

Title: Electrical stimulation approaches to the restoration and rehabilitation of swallowing: A review.

Running Title: Electrical stimulation of swallowing.

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swallowing:**

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Abstract

In recent years there has been a proliferation of interest in the use of electrical stimulation for the treatment of swallowing disorders. This review explores both the rationale and existing evidence for electrical stimulation approaches to swallowing rehabilitation. Although this is an exciting area of research which holds promise for future clinically relevant technology and/or therapy, a critical analysis of the existing literature will be presented to support the argument that implementation of electrical stimulation in clinical swallowing rehabilitation settings still remains premature.

Keywords: Electrical Stimulation, Functional Electrical Stimulation, Swallowing,
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Introduction

A *neuroprosthesis* is a device that delivers short bursts of electrical impulses to the nervous system to produce sensory and/or motor functions. Over the past four decades, neuroprostheses have been developed for a wide variety of applications¹. Some have achieved great success and are produced in large volume worldwide, such as cochlear implants for the hearing impaired²⁻⁴ and bladder management stimulators^{5,6}. Other neuroprostheses, such as those for upper limb function^{7,8} and lower limb function^{9,10}, have matured to the point that they are being successfully used in home and clinical settings. For example, the Parastep® system for paraplegic walking has been in use for over 20 years, and it has received approval from the United States Food and Drug Administration (FDA)^A as well as the U.S. Medicare and Medicaid programs^B.

Recently there has been a proliferation of interest in the use of electrical stimulation for the treatment of swallowing disorders (dysphagia). Attempts to develop electrical stimulation devices for assisted swallowing have been few, however researchers have begun building a foundation for future developments, and some devices are being marketed for clinical use.

Functional Electrical Stimulation

In nerve cells, information is coded and transmitted as a series of electrical impulses called action potentials, which represent a brief change in cell electric potential. Electrical stimulation is the process of eliciting an action potential in nerve axons through the delivery of an electrical charge to an axon. Nerve signals are frequency modulated; that is, the intensity of the transmitted signal is a function of the number of action potentials that occur in a unit of time. Where sufficient electrical current is provided to an axon, localized depolarization of the axon wall occurs resulting in an action potential that propagates towards the end of the axon (*orthodromic*

propagation). When applied to motor neurons, this can be used to generate muscle contractions. When this process is applied to elicit muscle contractions for the performance of a useful body function, it is called *functional electrical stimulation* (FES). A second way to activate muscles is to stimulate the ascending axons of sensory neurons that trigger reflex arcs or possibly contribute to cortical motor reorganization. When electrical stimulation is used in this manner, to stimulate sensory neurons and thereby alter reflexes or central nervous system functions, the process is called *neuromodulation*.

Neuroprostheses come in many different shapes and sizes and serve many different purposes. The common components in all neuroprostheses are: (1) a power source, (2) a stimulus generator, (3) a user-control interface, and (4) electrodes. Electrode placement must be carefully selected, as it will determine which nerves are stimulated and, consequently, which muscles will contract. A site on the skin where an active electrode will elicit a contraction of a certain muscle is called a *motor point*. A second electrode located nearby is necessary to complete the electrical circuit. Neuroprosthesis electrodes come in three varieties: transcutaneous (surface), percutaneous, and implanted. *Surface electrodes* contact the skin. They are non-invasive, easy to apply and generally inexpensive. However, high intensity signals (typically ranging from 10-150 mA) are required to elicit contraction of the underlying muscles, due to impedance of the skin and electrical current dispersion. Some nerves (for example, those innervating the hip flexors) may lie too deep to be stimulated by surface electrodes. *Percutaneous electrodes* consist of thin wires, which are temporarily inserted through the skin, directly into muscular tissue. The amplitude of the electrical current in percutaneous stimulation rarely needs to exceed 5 mA to induce muscle contraction, and stimulation selectivity is high, due to placement directly in the targeted muscle. The third class of electrodes is *implanted electrodes*, which are permanently

implanted through surgery. Like percutaneous electrodes, implanted electrodes have high stimulation selectivity and require only small electrical charges to elicit muscle contraction. One type of miniature implanted electrode is the BION™, which can be implanted via hypodermic needle¹¹. Once implanted, BION™ electrodes are powered and controlled via radio waves from an external controller that can be worn by the patient. The feasibility of implanting the BION™ in the lower jaw to deliver stimulation to the hypoglossal nerve was recently established in a cadaver study and an in vitro study on sheep¹².

