Development of a Swallowing Electrical Stimulation System for Treatment of Dysphagia in Stroke Patients

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Abstract

A swallowing electrical stimulation system (SESS) with four-channel electrotherapy modules was designed specifically for the treatment of swallowing disorders. The present study provides clinical experimental evidence that swallowing function can be restored by strengthening the masseter and digastric muscles with SESS. Eleven stroke patients (9 males, 2 females) were included in the study. Subjects were compared with themselves before and after SESS intervention. Electrical stimulation was applied to the skin above the masseter and digastric muscles in all subjects. Training consisted of 12 sessions of swallowing training, during which the intensity of the muscles of both the sound and affected side was displayed on the SESS screen. The myoelectrical activity of the muscles was recorded before and after the SESS intervention. The results indicated that 8 of the 11 subjects showed significant gains in myoelectrical activity of the muscles following SESS. Improvements in swallowing function were characterized by changes in electromyographic activity relative to the baseline recording and total time spent in each swallowing activity. These observations show the beneficial effects of SESS on the masseter and digastric muscles with the goal of improving swallowing function. The subjects showed increased electromyographic activity and a reduction in total time spent in each swallowing activity. These results indicate that restoring swallowing function by strengthening muscles via SESS facilitates improvement in the treatment of dysphagia.

Keywords: Electrical stimulation, Swallowing disorder, Digastric muscles, Dysphagia

1. Introduction

A transcutaneous peripheral electrical nerve stimulator is a device that delivers short bursts of electrical impulses to the nervous system to produce sensory and/or motor function. Electrical nerve stimulation of paralyzed muscles can be used to generate muscle contractions. Over the past four decades, the neuromuscular electrical stimulation (NMES) technique has been widely used in physical therapy to treat chronic hemiplegia and has been shown to improve motor function, such as walking [1,2], cycling [3,4], reaching, grasping [5,6], and even swallowing [7,8]. Recently, there has been increased interest in the use of NMES devices for the treatment of swallowing disorders (dysphagia) [9,10].

Oral, pharyngeal, and esophageal swallowing are sequential events that transport saliva, ingested solids, and fluid from the mouth to the stomach, and protect the airways during swallowing [11,12]. Pharyngeal function involves numerous interacting control mechanisms that ultimately link pharyngeal contraction patterns to the adjacent oral cavity and esophagus. From a functional viewpoint, the pharynx can be divided into two parts, namely muscles and nerves. The contraction of swallowing muscles occurs as a result of depolarization after acetylcholine release at the endplates. However, muscle contraction can also occur after direct electrical stimulation. NMES is used to re-educate patients to use the pharyngeal muscles in the throat for patterned activity to initiate swallowing. Spontaneous improvement in swallowing may occur in certain acute diseases that cause mild dysphagia [13]. However, in the USA only 2% of patients with neurological disorders and percutaneous enterostomal gastric tubes returned to full oral feeding after 1 year, suggesting that spontaneous improvement is rare in cases of severe dysphagia [14]. Electrical
stimulation appears to be safe and effective in post-stroke dysphagia patients [15] and is as effective as physical therapy [10]. This technique is widely used in North America, and appears to give satisfactory training effect results when used for restoring associated with swallowing function [16].

In this paper, a swallowing electrical stimulation system (SESS) with four-channel swallowing electrotherapy modules was designed specifically for the treatment of post-stroke dysphagia. The present study was based on the concept of neuromodulation, induced by peripheral electrical stimulation, and was performed to show that SESS could be used in clinical swallowing rehabilitation and could improve oropharyngeal dysphagia in chronic stroke patients.

2. Materials and methods

2.1 Patients

Eleven patients (2 female, 9 male, 50±18 years old) with stable chronic dysphagia and adapted feeding were recruited for the study. They exhibited moderate-to-severe dysphagia and had not responded to medical treatment for more than 2 months before being recruited for the study. The duration of dysphagia in these patients ranged from 6 to 48 months before the study. They did not suffer from other muscular disorders and had no contraindications to undergoing submental electrical stimulation. Oral intake function was assessed using the Functional Oral Intake Scale (FOIS) [17]. The procedures were approved by the local ethics committee. The subjects understood the aims of the study and volunteered to participate.

