Using Surface Electromyography to Characterize Swallows in Stroke Survivors

By

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Abstract

Background: 9.44 million adults in the United States experience swallowing difficulties (i.e., dysphagia), with the most common etiology being stroke (Bhattacharyya, 2014). Upon diagnosis, patients are typically referred to clinicians who prescribe swallowing exercises, however access to this therapy is limited (Nund et al., 2014). Researchers have suggested that providing surface electromyography (sEMG) biofeedback during therapy may improve functional outcomes (Langmore & Pisegna, 2015).

sEMG sensors are an inexpensive and simple tool used to evaluate muscle activity. Limited studies to-date have looked at characterizing these signals in patients with dysphagia after stroke. Furthermore, these studies have only included time-domain measures such as duration and amplitude (Crary & Baldwin, 1997; Kim et al., 2015).

Objectives: sEMG swallowing signals were characterized in patients with dysphagia after stroke in a novel manner using both frequency and time domain analyses. These signals were then used to test if an existing algorithm developed for swallow detection in head and neck cancer patients, can be used to provide accurate feedback in the stroke population. The primary objective of this research was to understand how swallow-detection can be optimized for stroke specific sEMG characteristics.

Methods: Two groups of participants were recruited: a post-stroke group with oropharyngeal dysphagia (n=10) and an age- and sex-matched healthy control group (n=10). All participants were outfitted with a wireless sEMG data acquisition system on their submental area. They completed a baseline measurement and 20 regular saliva swallows. Test-retest was evaluated by removing the device and repeating the study procedure. Two studies were completed.

The first study used five independent Mann-Whitney U tests to identify if significant differences existed between the sEMG swallow signals in the stroke and control groups. The signal parameters compared were: duration, normalized peak amplitude, median and mean frequency, and signal to noise ratio. Additionally, test-retest of all parameters was completed for the healthy and stroke groups using intraclass correlation coefficients.

In the second study, the performance of a swallow-detection algorithm, developed for home-based dysphagia therapy for head and neck cancer patients, was tested using swallows collected in stroke patients. Recall was used as the measure of algorithm performance. If the recall for the first algorithm presented unsatisfactory results, a modified stroke specific algorithm would be generated. In this case a one-tailed pairwise t-test would be completed to understand if the modified algorithm performed better than the original.

Results: The first study found that SNR was significantly higher in the healthy *(Mdn=13.7, SD=5.4)* group than in the stroke *(Mdn=8.1, SD=4.6)* group, $U=325$, $p<0.001$. None of the other tested parameters suggested that differences exist between the two groups. Additionally, test-retest reliability of normalized peak amplitude and duration were found to be poor in the stroke group. All other parameters suggested moderate to very good reliability.

In the second study, the original algorithm performed with a recall of 74.55%, which was deemed to be outside of the acceptable range. A modified algorithm was generated and tested. This modified algorithm *(M=84.24, SD=11.26)* performed significantly better than the original algorithm *(M=74.55, SD=16.55)*, $t(10)= -2.667$, $p=0.024$.

Significance: These results suggest that signal quality is lower in individuals who have dysphagia after stroke when compared with healthy individuals. Additionally, the findings of the second study suggest that the modified version of the algorithm created using stroke data can perform within the acceptable range but may be improved by taking into consideration more characteristics of stroke specific sEMG signals.

Preface

This thesis is an original work by Kristina Kuffel. No part of this thesis has been previously published. The research projects presented in this thesis received research ethics approval from the University of Alberta Health Research Ethics Board, Project Name "Using Surface Electromyography to Characterize Swallows in Stroke Survivors", Pro00071185, March 29, 2017.

Dedication

I would like to dedicate this work to my wonderful grandparents, Dr. Edmund and Dr. Alicja Kuffel. Without your love and support I may have never ended up pursuing such a fascinating and rewarding career combining engineering, medicine, and research.

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Chapter 1. General Introduction

The use of non-invasive sensors, such as surface electromyography (sEMG), is a popular research area in the field of rehabilitation. sEMG sensors are placed directly on the skin, over the muscle of interest, to measure the electrical potential across the belly of the muscle during contraction. These signals can be used to provide clinicians with an objective measure of muscle activity and patients with biofeedback during physical exercise (Gilmore & Meyers, 1983). The quantification of sEMG signal patterns specific to muscle dysfunction associated with stroke has been explored by many researchers, primarily in the fields of occupational therapy and physical therapy (Li et al., 2014; Toffola et al., 2001).

Although this technology has been used extensively in other clinical areas, it is relatively new in the field of swallowing therapy (Monaco, Cattaneo, Spadaro, & Giannoni, 2008). The muscles associated with swallowing, specifically the submental muscles found directly below the chin, have unique qualities that may make the findings of similar studies non-transferable. Evidence shows that these muscles can differ from other skeletal muscles developmentally, physically, and structurally (Kent, 2004). These differences make the transfer of theories developed in other muscle groups potentially inapplicable to the submental muscles, leaving an entirely independent area of research.

An estimated 9.44 million adults in the United States experience swallowing difficulties, with the most common etiology being stroke and other neurological disorders, which make up approximately 18% of all cases (Bhattacharyya, 2014). Upon presentation of symptoms patients are typically referred to clinicians who attempt to rehabilitate their swallow mechanism, often through the prescription of swallowing exercises (Langmore & Pisegna, 2015). Several studies have suggested that providing sEMG biofeedback during these exercises may improve functional outcomes and provide clinicians with an additional objective measure of muscle activity and motor performance (Michael A. Crary, Carnaby Mann, Groher, & Helseth, 2004; Gilmore & Meyers, 1983).

The characterization of swallow activity in stroke patients could potentially be used for long-term monitoring of changes or improvements in muscle activity and performance. Additionally, these findings can be utilized in the development of new technology to improve home-based and clinical therapy for patients suffering from dysphagia secondary to stroke. Such technological advances could include the development a swallow-detection algorithm, allowing patients to complete their exercises remotely with the ability to receive biofeedback and recognition.

The Normal Swallow

Swallowing is a complex sensorimotor process that is highly dependent on the coordination of the activation patterns in the oropharyngeal muscles (Kim et al., 2015). The controlled relaxation and contraction of the muscles in the throat create areas of positive and negative pressures, propelling the food, saliva, or liquid from the mouth to the stomach. The current understanding of swallowing is that it is one continuous process with four interdependent and overlapping stages: oral/preparatory, oral, pharyngeal, and esophageal (Michael A. Crary & Groher, 2003). Traditionally, swallowing was viewed as a reflexive action, but has been redefined as a programmed response to sensory stimuli because of its ability to be volitionally controlled under certain circumstances (Michael A. Crary & Groher, 2003). In a normal swallow, the bolus (i.e., chewed food) moves through the following spaces: the oral cavity, the oropharynx, the laryngopharynx, the esophagus, and the stomach.

The oral/preparatory stage involves all steps that precede the formation of a bolus. In the oral stage the bolus is cradled by the tongue, which then propels the bolus posteriorly through the contraction of the extrinsic tongue muscles, including the digastric, mylohyoid, and geniohyoid muscles. Anatomically, these muscles are all found in the submental area of the neck, with origins at the inferior portion of the mandible and attachments on the hyoid bone. Listed from superficial to deep their orientation is as follows: anterior digastric, mylohyoid, and geniohyoid (Corbin-Lewis & Liss, 2014).

The contraction of these submental muscles is also responsible for the elevation of the hyolaryngeal apparatus, which includes the hyoid bone and the larynx (Corbin-Lewis & Liss, 2014). The movement of the epiglottis to cover the laryngeal opening occurs in two steps and is the result of both laryngeal elevation and tongue base retraction (Pearson, Taylor, Blair, & Martin-Harris, 2015). This epiglottal movement creates a physical barrier between the larynx and the pharynx during food passage, preventing the bolus from entering the airway (Matsuo & Palmer, 2008). This movement acts as a primary source of airway protection and is critical in the ability to swallow safely.

The pharyngeal phase of swallowing begins as a result of sensation of the bolus where the oral and oropharyngeal cavities meet. Upon bolus entry to the oropharynx, multiple muscle groups act to shorten the pharynx and close the opening at the back of the mouth, increasing the pressure in the oropharyngeal cavity. Concurrently, hyolaryngeal elevation increases the size of the laryngopharynx which results in a pressure decrease. This pressure differential results in the movement of the bolus from the oropharyngeal cavity down to the laryngopharyngeal cavity and eventually to the level of the stomach (Matsuo & Palmer, 2008).

Dysphagia After Stroke

Dysphagia refers to difficulty swallowing and can affect different stages of the process (Cho et al., 2014). Stroke is the most common cause of dysphagia, with dysphagia affecting approximately 30-50% of all stroke survivors (Han et al., 2016). Most often, strokes result in oropharyngeal dysphagia, which affects motor and sensory abilities in the oral and pharyngeal stages of swallowing (Zhao, Liu, & Li, 2015). Currently, the standard for assessment of the swallowing mechanism in patients suspected of suffering from dysphagia is a videofluoroscopic swallowing study (VFSS) (East, Nettles, Vansant, & Daniels, 2014; Martin-Harris et al., 2008). In VFSS, a clinician is able to see the bolus and the associated physiological movements as it passes through the upper aerodigestive tract and into the esophagus (East et al., 2014).

Martin-Harris et al. (2008) created a tool that can be used to quantify swallowing impairment through the review of VFSS by observing timing, structural movements, bolus flow patterns, and airway protection. Using this assessment, clinicians can identify symptoms specific to the stages of swallowing. During the oral preparatory and oral stages these symptoms may include: difficulty in bolus preparation, the presence of oral residue, and impaired bolus transport and lingual motion. In the pharyngeal phase of swallowing patients with dysphagia can exhibit reduced soft palate and hyolaryngeal elevation, which in turn can affect epiglottic movement and laryngeal closure (Martin-Harris et al., 2008). It has been shown that the velocities of all structures involved in swallowing were lower in the stroke population when compared with a healthy control group resulting in delayed airway protection (Seo, Oh, & Han, 2016).

Improper airway closure is a key cause of laryngeal aspiration, where foreign substances fall below the level of the true vocal folds (Han et al., 2016). Laryngeal elevation is imperative to successful airway protection and is primarily caused by the suprahyoid muscles, including the anterior and posterior bellies of the digastric, mylohyoid, stylohyoid and geniohyoid muscles (Pearson, Hindson, Langmore, & Zumwalt, 2013; Pearson et al., 2015). Motor dysfunction in these muscle group can result in the inability to effectively protect the airway, increasing the risk for serious complications such as aspiration pneumonia, chemical pneumonitis, or death (Crausaz & Favez, 1988; Perlman, Grayhack, & Booth, 1992).

Surface Electromyography Background

To understand the principles of surface electromyography a basic understanding of muscular architecture is required. Muscle contraction is the result of many individual motor units. Each motor unit has three components: the lower motor neuron, the axon, and the muscle fibers that it innervates. The nerve action potential is transmitted from the lower motor neuron through the axon to the neuromuscular junction of the muscle fiber (Cram, 1990). Upon reaching the neuromuscular junction acetylcholine is released, which results in a synchronous discharge of all muscle fibers innervated by the motor unit and creates a motor unit action potential (MUAP)

(Cram, 1990). The superposition of all MUAP activity is the source of sEMG signals, resulting in an increase in voltage upon contraction (Gilmore & Meyers, 1983).

After a stroke occurs there can be architectural changes that occur in these motor units. Due to neurological damage the descending input from the motor cortex is decreased, leading to less signals successfully innervating their respective muscle fibers. However, during recovery unaffected lower motor neurons reorganize to compensate for the damaged ones. This results in a decrease in the total number of motor units and an increase in size of the motor units. Additionally, the motor units most vulnerable to damage are those responsible for fast twitch, resulting in a higher composition of larger and slower motor units in the muscle after stroke (Gray et al. 2012).

Signals collected using sEMG are both time and force dependent, resulting in an amplitude that fluctuates about the zero value. These signals can be represented in two ways: time-domain (temporal) and frequency-domain (spectral). Time-domain measures refer to the description of voltage as a function of time and are often plotted with the x and y axes representing time (seconds) and amplitude (voltage), respectively.

As previously mentioned, sEMG signals result from the superposition of all MUAP activity and can also be described by their frequency components. A relationship exists between the time and frequency components of the signal. The frequency components of a signal are commonly characterized using Fast Fourier transforms of the time-domain signal. This technique produces a power density spectrum of the signal, which represents the amount of energy that exists at each frequency. An example of this relationship can be seen in Figure 1.1.

