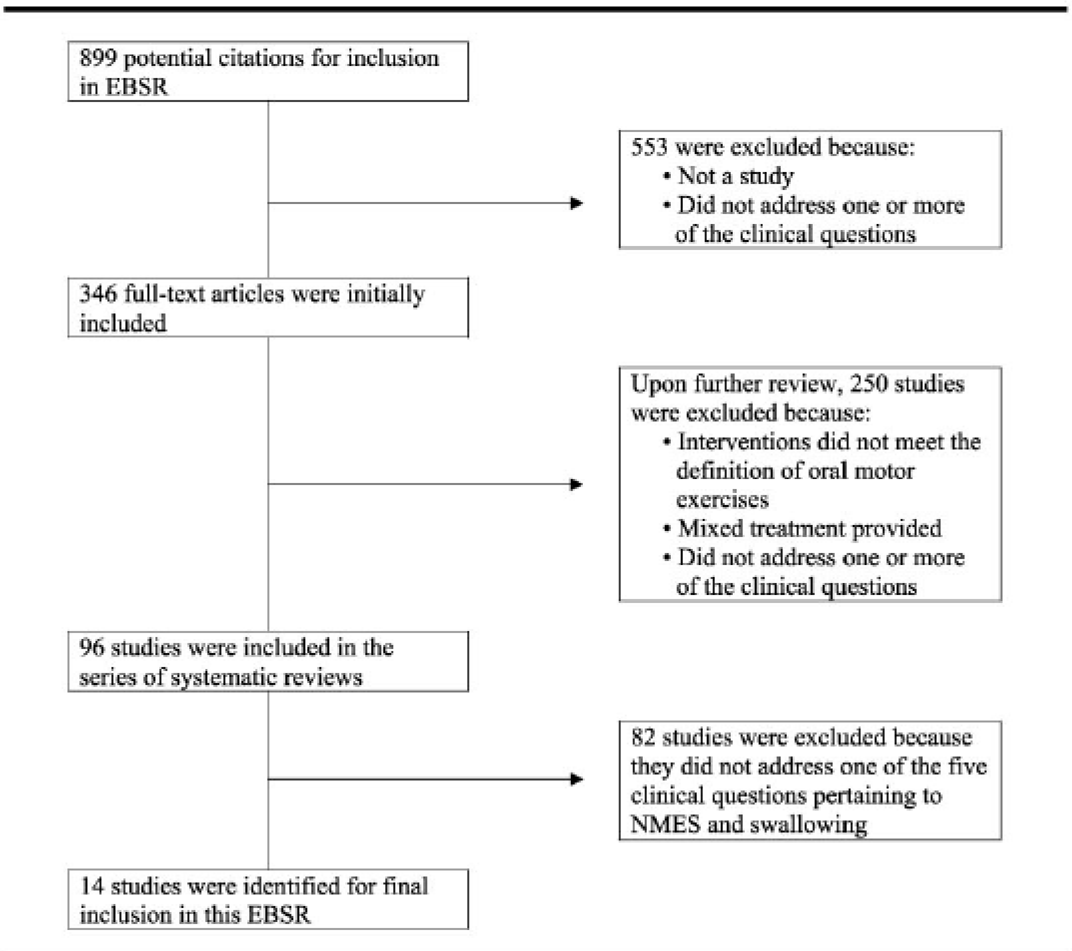
Method

Studies were initially considered for the review if they were published in a peer-reviewed journal from 1960 to 2007, were written in English, and contained original data addressing one or more of the clinical questions included in this series of EBSRs. Studies that administered NMES in the absence of volitional movement and those that superimposed NMES on volitional swallows were included in this review. Additionally, studies that targeted both surface and IM applications of NMES were considered. Studies that included surgical, medical, or pharmacological treatments were excluded.

Twenty-one electronic databases and other sources were searched using a total of 71 expanded key words related to OMEs, swallowing, and speech therapy. The full author panel generated the initial core set of key words. These key words were then expanded based on the medical subject headings from the National Library of Medicine. The following electronic databases were searched: Academic Search Premier, CINAHL, Communication & Mass Media Complete, EMBASE, ERIC, Evidence-Based Medicine Guidelines, Health Source: Nursing, High Wire Press, National Electronic Library for Health, PsycArticles, PsycINFO, PubMed, REHABDATA, Science Citation Index, ScienceDirect, Social Science Citation Index, SUMSearch, TRIP Database, and the Cochrane Database of Systematic Reviews. An electronic search of the American Speech-Language-Hearing Association (ASHA) journals and of Google Scholar as well as a manual search of references from all relevant articles were also completed.