2.2 Swallowing electrical stimulation system

The SESS is a four-channel swallowing electrotherapy system designed for neuromuscular rehabilitation. It consists of a power source, a stimulus generator, a user interface, and (4) electrodes. Electrical stimulation mimics the temporal sequence of swallowing events during oropharyngeal swallowing, especially in cases requiring the activation of muscles paralyzed after a stroke. Four sets of electrodes were placed on the left and right mandibular rami and subhyoid area, targeting the masseter on the left (channel 1) and right (channel 2) and digastric muscles on the left (channel 3) and right (channel 4) (Fig. 1). The stimulation potential was transmitted through a pair of square silicone rubber electrodes (5 cm × 4 cm) placed on the skin overlying both sides of the masseter and digastic muscles. The stimulation voltage was delivered as an asymmetric biphasic pulse at a frequency of 60 Hz. The amplitude of the stimulus could be adjusted from 0 to 80 mA, but was usually set at 20 mA.

2.3 Swallowing evaluations

Patients with suspected dysphagia can benefit greatly from preliminary screening to confirm the diagnosis before being referred for more extensive clinical and instrumental evaluations by a specialist. At present, the videofluorographic swallow study (VFSS) is the most commonly used tool in the assessment of oropharyngeal dysphagia, and is generally considered the gold standard in dysphagia workup. Unfortunately, VFSS has several drawbacks, including the patient needing to be transported to the radiology suite, and exposure to radiation. In addition, VFSS does not always identify neuromuscular abnormalities in pharyngeal or laryngeal physiology. A reliable, non-invasive, time-saving, and inexpensive procedure that can be easily learned and applied by primary health clinicians and nurses would be a valuable addition to the diagnostic armamentarium.

Given that the swallowing mechanism by which food is transmitted to the stomach is a complex action involving 26 muscles and 5 cranial nerves, electromyography (EMG) appears especially suited for the screening and early diagnosis of dysphagia and odynophagia. Surface EMG (sEMG) can provide information on the timing of selected muscle contraction patterns during swallowing [18-20] and the amplitude of the electrical activity of the muscles [21], and has been shown to be readily learned by medical personnel [22,23]. EMG has already been proposed for the screening of neurogenic dysphagia [24].

In this study, the sEMG signal was obtained using a Zebris DAB-Bluetooth EMG Measurement System (Zebris Medical GmbH, Isny, Germany). Round adhesive pads (3 mm in diameter) with three Ag/AgCl electrode contacts with press-stud connectors were placed on the masseter and anterior bellies of the digastic muscles, with the reference electrode on the clavicle. The peak amplitude and area of the sEMG signal were measured three times during the forceful swallowing of 2, 5, 10, and 150 mL of water (at a measurement rate of 1000 Hz and a resolution of up to 12 bits). To facilitate consistent electrode placement for the three recordings, the points of stimulation on the masseter and digastic areas were marked. Four sets of Meditrace 100 adhesive electrodes (No. 3111873; Tyco Healthcare Group, Kendall, CA) were used. The top sets were placed horizontally in the left (channel 1) and right (channel 2) zygomatic arch regions, over the region of the masseter muscle, above the lateral surface of the ramus of the mandible.
mandible. The bottom sets were placed on the left (channel 3) and right (channel 4) skin horizontally in the submental region, over the region of the digastric muscle, above the hyoid bone (Fig. 2).