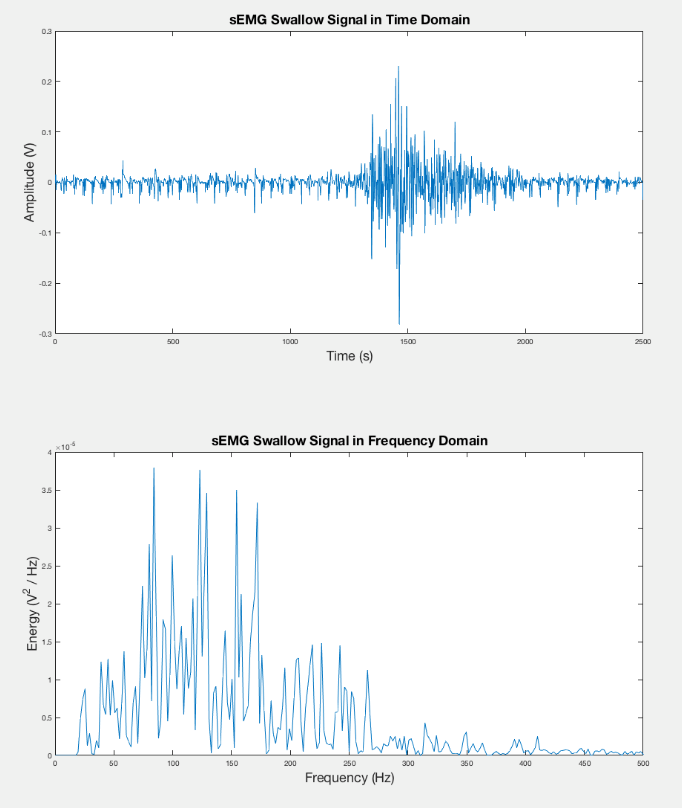

Figure 1.1 sEMG swallow signals shown in both time and frequency domain

Frequency analysis can provide useful information about the characteristics of active muscle fibers including their size, conduction velocity, and the rate at which they fire (Kendell et al., 2012). These values are used clinically to identify the effects of muscle fatigue and characterize muscle contraction strength (Clancy, Negro, & Farina, 2016; Gilmore & Meyers, 1983). Basmajian & Banks (1974) identified three primary measures of sEMG power spectrum density: the median frequency, the mean frequency, and the bandwidth of the spectrum (Basmajian & Banks, 1974).

In most clinical fields surface electromyography recordings are generally described in terms of amplitude, duration, and median or mean frequency. Signal amplitude acts a representation of force production caused by the muscle contraction and is dictated by the number, rate, and size of the active motor units. Although this parameter provides valuable information, it cannot be used to compare values in different people or muscle groups and is highly sensitive to electrode placement error (Gilmore & Meyers, 1983).

sEMG may be particularly susceptible to placement error because of the difficulty in identifying the innervation zone and the relatively large surface area of the electrodes (Naik, Kumar, & Palaniswami, 2012; Stepp, 2012). When using sEMG in areas with many muscles, such as the submental area, cross-talk can occur (Hermens, Freriks, Disselhorst-Klug, & Rau, 2000). Cross-talk refers to the detection of sEMG activity that is not the result of the targeted muscle, but instead is created by any adjacent muscle in close proximity to the electrode (Farina, Merletti, Indino, & Graven-Nielsen, 2004). To aid clinicians and researchers in minimizing the effects of improper placement, Hermens et al. (2000) developed guidelines to be used for surface electromyography for non-invasive measurement of muscles (SENIAM). These guidelines include information about electrode positioning, shape, size, and spacing (Hermens et al., 2000).

Swallowing Therapy using Surface Electromyography

After a swallowing assessment has been completed, speech-language-pathologists often prescribe exercise-based swallowing therapy with two primary intentions: compensation and rehabilitation. Compensation refers to short-term adjustments that can improve functional swallowing outcomes and minimize the risk of aspiration, whereas rehabilitation aims to improve the supporting physiology required for swallowing (Michael A. Crary & Carnaby, 2014). Providing sEMG biofeedback to patients while completing rehabilitative exercise therapy has been shown to potentially improve functional outcomes such as oral intake (Michael A. Crary et al., 2004). Unfortunately, limited resources often prevent patients from receiving this type of support and assistance throughout their post-treatment period (Nund et al., 2014).

In an effort to improve access to therapy, Constantinescu et al. (2014) developed a device that can be used for remote sEMG biofeedback therapy in patients suffering from swallowing difficulties secondary to head and neck cancer (Constantinescu, Stroulia, & Rieger, 2014). Using sEMG sensors, the device measures muscle activity and wirelessly presents the information to the patient on their mobile device. This device utilizes a swallow-detection algorithm to provide automatic feedback on the number and intensity of the swallows while patients complete their prescribed exercises at home. This algorithm was developed using data collected in healthy individuals and validated in ten head and neck cancer patients with dysphagia. It was accurately able to identify an average of 92.7% of swallows in all head and neck cancer participants (*M=92.7 , SD=9.15)* (Constantinescu et al., 2017).

In order to develop a robust algorithm for remote swallowing therapy, a detailed characterization of sEMG signal collected during swallowing in patients suffering from dysphagia after stroke must be completed. Constantinescu et al. (2017) have completed this analysis for the head and neck cancer population but limited data are available for other etiologies, specifically stroke (Constantinescu et al., 2017). Two previous studies have looked at identifying differences between stroke patients and healthy participants. One study found that peak amplitude values in stroke participants were higher (M. A. Crary & Baldwin, 1997), while the other found no significant differences between the two groups (Kim et al., 2015). Both studies suggested that swallow duration in stroke patients may be shorter than in healthy participants.

A literature review produced no results of studies that looked to characterize mean and median frequency in the submental muscles, however, this type of analysis has been completed for larger muscles (Liye, Xiaoli, & Xiao, 2012; Toffola et al., 2001). A study looking at these values on the tibialis anterior of healthy and post-stroke patients found that a significant difference exists between the two populations, with higher values in the healthy population (Toffola et al., 2001).

If the spectral and temporal characteristics of swallow signals in patients with dysphagia secondary to stroke are found to be similar to those in healthy individuals, it could be hypothesized that the same swallow-detection algorithm could be used in the stroke population. However, if significant differences exist between the two populations, a modified version of the swallow-detection algorithm would have to be implemented to provide accurate feedback during swallowing therapy.

An improved characterization of the sEMG signals collected from the submental muscles during swallowing could provide an opportunity to apply this algorithm to a new population. In doing so, this could increase access to much needed home-based therapy for stroke patients suffering from dysphagia.

Research Questions

This research answered two independent questions:

1. Do time domain and frequency domain differences exist between surface electromyography (sEMG) signals of the submental muscles measured in healthy adults and patients who suffer from dysphagia secondary to stroke?

   It was hypothesized that no significant differences in the normalized peak amplitude would exist between the two populations, however, the duration of the swallow events in the stroke populations may be smaller. It was expected that SNR values in the healthy individuals may be higher than those observed in the stroke group. A downward shift in the median and mean frequency values was expected for the stroke populations when compared with the healthy population.

2. Can an existing automated swallow detection algorithm developed for head and neck cancer patients, properly classify sEMG swallow signals in stroke patients? If not, can a modified algorithm using stroke-specific data provide more accurate feedback for this population?

If signal parameters such as median frequency, normalized peak amplitude, and duration differ between the stroke and head and neck cancer populations, the algorithm performance can be expected to be poor. In the case that algorithm performance is less than one standard deviation of the results observed by Constantinescu et al. (2017) when tested with half of the data, a modified algorithm would be generated using the remaining half of the data from this study. This modified version of the algorithm would then be tested and validated using the same data set used in the evaluation of the original algorithm.

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Chapter 2. Identifying sEMG Signal Differences in Healthy Participants and Stroke Survivors During Swallowing

Introduction

In the United States 9.44 million adults suffer from swallowing difficulties (i.e., dysphagia). Most commonly the cause of dysphagia is of a neurogenic nature, due to stroke or other traumatic brain injury (Bhattacharyya, 2014). Researchers have suggested that 30-50% of all stroke survivors experience some form of dysphagia (Han et al., 2016; Zhao, Liu, & Li, 2015). Damage from stroke can have profound effects on the swallowing mechanism, often disrupting the oropharyngeal phase of swallowing, which is heavily dependent on the coordination of the activation patterns in the oropharyngeal muscles (Kim et al., 2015; Zhao et al., 2015).

Symptoms of stroke may vary based on the severity and location of the lesion. Motor control for swallowing begins at the motor cortex, where a signal is produced and transmitted through upper motor neuron pathways. These pathways then synapse with the cranial nerve motor nuclei. If the lesion occurs before this synapse it is referred to as an upper motor neuron (UMN) lesion. Conversely, if an injury occurs between the motor nuclei and the neuromuscular junction of the muscle they innervate this is referred to as a lower motor neuron (LMN) lesion (Macdonell and Holmes 1992). Individuals who suffer from UMN lesions typically exhibit excessive spasticity due to increased muscle tone whereas LMN lesions present as flaccidity and muscle atrophy (Bach 2009).

Upon presentation of symptoms, patients are referred to speech-language pathologists who will assess their swallowing impairment and prescribe an exercise based swallowing therapy program (Michael A. Crary & Carnaby, 2014). It has been suggested that providing biofeedback to patients while completing these exercises may help to improve skill training required for specific swallow tasks, which may in turn improve functional outcomes (Athukorala, Jones, Sella, & Huckabee, 2014). Non-invasive sensors, such as surface electromyography (sEMG), can measure muscle activity of the submental muscles to provide this feedback, allowing patients to visually identify the amplitude and duration of their submental muscle contractions while completing their exercises (Michael A. Crary, Carnaby Mann, Groher, & Helseth, 2004).

During muscle contraction, individual motor units create action potentials resulting in the generation of an electrical potential or voltage. Surface electromyography sensors are placed directly on the skin, over the target muscle group, where they measure the voltage created by the superposition of each individual motor unit action potential (Gilmore & Meyers, 1983). This means that the sEMG signal represents the sum of all motor unit action potentials rather than any single one. There are two primary ways of representing these signals: time-domain (temporal) and frequency-domain (spectral).

Clinically, the time domain measures that are most commonly used are the amplitude, measured in volts, and the contraction duration (measured in milliseconds). However, researchers suggest that amplitude measures should not be compared within or between patients as they are highly sensitive to electrode placement and individual differences (Gilmore & Meyers, 1983) . Alternatively, frequency analysis can provide clinicians with additional information about the active muscle fibers including their size and firing rate, as well as give insights into muscle fatigue and contraction strength (Clancy, Negro, & Farina, 2016; Gilmore & Meyers, 1983). The median and mean frequency values are parameters that are commonly used to summarize the spectral components of a signal in other larger muscle groups (Basmajian & Banks, 1974).

The quantification of time and frequency domain characteristics of sEMG signals has been extensively studied in the fields of biomechanics and physiotherapy; however, researchers have suggested that findings from larger muscle groups may not be transferrable to the muscles responsible for swallowing as they exhibit unique developmental, structural, and physical qualities (Kent, 2004). Although several groups have evaluated time-domain characteristics of sEMG associated with neurogenic dysphagia, none have compared frequency-domain characteristics of swallowing in stroke patients with healthy participants (M. A. Crary & Baldwin, 1997; Kim et al., 2015).

Two previous studies have looked to identify differences between stroke patients and healthy participants. One study found that peak amplitude values in stroke patients were higher (M. A. Crary & Baldwin, 1997) whereas the other showed no significant differences exist between the two groups (Kim et al., 2015). These same researchers have suggested that swallow duration in stroke patients may be shorter than in healthy participants. A literature review produced no studies looking to characterize mean and median frequency in the submental muscles; however, this type of analysis has been completed in larger muscles (Liye, Xiaoli, & Xiao, 2012; Toffola, et al., 2001). It has been suggested that a decrease in the mean and median frequency values of sEMG signal may be indicative of fatigue. A study looking at these values on the tibialis anterior of healthy and post-stroke patients found that a significant difference exists between the two populations, with higher values in the healthy population (Toffola et al., 2001).

Further characterization of these signals, using both time and frequency domain analysis, has the potential to advance therapy for those suffering from swallowing impairment. Clinical sEMG biofeedback therapy could be improved by the implementation of automatic swallow detection algorithms and by software allowing for tracking of these characteristics. However, there are currently no standard values for the frequency characteristics in the submental muscles of stroke patients.

In the present study, we aimed to characterize sEMG signals related to swallowing in a novel manner and to identify signal differences that may exist between two groups of individuals: 1) a healthy control group age- and sex-matched individuals without dysphagia and 2) patients who experience dysphagia after stroke.

This work is exploratory and serves as pilot work for larger studies in the future. Expected results were proposed based on what is known from previous work. It was hypothesized that there would be no significant differences in the normalized peak amplitude between the two populations; however, the duration of the swallow events in the stroke group may be smaller (M. A. Crary & Baldwin, 1997; Kim et al., 2015). It was predicted that SNR would be higher in the healthy population than the stroke. This was hypothesized because individuals with swallowing impairment may complete more extraneous movement while completing the swallowing task, resulting in signal of lower quality. Also, a downward shift in both the median and mean frequency values was expected in the stroke group when compared to the healthy as this was observed in larger muscles (Toffola et al., 2001).

Methodology

Participants

This study involved the recruitment of two participant pools: a group of 10 stroke patients with current symptoms of oropharyngeal dysphagia and a group of 10 healthy controls. Inclusion for the stroke group did not specify specific lesion location or severity, allowing for the inclusion of both UMN and LMN lesions of varying severity. If any stroke participants presented with additional disorders that could affect the swallowing mechanism, such as a history of head and neck cancer, traumatic brain injury, or other degenerative neuromuscular disorders, they were excluded from this study. All participants included in the stroke population showed symptoms of dysphagia due to stroke and possessed the cognitive ability to follow two-step instructions (i.e., they could indicate that they were ready to swallow and then swallow when prompted). All participants were over 18 years of age.