As seen in Figure 1, a total of 899 citations were identified for inclusion in the EBSR series. Two reviewers (the fourth and fifth authors), blinded from one another's results, reviewed each abstract and initially identified 346 citations as meeting the inclusion criteria with 91% agreement. Of those preliminarily accepted, 250 were subsequently excluded because they did not directly address one or more of the larger set of clinical questions or report original data. A total of 96 studies were identified for inclusion in this series of EBSRs. Of these, 14 studies addressed one or more of the five clinical questions related to the effectiveness of NMES and were included in this EBSR report.

FIGURE 1. Process for identification of included studies.



Included studies were assessed for methodological quality based on the ASHA Levels of Evidence Scheme (Mullen, 2007). The two initial reviewers, still blinded to one another's results, assessed each study in the following areas: study design, assessor blinding, sampling/allocation, subject comparability/ description, outcomes, significance, precision, and intention-to-treat (when applicable), and determined a study quality marker score based on the number of indicators that met the highest level of quality in each area. A study received 1 point for each marker meeting the highest level of quality (see Table 1). For studies incorporating controlled trials, all eight quality indicators were relevant, leading to a maximum quality score of 8. For all other study designs, where an intention-to-treat analysis was not applicable, the highest quality score was 7. Final critical appraisals for each study were reviewed by at least one member of the evidence panel (i.e., the first three authors) who also completed the data extraction (i.e., participant demographics, intervention characteristics, etc.) for the study. Agreement between the two initial reviewers and panel reviewers was greater than 98%, and any discrepancies in ratings were resolved via consensus by the full author panel. After assessing methodological rigor, each study was characterized as either efficacy or exploratory research **(see Table 2).**

A final synthesis of the body of scientific literature was reported based on clinical question and corresponding research category (see Table 3). For efficacy studies, detailed information regarding participants, treatment characteristics, and individual scores for each quality indicator was given. For exploratory studies, a study summary and an overall quality score were reported.

Effect sizes were calculated for outcome measures from efficacy studies whenever possible. For group studies, Cohen's d was calculated from group means and standard deviations or estimated from results of analyses of variance or t tests. Magnitude of effect size was determined using Cohen's benchmarks for small, medium, and large as 0.2, 0.5, and 0.8, respectively (Cohen, 1988).

Results

Although the EBSR was not limited based on the age of the participants, all of the 14 studies that met the inclusion criteria were conducted with adult participants. Eleven examined the effects of NMES on swallowing physiology (Question 1), 7 examined functional swallowing outcomes (Question 3), and 4 examined neural activation during swallowing (Question 5). (This total exceeds 14 because several studies were found to address multiple clinical questions.) No studies were found that examined the effectiveness of NMES on pulmonary health (Question 2) or on drooling or secretion management (Question 4). Of the 14 included studies, 4 were considered efficacy research, and 10 were exploratory.

TABLE 1. Quality indicators.

Indicator	Quality marker
Study design	• **Controlled trial** • Cohort study • Retrospective case control or single-subject design • Case series • Case study
Blinding	• **Assessors blinded** • Assessors not blinded or not stated
Sampling/allocation	• **Random sample adequately described** • Random sample inadequately described • Convenience sample adequately described • Convenience sample inadequately described or hand-picked sample or not stated
Group/participant comparability	• **Groups/participants comparable at baseline on important factors (between-subjects design) or participant(s) adequately described (within-subjects design)** • Groups/participants not comparable at baseline or comparability not reported or participant(s) not adequately described
Outcomes	• **At least one primary outcome measure is valid and reliable.** • Validity is unknown but appears reasonable; measure is reliable. • Invalid and/or unreliable
Significance	• ***P* value reported or calculable** • *P* value neither reported nor calculable
Precision	• **Effect size and confidence interval reported or calculable** • Effect size or confidence interval, but not both, reported or calculable • Neither effect size nor confidence interval reported or calculable
Intention-to-treat (controlled trials only)	• **Analyzed by intention-to-treat** • Not analyzed by intention-to-treat or not stated

Note. Boldface indicates highest level of quality marker.

Clinical Question 1: What Is the Effectiveness of NMES on Swallowing Physiology?

One efficacy study and 10 exploratory studies reported data related to NMES and swallowing physiology outcomes.

Swallowing Physiology Efficacy Studies

Table 4 provides a description of the participants and interventions reported in Kiger, Brown, and Watkins (2006). This controlled trial compared the use of VitalStim therapy with a traditional swallowing treatment program in subjects with dysphagia secondary to a variety of medical conditions. Average amount of treatment varied widely between the control group and the intervention group. Individuals receiving traditional swallowing intervention showed greater improvement in the oral phase of swallowing than the VitalStim group. No significant differences in improvement were found between the two groups for the pharyngeal phase of swallowing.

TABLE 2. Stage of research definitions.

Stage of research	Definition
Efficacy	Studies incorporating an experimental or quasi-experimental design, which were conducted on a disordered population and examined the effects of NMES as a treatment and not just a condition in which swallowing skills were examined.
Exploratory	Studies that included nonexperimental designs were conducted on nondisordered populations or used NMES as a condition to examine swallowing abilities instead of as an intervention.

