

# This House Belie

Christine Matthews and Paula Leslie examine the evidence around the effectiveness of transcutaneous neuromuscular electrical stimulation in treating people with dysphagia.

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## This House Believes explained

In her teaching, Paula Leslie uses a debating idea from the *British Medical Journal* to get her students to critically review a controversial subject. By understanding the strengths and weaknesses of the arguments on both sides, the students are better prepared to develop their own views. Students are strictly limited in word count and number of references to foster concise and relevant writing. Their work is now being adapted for *Speech & Language Therapy in Practice*. The debating format means:

- the Proposition is required to prove its case, while the Opposition aims to show why the Proposition is wrong
- either side can interrupt with a 'point of information' while the other side is 'speaking'
- our authors reach a conclusion based on the evidence and
- readers can continue the floor debate via the Critical Friends process – see [www.speechmag.com/About/Friends](http://www.speechmag.com/About/Friends).



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## Defining the topic

Dysphagia is an impairment in swallowing function caused by neurological insults such as stroke, traumatic brain injury or tumours, progressive diseases such as Parkinson's Disease and motor neurone disease, or trauma to the oropharyngeal tract. Providing effective treatment is crucial because dysphagia affects nutritional status and overall health (Hudson *et al.*, 2000). In 2007-8, there were almost 27,000 finished consultant inpatient cases of *primary diagnosis dysphagia (ICD-10)* in England and Wales (Hospital Episode Statistics, 2009).

The traditional treatments for dysphagia are diet modification and/or compensatory postures, manoeuvres and swallowing exercises (Robbins *et al.*, 2007).

Transcutaneous neuromuscular electrical stimulation (shortened to and known as NMES, TES or e-stim) in dysphagia therapy has recently increased in popularity. Principles from NMES of limbs are being applied to swallowing musculature in the hope that this method is an effective treatment for people with acquired and

progressive dysphagia. The largest marketed system is VitalStim - currently the only company to 'license' clinicians in the use of NMES. As with most novel treatment methods about which great claims are made, NMES is a hot topic, with polarised views on its effectiveness in print and under discussion. Our debate considers the evidence for and against the use of NMES in dysphagia treatment.

For clarification, NMES is *not*:

- surface ElectroMyoGraphy (sEMG) which measures muscle activity and can be used in patient biofeedback and education
- Electrical Muscle Stimulation (EMS) / Trophic Electrical Stimulation (TES), used to retard muscle atrophy and to improve local blood flow
- Functional Electrical Stimulation (FES) used to promote functional activities such as gait therapy
- Transcutaneous Electrical Nerve Stimulation (TENS) used to manage pain. (Wijting & Freed, 2006)

## References

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# eves in e-stim

## The Proposition case: Effective for dysphagia

The proposition case is that NMES is an effective treatment for dysphagia.

In NMES, an electrical current is used to activate key swallowing muscles during swallowing activities, resulting in increased strength of these muscles. The effect of NMES is typically studied when used in conjunction with more traditional swallowing therapies such as the effortful swallow, Mendelsohn manoeuvre, and thermal-tactile stimulation. The VitalStim website (2009) information includes:

- The use of electrical stimulation seems to contribute significantly to the improvement in swallow function (Carnaby-Mann & Crary, 2007)
- NMES in conjunction with swallowing exercise seems to be more effective than traditional treatment techniques alone (Blumenfeld *et al.*, 2006).

### POINT OF INFORMATION:

The retrospective chart review study by Blumenfeld *et al.* (2006) did not compare traditional therapy with traditional therapy *plus* NMES – only traditional therapy *or* NMES. The authors only postulate that traditional therapy *plus* NMES *might* be more effective than traditional therapy alone. They acknowledge weaknesses such as the study being retrospective, that treating clinicians were also the evaluating clinicians, and that clinicians may not have used NMES on patients with a poorer prognosis.

NMES in combination with the effortful swallow demonstrated improvement in swallow function according to patient-reported change in functional oral intake (Permsirivanich *et al.*, 2009).

### POINT OF INFORMATION:

This study relied only on patient-reported measures to measure improvement in swallow function, not more objective measures using endoscopic or videofluoroscopic data.

Hyolaryngeal elevation has been seen to increase when NMES was used in conjunction with the effortful swallow in healthy, non-dysphagic participants (Park *et al.*, 2009).