The selection of appropriate stimulation parameters is of great importance for any neuroprosthesis, as these parameters will determine the number of nerve cells recruited and the intensity of the generated signals. FES signals typically consist of a train of pulses. In most applications, the duration of each pulse ranges from 50 to 300 μ s. The strength of an induced muscle contraction can be modulated by increasing or decreasing pulse duration, which is directly related to the number of nerve cells recruited. Altering the stimulation current can also modulate recruitment. Higher levels of current will penetrate the nerve deeper and create action potentials in greater numbers of nerve cells, resulting in more forceful contractions. A third way to modulate contractile force is to alter the stimulation frequency, i.e. the number of pulses delivered per second. In motor neurons, frequencies below 5 Hz will only generate small twitches; higher frequencies of stimulation will result in more forceful contractions, because the twitches overlap and sum up. At 50 Hz, the contraction becomes maximal or *tetanic*, and further increases in frequency will not produce greater muscle force.

Swallowing Neurophysiology

In order to consider the potential application of FES for swallowing rehabilitation, it is first necessary to understand the neurophysiology of swallowing. Swallowing is a complex sensory-motor behaviour, involving a chained sequence of contraction in more than 25 pairs of muscles in the upper aerodigestive tract. The swallowing sequence is typically divided into four stages or phases¹³: 1) the oral preparatory stage, 2) the oral propulsive stage, 3) the pharyngeal phase and 4) the esophageal phase. During the oral preparatory stage (also referred to as *Stage I transport*) the bolus is pulled into the mouth by the tongue, and solid boluses are directed laterally and positioned on the occlusal surface of the post-canine teeth for mastication. The oral propulsive stage (*Stage II transport*) involves movement of the prepared bolus from the mouth through the tonsillar pillars to the upper pharynx. To do this, the tongue moves in an anterior-superior direction towards the hard palate, and squeezes the bolus backwards along its midline groove¹⁴⁻¹⁷. When tongue control is impaired, the bolus may spill prematurely into the pharynx; pre-swallow collection of material in the pharynx is known as *pooling*. In a healthy swallow, the tongue delivers the bolus to the upper pharynx, and the pharyngeal phase of the swallow begins within 1 second¹³. The pharyngeal phase is associated with a stereotypical sequence of contraction in a *leading complex* of muscles, beginning with the mylohyoid and followed, after a delay of 30-40 ms, by the anterior digastric, internal pterygoid, genioglossus, geniohyoid, stylohyoid, styloglossus, posterior tongue, superior constrictor, palatoglossus, and palatopharyngeus muscles^{18,19}. This muscle-contraction sequence is illustrated in Figure 1. At a behavioural level, contraction of the leading complex musculature elicits first an upward, and then an anterior movement of the hyoid bone and larynx²⁰. Anterior displacement of the hyolaryngeal complex generates traction that assists with biomechanical opening of the upper

esophageal sphincter²¹. Additionally, anterior movement of the hyolaryngeal complex widens the pharyngeal lumen to facilitate epiglottic deflection and facilitates safe positioning of the laryngeal inlet, out of the direct pathway of the bolus²².

