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Title: There is limited evidence supporting the use of NMES paired with conventional swallowing interventions to treat dysphagia for the pediatric population.

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Clinical Scenario:

Dysphagia, or difficulty swallowing, can occur as a result of a congenital or medical condition. Functional or structural deficits of the oral cavity, pharynx, larynx, esophagus, or esophageal sphincters can lead to dysphagia. These structural deficits interfere with an individual's normal swallowing processes. The act of swallowing occurs in multiple stages. Food is ingested into the mouth, where it is then transported posteriorly by the tongue to be chewed and processed. A bolus is formed, and then transported to the pharynx and later the esophagus. Peristalsis moves the bolus down to the stomach (Matsuo & Palmer, 2009). Swallowing is a complex activity composed of both volitional and reflexive movements with the assistance of at least thirty nerves and muscles (Matsuo & Palmer, 2009). The inability to perform any or all of these functions due to muscle weakness, incoordination of movements, or sensory impairments secondary to a congenital, neurological, and/or developmental condition results in difficulty swallowing, or dysphagia.

Children with pre-existing developmental and/or medical conditions are at a higher risk of developing dysphagia. These conditions include, but are not limited to behavioral and neurological conditions, respiratory failure, gastroesophageal reflux, and structural deficits such as cleft lip or cleft palate. Dysphagia can lead to failure to thrive, aspiration pneumonias, gastroesophageal reflux, and an inability to establish/maintain proper nutrition and hydration (Prasse & Kikano, 2009).

Incidence/Prevalence

According to the American Speech-Language-Hearing Association, approximately 25-45% of typically developing children display some feeding and swallowing difficulties, while 30-80% of children with developmental disorders demonstrate a dysphagia. It is important to note that pediatric dysphagia is increasing in prevalence due to the improved survival rates of premature infants (Pediatric, 2008).

Impact of the Problem on Occupational Performance

The main area of occupation affected by dysphagia is feeding and eating. Depending on the nature of the dysphagia, the individual may be experiencing structural deficits impacting the individual's ability to perform the stages of swallowing. Some children develop behaviors to avoid eating as it can become a stressful event while others may exhibit sensory preferences to certain foods. Dysphagia can lead to multiple other health problems if it persists, with the most notable being failure to thrive and poor nutrition/vitamin deficiencies. Failure to thrive and nutritional deficiencies consequently affect the child's ability to perform other areas of occupation, such as play, social participation, and education. Additionally,

cultural habits and routines may become difficult for the child to engage in due to nutritional deficiencies and/or the inability to actively participate in eating.

Intervention:

Conventional Oral Treatment Intervention:

Conventional Oral Treatment was used in addition to NMES, and was performed at the beginning of sessions. Conventional Oral Treatment included various sensory stimuli applied to both groups of the cheeks, chin, lip, tongue, and oral palate using fingers, a vibrator, and an ice stick. Conventional Oral Treatment was done for ten minutes each session. After Conventional Oral Treatment concluded, NMES was applied and used for twenty minutes with the experimental group. A sham NMES was applied to the control group for twenty minutes, as well.

Neuromuscular Stimulation Intervention:

Neuromuscular electrical stimulation, specifically VitalStim, is used as the intervention. The NMES dual-channel device was attached to surface electrodes and the two, channel 1 electrodes were placed horizontally over the throat between the jaw and the hyoid bone – over the digastric muscles. The two, channel 2 electrodes were placed horizontally between the hyoid and the thyroid notch, approximately over the infrahyoid muscles. The parameters of the NMES device were set to 80 Hz of 300 milliseconds, with 1-second intervals. This was done for a total of twenty minutes.

During the intervention, the participants were sitting in an upright position in a chair with a head rest. The therapy room was separate from the public, so participants could concentrate on therapy interventions. During NMES, the occupational therapist facilitated voluntary swallowing by having the participant swallow a thickened liquid.

This intervention was received twice weekly for eight weeks. Evaluations were conducted immediately prior to and after the experimental or control intervention.

OT Theoretical Basis

Motor learning theory supports the use of neuromuscular electrical stimulation as it focuses on re-training movements important to the functional tasks of swallowing. The use of NMES does not focus on the isolation of musculature, but on the musculature throughout the swallow as a whole (Shumway-Cook & Woollacott, 2017). Motor learning theory applies to the practice schedule used with NMES and the swallowing function. It also applies to the experience of the individual learning the mechanism of swallowing to increase and lead to the automaticity of the task, leading to lasting changes over time (Shumway-Cook & Woollacott, 2017).