Ten healthy participants were included in this study as a control for parameter comparison. This group was matched for sex and age (+/- 10 years) to the stroke group to account for anatomical and physical differences that could be related to sex or aging. To be included in the control group, participants could have no medical history of any disorder affecting their swallowing mechanism.

This study was approved by the Health Research Ethics Board at the University of Alberta, the Northern Alberta Clinical Trials and Research Center (NACTRC), and Covenant Health. For the patient population, recruitment for this study was performed at several clinical sites in Edmonton, Alberta, Canada. The healthy control group was recruited through convenience sampling, advertising in the Faculty of Rehabilitation Medicine with posters, and by word of mouth.

All data were de-identified by applying a participant code and removing any personal identification, and were securely stored. All stroke participants were labelled with prefix “sEMG”, whereas healthy controls utilized “HC”.

Data Collection

A wireless data acquisition device with built in sEMG sensors was attached to a custom made skin-safe adhesive pad. The device was then placed on the participant's right submental area of their chin, with the ground electrode on the bony ridge of the mandible and the two active leads over the belly of the anterior digastric muscle as shown in Figure 2.1. In two participants the device was placed on the left side of the chin. One participant was only clean shaven on the left portion of his chin and the second patient had a superficial hematoma on the right side of their submental area. In this case it was confirmed that the patient had not suffered a traumatic brain injury that could have further impaired their swallowing ability. Electrode orientation was determined based on SENIAM guidelines (Hermens, Freriks, Disselhorst-Klug, & Rau, 2000). The right side was chosen arbitrarily as asymmetries in the anterior belly of the digastric muscle in healthy participants have been documented and the affected side was unknown to the researcher (Mangalagiri & Razvi, 2009).

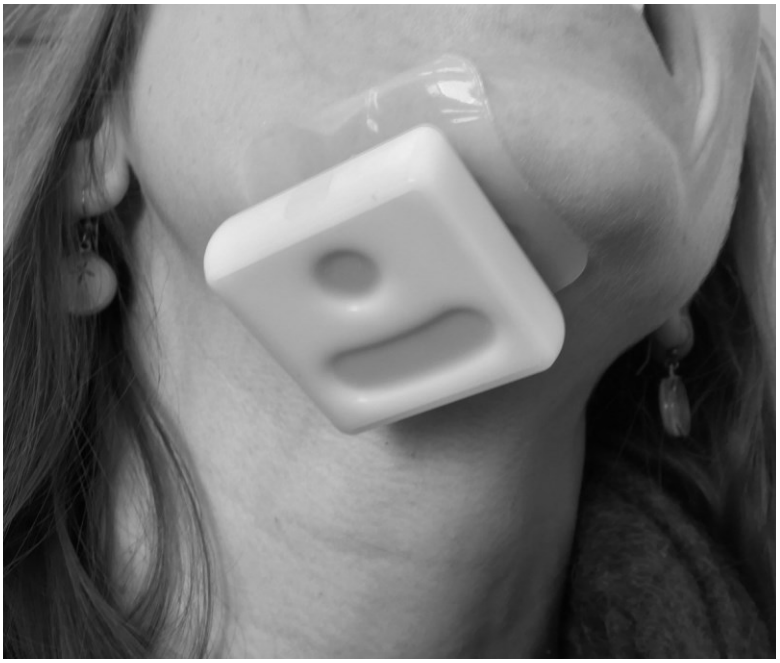
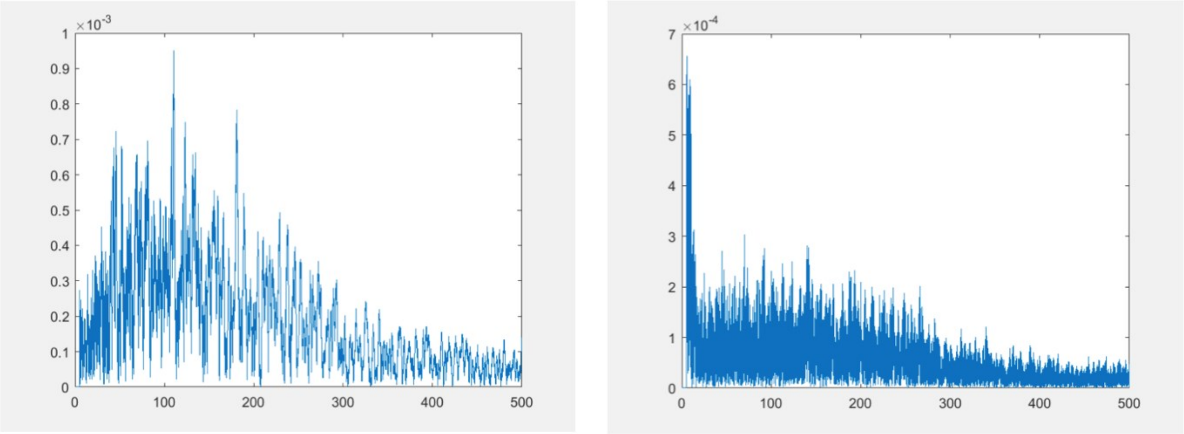


Figure 2.1 Wireless device placement on submental area

Efforts were made to try to ensure that there was good conduction between the skin and the electrodes during all instances of data collection. In the stroke group it was difficult for participants to complete the swallowing action without the presence of extraneous movements such as head, tongue, and lip movements. An example of the power spectrum density measured during swallow with and without these movements can be seen in Figure 2.2.



a) Normal frequency profile of saliva swallow

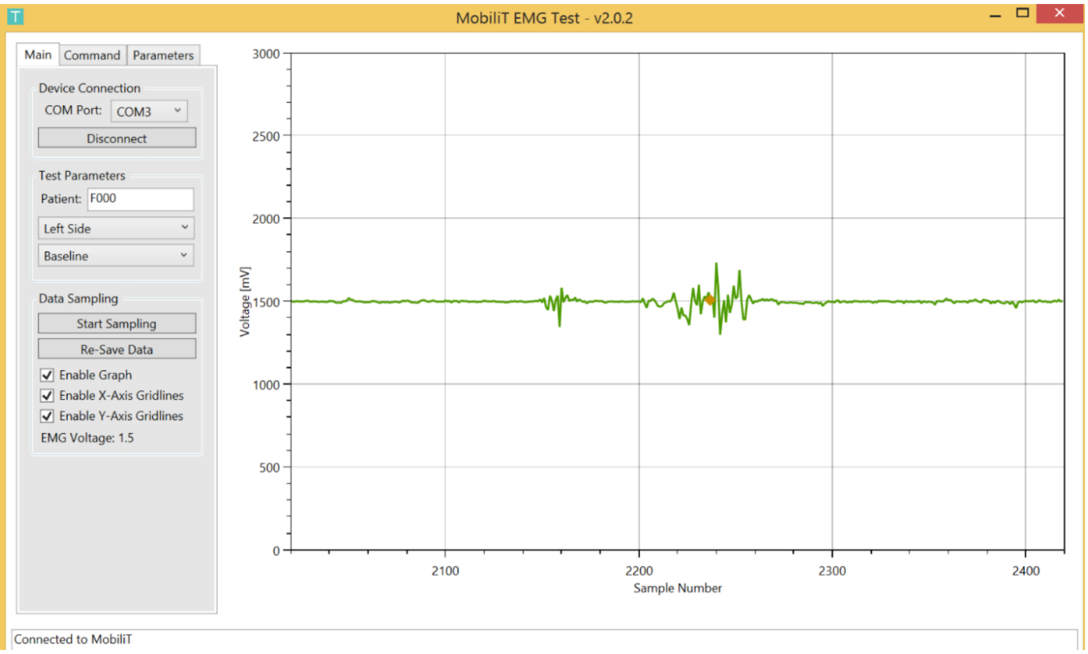
b) Frequency profile of saliva swallow contaminated with motion artefact

Figure 2.2 a) Normal frequency profile of sEMG during swallow b) Frequency profile of sEMG during swallow with low-frequency noise

Each participant was instructed to complete two trials, each consisting of two sets of tasks. Each trial involved the placement of the device followed by a baseline measurement and 20 regular dry swallows. The baseline signal recording required the participant to sit quietly for 15 seconds and avoid all tasks that activate muscles in the neck. If the researcher observed any movement the recording was discarded and restarted.

For the swallow tasks, the patient was instructed to inform the researcher when they were ready to swallow. At this time, the participant gave a visual indication that they were prepared to swallow (i.e., thumbs up). Once receiving this prompt, the researcher began data recording. Each swallow event was tagged by the researcher with a timestamp while the participant completed the task. The first five swallows of each trial were used to calculate a reference peak amplitude by taking the average peak amplitude value across all five swallows. This value was later used in the calculation for normalized peak amplitude.

Figure 2.3 shows a screenshot of the data acquisition software and the tagging. This timestamp was used for event identification during signal segmentation and to validate that the correct muscle activation was being compared if there were multiple periods of increased amplitude during one swallowing event. This was important when working with the stroke population because some participants lacked the ability to isolate swallowing tasks and often completed other associated movements such as head movements as they completed the swallowing tasks.



COM Port: COM3

Patient: F000

Left Side

Baseline

☑ Enable Graph

☑ Enable X-Axis Gridlines

☑ Enable Y-Axis Gridlines

EMG Voltage: 1.5

Connected to MobiliT

Figure 2.3 Data acquisition software with timestamp tagging

Data in the second trial was used to evaluate test retest reliability by removing the device from the participants' submental area and replacing the device in a similar position on the same side of the neck. Upon repositioning, the full testing procedure was repeated, including the baseline measurement and 20 regular saliva swallows.

Data Analysis

All data were pre-processed by applying a second order Butterworth band pass filter with cutoff frequencies of 5 Hz and 250 Hz. This was done for two reasons: the removal of low frequency noise associated with extraneous movements and to avoid aliasing. In addition, notch filters were applied at 60 Hz to prevent effects from line-noise and at harmonics of 25 Hz to remove spikes characteristic to the device used for data collection.

All recordings were analyzed using a custom MATLAB script. This script performed automatic signal segmentation that was cross-validated with the swallow timestamps recorded during swallow detection. The automatic segmentation used an amplitude threshold calculated using amplitude values collected during the baseline calibration (Equation 2.1) (Basmajian & Banks, 1974).

Equation 2.1 $$Amplitude\ Threshold = Baseline\ mean + 2 * Baseline\ standard\ deviation$$

The following five outcome measures were chosen to identify potential differences in the signal between the healthy and stroke populations: normalized peak amplitude, duration, signal to noise ratio (SNR), median frequency, and mean frequency. The time-domain measures include normalized peak amplitude, duration, and SNR. Normalized peak amplitude refers to the peak amplitude value of the segmented swallowing signal over the average values of peak amplitudes from all reference swallows. This value was chosen to act as a measure of consistency of swallowing amplitude between swallows, while accounting for placement error and individual differences. The duration of the segmented signal was calculated based on the period of time that the signal was continuously greater than the amplitude threshold. Finally, the SNR, which represents signal quality, was also measured (Equation 2.2). Clinically this provides information about how easily the muscle activity is discerned from background noise

$$Equation\ 2.2\quad SNR = 20log_{10}\left(\frac{RMS_{Signal}}{RMS_{Baseline}}\right)$$

Two frequency-based measures, median and mean frequency, were also selected for analysis. These values were calculated between 5 Hz and 250 Hz, to account for the bandpass filter applied during preprocessing. These parameters have been shown to correlate with localized muscle fatigue and are dependent on the firing rate of the motor units making up the muscle in question (Toffola et al., 2001).

Statistical Analyses

The assumption of normality was not satisfied for several parameters including duration and SNR in the both populations and normalized peak amplitude in the stroke group (Shapiro-Wilk, $\alpha=0.05$**)**. Because of this, five independent Mann-Whitney U tests were used to compare the differences between the healthy and stroke groups. Potential type 1 error from running multiple independent t-tests was controlled for by using a Bonferroni alpha adjustment ($\alpha = 0.01$). The assumption for equality of variance was met for all parameters except for median frequency comparisons. These tests were completed using JASP (Version 0.8.3.1).

Additionally, three parameter values were chosen to better understand the relationship between patient demographics and sEMG signal. These parameters included normalized peak amplitude, SNR, and median frequency. Three independent summaries were completed by grouping patients on the following: if the recording was captured on the affected or unaffected side, time passed since stroke, and self-reported severity.

Test-retest reliability was assessed by using two-way random intraclass correlation coefficients (ICC). This analysis was completed using the following agreement classes: very good (0.80), good (0.61–0.80), moderate (0.41–0.60), fair (0.20 –0.40), and poor (0.20) (Altman, 1990). This analysis was completed using IBM SPSS.

Results

Participants

In total 22 individuals participated in data collection: ten healthy and twelve stroke. Two stroke participants were excluded from analysis because of an inability to complete the required tasks. One participant experienced discomfort due to the presence of a nasogastric tube, resulting in the termination of data collection. The other excluded participant experienced severe apraxia of movement, resulting in the inability to initiate swallowing tasks without the use a thickened liquid. All healthy participants were age- (+/- 10 years) and sex-matched to a stroke participant. The demographics for all participants are summarized in Table 2.1.