Neurophysiological control of swallowing has been attributed to a central pattern generator (CPG) located in the brainstem. Numerous neurophysiological studies in animals have demonstrated that pools of motoneurons in the motor nuclei of cranial nerves V, VII, IX, X and XII, and interneurons located in two medullary subgroups (dorsal and ventrolateral) are active during swallowing^{18,23,24}. Jean¹⁸ argues that neurons in the dorsal subgroup, located in the nucleus tractus solitarius (NTS), function as *preswallowing* or *trigger* neurons with a re-excitation loop that allows them to fire rhythmically and repeatedly until the threshold for swallow initiation is achieved. Sensory input to the NTS occurs directly via afferent fibres of cranial nerves IX and X^{18,25,26}, which arise from a dense plexus of sensory nerve fibres located on the posterior tonsillar pillars, the posterior pharyngeal wall and the outer surface of the epiglottis²⁷. Trigeminal afferents also project sensory information from the mouth to the swallowing central pattern generator via corticobulbar pathways¹⁸. The ventrolateral subgroup of swallowing CPG interneurons is found in the region of the nucleus ambiguus (NA). Jean¹⁸ proposes that this ventral subgroup distributes the swallowing drive from the NTS to the various pools of motoneurons involved in swallowing. Once initiated, the central swallowing network fires in a linear rostrocaudal sequence, corresponding somatotopically to the proximal-distal anatomy of the alimentary tract. Jean¹⁸ suggests that, upon excitation, each successive neuron in the chain adds its voice to a growing chorus of polysynaptic connections, facilitating first the inhibition and then the successive excitation of subsequent neurons in the chain. For detailed review of neurophysiology of swallowing please consult Jean¹⁸.

Dysphagia

Dysphagia is a frequent outcome of a variety of neurologic disorders, such as stroke²⁸ and is also common in the head and neck cancer population²⁹. Dysphagia contributes significantly to mortality and morbidity³⁰. Among the most commonly reported abnormalities of swallowing physiology in dysphagia are delayed initiation of the pharyngeal swallow³¹⁻³³ and reduced strength of the swallow, characterized by reduced excursion of the hyolaryngeal complex and resultant residues in the pharynx^{21,34-38}. Penetration (passage of the bolus into the entrance to the airway, just above the vocal cords) and aspiration (passage of the bolus into the airway below the vocal cords)³⁹ is a risk associated with both of these abnormalities. Clinical interventions for the delayed pharyngeal swallow have traditionally involved a sensory stimulation paradigm, tapping the tonsillar pillars with a chilled instrument in an effort to prime afferent pathways to the swallowing central pattern generator so that subsequent swallows are initiated in a timelier manner. However, research has failed to demonstrate more than transient effects with this technique⁴⁰⁻⁴⁶. Interventions for weak pharyngeal swallows typically involve performing swallows of increased effort⁴⁷. In considering these clinical approaches to swallowing rehabilitation, it seems reasonable to propose that neuroprostheses could be utilized both for priming afferent pathways for swallowing and to enhance the contractile force of muscles responsible for pharyngeal swallow strength and hyoid excursion.

Research on Electrical Stimulation of Swallowing

Intra-oral and intra-pharyngeal electrical stimulation.

Neuromodulation for delayed swallow initiation has been attempted via intra-oral administration of electrical current. Reported studies of this method have used specially designed palatal

prostheses that deliver the electrical stimulation bilaterally to the faucial (tonsillar) pillars⁴⁸, or an electrode assembly mounted on a gloved finger that delivers unilateral stimulation⁴⁹. Stimulation to the faucial pillars targets the glossopharyngeal afferent pathways known to communicate afferent information directly to the swallowing central pattern generator^{18,25}. Park et al.⁴⁸ delivered a continuous train of electrical pulses bilaterally to this area at 1 Hz (a very low frequency), with a pulse duration of 200 μ s and electrical current intensity ranging from 0.5 to 39.5 mA, depending on the user's tolerance. This stimulation was well tolerated by the four participants, all of whom had dysphagia secondary to stroke. The authors reported positive results in the form of shorter overall transit times, and reduced pooling, penetration and aspiration immediately post stimulation. More recently, Power et al.⁴⁹ compared responses to 10 minutes of unilateral faucial pillar stimulation at 0.2, 1 and 5 Hz (0.2 ms pulse duration, 280V) to sham stimulation in 10 healthy male volunteers, and measured the effect on cortical excitability using transcranial magnetic stimulation and on swallow initiation patterns using videofluoroscopy. Stimulation at 0.2 Hz was observed to have an excitatory effect in the cortex, but did not alter latencies to swallow initiation. By contrast, stimulation at 5 Hz showed a dramatic inhibitory effect on cortical excitability, and led to prolonged latencies to swallow initiation. These data suggest, therefore, that twitch-like stimulation of the tonsillar pillars may influence the neural pathways involved in swallowing initiation, but that the effect has potential to be either beneficial or detrimental, depending on the stimulation frequencies used.