The biomechanical frame of reference in occupational therapy supports the use of neuromuscular electrical stimulation to address the client factors and occupational performance areas that are impacted by dysphagia. The biomechanical frame of reference focuses on the movements required to engage in occupational performance and the basis of intervention is focused improving the movement limitations through practice and repetition (Pendelton & Schultz-Krohn, 2013). The biomechanical frame of reference is focused on addressing the basic client factors to improve occupational performance. The use of NMES is used to facilitate and improve movement of the digastric muscle group and the infrahyoid muscle group

by strengthening and lengthening the muscles, in turn hoping to enhance occupational performance in the task of swallowing. (Pendelton & Schultz-Krohn, 2013).

Science behind the intervention:

In order for muscles to contract and cause movement, an action potential needs to be sent to the muscle fibers responsible for carrying out the wanted movement (Bracciano, 2008). A signal sent from the brain (CNS) causes depolarization of a motor unit in the periphery, causing an action potential (Bracciano, 2008). When an action potential occurs, the muscle contracts (muscle fibers overlap, causing the unit to shorten, resulting in movement) (Bracciano, 2008). The nerve fibers that send the message from the CNS to periphery fire asynchronously, recruiting small motor units first, then large motor units (if the movement requires increased strength) (Bracciano, 2008). When the action potential has stopped, the muscle fibers will release from one another, allowing the muscle to relax (Bracciano, 2008).

When there are pathologies in the motor pathway, electrical stimulation can be used to cause smooth muscle to contract, or relax based on the intensity (Bracciano, 2008). Electrical stimulation devices send electricity to the nerves, starting an action potential, which will lead to muscle contraction (Humbert, Michou, MacRae, & Crujido, 2012). Typically, two electrodes (a positive and a negative) are placed on the skin overlying the targeted muscles (Humbert, Michou, MacRae, & Crujido, 2012). When the device is turned on, electricity will flow within the body between the two electrodes (Humbert, Michou, MacRae, & Crujido, 2012). The goal is to locate and stimulate the motor point with minimal electrical current (Humbert, Michou, MacRae, & Crujido, 2012). The electrical current does not have the ability to target specific muscles, or control where the current travels (Humbert, Michou, MacRae, & Crujido, 2012). This may become a problem when trying to stimulate small muscles in the neck, which are required for swallowing (Humbert, Michou, MacRae, & Crujido, 2012). Transcutaneous, or surface electrical stimulation is a non-invasive technique used to stimulate muscle movement (Humbert, Michou, MacRae, & Crujido, 2012).

The neuromuscular electrical stimulation can improve the performance and efficiency of recruiting muscles for movement (Bracciano, 2008). Electrical stimulation sends sensory information to the CNS, which can increase the patient's ability to activate specific muscle groups (Bracciano, 2008). Opposite of a voluntary muscle contraction (as mentioned above), electrical stimulation causes large motor units to be recruited before small motor units (Bracciano, 2008). This is because the large motor units are more superficial than small motor units, so the electrical stimulation easily stimulates the large motor units with less intensity (Bracciano, 2008). Because of this, the movement may not be as coordinated as voluntary movements (Bracciano, 2008). With active participation, a patient can strengthen weak muscles that are involved in swallowing (Humbert, Michou, MacRae, & Crujido, 2012).

Conventional Oral Treatment helps a child recognize the input of the bolus in their mouth, and be able to use the tongue and muscles to complete the necessary movements that are required for swallowing a bolus (Song, Park, Lee, Kim, 2015). This technique helps normalize the abnormal muscle tone in the muscles needed for feeding activities (Song, Park, Lee, Kim, 2015). Thermal, tactile, and pressure stimuli is facilitated and results in improved chewing and swallowing function in children with cerebral palsy (Song, Park, Lee, Kim, 2015).

Why is this intervention appropriate for OT?