Table 5 displays the methodological quality ratings for Kiger et al. (2006). This study reported data in a manner in which statistical significance was calculable, but it was lacking in other areas such as blinding of the assessors to the treatment condition, random allocation of participants, comparability of groups at baseline, and analysis of data by an intention-to-treat protocol. The type of swallowing physiology outcome measure used and the data reported did not provide sufficient information to allow for the calculation of effect size.

TABLE 3. Included studies by clinical question and stage of research.

Question	Efficacy	Exploratory	Total
1. Swallowing physiology	1	10	11
2. Pulmonary health	0	0	0
3. Functional swallowing	4	3	7
4. Drooling	0	0	0
5. Neural activation	0	4	4
Total	5	17	22

TABLE 4. Participant and treatment characteristics—swallowing physiology efficacy studies (Question 1).

Citation	N	Age (years)	Gender	Medical and/or SLP diagnosis as reported in article	Intervention	Treatment schedule and amount	Outcome measure(s)	Significance	Effect size	Quality marker score
Kiger et al. (2006)	22	18–91; $M = 67.5$	12 M, 10 F	Swallowing disorder secondary to one or more of the following: CVA, pneumonia, carcinoma of tongue, respiratory failure, deconditioning, subdural hematoma or debility	Intervention group—surface NMES (VitalStim)	Intervention group—between 2 and 13 individual sessions ($M =$ 8.72 sessions)	7-point ordinal scale of swallowing severity at oral and pharyngeal phases (Level 1 = profound impairment, Level 7 = normal swallow)		NR	2/8
					Control group—intervention consisted of 1 or more of the following: OMEs, pharyngeal swallowing exercises, compensatory strategies during meals, or thermal stimulation via deep pharyngeal neuromuscular stimulation	Control group—between 1 and 6 treatment sessions ($M =$ 3.36 sessions)	Oral phase Pharyngeal phase	$p = .05$ NS		

Note. SLP = speech-language pathologist; CVA = cerebrovascular accident; NMES = neuromuscular electrical stimulation; NR = not reported or calculable; OMEs = oral motor exercises; NS = not significant.

TABLE 5. Appraisal summary of swallowing physiology efficacy studies (Question 1).

Citation	Study design	Blinding	Allocation	Subjects	Outcomes	Significance	Precision	Intention-to-treat
Kiger et al. (2006)	**Controlled trial**	Not stated	Not stated	Groups/subjects not comparable at baseline	Validity unknown, but appears reasonable; reliable	***P* value reported or calculable**	Neither effect size nor confidence interval reported or calculable	Not stated

Note. Boldface indicates highest level of quality in each category.

Swallowing Physiology Exploratory Studies

Ten exploratory studies (see Table 6) contributed data to address this clinical question and examined the effects of NMES applied to (a) the surface of the neck (five studies), (b) the faucial pillars (two studies), (c) the pharynx (one study), (d) the thyrohyoid and mylohyoid muscles (one study), and (e) the soft palate (one study). Three studies (Burnett, Mann, Stoklosa, & Ludlow, 2005; Humbert et al., 2006; Power et al., 2004) investigated the use of NMES on healthy, nondisordered participants, and the remainder targeted participants with dysphagia. Multiple swallowing physiology outcomes were addressed by these studies, including muscle activation, swallowing duration and timing, movement or displacement, and aspiration. Three studies (Burnett et al., 2005; Park, O'Neil, & Martin, 1997; Power et al., 2006) reported no effects of NMES on swallowing physiology. Significant improvement following NMES was reported in three studies (Fraser et al., 2002; Leelamanit, Limsakul, & Geater, 2002; Oh, Kim, & Paik, 2007). In three additional studies, each incorporating a number of dependent variables, one reported an equal number of significant and nonsignificant outcomes (Shaw et al., 2007), and two reported primarily nonsignificant outcomes (Ludlow et al., 2007; Power et al., 2004). Humbert et al. (2006) reported a significant decline in swallowing physiology outcomes following NMES.

Clinical Question 2: What Is the Effectiveness of NMES on Pulmonary Health?

No studies were identified to address this clinical question.

Clinical Question 3: What Is the Effectiveness of NMES on Functional Swallowing Outcomes?

Seven studies related to NMES and functional swallowing outcomes (e.g., oral feeding, weight gain, and quality of life) were identified. Four of the studies met the criteria for efficacy research, and three were considered exploratory.

Functional Swallowing Outcomes Efficacy Studies

Of the four efficacy studies identified (see Table 7), three (Blumenfeld, Hahn, Lepage, Leonard, & Belafsky, 2006; Freed et al., 2001; Kiger et al., 2006) compared the effectiveness of NMES applied to the neck with traditional swallowing treatments (e.g., diet modifications, compensatory maneuvers, and OMEs). The fourth study (Talal, Quinn, & Daniels, 1992) evaluated the use of NMES to the tongue compared with sham stimulation in adults with Sjogren's syndrome.