Table 2.1 Comparison of age in healthy and stroke groups

Group	Sex	n	Mean (years)	Range (years)
Healthy	Female	6	63	48-73
	Male	4	57	43-70
	Overall	10	61	43-70
Stroke	Female	6	64	49-74
	Male	4	58	49-68
	Overall	10	62	49-69

No significant difference between the ages in the stroke *(M=62)* and healthy *(M=61)* groups was identified (p=0.828). This was tested using an independent Student's t-test. The assumptions of normality and equality of variances were met in both groups.

Before data collection, all stroke participants were asked several questions by the researcher including: self-reported severity of swallowing impairment, side of weakness after the stroke, food intake consistency, and the date of their stroke. All questionnaire details for stroke participants are summarized in Table 2.2

Table 2.2 Stroke participant demographics

Participant	Sex	Age	Severity	Side of weakness	Oral intake (food consistency)	Days since stroke
sEMGM002	Male	52	Mild	Right	Solid foods	9
sEMGM003	Male	62	Mild	Right	Solid foods	1859
sEMGF004	Female	49	Moderate	Right	Pureed foods	30
sEMGF006	Female	74	Moderate	Right	Pureed foods	41
sEMGF007	Female	63	Mild	Right	Solid foods	3229
sEMGF008	Female	65	Mild	Left	Pureed foods	113
sEMGM009	Male	68	Mild	Left	Solid foods	10
sEMGM010	Male	49	Severe	Left	No oral intake	12
sEMGF011	Female	60	Moderate	Left	Solid foods	4527
sEMGF012	Female	73	Moderate	Right	Solid foods	83

Signal Characteristics

All signals collected during dry swallows from trial 1 and trial 2 were pooled and run through an automatic segmentation algorithm. If incoming signals did not exceed the amplitude and duration thresholds, they were discarded from this analysis. In the healthy and stroke groups 300 swallows from each group were fed into the segmentation algorithm, and 300 and 281 swallows were successfully segmented, respectively. Each of the signals that was successfully segmented was included in the calculation for each parameter. Box-plots and summaries for the distributions of each parameter can be found in Table 2.3 and Figure 2.4 both the healthy and stroke groups.

Table 2.3 Summary of parameter characteristics in healthy and stroke participants

	Normalized peak amplitude		**Duration (ms)**		**SNR (dB)**		**Median frequency (Hz)**		**Mean frequency (Hz)**	
	Healthy	**Stroke**	**Healthy**	**Stroke**	**Healthy**	**Stroke**	**Healthy**	**Stroke**	**Healthy**	**Stroke**
Valid	20	20	20	20	20	20	20	20	20	20
Missing	0	0	0	0	0	0	0	0	0	0
Mean	1.23	1.05	1342	1138	15.6	8.8	111.5	102.1	163.6	165.0
Median	1.23	0.97	1211	904	13.7	8.1	119.0	116.5	163.5	169.7
Std. deviation	0.29	0.31	596	878	5.4	4.6	27.4	39.1	7.7	16.7
Range	1.08	1.25	2200	4046	16.3	14.4	102.0	130.8	24.7	62.9
Minimum	0.66	0.67	768	519	7.9	2.9	37.9	21.2	149.6	125.3
Maximum	1.75	1.92	2968	4565	24.2	17.3	139.9	152.0	174.3	188.1

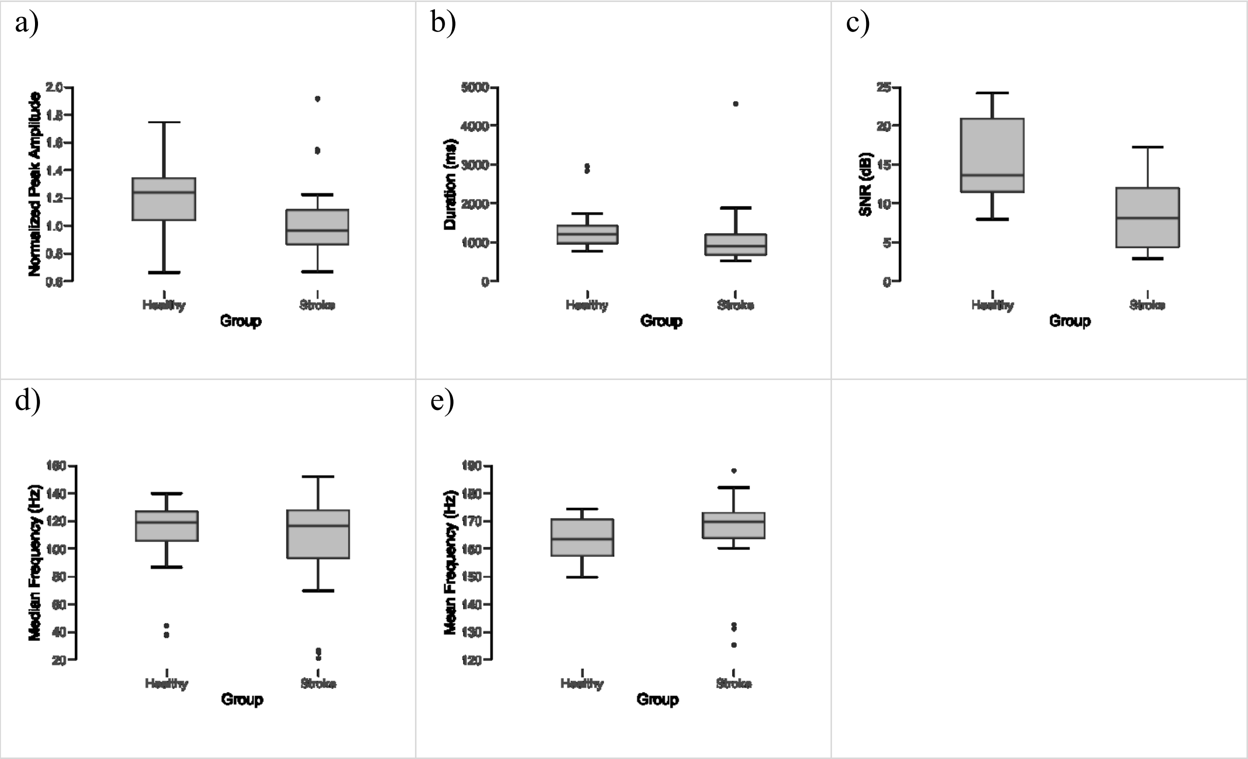


Figure 2.4 Box-plot comparison of healthy and stroke group values for: a) Normalized Peak Amplitude, b) Duration (milliseconds), c) SNR (dB), d) Median Frequency (Hz), e) Mean Frequency (Hz)

Mann-Whitney U tests were used to compare each parameter between the two groups. The only parameter to demonstrate significant differences between the two groups was SNR. SNR was found to be significantly higher in the healthy *(Mdn=13.7, SD=5.4)* group than in the stroke *(Mdn=8.1, SD=4.6)* group, U=326, p<0.001. Cohen's d *(d=1.62*) for SNR indicates a large effect size between the two groups. Results for each of these tests can be found in Table 2.4.

Table 2.4 Mann-Whitney U-test for Normalized Peak Amplitude, Duration, SNR, Median Frequency, and Mean Frequency Values between stroke and healthy groups

					95% CI for Rank-Biserial Correlation	
Parameter	**U**	**p**	**Rank-Biserial Correlation ®**	**Cohen's d**	**Lower**	**Upper**
Normalized Peak Amplitude	294	0.01	0.47	1.06	0.15	0.70
Duration (ms)	279	0.034	0.40	0.86	0.06	0.65
SNR (dB)	326	< .001	0.63	1.62	0.36	0.80
Median Frequency (Hz)	226	0.495	0.13	0.26	-0.23	0.46
Mean Frequency (Hz)	144	0.134	-0.28	-0.58	-0.57	0.07

Note. Mann-Whitney U Test.

Signal Parameter Relationships to Patient Demographics

When looking at the potential effects of patient demographics, it was chosen that normalized peak amplitude, SNR and median frequency would be summarized for each group as these measures showed the largest difference between the stroke the healthy groups. Each parameter was summarized and split based on self-reported severity, time passed since stroke, and if the side of measurement was on the affected or unaffected side. No formal statistical tests were used to compare between patient reported responses as sample sizes were too small.

All participants identified a side of weakness after having had their stroke. Their response was then compared with the side of the submental area measured during testing. If the side of weakness and the side used for measurement was the same, the patients were sorted in the "Affected" group and if they differed they were grouped as "Nonaffected". Extremity weakness on one side suggests that the site of lesion is contralateral to that side (i.e., if right limb is affected, left stroke can be expected). No notable differences existed between the measures of central tendency in any of the three parameters, however SNR appeared to be higher in the Affected group. The summary of each of the parameters can be found in Table 2.5.

Table 2.5 Comparison of normalized peak amplitude, SNR, and median frequency between measurements on affected vs. unaffected side

	Normalized Peak Amplitude		**SNR (dB)**		**Median Frequency (Hz)**	
	Affected	**Nonaffected**	**Affected**	**Nonaffected**	**Affected**	**Nonaffected**
Valid	12	8	12	8	12	8
Missing	0	0	0	0	0	0
Mean	1.01	1.10	10.51	6.32	97.45	109.2
Median	0.90	1.06	11.04	6.20	116.5	107.7
Std. Deviation	0.36	0.22	4.82	2.88	48.96	16.62
Range	1.25	0.69	12.94	7.93	130.8	40.79
Minimum	0.67	0.86	4.35	2.93	21.19	93.16
Maximum	1.92	1.55	17.29	10.86	152	134

All participants self-identified a date or date range (within 1 year) of when their stroke had occurred. These values were then used to evaluate if signal differences could potentially be related to time that has passed since the stroke occurred. Participants were split into two groups: seven subacute (<1 year) participants, and three chronic (>5 years) participants as shown in Table 2.6. Participants in the sub-acute *(M=7.62, SD=4.07)* group showed a lower mean and median SNR than those in the chronic group *(M=11.67, SD=4.78).* No notable differences were observed between the median frequency or normalized peak amplitude values in the two groups.

Table 2.6 Comparison of normalized peak amplitude, SNR, and median frequency between different time periods since stroke

	Normalized Peak Amplitude		SNR (dB)		Median Frequency (Hz)	
	< 1 year	**> 5 years**	**< 1 year**	**> 5 years**	**< 1 year**	**> 5 years**
Valid	14	6	14	6	14	6
Missing	0	0	0	0	0	0
Mean	1.02	1.11	7.62	11.67	97.36	113.3
Median	0.97	0.95	6.94	12.21	120.1	106.9
Std. Deviation	0.30	0.34	4.07	4.78	44.29	21.93
Range	1.25	0.73	13.62	13.09	130.8	52.64
Minimum	0.67	0.82	3.68	2.93	21.19	93.16
Maximum	1.92	1.55	17.29	16.02	152	145.8

All participants were asked to describe the severity of their swallowing impairment as mild, moderate, or severe. Based on these responses they were split by self-reported severity score. Five of the participants reported mild severity of dysphagia, four reported moderate, and only one participant identified as experiencing severe dysphagia. These descriptive statistics can be found in Table 2.7. The participant with self-reported severe dysphagia had the largest normalized peak amplitude of all groups (*M=1.43, SD= 0.68*) and the lowest median frequency values (*M = 48.3, SD=30.3*) of all groups. However, when comparing SNR, the moderate dysphagia group experienced the lowest SNR *(M=5.70, SD =2.50)*, whereas the group with mild impairment experienced the highest SNR *(M=11.62, SD=4.43)*.

Table 2.7 Comparison of normalized peak amplitude, SNR, and median frequency between self-reported dysphagia severity scores

	Normalized Peak Amplitude			SNR (dB)			Median Frequency (Hz)		
	Mild	**Moderate**	**Severe**	**Mild**	**Moderate**	**Severe**	**Mild**	**Moderate**	**Severe**
Valid	10	8	2	10	8	2	10	8	2
Missing	0	0	0	0	0	0	0	0	0
Mean	1.03	0.97	1.43	11.62	5.70	7.41	103.6	113.7	48.3
Median	0.95	0.93	1.43	12.21	4.73	7.41	120.3	107.7	48.3
Std. Deviation	0.23	0.26	0.68	4.43	2.50	4.23	44.1	22.8	30.3
Range	0.78	0.88	0.97	13.62	7.93	5.98	124.6	58.8	42.9
Minimum	0.75	0.67	0.95	3.68	2.93	4.42	21.2	93.2	26.9
Maximum	1.53	1.55	1.92	17.29	10.86	10.40	145.8	152.0	69.8

Test-Retest Reliability

Intraclass correlation coefficients (ICC) using a two-way random model for absolute agreement were used to evaluate the reliability of each parameter for the healthy and stroke groups. The average ICC values for each comparison can be found in Table 2.8. Normalized peak amplitude (*ICC=0*) and duration (*ICC=0*) exhibited poor test-retest reliability in stroke participants. However, in the healthy group, normalized peak amplitude (*ICC=0.520)* and duration *(ICC=0.935)* showed moderate and very good reliability in healthy participants, respectively. All other parameters in both groups demonstrated good to very good test-retest reliability.