Electrical stimulation has also been applied directly to the pharyngeal mucosa using a pair of bipolar ring electrodes housed in an intraluminal catheter⁵⁰. Although this type of catheter hangs within the airspace of the pharyngeal cavity, it comes into contact with both the base of tongue and posterior pharyngeal wall when those structures generate pharyngeal constriction.

Using this approach, Fraser et al.⁵⁰ investigated the effects of varying stimulation frequency, intensity and duration. Frequencies of 1, 5, 10, 20 and 40 Hz were used at a pulse duration of 0.2 ms, 280V; stimulation intensities of 25, 50 and 75% of maximum tolerance were used; and stimulation duration was tested up to 150 minutes. Two of the 8 healthy subjects experienced occasional twitch contractions during stimulation. The researchers used functional MRI and Transcranial Magnetic Stimulation to measure neuromodulation of the pharynx, and concluded that the applied stimulation resulted in reorganization of cortical projections to the swallowing muscles. They also showed that the pharyngeal excitability depends on the stimulation parameters. Of particular importance was the finding that stimulation at 10, 20 and 40 Hz resulted in inhibition of pharyngeal excitability and longer delays in pharyngeal swallow initiation on videofluoroscopy⁵⁰. These data again suggest that certain frequencies of electrical stimulation may actually be detrimental to facilitation of the swallowing process. Application of a 5 Hz stimulus at 75% of maximum tolerance for a period of 10 minutes was reported to be most effective in increasing the amplitude of evoked pharyngeal swallowing EMG⁵⁰ and was correlated with radiographic evidence of functional improvements in swallowing, both in the form of reduced swallowing latency times and reduced aspiration. Interestingly, Fraser et al.⁵⁰ also demonstrated that the pharyngeal excitability following intraluminal electrical stimulation continued to grow for at least 90 minutes following the end of stimulation, whereas a subsequent study has shown that this effect is not seen after volitional swallowing⁵¹. These results suggest that there is potential for neuromodulation in the pharynx to stimulate cortical motor reorganization. How this can be harnessed to bring about recovery of swallowing function is not known. Further careful study is needed to determine dose-response effects, response durations,

and which frequencies of stimulation involve risk of harm in the form of further delayed swallow elicitation. This technique should be considered experimental for the time being.

Transcutaneous Electrical Stimulation of Swallowing

Some preliminary studies of transcutaneous FES of swallowing have also been carried out, but the results are suggestive at best^{52,53}. One of the major challenges in designing a neuromuscular stimulation device for swallowing is selecting which muscles to target in the swallowing sequence, and in designing a device that might trigger a chain of successive muscle excitations and inhibitions similar to that seen in the leading complex¹⁸. To date, research has used primitive forms of electrical stimulation, and has failed to target specific muscle actions that contribute to the dynamic process of swallowing.

One of the most debated electrical stimulation devices for swallowing rehabilitation is the device developed by Freed et al.⁵⁴, a 2-channel neuroprosthesis marketed under the name VitalStim™. Although this device has received approval from the Food and Drug Administration and anecdotal success has been reported in the nursing literature⁵⁵, a substantial number of experimental design concerns raise doubts as to the validity of reported treatment benefits. These concerns include the lack of a clearly articulated physiological rationale guiding the site of stimulation, subject eligibility criteria and similarity, failure to control for spontaneous recovery, randomization, validity of the measure used to determine outcome, and experimenter bias. Freed et al.⁵⁴ applied electrical stimulation through a pair of surface electrodes located on the neck. The electrodes were placed in one of two configurations: one electrode above the lesser horns of the hyoid bone and the other roughly 4 cm below it; or both electrodes above the lesser hyoid bones bilaterally. These locations were reportedly chosen with the intent of stimulating the anterior