Table 8 indicates the methodological quality ratings for each study. Three of the four studies were controlled trials, so all eight quality markers were evaluated. Blumenfeld et al. (2006) was considered a cohort study; therefore, the eighth marker (intention-to-treat analysis) was not relevant. All of the studies reported or provided data to calculate statistical significance. However, none of the studies used valid and reliable functional swallowing outcome measures. Two studies (Blumenfeld et al., 2006; Talal et al., 1992) reported group comparability at baseline. Only one of the studies (Talal et al.) reported blinding of the assessors to the treatment condition and randomly allocated subjects to group assignments. None of the controlled trials reported using an intention-to-treat standard in data analysis.

Cohen's d values were calculable for one study. In Blumenfeld et al. (2006), NMES had a large positive effect ($d = 0.88$) on a swallowing severity rating scale compared with OMEs used in conjunction with other swallowing treatments (e.g., compensatory maneuvers and diet modifications). Three other efficacy studies provided data to answer this clinical question; however, effect sizes were not calculable. Two studies reported positive changes, and one study reported no significant differences following NMES. In Talal et al. (1992), adults with Sjogren's syndrome reported a decrease in swallowing difficulties following NMES to the tongue, and in Freed et al. (2001), a group receiving NMES performed significantly better than a group receiving thermal-tactile stimulation on a swallow function scale. Kiger et al. (2006) compared the use of NMES to OMEs plus swallowing maneuvers and compensatory strategies in patients with dysphagia and found no significant differences on measures of diet consistency and advancement or return to oral feeding.

Functional Swallowing Outcomes Exploratory Studies

Three exploratory studies addressed this clinical question and examined the use of NMES applied to the neck in adults with dysphagia (see Table 9). Two studies (Oh et al., 2007; Shaw et al., 2007) reported significant improvement in functional swallowing measures (e.g., diet intake scales and dysphagia severity scales), and one study (Leelamanit et al., 2002) did not analyze the findings statistically.

Clinical Question 4: What Is the Effectiveness of NMES on Drooling/Secretion Management?

No studies were identified to address this clinical question.

Clinical Question 5: What Is the Effectiveness of NMES on Neural Activation During Swallowing?

Neural Activation Efficacy Studies

No efficacy studies were identified to address this clinical question.

TABLE 6. Summary of swallowing physiology exploratory studies (Question 1).

Citation	*N*	Age (years)	Gender	Medical and/or SLP diagnosis as reported in article	Intervention	Treatment schedule and amount	Outcome measure(s)	Significance	Quality marker score
Burnett et al. (2005)	9	28–71; M = 43	8 M, 1 F	None	Functional intramuscular NMES thyro- and mylohyoid muscles bilaterally via stimulating hooked wire electrodes	Data collected on 3 prestimulation swallows, 9 stimulated swallows, and 1 foil swallow	EMG measurement of amplitude of mylo- and thyrohyoid muscle activation between baseline and foil	NS	2/7
							EMG measurement of duration of mylo- and thyrohyoid muscle activity between baseline and foil	NS	
Fraser et al. (2002)	16	56–93; M = 74	10 M, 6 F	Acute hemispheric stroke and dysphagia	Pharyngeal NMES at 5 Hz and 75% maximum tolerated intensity (16 ± 2 mA)	10 min of NMES	Pharyngeal transit time Swallowing response time Aspiration score	$p < .01$ $p < .01$ $p < .01$	3/8
Humbert et al. (2006)	29	20–60; M = 39.5	14 M, 15 F	None	Surface NMES (VitalStim)	Stimulation applied for 3 s during 1 swallow trial	NIH Swallowing Safety Scale (stimulated swallows judged to be less safe)	$p = .0275$	4/7
							Peak elevation of larynx and hyoid bone (significant reductions in both during stimulated swallows)	$p \leq .01$	
Leelamanit et al. (2002)	23	35–87; M = 65	11 M, 12 F	Moderate to severe dysphagia	Synchronized surface NMES applied to the neck	4 hr per day of treatment until criteria met for improved swallow (range = 2–30 days)	Laryngeal elevation (in cms) during swallowing	$p < .0001$	3/7
Ludlow et al. (2007)	11	25–78; M = 54.8	9 M, 2 F	Chronic pharyngeal dysphagia subsequent to one of the following: CVA, TBI, craniotomy, or PD	Surface NMES (VitalStim)	1–3 swallows under stimulated and nonstimulated conditions	Hyoid depression Posterior movement of hyoid Descent in laryngeal position Pen-Asp Scale Low sensory stimulation High sensory stimulation NIH Swallowing Safety Scale Low sensory stimulation High sensory stimulation	$p = .016$ NS NS NS NS $p = .025$ NS	3/7
Oh et al. (2007)	8	46–69; M = 57	4 M, 4 F	Hemispheric stroke or lesions in the brainstem or lower cranial nerves and dysphagia	Surface NMES, 70-Hz pulse frequency. Intensity adjusted to elicit a muscle contraction and increased as tolerated by subject.	1 hr per day; 5 days/week for 2 weeks	Functional Dysphagia Scale	$p = .035$	3/7
Park et al. (1997)	4	71–79; M = 74.5	3 M, 1 F	18+ months post CVA with chronic dysphagia	Surface NMES applied to the soft palate	4 swallows—2 stimulated and 2 nonstimulated	Presence or absence of pooling/penetration/aspiration	NR	2/7
							Total transit time (oral + pharyngeal transit time)	NS	