Table 2.8 Intraclass correlation coefficients to evaluate test retest of parameters in healthy and stroke participants

			95% Confidence Interval		**F Test with True Value 0**			
Group	**Parameter**	**Intraclass Correlation^b**	**Lower Bound**	**Upper Bound**	**Value**	**df1**	**df2**	**Sig**
Healthy	Normalized Peak Amplitude	0.520	-1.196	0.884	1.994	9	9	0.159
	Duration	0.935	0.736	0.984	14.08	9	9	0.000
	SNR	0.835	0.438	0.963	6.711	9	9	0.005
	Median Frequency	0.975	0.892	0.994	49.70	9	9	0.000
	Mean Frequency	0.919	0.689	0.980	11.96	9	9	0.001
Stroke	Normalized Peak Amplitude	-0.182	-4.514	0.716	0.851	9	9	0.593
	Duration	-0.134	-3.828	0.722	0.883	9	9	0.572
	SNR	0.811	0.263	0.953	5.149	9	9	0.011
	Median Frequency	0.957	0.744	0.990	34.99	9	9	0.000
	Mean Frequency	0.761	0.053	0.940	4.053	9	9	0.024

Discussion

This study aimed to identify potential differences between sEMG signals collected in healthy individuals and those who have experienced a stroke. Two trials, each consisting of 20 saliva swallows were used to compare five parameters in ten healthy participants and ten stroke patients with dysphagia. These five parameters included normalized peak amplitude, duration, SNR, and median and mean frequency. The intention behind choosing these parameters was to further understand how activity in the submental muscles changes after stroke and how these changes could affect the use of sEMG biofeedback therapy in stroke patients. These values also were grouped based on stroke participants' self-reported side of weakness, time since stroke, and severity.

Signal Characteristics

A comparison of signal parameters between the two groups revealed that the only variable to show a significant difference was SNR. As hypothesized, the SNR in the healthy group was found to be significantly higher than in the stroke group. This suggests that the sEMG signals collected in healthy participants were of higher quality than the sEMG signals collected in participants with dysphagia after stroke. There are two likely factors that could have contributed to this difference: a difference in amplitude values of the segmented signals, and a difference in amplitude of the baseline signal.

Amplitudes of sEMG can be indicative of levels of force produced by muscle contraction (Diseehlhort-Klug, Schmitz-Rode, & Rau, 2009). While it is unknown how stroke affects force generation in the submental muscles, stroke has been demonstrated to result in reductions in muscle fiber length in larger muscles such as the gastrocnemius and brachialis (Gao & Zhang, 2006; Li, Tong, & Hu, 2007). These changes have been linked to decreased generated force (Gordon, Huxley, & Julian, 1966). Therefore, it is possible that a decrease in force generated could cause the root mean square of the amplitude values of the segmented signals (i.e., swallows) in stroke participants to be smaller than in healthy participants. A post-hoc analysis supported this hypothesis and demonstrated that the root mean square values of the segmented signals in stroke participants (*Mdn=0.0050, SD= 0.0030*) were significantly smaller than those observed in healthy participants *(Mdn=0.0075, SD=0.0086),* U=295.0, p=0.009.

Another possible cause of the lower SNR values in the stroke group could be the presence of higher amplitude values in the baseline recording while a patient is at rest. In order to understand whether this was a factor in the present study, amplitude thresholds calculated using the baseline signal, were examined post-hoc. When the calculated amplitude thresholds were compared between the two groups in the present study, the stroke thresholds *(M=0.011, SD=0.003)* were significantly larger than those in the healthy group *(M=0.015, SD=0.004),* t(19)=-2.739, p=0.009. These findings are consistent with those observed in the infrahyoid muscles (i.e., muscles below the level of the hyoid). Crary et al (1997) found that stroke participants exhibited significantly higher sEMG amplitudes at rest than the healthy controls at rest. They attributed this difference to hypertonicity of the submental muscles, symptomatic of an UMN lesion, or to increased anxiety in participants with swallowing impairment causing more muscle activity (M. A. Crary & Baldwin, 1997). Based on these findings, it can be suggested that a combination of the altered amplitude characteristics of both the segmented and baseline signals was the cause of lower SNR in the stroke participants in this data set.

Although no significant differences existed between the two populations for the frequency-domain parameters evaluated in this study, several inherent limitations related to the muscles of interest should be noted. The relatively small size of the submental muscles make correct placement difficult, potentially resulting in poor electrode alignment over the muscle belly and fibers of the muscle (Hermens et al., 2000). Poor alignment of sEMG electrodes can lead to greater attenuation of the signals, specifically in frequencies below 110 Hertz (Beck et al., 2009). In previous studies completing similar comparisons this is less likely to have been a problem because of the larger muscle size, allowing for simplified placement of sEMG sensors. For example, Toffola et al. (2001) compared the properties of sEMG after stroke in the tibialis anterior muscle which is much larger than the anterior belly of the digastric. Therefore, studies targeting larger muscles have less risk of incorrect sensor placement, potentially making the frequency components of the sEMG signal collected in these studies more robust.

Another factor that could have influenced the frequency domain characteristics is related to the location of the muscles of interest in this study and the surrounding musculature, making the results susceptible to cross talk (Hermens et al., 2000; Stepp, 2012). Although the anterior belly of the digastric was targeted, sEMG signal collected in the submental area is a combination of muscle activity from the anterior belly of the digastric, geniohyoid, and mylohyoid muscles. As the innervations of these muscles differ, there is a possibility that, after a stroke, some of the muscles are behaving normally while others are not (see Table 2.9).

Table 2.9 Summary table of submental muscle innervations and roles in swallowing activity (Kenneth Walker, Dallas Hall, & Willis Hurst, 1983; Shaw & Martino, 2013)

Muscle	**Cranial nerve innervation**	**UMN Infarct**	**LMN Infarct**
Anterior belly of the digastric	CN V	contralateral	ipsilateral
Geniohyoid	CN XII	contralateral	ipsilateral/bilateral
Mylohyoid	CN V	contralateral	ipsilateral

Signal Parameter Relationships to Patient Demographics

Three of the signal parameters were chosen to be compared between stroke participants who were grouped based on if the sEMG signal was collected on their affected versus non-affected side, time passed since stroke, and self-reported severity of swallowing impairment. The three parameters chosen were normalized peak amplitude, SNR, and median frequency. No formal statistical tests were used as the sample sizes for each of the groups were too small.

With respect to affected versus unaffected side, several limitations existed within the comparison. The definition of affected versus unaffected side only took into consideration if the measurement was taken on the side of peripheral weakness. This cannot act as an indication as to which submental muscles on that side were affected by the stroke (as per Table 2.9). This information cannot be predicted without further knowledge of the stroke severity and location.

When evaluating the relationship between SNR and time passed since stroke, the data in the present study demonstrate that the chronic group (> 5 years) exhibited higher SNR values than the subacute group (<1 year). Researchers have found that many individuals experience large improvements in swallowing ability within 6 months of their stroke (Wade & Hewer, 1987). This may be the result of activity at the level of the motor units in the submental muscles. As early as 9 days post stroke motor units begin to reorganize themselves, allowing for the reinnervation of motor units that were no longer receiving motor inputs. This reorganization does not stabilize for approximately 3 months (Gray, Rice, & Garland, 2012). Six of the seven participants in the subacute group had experienced their stroke within three months of data collection, suggesting that reorganization may not have yet stabilized and that they may show more functional improvement in the future. Currently, there is no research exploring the relationship between functional swallowing ability and SNR. Future research is warranted to better understand how severity of swallowing impairment affects signal quality of sEMG signals and the potential effects on sEMG biofeedback therapy.

The relationship between self-reported severity scores and the three signal parameters also was summarized. The results suggest that the participants with mild dysphagia exhibit higher SNR than those who identify as having a more severe swallowing impairment, indicating that the signals are of better signal quality. At a muscular level more severe swallowing impairment may be the result of a decrease in functional range and force produced by the submental muscles, preventing individuals from effectively protecting their airways (Gray et al., 2012; Perlman, Grayhack, & Booth, 1992). A decrease in functional range may be associated with higher levels of hypertonicity in the muscles, which would also result in larger amplitude values during baseline sEMG (M. A. Crary & Baldwin, 1997). A combination of these two factors may have contributed to the lower SNR values in participants who self-identified has having more severe swallowing impairment.

Test-Retest Reliability

The test-retest reliability of the sEMG signals collected in trial one and trial two were compared for the healthy and stroke groups. The results suggest that test retest reliability was moderate to very good for all parameters with the exception of normalized peak amplitude and duration in the stroke group. Both of these parameters demonstrated very poor test-retest reliability. These results suggest that although normalized peak amplitude and duration are reliable measures in healthy participants they are not reliable in stroke survivors with swallowing impairment. The poor test-retest reliability of these measurements may be associated with the inconsistent presence of associated movement during swallowing tasks. Future research is warranted to better understand why these values exhibit such poor repeatability.

Conclusion

This study aimed to act as a proof of concept to compare both time and frequency domain characteristics of sEMG signal collected in the submental area during swallowing. For this reason, the frequency measures selected provide a simplified comparison of the power spectrum rather than a detailed characterization of the changes in frequency profile observed between healthy participants and participants who experience swallowing impairment following stroke. In order to further characterize changes in sEMG signals that may be due to fatigue and other such factors, additional techniques such as wavelet analysis, averaged instantaneous frequency, and bi-modal analysis of fast twitch and slow twitch muscle fibers could be utilized.

In regard to patient demographics observed in this study, self-reported severity scores may have been an unreliable measure of dysphagia severity. The responses of the individuals could have been impacted by several psychosocial factors including relative improvement in their swallowing function, a lack of understanding what “severity” meant in the context of this study, and unawareness of their impairment despite observations of choking or frequent throat clearing during data collection. Collecting more reliable information about the type and location of stroke and severity of dysphagia, as well as increasing the sample size would strengthen this study.

The findings of the present study suggest that the only parameter to differ between swallowing sEMG signals in healthy participants and participants with dysphagia after stroke was SNR.

Additionally, the data suggest that patients who had their stroke at least 5 years prior to data collection and patients who identify as having mild swallowing impairment may have higher SNR values. Clinically, this means that sEMG signals associated with swallowing may be more difficult to differentiate from background noise in stroke patients, specifically those who are in the acute stages of recovery or who identify as having more severe swallowing impairment.

This lower signal quality may impact the effectiveness of sEMG biofeedback therapy in some stroke patients. Further research is warranted to confirm if time since stroke and severity of swallowing impairment reduce sEMG SNR values, and to better understand when sEMG biofeedback therapy would be most effective. In order for biofeedback therapy to be successful the patient must be able to recognize visualized sEMG signals specifically associated with the desired muscle activity and level of effort. Low SNR values may result in the inability to differentiate muscle activity from background noise. Further evaluation of how SNR values impact the efficacy of sEMG biofeedback during swallowing therapy is required.

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Chapter 3. Evaluating the Performance of a Swallow Detection Algorithm Designed for Head and Neck Cancer Patients in the Stroke Population

Introduction

Stroke is the most common cause of dysphagia, also known as swallowing difficulties, affecting approximately 30-50% of all stroke survivors (Han et al., 2016). Most often, strokes result in oropharyngeal dysphagia, which impacts motor and sensory abilities in the oral and pharyngeal stages of swallowing (Zhao, Liu, & Li, 2015). This dysfunction can result in the inability to effectively protect the airway, increasing the risk for serious complications such as aspiration pneumonia, chemical pneumonitis, or death (Crausaz & Favez, 1988; Perlman, Grayhack, & Booth, 1992). After having a stroke the patient's swallowing abilities are assessed. Assessment can identify the severity of dysphagia and stages of swallowing that were most profoundly affected. Following this, speech-language-pathologists will often prescribe exercise-based swallowing therapy (Nund et al., 2014). Several researchers have suggested that providing surface electromyography (sEMG) biofeedback to patients, while completing rehabilitative exercise therapy, may improve functional outcomes such as oral intake (i.e., food consistency) and assist in the adoption of proper technique during more complex exercises (Athukorala, Jones, Sella, & Huckabee, 2014; Crary, Carnaby, Mann, Groher, & Helseth, 2004). sEMG sensors measure muscle activity and can be used to target the submental muscles responsible for hyolaryngeal elevation during swallowing, providing a representation of muscle force and timing to patients and clinicians. However, in order to provide the best opportunity for long term improvement, patients need ongoing and consistent intensive therapy (Burkhead, Sapienza, &

Rosenbek, 2007). Unfortunately, limited resources often prevent patients from receiving this type of support throughout their post-treatment period (Nund et al., 2014).