Neuromuscular electrical stimulation (NMES) is an adjunctive modality used on the client, or while the client practices activating muscles used to swallow. Swallowing is not the whole occupation, but an important component that helps support a client's occupational performance in feeding. This is a preparatory method used to advance the success of feeding. This is performed on the client using the e-stim modality, and occasionally the client concurrently activates the muscles used to swallow while the e-stim stimulates the contractions (American Occupational Therapy Association, 2014).

Swallowing is important in maintaining sufficient hydration and nutrition, as well as a quality life. For individuals experiencing dysphagia, these purposes of swallowing are significantly compromised. The main goal and focus of VitalStim is to attempt to restore muscles to have effective swallowing by improving the swallowing contractions. The rehabilitative purposes of this technique are to allow the electrical current from the device to flow through the body and cause contractions of the swallowing muscles to effectively pass the bolus through the oral, pharyngeal, and esophageal structures for proper feeding. Dysphagia can result from a deficit either structurally or functionally with one of these stages of swallowing (Humbert, Michou, MacRae & Crujido, 2012.).

NMES is used by occupational therapists in an effort to improve swallowing function to allow clients to effectively engage in their feeding occupations.

Focused Clinical Question: In children with dysphagia, how does neuromuscular electrical stimulation (NMES) paired with conventional oral stimulation compare to only using conventional oral stimulation to improve safe swallowing?

Search Summary: A literature review was conducted using two different databases to determine the effectiveness of using NMES concurrently with conventional oral treatment to address patients with dysphagia. Several studies were found and the most rigorous three were critiqued, but only one of the three studies was specific to pediatrics. The other two studies were based on stroke patients, and the information was generalized to the pediatric population based on the strength of the studies. The pediatric-specific study (Song et al., 2015) was a 1b level of evidence as well as the Li et al., 2015 study, while the Freed et al., 2001 study was a 3b study.

Clinical Bottom Line: There's limited evidence supporting the concurrent use of NMES and conventional swallowing to treat dysphagia. Currently this treatment should be treated as an experimental intervention, and more research needs to be done. Patients receiving this intervention should be primed with the notion that this is still in its experimental stages.

Limitation of this CAT: This critically appraised paper has been reviewed by occupational therapy graduate students and the course instructor

Table 1: Search Strategy

	Study 1: Song et al., 2015	Study 2: Freed et al., 2001	Study 3: Li et al., 2015
Search Engine	Clinical Key	CINAHL	CINAHL
Key Words Used	Cerebral palsy + dysphagia	Swallowing + electrical stimulation	Swallowing + electrical stimulation

	Dysphagia + electrical stimulation Dysphagia + oral sensory stimulation Dysphagia + cerebral palsy + electrical stimulation	Stroke + dysphagia Dysphagia + electrical stimulation	Dysphagia + electrical stimulation
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Table 2: Summary of Study Designs of Articles Researched

Level	Study Design/ Methodology of Articles Retrieved	Total Number Located	Citation (Name, Year)
1a	Systematic Reviews or Meta-Analysis of Randomized Control Trials	-	
1b	Individualized Randomized Control Trials	2	<p>Song, W., Park, J., Lee, J., & Kim, M. (2015). Effects of neuromuscular electrical stimulation on swallowing functions in children with cerebral palsy: A pilot randomized controlled trial. <i>Hong Kong Journal of Occupational Therapy</i>, 8, 1-6. http://dx.doi.org/10.1016/j.hkjot.2015.05.001</p> <p>Li, L., Li, Y., Huang, R., Yin, J., Shen, Y., Shi, J. (2015). The value of adding transcutaneous neuromuscular electrical stimulation (VitalStim) to traditional therapy for post-stroke dysphagia: a randomized controlled trial. <i>European Journal of Physical and Rehabilitation Medicine</i> 51(1): 71-78</p>
2a	Systematic reviews of cohort studies	-	
2b	Individualized Cohort studies and low quality RCT'S (PEDro \leq 4)	2	<p>Leelamanit, V., Limsakul, C., & Geater, A. (2002). Synchronized Electrical Stimulation in Treating Pharyngeal Dysphagia. <i>Laryngoscope</i>, 112, 2204-2209.</p> <p>Jungheim, M., Janhsen, A.M., Miller, S., Ptok, M. (2015). Impact of Neuromental Electrical Stimulation on</p>