(table continues)

TABLE 6 (*continued*).

Citation	N	Age (years)	Gender	Medical and/or SLP diagnosis as reported in article	Intervention	Treatment schedule and amount	Outcome measure(s)	Significance	Quality marker score
Power et al. (2004)	10	26–55; $M = 40$	8 M, 2 F	None	Surface NMES to faucial pillars at a frequency of 5, 1, or 0.2 Hz and at an intensity of 75% of pain threshold	Stimulation applied for 10 min	Outcomes measured for 2 stimulus levels that changed corticobulbar excitability (0.2 Hz and 5 Hz) and sham stimulus at 3 different times (immediately following stimulation, 30 min poststimulation, and 60 min poststimulation)		3/7
							Oral transit time—all levels and all times	NS	
							Swallow response time		
							0.2 Hz—all times	NS	
							5 Hz immediate	$p < .05$	
							5 Hz 30 min post	$p < .01$	
							5 Hz 60 min post	$p < .05$	
							Sham	NS	
							Pharyngeal transit time—all levels and all times	NS	
							Airway closure duration—all levels and all times	NS	
							Cricopharyngeal opening time—all levels and all times	NS	
Power et al. (2006)	16	61–85; $M = 73$	12 M, 4 F	Hemispheric stroke and dysphagia	Surface NMES to base of faucial pillars at a frequency of 0.2 Hz and at an intensity of 75% of pain threshold	Stimulation applied for 10 min total, 5 min to each side	Oral transit time	NS	4/8
							Pharyngeal transit time	NS	
							Swallow response time	NS	
							Laryngeal closure duration	NS	
							Cricopharyngeal opening duration	NS	
							8-point aspiration-penetration scale	NS	
Shaw et al. (2007)	18	42–82; $M = 59.3$	12 M, 6 F	Mild to severe dysphagia secondary to one or more of the following: CVA, vagal neuropathy, progressive neurological disease, or cancer	Surface NMES (VitalStim)	1-hr sessions, 7–28 sessions	3-point scale for laryngeal elevation	NS	3/7
							4-point scale for penetration/aspiration during swallowing	$p = .04$	
							4-point scale for residue severity	$p = .003$	
							3-point scale for swallow delay	NS	

Note. EMG = electromyogram; NIH = National Institutes of Health; Pen-Asp Scale = Penetration-Aspiration Scale; TBI = traumatic brain injury; PD = Parkinson's disease.

TABLE 7. Participant and treatment characteristics—functional swallowing efficacy studies (Question 3).

Citation	*N*	Age (years)	Gender	Medical and/or SLP diagnosis as reported in article	Intervention	Treatment schedule and amount	Outcome measure(s)	Significance	Effect size	Quality marker score
Blumenfeld et al. (2006)	80	$M = 72$	NR	Dysphagia secondary to respiratory failure, stroke, sepsis, or other chronic condition	Cohort 1—surface NMES (VitalStim) Cohort 2—treatment with 1 or more of the following: therapeutic exercise, compensatory maneuvers, or diet-texture modifications	Average = 10 30-min sessions Average = 13 30-min sessions	7-point swallowing scale (adjusted difference between two cohorts)	$p = .003$ favoring Cohort 1	0.88	3/7
Freed et al. (2001)	99	49–101; $M = 76.5$	53 M, 46 F	Primary diagnosis of stroke with dysphagia	Intervention group—surface NMES (VitalStim) delivered at 80 Hz and at an intensity level set by the subject's tolerance Control group—thermal tactile stimulation	Daily 60-min sessions until criteria reached 3 20-min sessions per day	Swallow Function Scoring System (7-point swallowing scale)	$p < .0001$	NR	2/8
Kiger et al. (2006)	22	18–91; $M = 67.5$	12 M, 10 F	Swallowing disorder secondary to one or more of the following: CVA, pneumonia, carcinoma of tongue, respiratory failure, deconditioning subdural hematoma, or debility	Intervention group—surface NMES (VitalStim)	Between 2 and 13 individual sessions; $M = 8.72$	SLP recommendation of diet consistency advancement	NS	NR	2/8
					Control group—1 or more of the following: OMEs; pharyngeal swallowing exercises, compensatory strategies during meals, thermal stimulation via deep pharyngeal neuromuscular stimulation	Between 1 and 6 treatment sessions; $M = 3.36$	Return to oral feeding	NS	NR	
Talal et al. (1992)	71 or 77	20–86	Mostly female	Xerostomia due to Sjögren's syndrome	Intervention group—surface NMES to tongue Control group—sham device	Stimulation (both groups): 3 min, 3 times per day; 4 weeks	Patient questionnaire rating difficulty of swallowing	$p = .008$	NR	5/8