The EMG signals of the masseter and digastic muscle were targeted because they are known to be responsible for hyoid movement associated with swallowing [25-29]. Each patient initially attended two pre-treatment accommodation sessions to allow familiarization with the equipment and procedures to be used and to establish the baseline amplitudes for electrical stimulation. Accommodation sessions also served to minimize any anticipatory bias that may occur on commencing a new therapeutic activity. All subsequent treatment sessions were conducted within 1 h and followed a standard protocol. After the four pairs of EMG electrodes were attached, subjects were instructed to perform a total of 15 swallows with 2, 5, and 10 mL of water and a swallow with 150 mL of water. A simple swallowing technique (with verbal cues) that required the patient to place the water in the mouth, close the mouth, breathe through the nose, and then swallow hard and fast with a single attempt was used. The subject was then instructed to keep the mouth closed and, if needed, inhale gently via the nose and clear the throat. This sequence was repeated until the water (2, 5, 10, and 150 mL) was swallowed or until the subject coughed.

**Figure 2.** Example of electrodes placed on the skin overlying the masseter and digastic muscles, two pairs on each side, and one placed at the clavicle as a ground (reference).

EMG data were used to confirm the presence of dysphagia, identify the volume of starting liquid to be used in the evaluation, and to document specific clinical indicators of airway compromise for each subject (e.g., cough, throat clearing, eye watering). In addition, the EMG activity of the swallowing study was used in the evaluation of biokinematic changes after intervention.

### 2.4 Electrical stimulation treatment protocols

Treatment began within 24 h of the initial evaluation in all cases. Patients were treated three times per week for 32 min per treatment. If a patient became fatigued, treatment was continued later in the day as often as was required to obtain the full 32 min. Treatment was continued for 12 sessions in total.

Electrical stimulation was administered by a physical therapist in conjunction with a speech therapist using the SESS. Four sets of electrodes were placed in the left and right mandibular ramus and suprahoid areas, targeting the masseter and digastic muscles, and were repositioned until muscle fasciculations occurred or the strongest contraction was observed during the swallow response. With the SESS employed, the patient was required to close the mouth by stimulating the massater muscle (channels 1 and 2) simultaneously and breathe through the nose, and then swallow hard by activating the digastic muscle (channels 3 and 4) simultaneously with a single attempt (Fig. 3). The patient was then instructed to keep the mouth closed and, if needed, inhale gently via the nose and clear the throat. This sequence was repeated until the water was swallowed or until the patient expectorated. The frequency and pulse width were fixed at 60 Hz and 230 μs, respectively. The current intensity was set according to the patient’s tolerance and comfort level. Most patients first experienced a very slight “tugging” sensation at around 7 or 8 mA. As the intensity was increased (in 2-mA increments, starting at 2.0 mA, up to a maximum of 30 mA), the patient perceived a strong vibration or a sensation that the electrodes were coming loose from the cheek. Most individuals accommodated rapidly enough to the sensations that the intensity could be increased continuously until contractions were consistently visible (designated as the therapy current level). When electrical stimulation was successful in obtaining a voluntary swallow response, the patient was asked to attempt a swallow with a specific oral consistency. Electrical stimulation was delivered at the therapy current level for a total of 32 min per treatment in continuous mode with a 1.6-s pause between each minute (Fig. 3).

**Figure 3.** “on” and “off” stimulation cycle of SESS.

All patients were monitored continuously by electrocardiography and pulse oximetry. A pulse-oximeter-measured blood oxygen saturation (SpO₂) decrease of more than 2% was considered desaturation due to aspiration.

### 2.5 Data analysis

The swallowing times for liquids with and without self-triggering were compared. The EMG data for the masseter and digastic muscles were compared only for those subjects who swallowed the same amount of water at both the pre-treatment and post-treatment examinations after completion of all 12 treatment sessions. In total, 12 measurements were made for each swallow and variables pertaining to EMG signals (root mean square (RMS) of the EMG signals), divided into three categories: RMS of EMG activity at each electrode...
location during the swallow, duration (offset time minus onset time) of EMG activity at each electrode location, and improvement ratio (IR). After the end of the treatment periods, the pre- and post-treatment total scores were evaluated for the EMG of each channel. The difference between pre- and post-treatment total scores was defined as the improvement ratio. The treatment outcome was classified as successful, unsuccessful, and moderate improvement when the improvement ratios were 100%, > 50, and 50-90%, respectively. The improvement ratio in EMG activity at each electrode location during a swallow was calculated using the following equation:

$$IR = \frac{\text{pre-treatment total score - post-treatment total score}}{\text{pre-treatment total score}} \times 100\%$$

Results are expressed as means ± standard errors (SE). Differences were assessed using the Wilcoxon paired test. Differences were considered significant when the probability (P) of a type I error was 0.05 or less. SPSS software (ver. 11.0; SPSS Inc., Chicago, IL) was used for all statistical analyses.