			Upper Esophageal Sphincter Dynamic: A High-Resolution Manometry Study. <i>Annals of Otolaryngology, Rhinology & Laryngology</i> , 124 (1), 5-12.
3a	Systematic review of case-control studies	-	
3b	Case- Control studies and non-randomized controlled trials (quasi experimental or clinical trials)	3	<p>Freed, M., Freed, L., Chatburn, R., & Christian, M. (2001). Electrical stimulation for swallowing disorders caused by stroke. <i>Respiratory Care</i> 46(5): 466-473.</p> <p>Gallas, S., Marie, J. P., Leroi, A. M., & Verin, E. (2009). Sensory Transcutaneous Electrical Stimulation Improves Post-Stroke Dysphagic Patients. <i>Springer</i>, 25, 291-297.</p> <p>Ludlow, C., Humbert, I., Saxon, K. Poletto, C., Sonies, B., Crujio, L. (2007). Effects of electrical stimulation both at rest and during swallowing in chronic pharyngeal dysphagia. <i>Dysphagia</i> 22(1): 1-10. doi: 10.1007.s00455-006-9029-4</p>
4	Case-series and poor quality cohort and case-control studies	-	
5	Expert Opinions	-	

Table 3: Studies Included

	Study 1 : Song et al., 2015	Study 2: Freed et al., 2001	Study 3: Li et al., 2015
Design	Randomized control Trial	Case-Control	Randomized Control Trial
Level of Evidence	1b	3b	1b
Rigor Score	10/14	9/14	9/14
Population	N: 20 Age: 3-9 Diagnosis of cerebral palsy and dysphagia	N:99 Age: 49-100 Post stroke with dysphagia diagnosis	N: 135 Age: 50-80 years More than 3 months post-stroke with dysphagia diagnosis

<p>Intervention Investigated</p>	<p>NMES combined with conventional oral treatment</p> <p>Dosage: 2x/week, for 8 weeks</p>	<p>NMES treatment versus conventional oral treatment</p> <p>NMES treatment: In-patient: 1 hour/day for at least five days or until discharge when scoring a 5 on swallow scale. Outpatient: 1 hour/day 3 times a week. Conventional Oral Treatment: 20 minute treatments, three times a day</p>	<p>NMES paired with conventional oral treatment.</p> <p>Dosage: 1 hour/day, 5 days/week for 4 weeks</p>
<p>Dependent Variable</p>	<p>Jaw closure, lip closure over spoon, tongue control, lip closure while swallowing, swallowing food without excess loss, chewing food, sipping liquid, swallowing liquid without excess loss, swallowing without cough, and severity of dysphagia (ASHA NOMS score).</p>	<p>Swallow function and safe liquid consistency</p>	<p>Pain, swallowing, and pharyngeal function.</p>
<p>Outcome Measures</p>	<p>Behavioural Assessment Scale of Oral Functions in Feeding (BASOFF) to measure variations of 9 (above mentioned) behaviors related to feeding.</p> <p>American Speech-Language-Hearing Association's National Outcomes Measurement System Swallowing Scale (ASHA NOMS) to determine severity of dysphagia.</p>	<p>Modified Barium Swallow- for aspiration.</p> <p>Swallow function score based upon MBS</p>	<p>Visual Analog Scale, Likert scale rating for difficulty swallowing, patients' interpretation of pain, Standardized Swallowing Assessment, Surface electromyography signals (sEMG) were collected through a Flexcomp Biomonitoring system, videofluoroscopic barium swallow, and Images were also taken.</p>
<p>Results</p>	<p>Significant difference in both groups post-test BASOFF ($p < .05$)</p>	<p>This study found that electrical stimulation resulted in higher final swallow scores than</p>	<p>This study found that using NMES and conventional oral treatment concurrently</p>