Note. Talal et al. (1992) inconsistently reported *N* as 71 or 77 and inconsistently reported gender as mostly female.

TABLE 8. Appraisal summary of functional swallowing efficacy studies (Question 3).

Citation	Study design	Blinding	Allocation	Subjects	Outcomes	Significance	Precision	Intention-to-treat
Blumenfeld et al. (2006)	Cohort study	Assessors not blinded	Convenience sample/ Hand-picked sample	**Groups comparable at baseline on important factors (between-subjects design)**	Validity unknown, but appears reasonable; reliable	***P* value reported or calculable**	**Effect size and confidence interval reported or calculable**	Not applicable
Freed et al. (2001)	**Controlled trial**	Not stated	Convenience sample/ Hand-picked sample	Groups/subjects not comparable at baseline	Invalid and/or unreliable	***P* value reported or calculable**	Neither effect size nor confidence interval reported or calculable	Not analyzed by intention-to-treat
Kiger et al. (2006)	**Controlled trial**	Not stated	Not stated	Groups/subjects not comparable at baseline	Validity unknown, but appears reasonable; reliable	***P* value reported or calculable**	Neither effect size nor confidence interval reported or calculable	Not stated
Talal et al. (1992)	**Controlled trial**	**Assessors blinded**	**Random sample adequately described**	**Groups comparable at baseline on important factors (between-subjects design)**	Validity unknown, but appears reasonable; reliable	***P* value reported or calculable**	Neither effect size nor confidence interval reported or calculable	Not stated

Note. Boldface indicates highest level of quality in each category.

TABLE 9. Summary of functional swallowing exploratory studies (Question 3).

Citation	N	Age (years)	Gender	Medical and/or SLP diagnosis as reported in article	Intervention	Treatment schedule and amount	Outcome measure(s)	Significance	Quality marker score
Leelamanit et al. (2002)	23	35–87; $M = 65$	11 M, 12 F	Moderate to severe dysphagia	Synchronized surface NMES to neck	4 hr per day until criteria for improved swallow met (range = 2–30 days)	Weight gain	NR	2/7
Oh et al. (2007)	8	46–69; $M = 57$	4 M, 4 F	Hemispheric stroke or lesions in the brainstem or lower cranial nerves and dysphagia	Surface NMES to neck with 70-Hz pulse frequency. Intensity adjusted to elicit a muscle contraction and increased as tolerated by subject	1 hr per day; 5 days per week for 2 weeks	Dysphagia Outcome & Severity Scale	$p = .042$	3/7
Shaw et al. (2007)	18	42–82; $M = 59.3$	12 M, 6 F	Mild to severe dysphagia secondary to one or more of the following: CVA, vagal neuropathy, progressive neurological disease, or cancer	Surface NMES (VitalStim)	1-hr sessions, 7–28 sessions	3-point diet intake scale 5-point severity of dysphagia scale	$p = .014$ $p = .005$	3/7

Neural Activation Exploratory Studies

Four exploratory studies (see Table 10) investigated neural activation during swallowing following NMES applied to the surface of the neck (Oh et al., 2007), the faucial pillars (Power et al., 2004), or the pharynx (Fraser et al., 2002, Studies 1 and 2). Two studies (Fraser et al., Study 2; Oh et al.) examined these effects in participants with dysphagia, and the other two in healthy adults. Fraser et al. (Studies 1 and 2) reported positive effects on cortical activation, cortical excitability, and topographic representation following electrical pharyngeal stimulation. Oh et al. found no significant difference in the number of active scalp points in participants who received NMES to the neck. Power et al. (2004) reported that cortically evoked pharyngeal electromyogram responses varied depending on the characteristics of the stimulation applied to the faucial pillars. Stimulation applied at 0.02 Hz increased excitability 60 min after stimulation, whereas 5-Hz stimulation decreased excitability 30 min after stimulation.