The emergence of mobile health (mHealth) technologies have become increasingly popular due to limited access to healthcare. mHealth technologies provide a unique opportunity to improve health service delivery, patient support, and therapy monitoring and management (Gagnon, Ngangue, Payne-Gagnon, & Desmartis, 2016). This new field of medicine has led to an increased interest in how to best provide therapy that is comparable to what a patient would receive in clinic regardless of a patient's location. Constantinescu et al. (2014) suggested that an mHealth device could help to address concerns in dysphagia management, specifically if it were capable of providing sEMG biofeedback (Constantinescu, Stroulia, & Rieger, 2014). Mobili-T®, is an mHealth system developed in Edmonton, Canada to facilitate remote swallowing therapy for patients experiencing dysphagia after head and neck cancer. The system contains both a hardware component, with built in sEMG sensors and Bluetooth capabilities, and a mobile application (app). The Mobili-T® provides therapy similar to what would be observed in clinical biofeedback therapy. It does so by measuring muscle activity in the submental muscles during swallowing and wirelessly transmitting these signals to provide visual biofeedback to the patient on their smartphone. However, other non-swallowing tasks can also produce sEMG signal.

Surface electromyography sensors measure the voltage difference that exists between the two pick-up electrodes. Head movements can cause these electrodes to move, resulting in high amplitude, low frequency spikes in sEMG signal. Additionally, other non-swallow tasks such as tongue and lip movements also cause an increase in sEMG amplitude that can look similar to signals produced by swallowing (Constantinescu et al., 2017). To address this, a swallow-detection algorithm was developed to ensure correct feedback was provided for any type of sEMG activity, including swallow and non-swallow actions. By classifying incoming sEMG signals as swallows or non-swallows, this algorithm allows patients and clinicians to monitor the number of swallows completed and their progress through treatment plans without having to be in clinic.

To use the device, the patient must first begin with calibration. This requires the recording of a 15 second baseline signal. This signals acts as a reference of sEMG signal while no muscle activity is taking place. After this, the patient must then complete five saliva swallows that are used to calculate normalized amplitude values of incoming sEMG signals (Equation 3.1). This is particularly important because of the poor repeatability of amplitude measures in sEMG (Gilmore & Meyers, 1983). Using this value allows for a comparison of amplitude consistency within trials rather than a comparison of raw amplitude values, which may differ significantly each time the device is placed.

$$Equation\ 3.1\ Normalized\ Peak\ Amplitude = \frac{Segmented\ Peak\ Amplitude\ (mV)}{Average\ Peak\ Amplitude\ Calibration\ (mV)}$$

This algorithm involves two stages: event segmentation and event classification. Before segmentation begins, the signal is smoothed using a 100 ms discrete moving average filter. Segmentation is completed using a dual-threshold method, identifying periods of increased sEMG amplitude that exceed both the duration threshold and amplitude thresholds. The duration threshold is calculated based on the average duration observed in the five calibration swallows. The amplitude threshold is calculated by values from the baseline recording, as defined in

Equation 3.2. The initial and final amplitude threshold crossings are used to identify the points where events are segmented from the raw sEMG signal. If the signal amplitude never exceeds the amplitude threshold, these signals are not successfully segmented and are categorized as non-swallows.

$$Equation\ 3.2\ Amplitude\ Threshold = Baseline\ mean + 2 * Baseline\ standard\ deviation$$

After the events have been segmented from the raw signal, the algorithm performs both time and frequency domain analyses, classifying the incoming signals based on characteristics of both. Classification is completed using a probability equation, which compares the characteristics of the incoming signal to task models that were created using a generic data set of six healthy individuals. These task models include both swallow and non-swallow tasks that are commonly associated with swallowing such as tongue, lip, and head movements. The parameters that were used to compare these models were the normalized peak amplitude, duration, and the 50th and 15th percentile of the power spectrum density obtained by performing a Fast Fourier Transform (FFT).

Commonly, algorithm performance is evaluated using measures such as recall (sensitivity), precision, specificity, and accuracy. These values can provide information about an algorithm's ability to classify incoming information correctly and as expected. However, recall is one of the preferred measures when data sets consist of an unequal proportion of true negative and true positive inputs (Davis & Goadrich, 2006). Constantinescu et al. (2017) evaluated the same Mobili-T® algorithm in ten head and neck cancer patients with oropharyngeal dysphagia and ten healthy participants. The ratio of swallow inputs to non-swallow inputs was 1:2. In head and neck cancer patients the algorithm performed with an average recall of 92.7% *(SD = 9.15%)* (Constantinescu et al., 2017).

The intent of the present study was to evaluate the same automated swallow detection algorithm in stroke patients, which is the largest demographic affected by dysphagia. As part of this evaluation, if the results suggested that the performance was outside of the acceptable performance range (i.e., one standard deviation of the values observed in head and neck cancer patients), the algorithm would be modified specifically for the stroke population. This would be done by generating a modified version of the algorithm using data from five stroke participants and re-evaluating its performance in the remaining participants.

Due to the heterogeneous nature of the stroke population, it was expected that algorithm performance would vary between participants. However, it was hypothesized that a modified version of the algorithm using signal characteristics specific to stroke could improve recall, if necessary.

Methodology

Participants

Recruitment for this study included twelve participants currently experiencing oropharyngeal dysphagia after stroke, however only eleven participants were included in the analysis as one was unable to initiate swallows using only saliva. All participants had no history of other comorbidities that could affect their swallowing mechanism and all were over the age of 18. Ethical approval was received from the Research Ethics Office at the University of Alberta, the Northern Alberta Clinical Trials and Research Center (NACTRC), and Covenant Health prior to beginning this study.

Data Collection

An updated version (V2.0) of the device used by Constantinescu et al. (2016) was attached to the participants' submental area using a custom manufactured 3M medical grade adhesive. Efforts were made to outfit all participants with the device on the right side of their neck, however in two participants the left side was used. One of these participants was clean shaven only on the left submental area making it the only viable location for the sEMG device and the other participant had a superficial hematoma on the right side of their submental area. In this case it was confirmed that this injury was unlikely to affect the swallowing mechanism. The device utilized a sampling frequency of 1000 Hz and wirelessly transmitted sEMG data to a custom software suite developed for data collection.

Each participant was required to complete two trials, each consisting of two sets of tasks: one baseline measurement, where they were instructed to relax all submental muscles for 20 seconds, followed by 20 regular saliva swallows. However, in one participant only one trial, consisting of a baseline measurement and 15 swallows, was completed as they were unable to complete the second trial because of discomfort from a nasogastric tube. One other participant was also using a nasogastric tube at the time of data collection and presented no discomfort during swallowing repetitions. Signal quality was verified before beginning data collection using a custom

MATLAB script to ensure the device was properly placed, allowing for good conduction between the skin and the pickup electrodes.

Before beginning data collection each of the 11 participants were asked several questions about their swallowing impairment including:

1. If they would rate their swallowing impairment as mild, moderate, or severe.
2. If their normal diet consists of solid food, pureed foods, or no oral intake.
3. The date of their stroke, from which the days that had passed since stroke was calculated. They were then split into three groups: less than one month, one month to one year, and more than one year

During the swallow tasks, each participant was instructed to try to complete all swallow preparation and saliva collection movements before recording began. This was done in order to assist with isolating swallow signals. This proved to be difficult because many participants were unable to complete the swallowing tasks without the presence of associated movement. In some cases participants were limited by their swallowing abilities and in others they struggled with multiple stage instructions. For example, some participants were able to understand that they should indicate when they are ready to swallow and then swallow upon the researcher's instruction; however, they were unable to complete the swallowing task without the presence of associated movements such as head and lip movements. A schematic of the data collection procedure can be seen in Figure 3.1.

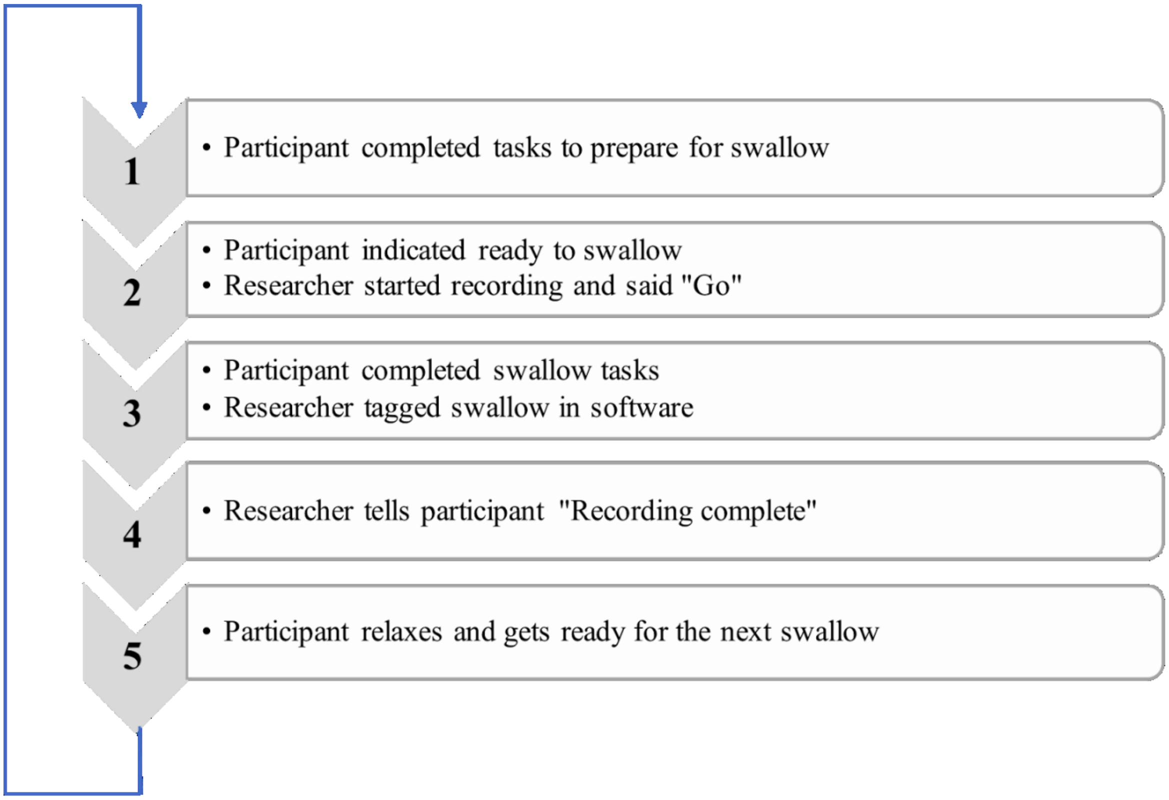


Figure 3.1 Data collection procedure schematic

The researcher was signaled to begin the recording of the sEMG signal by the participant when they were prepared to swallow. During data collection, all swallow events were tagged in real-time by placing timestamps in the sEMG data stream where a swallow occurred. After each signal was captured, it was saved in an individual file and named according to participant and task number.

Data Processing

For each participant, one baseline signal and all dry swallows completed were used to evaluate the performance of the algorithm. All data were pre-processed using a second order Butterworth band pass filter with cutoff frequencies of 5 and 250 Hz to remove low-frequency noise and prevent aliasing. Additionally, notch filters were included at harmonics of 25 Hz and at 60

Hz. The first five swallows from each trial were used for calibration and subsequently in the calculation of normalized peak amplitude. Six participants were randomly selected to be included in the Testing group which was used in the evaluation of the algorithm. The remaining five participants were assigned to the Training group. If recall was low, the Training group would be used to generate a modified version of the algorithm, to be retested with the data from the Testing group. The only modification to be made to the algorithm would be the inclusion of a "stroke saliva swallow" classifier specific to the data included in the Training group. If recall was within the predetermined limits, the Training group and Testing group files would be pooled to evaluate performance with a larger data set. The participants included in each group can be found in Table 3.1.

Table 3.1 Participants included in training and testing groups

Training group	**Testing group**
sEMGM002	sEMGF001
sEMGM003	sEMGF004
sEMGF006	sEMGF007
sEMGF011	sEMGF008
sEMGF012	sEMGM009
	sEMGM010

In the original version of the algorithm, the classification stage was completed using task models that were developed for different swallowing and non-swallowing tasks in 6 healthy individuals. These task models included 3 swallowing tasks: dry saliva swallows, effortful swallows, the Mendelsohn maneuver (a swallowing exercise commonly used in clinic), and several non-swallowing tasks such as extraneous head and lip movements (Constantinescu et al., 2017).

Outcome Measures

During data collection, all swallow recordings were tagged at the point when a swallow was completed. This was done to minimize uncertainty and avoid the need for post-hoc swallow identification, which could potentially introduce rater error. All data included in the Testing Group was used as an input to the two-stage algorithm. As all signals that were run through the algorithm contained true swallow activity, there were only three potential outputs from the algorithm: True Positives (TP) if there was a tag present and signal was classified as a swallow, False Negative (FN) if there was tag present and the signal was classified as noise, and Swallows Not Segmented (SNS) if there was a tag present but no events of interest were segmented. A summary table of this system can found below in Table 3.2.

Table 3.2 Summary of algorithm classifications

	Classified as "Swallow"	**Classified as "Noise"**	**Signals not segmented**
Swallow Tag Present	True Positive (TP)	False Negative (FN)	Swallow Not Segmented (SNS)

The proposed outcome measure for the evaluation of the algorithm is calculated as shown in Equation 3.3

$$\text{Equation 3.3} \quad Recall = TP / (TP + FN + SNS)$$

Recall was chosen as the primary evaluation parameter for this study. Recall refers to the percentage of swallows that the algorithm classifies correctly over the total number of swallows that occur. In the event that a modified algorithm was generated a one-tailed Student's t-test would be used to identify if the average recall values achieved by the modified algorithm were higher than those in original algorithm when tested with stroke data. Additionally, recall values for each trial were calculated and summarized.