### POINT OF INFORMATION:

This study showed no statistically significant differences between the control and treatment groups, and any effects faded within two weeks of treatment.

Patients post stroke who used NMES with thermal-tactile stimulation reported more benefits than a control group who used thermal-tactile stimulation only (Lim *et al.*, 2009).

### POINT OF INFORMATION:

The patients were not blinded to which “treatment” they received and no control was made to avoid bias from patients knowing which treatment they received.

## Sensory facilitation

There is some controversy about the placement of surface electrodes for stimulating muscles deep within the pharynx which are used in swallowing. Ludlow *et al.* (2007) hypothesised that low levels of electrical stimulation might improve swallow function as a result of sensory facilitation (stimulation great enough for the participants to feel a “tingle” but not to cause muscle activation). They concluded that sensory levels of stimulation may be useful for patients who have difficulty

clearing the bolus from the pharynx, by increasing their sensitivity to its presence.

Stronger evidence for the use of electrical stimulation in treating dysphagia comes from the results of a meta-analysis that summarised findings from 7 studies. The aetiologies of dysphagia in the studies were a mix of stroke, cancer, head trauma, and respiratory failure. The results of the meta-analysis demonstrated a significant summary effect size that supports the use of NMES to treat dysphagia. Improvements in swallowing function were measured by examining changes in swallowing scores and the meta-analysis revealed an overall twenty percent change in swallowing performance following the treatment (Carnaby-Mann & Crary, 2007).

### POINT OF INFORMATION:

The meta-analysis findings should be interpreted cautiously due to the small number of studies included and their low methodological grading.

## Summing up the case for the proposition

The evidence supports the use of NMES in conjunction with traditional swallowing treatment techniques to improve swallow function. Patient reports demonstrate clear support of the technique, and we owe it to them to try all options.

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

Park, J., Oh, J., Lee, H., Park, S., Yoon, T. & Kwon, B. (2009) 'Effortful swallowing training coupled with electrical stimulation leads to an increase in hyoid elevation during swallowing', *Dysphagia*. Published online 3 March 2009 at <http://www.springerlink.com/content/r73610572875004x/>.

Permsirivanich, W., Tipchatyotin, S., Wongchai, M., Leelamanit, V., Setthawatcharawanich, S., Sathirapanya, P., Phabphal, K., Juntawises, U. & Boonmeprakob, A. (2009) 'Comparing the effects of rehabilitation swallowing therapy vs. neuromuscular electrical stimulation therapy among stroke patients with persistent pharyngeal dysphagia: a randomized controlled study', *J Med Assoc Thai*, 92(2), pp.259-265.

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## ◀ The Opposition case: Evidence is lacking

Speech and language therapists are using NMES without the publication of appropriate levels of evidence to support its use. There have been no sufficiently well designed clinical trials to date that support this method as a valid treatment for dysphagia. Indeed, there is more evidence in the literature that finds either no effect or adverse effects.

Current electrical stimulation techniques, like those in VitalStim, claim to use surface electrodes to deliver the signal to “target muscles”. These muscles for laryngeal elevation are located deep within the neck and there is little evidence to suggest that the current reaches these muscles. Surface electrical stimulation is unlikely to reach the thyrohyoid, intrinsic or extrinsic tongue muscles, velopharyngeal muscles, buccinator, pharyngeal constrictors, and intrinsic laryngeal muscles. These all play a major role in oral and / or pharyngeal swallowing function.

Movement of the hyolaryngeal complex anteriorly and superiorly protects the airway during swallowing; when this is inadequate the risk of aspiration increases. Traditional treatment for reduced hyolaryngeal elevation has involved exercises to improve the excursion of the complex. This may be combined with alterations in diet consistency, postures or swallowing manoeuvres (Humbert *et al.*, 2006). It is of concern that one effect of NMES they report is increased depression of the hyoid bone while at rest. Similarly, while one of Ludlow *et al.*'s hypotheses (2007) was that stimulation would produce motor movement, the consistent motor movement was limited to *depression* of the hyoid bone.

### POINT OF INFORMATION:

While the hyoid movement was in the opposite direction of that required for swallowing, it did not adversely affect swallow function in either study (Humbert *et al.*, 2006; Ludlow *et al.*, 2007).