Discussion

The purpose of this EBSR was to assess the impact of NMES in dysphagia management. The specific clinical questions addressed in this review related to clinical outcomes, ranging from physiological impacts to functional impacts. An alternative framework for considering the findings is with respect to treatment method. From this framework, it is possible to synthesize the outcomes that were observed across therapeutic targets and stimulation methods.

NMES for Muscle Strengthening

Transcutaneous NMES to the Neck Musculature The majority of studies reviewed examined the effects of surface NMES applied to the neck. Four treatment studies examined the effectiveness of VitalStim, a specific treatment protocol that superimposes NMES upon volitional swallows. Three controlled trials compared VitalStim to traditional swallowing treatment. The two largest of these studies (Blumenfeld et al., 2006; Freed et al., 2001) reported an advantage of VitalStim over the traditional treatment, whereas the remaining study (Kiger et al., 2006) found no differences between treatment groups. Finally, an exploratory study (Shaw et al., 2007) that compared pre- and posttreatment outcomes for patients undergoing VitalStim treatment reported significant improvement in swallowing function in mild and moderately affected patients but not severely affected patients. Although these findings suggest some promise for the use of VitalStim in dysphagia management, it is critical to consider the quality marker scores for each of these studies. As noted in Table 8, the efficacy studies suffered from a variety of methodological flaws that limit the usefulness of the findings. For example, two studies (Freed et al.; Kiger et al.) utilized treatment groups that were dissimilar prior to treatment, thus making it impossible to interpret the significant differences in performance noted after treatment. Methodological limitations that are not reflected in the quality marker score also influence the interpretation of findings. For example, the intervention and control groups in Kiger et al.

differed not only in the type of treatment but also the number of treatment sessions (see Table 7). Additional research with stronger designs is needed to support the efficacy of VitalStim.

Two additional exploratory studies (Leelamanit et al., 2002; Oh et al., 2007) examined the effects of surface NMES using protocols other than VitalStim. In both studies, posttreatment measures of swallowing function were significantly improved over pretreatment measures. Unfortunately, because no control condition was included in these studies, it is unclear whether the changes in swallowing function were due to NMES or other factors such as spontaneous recovery or repeated swallowing.

The studies described above examined the effects of continuous treatment with surface NMES to the neck on swallowing performance. Two additional studies examined the immediate effects of VitalStim on swallowing movements. Such studies of immediate effects provide insight into potential therapeutic mechanisms driving any changes in swallowing performance but do not provide direct evidence to support the use of NMES in swallowing intervention.

IM NMES

None of the studies included in this review examined longterm effects of IM NMES. Future research utilizing this relatively invasive stimulation procedure will provide insight into whether the advantage of localized stimulation provided by IMNMES outweighs the convenience afforded by surface NMES.

NMES for Sensory Stimulation

Unlike the NMES targeting muscle strengthening, which primarily has been applied to the hyolaryngeal musculature, NMES for sensory stimulation has targeted a variety of stimulation sites. Park et al. (1997) applied NMES to the soft palate with mixed results. Power et al. (2004, 2006) applied surface NMES to the base of the faucial pillars. Although no stimulation parameters evoked significant changes in swallowing measures in patients with dysphagia (Power et al., 2006), stimulation at 5 Hz resulted in significant lengthening of swallow response time in healthy adults (Power et al., 2004). More promising findings were reported by Fraser et al. (2002) when surface NMES was applied to the pharyngeal mucosa via electrodes attached to a pharyngeal catheter. The patients in this study demonstrated improvements in several swallowing parameters after 10 min of stimulation. Ludlow et al. (2007) reported significant improvement in swallowing physiology following sensory-level NMES to the neck. The mixed findings reported across these studies suggest that some forms of sensory NMES have the potential to benefit individuals with dysphagia, but that much more research is needed to elucidate the stimulation parameters best suited to the various outcomes of interest.

TABLE 10. Summary of neural activation exploratory studies (Question 5).

Citation	N	Age (years)	Gender	Medical and/or SLP diagnosis as reported in article	Intervention	Treatment schedule and amount	Outcome measure(s)	Significance	Quality marker score
Fraser et al. (2002) Study 1	8	23–34; $M = 26$	6 M, 2 F	None	Pharyngeal NMES at 1, 5, 10, 20, or 40 Hz at 75% of maximum tolerated intensity	10 min	Functional MRI to determine cortical activation (number of activated voxels)	$p = .047$	3/7
Fraser et al. (2002) Study 2	16	56–93; $M = 74$	10 M, 6 F	Acute hemispheric stroke and dysphagia	Pharyngeal NMES. Corticobulbar projections from both hemispheres were mapped using stimulus intensity of 110% cortical threshold for undamaged hemisphere before and 1 hr afterward.	10 min	Functional MRI to map: corticobulbar excitability Topographic representation	$p < .05$ $p < .05$	3/8
Oh et al. (2007)	8	46–69; $M = 57$	4 M, 4 F	Hemispheric stroke or lesions in the brainstem or lower cranial nerves and dysphagia	Surface NMES applied to the neck with a pulse frequency of 70 Hz. Intensity was adjusted to elicit a muscle contraction and increased as tolerated by subject.	1 hr per day 5 days per week for 2 weeks	Transcranial magnetic stimulation mapping of number of active scalp points	NS	3/7
Power et al. (2004)	10	26–55; $M = 40$	8 M, 2 F	None	Surface NMES to the faucial pillars at a frequency of 5, 1, or 0.2 Hz and at an intensity of 75% of pain threshold.	10 min	Pharyngeal EMG responses to transcranial magnetic stimulation at 3 different times (immediately following stimulation, 30 min poststimulation, and 60 min poststimulation) 0.2 Hz Immediate 30 min post 60 min post—facilitating effect 1 Hz—all times 5 Hz Immediate 30 min post—inhibitory response 60 min post Sham—all times	 NS NS $p < .01$ NS NS $p < .05$ NS NS	3/7