	<p>-NMES group demonstrated significantly greater improvement in all subcategories, while control group demonstrated no significant improvement in three subcategories (jaw closure, sipping liquid, and swallowing liquid without excess loss) ($p < .05$)</p> <p>Significant functional changes in NMES group, demonstrating significantly greater improvement than control group in lip closure while swallowing, swallowing food without excess loss, sipping liquid, swallowing liquid without excess loss, swallowing without cough, and total score ($p < .05$)</p> <p>No significant change between or without groups for ASHA NOMS</p>	<p>conventional oral treatment.</p> <p>Initial swallow scores for both groups were similar ($p = .74$).</p> <p>Both groups showed improvement following therapy. Conventional oral treatment: $p = .0048$ NMES: $p < .0001$</p> <p>The NMES group had higher final swallow scores than the conventional oral treatment group.</p>	<p>was the most effective approach to treating patients experiencing dysphagia.</p>
Effect Size	<p>BASSOFF: between groups post score = .3648 (small) ASHA NOMS: between groups post score = .1818 (no effect)</p>	<p>Effect size was not reported and was not calculated, as an inappropriate statistical analysis was used in this study.</p>	<p>Effect size was not reported and was not calculated as an inappropriate statistical analysis was used in this study.</p>
Conclusion	<p>This study concluded that NMES facilitated oral function related to swallowing, including lip closure while swallowing, ability to swallow food without excess liquid without excess loss, and ability to swallow without cough. NMES might be an effective therapeutic tool to facilitate conventional oral treatment for dysphagia on children with CP and dysphagia.</p>	<p>This study concluded that the use of NMES resulted in higher final swallow scores than the conventional oral treatment methods. It was concluded that NMES appeared to be a safe and effective method for treatment of dysphagia.</p>	<p>The authors of this study concluded that it is clinically beneficial to use NMES and conventional oral treatment concurrently to address patients with dysphagia.</p>

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Synthesis for Vital Stimulation for Swallowing:

PICO Question: In pediatrics with dysphagia, how does neuromuscular electrical stimulation (NMES) paired with conventional oral stimulation compare to only using conventional oral treatment to improve safe swallowing?

Variables/Outcome measures:

All three studies measured swallowing function using different measures:

Song et al., 2015 used the Behavioral Assessment Scale of Oral Functions in Feeding (BASOFF) was used to measure nine aspects of feeding: jaw closure, lip closure over spoon, tongue control, lip closure while swallowing, swallowing food without excess loss, chewing food (tongue /jaw control), sipping liquids, swallowing liquids without excessive loss, swallowing food without excessive coughing. The BASOFF was found to have a poor inter-rater reliability between .72 and .76, and poor test-retest reliability between .68 and .79. The other outcome measure used in Song, et al., 2015 was the American Speech-Language-Hearing Association National Outcomes Measurement system swallowing scales (ASHAMONS), determines the severity of dysphagia by assesses supervision and diet level on a functional scale between 1-7. Level 7 means a person can eat independently without limitation, and level 1 indicates a person does not have ability to swallow anything safely by mouth.

Freed et al., 2001 evaluated the swallowing function using the standardized Modified Barium Swallow (MBS). Patients swallowed various consistencies of food mixed with barium powder while being observed under fluoroscopy. A swallowing score of zero to six based upon the type of food that was able to be swallowed and gave a description of safe liquid consistency, the clinical implication, and the level of swallowing deficit.

Li et al., 2015 used the Visual Analog Scale (VAS) to compare differences in pain pre- and post-treatment. The patients rated the difficulty of swallowing on a 1-10 scale, with 1 being no difficulty with swallowing and 10 being unable to swallow. The researchers compared the patients' subjective interpretation of pain with the objective pharyngeal function. The Standardized Swallowing Assessment (SSA) was used to assess swallowing function. Surface electromyography signals (sEMG) were collected through a Flexcomp Biomonitoring System. Videofluoroscopy swallowing was evaluated using a standardized videofluoroscopic barium swallow. Images were also taken.

Similar findings:

The three studies reported that the best results for swallowing function were found when NMES was combined with conventional oral treatment.

Song et al., 2015 found that NMES combined with conventional oral treatment might be an effective tool for children with cerebral palsy experiencing dysphagia. NMES allowed the participants to complete the oral functions related to swallowing: lip closure while swallowing, ability to swallow without excess loss, ability to sip liquid, ability to swallow liquid without excess loss, and ability to swallow without cough. NMES combined with conventional oral treatment resulted in significant improvements in all

subtleties, while the control group of conventional oral treatment and sham-NMES only showed no significant improvements in 3 of the subcategories.

Li et al., 2015 found that of the three groups, the most effective treatment was the NMES paired with the conventional oral treatment. The other two groups (one of the NMES alone, and one with the conventional oral treatment) demonstrated improvement, but not to the degree when used concurrently. The statistics for this study were poor, and cannot be generalized for clinical practice.