Humbert *et al.* (2006) trialled several other electrode placements in the submental and laryngeal areas and found that, no matter where the electrodes were placed, stimulation resulted in decreased hyolaryngeal elevation during the swallow in healthy adults. They used the National Institutes of Health - Swallowing Safety Scale (NIH-SSS) as a measure of swallowing safety and blinded judges rated the stimulated swallowing trials as less safe. These authors suggest that surface electrical stimulation will result in reduced elevation during swallowing for people with dysphagia.

### POINT OF INFORMATION:

The NIH-SSS is not currently standardised.

## Treatment intensity

Kiger *et al.* (2006) directly compared the effectiveness of VitalStim to traditional swallowing therapy techniques for improving dysphagia in 22 subjects with various aetiologies. The subjects were assigned to the treatment (Vi-

talStim) and control (traditional approaches) groups. The traditional approaches were comprised of a variety of treatments based on findings from their baseline instrumental swallowing assessments. This aimed to ensure that the individual needs of the participants were met. The authors examined change scores in oral and pharyngeal swallowing function and diet advancement from pre and post treatment. The only statistically significant difference between the two groups was that the control group improved in the oral stage of swallowing. There was no true control group (i.e. with no intervention) so the effect of spontaneous recovery cannot be ruled out. Also, a greater proportion of the experimental group had conditions that were likely to improve.

It is important to note that participants who underwent NMES received more treatment than those in the control group. Treatment intensity may have more to do with reported improvement in studies where NMES is used rather than the method itself.

## Side effects

Treatment candidate selection is important when considering the use of NMES. While insufficient data exists regarding the efficacy in certain populations, there are some types of patients for whom NMES should *not* be used such as those with diseased motor and/or sensory nerves. NMES stimulates the axons that innervate the muscle fibres, not the muscles fibres themselves. Patients with motor neuron disease should not receive the electrical stimulation because of their existing motor neuron death (Ludlow, 2008). The same is true for patients with peripheral nerve injuries or those with Myasthenia Gravis (Ludlow, 2008).

Reported possible side effects of NMES include laryngospasm, cardiac arrhythmias, hypotension, glottic closure, and burns (Lim *et al.*, 2009).

## Summing up the opposition case

Due to the lack of quality evidence that NMES has positive effects on swallowing function, this should not be considered an effective treatment method for dysphagia. There is no evidence that the signal delivered reaches the majority of the deep neck muscles involved in swallowing. There is evidence that the muscles involved in hyolaryngeal elevation are adversely affected resulting in reduced movement. Worse than no effect, this may increase a patient's risk of aspiration, which is unacceptable.

## Judgement: The motion is defeated

We owe our patients the best standard of practice available. The best standard is a combination of what our patients tell us, what we think to be good based on our training and experience, and what the literature tells us. NMES has not been around long in the treatment of dysphagia, but there have still been ample opportunities for substantive rigorous investigations of its efficacy. So far, there is mainly anecdotal evidence declaring effectiveness with very little research to support the claims made by its proponents.

The papers cited here are the best available in our opinion. Variables that confound the true effectiveness of this method include patient selection, treatment intensity, and the pairing of traditional treatments with the method, often with poor control conditions. In our opinion, NMES has not been demonstrated in the literature to be an effective treatment method for dysphagia. Before jumping onto this bandwagon, clinicians should demand solid studies for all groups and patient specific populations that:

- control for major threats to validity
- are randomised
- are double blinded
- are funded independently of companies who market NMES systems.

Clinicians must read the evidence regarding the effectiveness of NMES and carefully consider the flaws in most of these studies. The ASHA (American Speech-Language-Hearing Association) Code of Ethics Principle IG states that:

“Individuals shall evaluate the effectiveness of services rendered and of products dispensed and shall provide services or dispense products only when benefit can reasonably be expected.”

Although the Royal College of Speech & Language Therapists does not have such a clear statement, the sentiment of evidence based practice is the same for both organisations. We must consider if spending healthcare resources on such an intervention is appropriate? And if giving patients unfounded hope is ethical?

Until there is more evidence citing the effectiveness of this method in well-controlled and well-designed studies, we propose that it would be unethical to support the use of NMES in dysphagia treatment. Clinicians should continue to use methods that they know to be effective through clinical practice, patient report, and published evidence.