belly of the digastric and the thyrohyoid muscle. Electrical pulses were delivered continuously at 80 Hz with a duration of 300 μ s, and intensity ranging from 2.5 to 25 mA, depending on the subject's tolerance. The neuroprosthesis was applied as an intervention for 60 minutes per day, and outcomes were compared to those for patients receiving thermal-tactile stimulation⁴². While the authors reported overwhelming success, their methodology raises serious concerns. The treatment groups were not randomized, and there was no attempt to ensure similarity of subjects in the various treatment arms, either at the outset or during conduction of the study⁵⁶. Some subjects were reportedly enrolled in the study within 24 hours of their initial swallowing evaluation in the acute care hospital. Others had dysphagia of long-standing and participated in treatment on an outpatient basis. Treatment assignment decisions were made prior to conducting the videofluoroscopic assessment that confirmed eligibility of the subject to participate in the study (i.e., presence of dysphagia). Furthermore, subjects with longstanding dysphagia (who had failed to recover with previous courses of traditional treatment) were all assigned to the electrical stimulation treatment arm on compassionate grounds. The authors fail to acknowledge the possibility that spontaneous recovery may have contributed to positive outcomes in some subjects, or that patient complexity might have contributed to less favourable outcomes in others. Given other literature on the limited and transient effects of thermal-tactile stimulation⁴³⁻⁴⁶ the fact that the control group was reported to show measurable signs of improvement on videofluoroscopy suggests that other factors may have confounded the study results. The duration of treatment was not equal in the different groups, and was acknowledged to be "much longer" for those participants receiving electrical stimulation. Outcomes on videofluoroscopy were scored by a clinician who was not blind either to treatment assignment, nor the timing (pre vs. post-treatment) of the studies she was evaluating. And, most seriously, the original article

failed to report that subjects in the electrical stimulation group also underwent esophageal dilatation as part of their treatment, although this has been verbally disclosed in subsequent oral presentations and is discussed on the VitalStim™ website⁵⁷.

More recently, Ludlow et al.⁵⁸ reported results of a controlled study replicating the infrahyoid electrode placement used by Freed et al.⁵⁶. Of particular concern is the finding of Ludlow et al.⁵⁸ that this electrode placement resulted in a reduction of anterior-superior hyolaryngeal excursion during the swallow, presumably due to the fact that the stimulation reached muscles responsible for aiding descent rather than elevation of the hyolaryngeal complex.

A second example of transcutaneous FES for swallowing rehabilitation can be found in an article by Leelamanit et al.⁵⁹. These authors introduced the first event-related neuroprosthesis for assisted swallowing, linking the delivery of the electrical stimulus to the onset of floor-of-mouth muscle activity for swallowing, measured using surface electrodes placed submentally. Two stimulation electrodes were placed in an infrahyoid location, reportedly intended to stimulate the thyrohyoid muscle; the authors do not explore the difficulty of specifically targeting this muscle without also influencing neighbouring muscles. These electrodes on the neck delivered FES at 60 Hz with the aim of eliciting laryngeal elevation. The stimulus intensity was controlled by voltage instead of current (an outdated stimulation method). The pulse duration was not reported. Twenty of the 23 patients who used the device for 4 hours per day were reported to improve in their swallowing. Unfortunately, some weaknesses in the design of this study (i.e. selective recruitment and subjective outcome measure) do not allow a strong conclusion to be drawn. The pre-treatment duration of dysphagic symptoms was not controlled, ranging from 3 to 12 months. Etiologies were mixed and included aging as the primary diagnosis

in 10 of the 23 subjects. All subjects underwent videofluoroscopic swallowing evaluation (VFSS) at baseline and following treatment; ratings were performed by the first author, and no intra-rater reliability data were reported. Unfortunately, the rater was not blinded to the time-point of each VFSS during rating. Participants were grouped based on the severity of their swallowing difficulty, however, little information was provided regarding the criteria by which severity was judged. Specifically, Leelamanit et al.⁵⁹ failed to report specific data regarding change in the physiological feature of interest (i.e., the extent of laryngeal elevation or upper esophageal sphincter opening achieved by their subjects).