3. Results

The characteristics of the patients are presented in Table 1. Of the eleven post-stroke patients, nine had ischemic strokes and two had had hemorrhagic strokes. All patients had moderate oropharyngeal dysphagia (FOIS score above level 4).

Table 1. Characteristics and anthropometric data of the 11 patients.

<table>
<thead>
<tr>
<th>Patients</th>
<th>Gender</th>
<th>FOIS</th>
<th>Hemisphere</th>
<th>Type</th>
<th>Dysphagia</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male</td>
<td>5</td>
<td>Right</td>
<td>ischemic</td>
<td>142 months</td>
</tr>
<tr>
<td>2</td>
<td>Male</td>
<td>6</td>
<td>Right</td>
<td>ischemic</td>
<td>65 months</td>
</tr>
<tr>
<td>3</td>
<td>Male</td>
<td>6</td>
<td>Bilateral</td>
<td>ischemic</td>
<td>65 months</td>
</tr>
<tr>
<td>4</td>
<td>Male</td>
<td>6</td>
<td>Right</td>
<td>hemorrhagic</td>
<td>59 months</td>
</tr>
<tr>
<td>5</td>
<td>Male</td>
<td>5</td>
<td>Right</td>
<td>ischemic</td>
<td>58 months</td>
</tr>
<tr>
<td>6</td>
<td>Male</td>
<td>6</td>
<td>Right</td>
<td>ischemic</td>
<td>58 months</td>
</tr>
<tr>
<td>7</td>
<td>Male</td>
<td>6</td>
<td>Right</td>
<td>hemorrhagic</td>
<td>47 months</td>
</tr>
<tr>
<td>8</td>
<td>Female</td>
<td>6</td>
<td>Left</td>
<td>ischemic</td>
<td>39 months</td>
</tr>
<tr>
<td>9</td>
<td>Male</td>
<td>6</td>
<td>Right</td>
<td>ischemic</td>
<td>37 months</td>
</tr>
<tr>
<td>10</td>
<td>Male</td>
<td>4</td>
<td>Left</td>
<td>ischemic</td>
<td>29 months</td>
</tr>
<tr>
<td>11</td>
<td>Male</td>
<td>6</td>
<td>Right</td>
<td>ischemic</td>
<td>20 months</td>
</tr>
</tbody>
</table>

A total of 12 treatment sessions were provided to all subjects (not including the accommodation sessions). During each treatment session, the physical therapist recorded the SESS stimulation level. The RMS of EMG activity, duration, and IR of EMG signals after electrical stimulation were calculated for each session.

3.1 RMS of EMG activity at each electrode location during a swallow

The original EMG signal was smoothed by the RMS method. This method uses the square root of the average of the squared values of the preceding data points over the time set (20 ms here). This method allowed us to determine the modified moving-average EMG signal, set by time, and not by number of samples, ignoring whether peaks were positive or negative. Standards for analysis include assessment of duration (in s) of the swallowing act and amplitude of electric activity (RMS, in µV) as shown in Table 2.