Results

Participants

Eleven participants were included in this study. The demographic information collected for each participant can be found in Table 3.3.

Table 3.3 Patient reported demographics in regard to age, severity, side of weakness, oral intake, and time passed since stroke

Participant	**Sex**	**Age**	**Severity**	**Side of weakness**	**Oral intake (food consistency)**	**Days since stroke**
sEMGF001	Female	79	Mild	Left	No oral intake	9
sEMGM002	Male	52	Mild	Right	Solid foods	9
sEMGM003	Male	62	Mild	Right	Solid foods	1859
sEMGF004	Female	49	Moderate	Right	Pureed foods	30
sEMGF006	Female	74	Moderate	Right	Pureed foods	41
sEMGF007	Female	63	Mild	Right	Solid foods	3229
sEMGF008	Female	65	Mild	Left	Pureed foods	113
sEMGM009	Male	68	Mild	Left	Solid foods	10
sEMGM010	Male	49	Severe	Left	No oral intake	12
sEMGF011	Female	60	Moderate	Left	Solid foods	4527
sEMGF012	Female	73	Moderate	Right	Solid foods	83

These participants were randomly split into Training and Testing groups to be used during algorithm evaluation. The responses of the individuals in each group were summarized and are presented in Table 3.4. The Testing group included individuals with self-reported mild, moderate, and severe dysphagia whereas the Training group only included individuals who identified as having mild to moderate swallowing impairment. In regard to oral intake, two participants included in the Testing group had no oral intake, whereas all participants in the Training group were on diets consisting of solid or pureed foods. When comparing time that had passed since the stroke had occurred both groups had participants who fell in all three categories (i.e., < 1 month, 1 month to 1 year, and 1 year).

Table 3.4 Patient demographics summary of training and testing groups

	Self - Reported Rating	**Testing Group**	**Training Group**
Severity	**Mild**	**4**	**2**
	Moderate	**1**	**3**
	Severe	**1**	**0**
Oral Intake	**Solid foods**	**2**	**4**
	Pureed foods	**2**	**1**
	No oral intake	**2**	**0**
Time Since Stroke	**< 1 month**	**3**	**1**
	1 month - 1 year	**2**	**2**
	> 1 year	**1**	**2**

Algorithm Evaluation

Fifteen saliva swallow signals for each trial were run through a two-stage algorithm, except for one participant who was only able to complete 15 saliva swallows, 10 of which were run through the algorithm. When tested in the original algorithm the recall was 74.54%. When compared with the values (*M = 92.7, SD = 9.15)* achieved by Constantinescu et al. (2017) this performance was less than one standard deviation below the outcomes of that study and therefore deemed not within the acceptable range.

A modified version of the algorithm was then generated using the data from the five participants included in the Training Group. Using these signals, a model for "stroke saliva swallows" was developed and introduced in the classification stage of the algorithm. The data from the Testing Group was then re-run through the modified version of the algorithm. The recall values from the original and modified algorithms for each trial can be found in Figure 3.2.

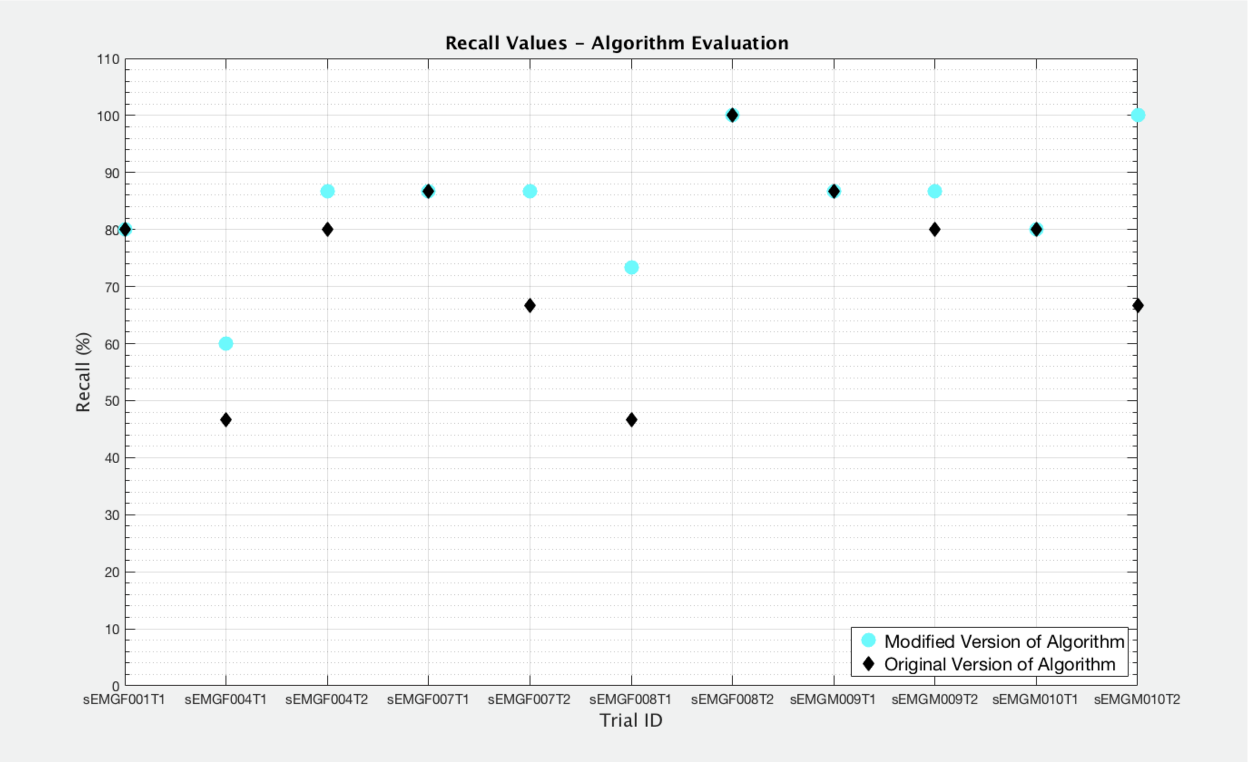
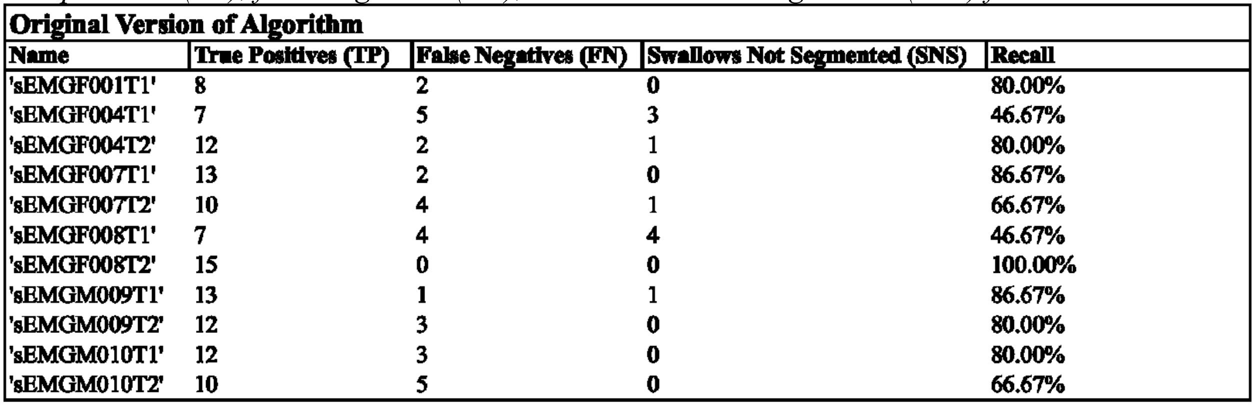


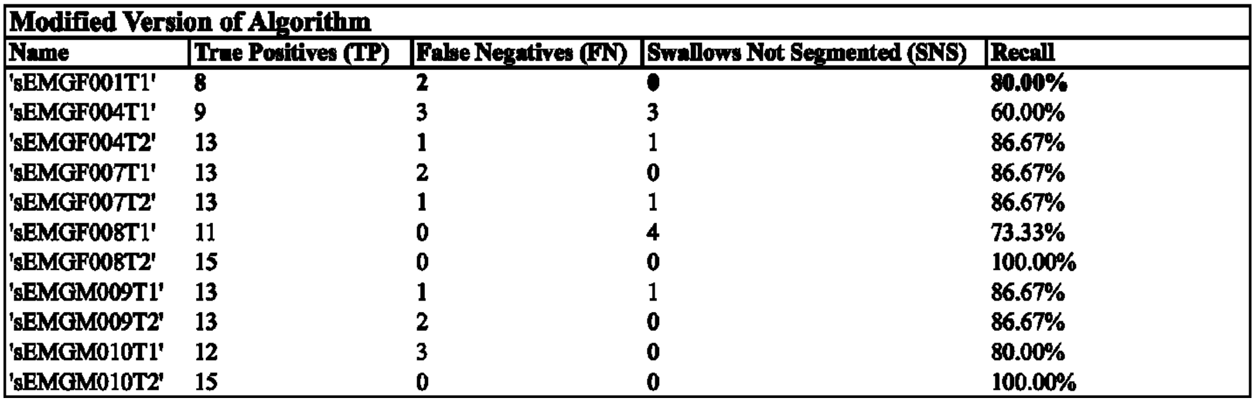
Figure 3.2 Individual recall values for each trial

The number of TP, FN, and SNS from each individual trial for the original and modified algorithm are presented in Table 3.5. Six of the trials included in the Testing group demonstrated improved recall values in the modified algorithm, whereas five demonstrated no change. No changes to the number of SNSs occurred between the original and modified algorithm.

Table 3.5 Summary of original and modified algorithm performance including the number of true positives (TP), false negatives (FN), and swallows not segmented (SNS) for each trial



Original Version of Algorithm				
Name	**True Positives (TP)**	**False Negatives (FN)**	**Swallows Not Segmented (SNS)**	**Recall**
'sEMGF001T1'	8	2	0	80.00%
'sEMGF004T1'	7	5	3	46.67%
'sEMGF004T2'	12	2	1	80.00%
'sEMGF007T1'	13	2	0	86.67%
'sEMGF007T2'	10	4	1	66.67%
'sEMGF008T1'	7	4	4	46.67%
'sEMGF008T2'	15	0	0	100.00%
'sEMGM009T1'	13	1	1	86.67%
'sEMGM009T2'	12	3	0	80.00%
'sEMGM010T1'	12	3	0	80.00%
'sEMGM010T2'	10	5	0	66.67%



Modified Version of Algorithm				
Name	**True Positives (TP)**	**False Negatives (FN)**	**Swallows Not Segmented (SNS)**	**Recall**
'sEMGF001T1'	8	2	0	80.00%
'sEMGF004T1'	9	3	3	60.00%
'sEMGF004T2'	13	1	1	86.67%
'sEMGF007T1'	13	2	0	86.67%
'sEMGF007T2'	13	1	1	86.67%
'sEMGF008T1'	11	0	4	73.33%
'sEMGF008T2'	15	0	0	100.00%
'sEMGM009T1'	13	1	1	86.67%
'sEMGM009T2'	13	2	0	86.67%
'sEMGM010T1'	12	3	0	80.00%
'sEMGM010T2'	15	0	0	100.00%

The average percentage of signals classified as true positives, false negatives, and swallows not segmented can be found in Figure 3.3. The average number of swallows that were classified as TPs increased in the modified algorithm, also resulting in a decrease in the number of signals classified as FNs. However, on average 6.06% of signals were classified as SNSs. This value did not change between the two algorithm iterations as the modification to the algorithm did not affect the segmentation stage.