Freed et al., 2001 included participants who had completed unsuccessful traditional swallowing interventions, and were included in the study to receive the NMES intervention as a last resort to restore the ability to swallow. While both the intervention group and control group showed improvements on the swallowing scale, the NMES intervention produced higher scores and demonstrated more improvement and restoration in the dysphagia of post-stroke patient.

Result Differences:

All three studies differed in outcome measures, patient population, treatment dosage, and schedule.

- Populations: Freed et al., 2001 and Li et al., 2015, compared post-stroke dysphagia, while Song et al., 2015 was specific to pediatric cerebral palsy dysphagia.
- Outcome measures: Song et al., 2015 used the Behavioural Assessment Scale of Oral Functions in Feeding (BASOFF), and American Speech-Language-Hearing Association's National Outcomes Measurement System Swallowing Scale (ASHANOMS) outcomes measures within their study. Freed et al., 2001 used Modified Barium Swallow (MBS). Li et al., 2015 used the Visual Analog Scale, Likert scale rating for difficulty swallowing, patients' interpretation of pain, Standardized Swallowing Assessment, Surface electromyography signals (sEMG) were collected through a Flexcomp Biomonitoring System, videofluoroscopy, modified barium swallow, and Images were also taken.
- Frequency of intervention: Freed et al, 2001 was different from the other two studies, in that it had an unsuccessful first treatment intervention of traditional therapy before beginning NMES. Whereas, the other two studies used conventional oral treatment and NMES concurrently.
- Duration of intervention: Song et al., 2015 had a treatment session for thirty minutes two times a week for eight weeks. Freed et al., 2001 treated patients until discharge, or until goals were met for one-hour sessions three times a week. Li et al., 2015 used one-hour sessions, five times a week for four weeks.
- Method: The control groups varied among the 3 studies. Song et al., 2015 and Li et al., 2015, were randomized control. Freed et al., 2001, allowed participants to decide which treatment group to be involved with.
- Statistical analysis: The data collected from Song et al., 2015 was used to mathematically calculate an effect size of .3648 for BASOFF, and .1818 for between groups when using the ASHA NOMS. An effect size of .3648 is considered small, and an effect size of .1818 is considered to have no effect. Neither Freed et al., 2001, or Li et al., 2015, had accurate data to include when attempting to calculate an effect size based on data the studies provided.

Boundaries:

Only one study, Song et al., 2015, investigated the use of NMES with the pediatric population. The participants included in Song et al., 2015 were children were diagnosed with cerebral palsy by a rehabilitation doctor, dysphagia confirmed by video fluoroscopy swallowing studies (VFSS), or a rehabilitation doctor. These children had no disorder in vision, hearing, or seizures, and no pacemaker. There were a total of twenty participants in this study, with an average age of 6.1 and various types of cerebral palsy including: hemiplegia, diplegia, quadriplegia, and flaccid.

Supporting studies done using NMES post-stroke conducted the assessment with two hundred thirty-four patients. Some of the inclusion criteria for the Li et al., 2015 study included: patients aged fifty to eighty with a stroke at least three months prior to the study. These patients could not have brainstem involvement, or nasogastric tubes, but could have a PEG tube. Patients needed to elicit some pharyngeal swallow, and have the ability to communicate. Patients were excluded from the study if they had progressive Cerebral Vascular Disease, other neurologic diseases, neoplastic diseases that required radiation of the neck, and patients that underwent surgery of the swallowing apparatus.

Freed et al., 2001, included patients with a primary diagnosis of stroke and a confirmation of swallowing disorder by the MBS. Exclusion criteria for this study was the inability to complete at least two consecutive days of therapy, a behavioral disorder that interfered with therapy administration, substantial reflex from a feeding tube, and dysphagia diagnosis from drug toxicity.

Implications for Practice:

The review of the evidence reported by these three studies, showed that the overall statistical analysis of effect size and sample sizes were too poor to make conclusive statements about the effectiveness of NMES paired with conventional oral treatment to improve swallow function in pediatric patients. Clinically, going forward more research, using good methodology and measurable outcomes, needs to be conducted to support the effectiveness of NMES to improve swallowing due to dysphagia with the pediatric population.

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