<table>
<thead>
<tr>
<th>Channel 3</th>
<th>Channel 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>(left digastric muscle)</td>
<td>(right digastric muscle)</td>
</tr>
<tr>
<td>RMS Pre 2 mL</td>
<td>RMS Post 2 mL</td>
</tr>
<tr>
<td>7.38 ± 2.63</td>
<td>7.16 ± 3.04</td>
</tr>
<tr>
<td>6.98 ± 2.57</td>
<td>6.87 ± 3.06</td>
</tr>
<tr>
<td>10 mL</td>
<td>3.1 ± 2.7</td>
</tr>
<tr>
<td>150 mL</td>
<td>8.91 ± 4.04</td>
</tr>
</tbody>
</table>

3.2 Duration of EMG activity at each electrode location

The durations offset time minus onset time of swallow attempts for each electrode site were measured only for those attempts in which the onset and offset could be identified. Swallow durations were highly similar across the four measurement channels. Thus, the digastic channel was chosen as representative of the duration of swallow attempts. Fig. 4 shows the swallow durations, measured in the respective groups, for each bolus condition. Significant effects of swallowing duration were obtained in the 2, 5, 10, and 150 mL swallowing tasks; significant differences were identified (P = 0.01). In each instance, swallow durations for the dysphagic patients were shorter than those obtained in pre-treatment evaluations.

Figure 4. Swallowing time for various amounts of water (2, 5, 10, and 150 mL) before and after treatment.

The swallowing time varied across the four water volumes between pre- and post-treatment evaluations. The experimental results demonstrated that patients spent less time (2.55, 3.37, 4.4, and 28.44 s, respectively) in swallowing the 2, 5, 10, and 150 mL of water in the post-treatment examination. Time spent on the swallowing of 150 mL of water decreased more (on average 28 s) compared with the swallowing time change for the swallowing of 2, 5, or 10 mL of water after therapy.

3.3 Improvement ratio

The IR was calculated to evaluate swallowing performance in terms of myoelectrical activity pre- and post-treatment to assess the SESS effect created by swallowing differing amounts of water by patients with dysphagia. Table 2 presents IR results from each measurement site for the respective amount of water for each subject. A significant IR was noted for 10ml water swallowing Myoelectrical activity was greater for swallowing 150 mL of water before subjects received SESS treatment. There were no significant differences between the 2, 5, and 150 mL conditions.
4. Discussion

The demographic similarities between the patients (Table 1) indicated that all patients had more than 20 months in Dysphagia which was the reason why they had been referred for this study. The longer the period after the stroke, the less success is expected with dysphagia treatment. Despite this potential bias against electrical stimulation treatment, the patients did show improvements after treatment.

Application of electrical stimulation to muscles associated with swallowing links swallowing therapy with general physical therapy. A fundamental principle of physical therapy is that disuse of a striated muscle leads to atrophy of that muscle, even if the medical condition leading to disuse had no direct effect on the muscle or associated nerves [30]. Loss of muscle tone is identified by physical therapists as little or no measurable contractility or strength. When attempts at exercise alone fail to result in contraction of an atrophied muscle, electrical stimulation may enhance tone to the point where exercise may again strengthen the muscle.

There may be an analogy with dysphagia. A medical event, such as a stroke, may block the primary neural pathway for swallowing. There are fewer myofibrils per motor unit of the digastic muscles relative to larger muscles (4-6 vs. 4000), and numerous small muscles of this type participate in the oropharyngeal phase of swallowing [31]. In addition, the motor units within each digastic muscle tend to fire asynchronously during a normal swallow, in contrast with the more synchronous firing of larger muscles designed for strength [31]. Given this model, even a few days without the typical 600-2400 normal swallows per day [32] could lead to long-term dysphagia. Although this characteristic of small muscles may make them more susceptible to failure from lack of use, it is also possible that they may respond more fully to electrical stimulation. This may be why electrical stimulation restored effective swallowing with fewer treatments than typically required for restoration of appropriate function by electrical stimulation of other muscles in the body [33].

The patients in this study were not stratified by severity of cerebrovascular accident (CVA) or time post-onset. The participants were specifically not identified by severity of CVA, because this was a preliminary study with small numbers. Stratification by lesion or isolation of just one particular type of lesion would have lengthened participant enrolment long past the time of interest for this study. Larger controlled studies will have to stratify their participants according to these variables. Future studies may also stratify individuals with CVA by time post-onset and severity to determine the effectiveness of SESS as a function of CVA-related variables.