Intramuscular Electrical Stimulation of Swallowing

Electrical stimulation of the nerves and muscles related to swallowing using percutaneous electrodes is a method frequently used in neurophysiological experiments^{60,61,62}. However, studies on the use of intramuscular electrical stimulation for the restoration of swallowing are very few. Burnett et al.⁶³ are in the process of developing an implanted FES system to help people with chronically delayed or deficient laryngeal elevation. They first conducted a series of experiments using percutaneous electrodes to compare different muscle recruitment strategies for augmenting laryngeal elevation⁶³. Bipolar hooked-wire electrodes were inserted directly into the geniohyoid, right and left mylohyoid, and right and left thyrohyoid. Biphasic 200 μ s pulses were delivered for 1–2 s at 30 Hz and 0.5–6.0 mA. These experiments were conducted with able bodied individuals with an intact neuromuscular swallowing system. It was concluded that stimulating the mylohyoid and the thyrohyoid each bilaterally (or both ipsilaterally) increased the laryngeal elevation and the swallow velocity compared to stimulation of any muscle by itself⁶⁴. This group reported that bilateral stimulation of the mylohyoid and/or thyrohyoid produced

approximately 50% of the laryngeal elevation with about 80% of the velocity that normally occurs during a swallow⁶⁴. It was also suggested that the geniohyoid muscle, rather than the thyrohyoid, contributes most significantly to anterior displacement of the hyoid⁶³. Clearly, specificity is required in selecting the appropriate musculature to stimulate, in order to elicit the desired physiological effect.

The timing of stimulation is also very important. Synchronizing volitional action with involuntary stimulation is a persistent challenge in the development of FES systems. Burnett et al. recently assessed the efficacy of self-triggering FES for swallowing⁶⁵. They used the same percutaneous system as described above and allowed the subjects to trigger the stimulation with a pushbutton. Nine healthy adults were able to synchronize the FES with the onset of swallow-related thyrohyoid activity in a very short period of time⁶⁵. To assess the efficacy of the neuroprosthesis, the researchers disabled the pushbutton during the experiments without telling the subjects. This, however, resulted in no change in the muscle activation patterns⁶⁵. It remains to be demonstrated what effect this approach might have in people with dysphagia. Finally, there may be a potential role for fully implanted intramuscular stimulators, such as the BION¹², in treating chronic dysphagia.

Conclusions

The first modern FES devices were developed over 40 years ago. Since then, there has been a great deal of innovation resulting in neuroprostheses for many different applications, the most successful of which are cochlear implants and bladder management stimulators. Neuroprostheses for restoring swallowing function in patients with chronic dysphagia are a relatively new technology that is currently generating a great deal of interest in the rehabilitation community. A scientific foundation for these applications is just beginning to form.

Thus far, three general approaches to FES-assisted swallowing have been applied. The first approach involves stimulation of the oropharyngeal cavity with constant, low-level stimulation to modulate the swallow reflex. This approach has had some success, and it appears that there is a potential role for neuromodulation in improving swallowing function based on the evidence of cortical motor reorganization. The second approach involves transcutaneous stimulation of the neck muscles. The main challenge for this approach is limited muscle specificity. One device that uses transcutaneous FES for swallowing has been commercialized, but the evidence for its efficacy is debated. It is also unclear if their application operates on direct muscle stimulation or the principle of neuromodulation. In the case that the device operates on direct muscle stimulation principles, it is not clear if the reported effects of the prescribed application of performing swallowing exercises during the continuous and intensive stimulation it applies should be attributed to a resistance training effect¹. The third approach involves direct intramuscular FES of the muscles involved in swallowing. One group has made significant progress in determining optimal muscle recruitment and a method of synchronizing FES with volitional swallowing, however their studies to date involve only unimpaired subjects.

The body of knowledge in FES-assisted swallowing is growing steadily, but is still very small. We are of the opinion that FES-assisted swallowing is an exciting research topic that could potentially lead to clinically relevant discoveries. However, in light of how little is known, it certainly seems premature to consider applying FES to those with swallowing disorders except in the context of carefully controlled research studies. Indeed, the data reported by Fraser et al.⁵⁰ and Power⁴⁹ suggest that potential harm issues must be carefully considered, and closely scrutinized in future FES experiments. We propose that electrical stimulation of the oropharyngeal swallowing process should not be adopted in clinical settings until proper evidence based results demonstrate its efficacy.

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Figure Captions

Figure 1: Muscle contraction sequence during normal swallowing, adopted from Jean [18].