Note. MRI = magnetic resonance imaging.

Comparing NMES to Alternative Dysphagia Treatments

The controlled trials examining the effects of surface NMES applied to the neck utilized alternative dysphagia treatments as the control condition. Freed et al. (2001) utilized a single treatment (thermal-tactile stimulation) as the comparative condition. In contrast, the participants in the Blumenfeld et al. (2006) and Kiger et al. (2006) studies who did not receive NMES received intervention consisting of thermal-tactile stimulation, strengthening, compensatory maneuvers, and/or diet modifications. The available data are inadequate to determine the contexts in which each of the various interventions applied were most beneficial.

Quality Indicators

As noted in Tables 4-10, the studies included for review typically failed to meet many of the standards of scientific rigor appropriate for treatment research. A common limitation was a lack of examiner blinding. Without blinding, potential bias is introduced as examiners are aware of the treatment condition that is being evaluated. Other potential sources of bias found in several of the reviewed studies were a lack of randomized assignment and comparison groups that were dissimilar prior to treatment. Finally, none of the efficacy studies included in this review utilized outcome measures with established validity.

Similar methodological limitations were noted by Carnaby-Mann and Crary (2007) in their meta-analysis of the benefits of surface NMES to the neck for improving swallowing function. Thus, although their meta-analysis yielded medium effect sizes, the authors cautioned that the bias inherent in the studies reviewed likely overestimated treatment effects. Future studies should be designed with these quality indicators in mind to provide data that are easily interpreted and incorporated into systematic reviews and meta-analyses.

Research Needs

One of the purposes of systematic reviews is to identify areas of need in the research base. In the current review, several areas of need became apparent. It is relevant to note that all of the studies reviewed examined the use of NMES with adult participants. Given that the use of NMES with children appears to be expanding (e.g., Ivanhoe Broadcast News, 2005), it is critical that future research address the benefits of NMES for this age group.

Another issue left unaddressed by the current literature is treatment dosage and how optimal dosage may vary across stimulation parameters (e.g., surface vs. IM, continuous vs. intermittent stimulation) and populations. A related question is at what point in the disease process or recovery NMES is most beneficial, and whether optimal timing varies across populations. Additional research is needed to address these clinical questions.

Conclusions

Consideration of the current best evidence is one of the three principles guiding EBP, along with client /patient values and clinical expertise (Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000). This systematic review of NMES for swallowing intervention reveals that surface NMES to the neck for the purpose of muscle strengthening has been most extensively studied with promising findings, yet high-quality controlled trials are needed to provide evidence of efficacy. Additional Phase IV and V research examining effectiveness and cost-effectiveness (Robey, 2004) will assist clinicians further in determining the contexts in which surface NMES to the neck might be most beneficial. Sensory NMES to the neck, palate, faucial pillars, and pharynx has been explored in Phase I research, but no evidence of efficacy is currently available. Clinical application of these interventions should be considered experimental and conducted under controlled conditions in which both positive and negative outcomes can be carefully monitored.

The assessment of evidence reported in this review should be considered current as of September 2007. Relevant publications appearing in print after the close of the review (e.g., Baijens, Speyer, Roodenburg, & Manni, 2008; Bulow, Speyer, Baijens, Woisard, & Ekberg, 2008; Carnaby-Mann & Crary, 2008; Ryu et al., 2009) were not included in the systematic review. Because evidence continues to accumulate regarding the effects of NMES on swallowing function, clinicians are encouraged to reevaluate frequently the level of evidence available regarding the various forms of NMES. Moreover, the NMES literature must be systematically reviewed on a regular basis (Shojania et al., 2007). EBSRs can be a valuable resource to clinicians seeking evidence. These reports provide a synopsis of the available evidence on a clinical topic. Taken in conjunction with clinical expertise and patient values, this information can be used to determine the best treatment course for individuals with dysphagia.

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