Overall, the patients responded positively to the four-channel SESS intervention to restore swallowing function by strengthening the masseter and digastic muscles. Post-treatment swallowing evaluations revealed significant improvements in swallowing function, characterized by decreases in swallowing duration. In addition, decreases in RMS of EMG during the swallowing of 2, 5, and 10 mL of water were observed. We consider these changes to be related to a better-coordinated firing pattern of the masseter and digastic muscles, as targeted by the SESS treatment program. The significant increase in RMS of EMG during the swallowing of 150 mL of water is believed to be associated with improvement in continuous drinking and decreased time spent on swallowing the water. The EMG amplitude remains an important indicator of aspect in the relationship between muscle force and the associated electrical activity [34]. There is, however, no simple relationship between the EMG signal and muscle force. When all the different types of neuromuscular disorders are considered together, amplitudes are by far the most informative features [35]. Some authors have argued that amplitudes are the only components that have a direct relationship with clinical symptoms (muscle weakness) in neurogenic lesions [35-38]. The present study did not find a clear increase in EMG amplitude during the swallowing of 2, 5, or 10 mL of water, and additional research may reveal whether this is clinically relevant. In addition, during EMG testing, there was a certain amount of impedance noise that arose directly from the resistance of the electrodes’ connection to the skin. This makes skin resistance a significant factor when working with the low- level EMG signals typical of the small muscles involved in swallowing. To avoid mitigate this problem, an alcohol swab was can be used to remove dead skin and surface oils and water was can be used to moisten the skin and improve ion flow.

By training the masseter and digastic muscles, subjects improved the timing and magnitude of muscle activity, which led to improvements in swallowing ability. The longer the period after the stroke, the less success is expected with dysphagia treatment [15]. Despite this potential bias against SESS treatment, the experimental post-treatment results were better compared to pre-treatment results. In addition, evaluations are important in determining the safety of treatment, to estimate the patient’s progress during the treatment period, and to justify further SESS treatment. In this study, sEMG was used to evaluate the firing patterns of the masseter and digastic muscles before and after treatment. This non-invasive, radiation-free examination has a low level of discomfort, and is simple, time-saving, and inexpensive. With an appropriately standardized technique and an established normative database, sEMG may serve as a reliable screening method for the assessment of dysphasia of unknown origin for referring patients to neurologists or another appropriate specialists for further investigation. The findings should be the impetus for further study regarding the mechanisms of muscle activity changes in disorders affecting swallowing.

The variance in the study outcomes may be related to the small number of subjects and short time periods used in this study. Nevertheless, the trials showed benefits with regard to motor power and swallowing performance. In this study, it was not possible to assess whether the observed benefits were maintained or tended to decrease over time. There is a need for a randomized clinical trial with adequate power, using standardized assessment scales and robust reporting of adverse events, to further assess the effectiveness of SESS.
5. Conclusion

A preliminary study was performed to determine the efficacy of a four-channel SESS to restore swallowing function by strengthening the masseter and digastric muscles in post-stroke individuals with swallowing disorders. Significant changes were seen in most of the subjects, which was interpreted as a general indication of a positive response to the intervention. Rectified and filtered sEMG provides a non-invasive means for assessing the complex muscle activity in swallowing. sEMG during swallowing is a simple non-invasive method with a low level of discomfort that can be included in the screening and evaluation of swallowing issues. Stage by stage evaluation of duration can be important for diagnosing the etiology of dysphagia. The parameters (i.e., RMS of EMG duration of EMG activity and IR) were proposed as the important indicators to be assessed in swallowing performance after SESS treatment. The values reported here may be useful for comparison with future studies of pathological conditions so that recorded sEMG data can be applied for differential diagnosis, for pre-treatment and post-treatment comparisons, for monitoring treatment, and for screening. The results obtained after SESS intervention are encouraging for the use of electrical stimulation as a form of therapy and indicate that improvements in swallowing function can be achieved even several years post-stroke.

References