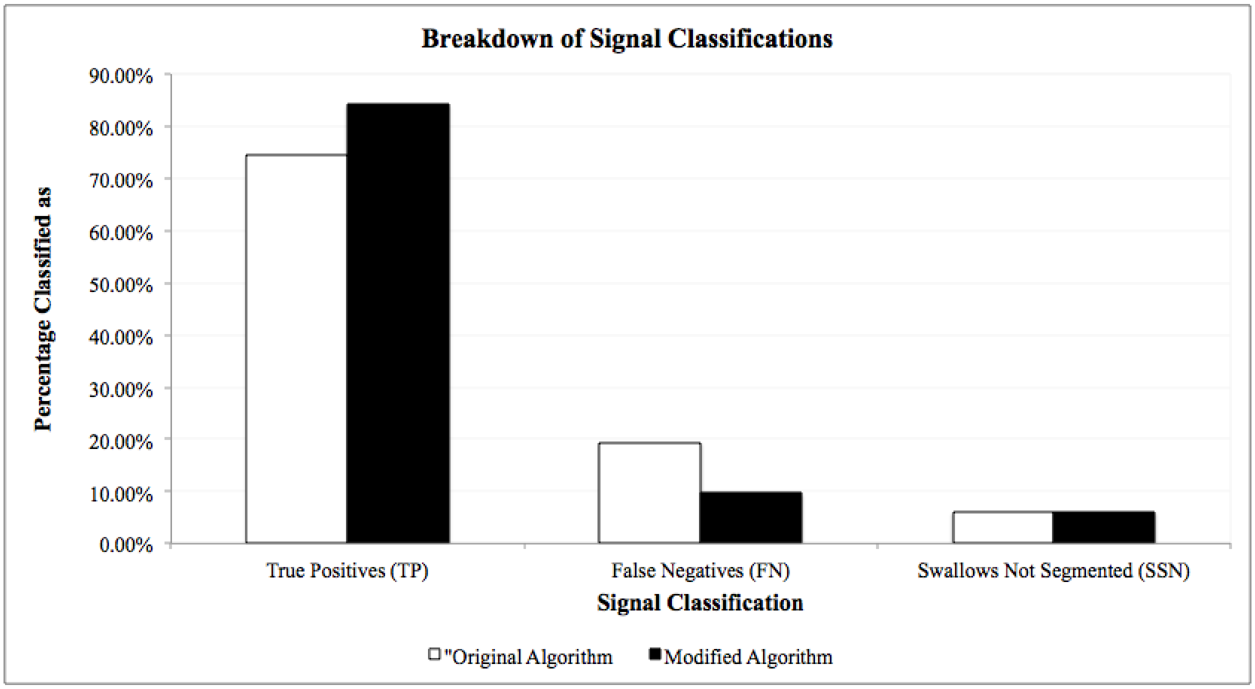


Figure 3.3 Percentage of signals classified as true positives, false negatives, and swallows not segmented for original and modified algorithm

A summary of the central tendency and variability measures for the recall values in the original and modified algorithms can be found in Table 3.6.

Table 3.6 Descriptive statistics for recall performance in original and modified algorithms

	N	**Mean**	**Std. Deviation**	**Std. Error Mean**
Recall - Original Algorithm	**11**	**74.55%**	**16.55%**	**4.99%**
Recall - Modified Algorithm	**11**	**84.24%**	**11.26%**	**3.40%**

All data passed Shapiro-Wilk test for normality (α=0.05) and therefore a one-tailed pairwise Student's t-test was used to identify if the recall values achieved by the modified algorithm were higher than those achieved by the original algorithm. This test revealed that the modified algorithm *(M=84.24, SD=11.26)* performed significantly better than the original algorithm *(M=74.55, SD=16.55)*, t(10)= -2.667, p=0.024.

Discussion

The primary purpose of this study was to determine if an already existing swallow detection algorithm, developed for a remote biofeedback therapy device, could be used to provide accurate feedback to individuals with dysphagia after having had a stroke. All data from six randomly selected participants were chosen to be included in the Testing group, while the data from the other five participants were included in the Training group. Although the performance of the original algorithm was outside of the acceptable range, the modified version of the algorithm performed significantly better than the original and was within the acceptable range.

There are several potential reasons why the original algorithm may have performed so poorly. As mentioned earlier the algorithm classifies incoming signals based on four parameters: normalized peak amplitude, duration, and the 15th and 50th (i.e., median frequency) percentile of the power spectrum density. The original version of the algorithm was developed using signals from healthy individuals, which may exhibit different time and frequency domain characteristics to those collected in the stroke population. That is to say that notable differences in these parameters between the data being fed into the algorithm and the data used to create the original task models in the algorithm, could hinder algorithm performance.

One potential cause of changes to these parameters could be the more prominent presence of associated movements during swallows in the stroke participants as opposed to the healthy individuals used to create the original algorithm. During data collection many participants struggled to successfully complete the preparatory movements before signaling that they were ready to complete the swallow. Instructions were often simplified for these patients to ensure that the researcher captured too much (i.e., preparatory movements and the swallow) instead of too little (i.e., participant swallows before they signal to the researcher to begin recording). This resulted in some signals that were contaminated with movement.

The parameters most likely to be affected by the presence of associated movement were the normalized peak amplitude, and 15th and 50th percentile of the power spectrum density. Associated movement often presents as low-frequency, high amplitude spikes. These spikes would be especially problematic if the presence of associated movement was inconsistent throughout the same trial (i.e., when the participant has more difficulty swallowing they are more likely to complete these movements). This would result in inconsistent values for normalized peak amplitude within a trial, suggesting that amplitude values were deviating from those observed in the calibration swallows. Additionally, more low-frequency energy would cause a downward shift in the power spectrum density, resulting in a decrease of both the 15th and 50th percentile values. If any of these three parameters were affected by the movements this could have resulted in the algorithm classifying true swallow signals as FN.

Another potential cause of the poor performance of the original algorithm could be associated with the pre-processing techniques that were used in this data. Because of the large amounts of low frequency noise present in the signals all data were pre-processed to remove frequency content below 5 Hz, and apply notch filters at harmonics of 25 Hz. These noise characteristics were likely caused by two factors: the hardware and software used for data collection, and the presence of more associated movements. Although the filtering resulted in sEMG signals that more closely resembled those used to train the original algorithm, the same pre-processing was not completed in the original version of the algorithm. This may have resulted in changes to the power spectrum density and bandwidth of the sEMG signals collected in this study, potentially changing the 15th and 50th percentile values in this data set.

In theory, these problems should have been addressed through the creation of a modified algorithm, using the same data collection setup and pre-processing techniques, in the same population. As predicted, the modification of the algorithm using these data was shown to significantly improve the recall values in this data set. The recall values improved from 74.55% in the original algorithm to 84.24% in the modified algorithm. This suggests that the inclusion of a task model for “stroke saliva swallows”, that contains characteristics specific to this data set, can improve the algorithm’s ability to correctly classify sEMG signals.

When looking at the original and modified algorithm performance for each trial, several observations can be made. Recall values improved in six of eleven included trials. The largest improvement observed was a recall value of 66.7% in the original algorithm and 100% in the modified algorithm. On the other hand, five of the trials showed no improvement between the original and modified versions of the algorithm. This failure to correctly classify these signals is likely due to heterogeneity of the stroke participants included in this study, specifically differences that may have existed between the Testing and Training groups.

The “stroke saliva swallow” task model that was developed in the modified algorithm was entirely based on the data from the participants included in the Training group. However, demographic differences existed between the Training and Testing groups. This potentially resulted in a task model that does not accurately represent the characteristics of the swallows in the Testing group. The Training group did not include any individuals who self-identified as having severe swallowing impairment and also did not include any individuals who were currently on restrictive diets with no oral intake. Moreover, there were more people in the Training group who were further out from the original date of their stroke. This, theoretically, could have allowed for more time for recovery in this group and, hence, better swallowing muscle behavior. These factors may have skewed characteristics as the individuals in the Training group may have had less impaired swallowing ability than those in the Testing group. Also, the small number of samples included in the Training set make the developed task model vulnerable to outliers. The inclusion of one trial that greatly differed from the others could result in further differences between the Training and Testing groups, decreasing the likelihood that the algorithm would correctly classify the signals.

When the performance of the modified algorithm (*M=84,24, SD=11.26*) in stroke participants was compared with the results achieved by Constantinescu et al. (2017) in the head and neck cancer population (*M=92.7, SD=9.15*), they still appear to be lower. There are several factors that may have contributed to lower recall values in the present data set. As mentioned earlier, all other task models used for classification were created with signals collected in healthy adults using different versions of the hardware and software and were not pre-processed. These factors may have contributed to signal characteristics specific to this data set that were independent of swallowing abilities of the stroke participants. These differences, may have contributed to the number of swallows that were incorrectly classified during the classification stage of the algorithm.

Failures during the segmentation stage may have also played a role in the poorer performance of the modified version of the algorithm. The segmentation stage of the algorithm is completed when the sEMG signal exceeds the amplitude threshold value, which is determined by the baseline signal. Five trials out of eleven contained at least one swallow that was not successfully segmented, with the highest number reaching four SNSs in one participant. The failure to successfully segment these signals could be due to two factors: a low peak amplitude value in the sEMG signal being segmented or larger amplitudes in the baseline signal, resulting in a larger amplitude threshold. This suggests that changes to the technique used to calculate amplitude threshold may improve algorithm performance in stroke survivors as more signals would progress to the classification stage.

Although the recall values of the modified version of the algorithm in this study were not as high as those achieved in the head and neck cancer group by Constantinescu et al. (2017), the results of the present study suggest that such an algorithm may be used to detect swallows in persons with swallowing impairment after stroke. In the modified algorithm a recall of at least 80% was achieved in all but two trials, both of which demonstrated at least 20% of signals failing to be segmented successfully. This further suggests that improvements to the segmentation stage may be critical to further improve recall values.

The feasibility of using an algorithm in an independent sEMG biofeedback therapy device appears promising, especially with further modifications to the existing algorithm. Algorithm performance appeared to remain consistent across different participant self-reported severity, time since stroke, and oral intake food consistencies. For example, the signals collected in participants with no oral intake who were currently on nasogastric tubes still demonstrated high recall range (80-100%). This suggests that such an algorithm could be used at different points of a patient's recovery and for patients exhibiting different severities of swallowing impairment. However, it should be noted that further exploration is required to understand how cognitive or other impairments in persons after stroke could inhibit independent swallowing therapy. For example, patients may be incapable of attaching the adhesive to the device, self-placing the device, or navigating through the therapy app. These usability aspects of the device should be evaluated further.

Conclusion

To understand if the findings from this study could be generalized to the stroke population, additional research should be completed including more stroke participants with dysphagia. This would allow for a larger set of data to be allocated to training this modified version of the algorithm, allowing for more robustness in classification. Additionally, a larger sample size should be used for the evaluation of the algorithm. Ideally, these participants would be at different stages in their post-stroke recovery and researchers also would have access to their formal swallowing assessments and medical history. This would provide more information on how severity of swallowing impairment and time passed since stroke influences the recall of the swallow detection algorithm. This information would allow researchers to better understand the best-use cases for such an algorithm.

This study was intended to act as a proof of concept that a currently existing algorithm, designed for head and neck cancer patients, could be modified to be used in the stroke population. The findings suggest that the modified algorithm performs within an acceptable range with stroke patients, however this performance could be further improved with modification to the segmentation stage of the algorithm and by the inclusion of more participants. The findings from the present study suggest that this swallow-detection algorithm could be an effective tool for swallow detection in stroke patients with different severities of dysphagia and at different periods throughout their treatment.

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Chapter 4. General Conclusions and Recommendations

Conclusions

Two studies were conducted with the overarching goal of better characterizing swallows in stroke survivors to understand how these signals can be used to clinically benefit patients. Both of the studies were designed to act as proof of concept, allowing researchers to know how to focus later, more powerful studies.

In Chapter Two, ten healthy participants and ten stroke participants were required to complete two trials of 20 saliva swallows. These swallows were then characterized and averaged for each of the trials using the following five parameters: normalized peak amplitude, duration, signal to noise ratio (SNR), median frequency, and mean frequency. Five independent Mann-Whitney U tests were used to compare each of the parameters between the stroke and healthy groups. The findings suggest that of the five parameters compared SNR was the only to differ significantly. SNR values in the healthy participants *(Mdn=13.7, SD=5.4)* was significantly higher than those observed in the stroke participants *(Mdn=8.1, SD=,4.6)*, U=325, p=0.004.

In addition to this test-retest reliability was evaluated for each of the parameters in the healthy and stroke groups using intraclass correlation coefficients (ICC). The results from this suggest that normalized peak amplitude *(ICC=0)* and duration (*ICC=0)* in the stroke group demonstrated very poor test-retest reliability. However, the same trend was not observed in healthy participants who demonstrated moderate to very good test retest reliability in all parameters.

In Chapter Three, an existing algorithm that was designed for swallow detection in head and neck cancer patients was tested to see if it could accurately classify incoming sEMG signals in stroke survivors. This algorithm involved two stages: segmentation and classification. During the segmentation stage signals were segmented into events of interest using an amplitude threshold that was calculated using a baseline recording, specific to that trial. If signals successfully exceeded the amplitude threshold they were segmented and moved onto the classification stage.

This study included eleven stroke participants. Six participants were randomly assigned to the Testing Group, and the remaining five were assigned to the Training Group. Recall (i.e., the proportion of swallows that were classified correctly) was used as the measure to evaluate algorithm performance. It was predetermined that if the recall of the original algorithm was outside of the acceptable range (+/- 1 standard deviation) of the results in head and neck cancer patients (*M= 92.7% ,SD = 9.15*) published by Constantinescu et al. (2017) a modified version of the algorithm would be generated and re-tested *(Constantinescu et al., 2017)***.**

The original version of the algorithm performed with a recall of 74.55%. Because this value fell outside of the acceptable range a modified version of the algorithm was generated using the data included in the Training Group. The results from a one-tailed pairwise Student's t-test suggested that the modified algorithm (*M=84.24, SD=11.26*) performed significantly better than the original algorithm (*M=74.55, SD=16.55*), t(10)= -2.667, p=0.024. When comparing the recall values from this study with those achieved in the head and neck cancer population, the performance of the modified algorithm falls within the acceptable range but are lower.

The lower recall values associated with the stroke data set analyzed in Chapter 3 may be a result of the signal characteristics presented in Chapter 2. For instance, the SNR values of the stroke participants *(Mdn=8.1 dB, SD=4.6 dB)* were quite low. Although there is no specific value for sEMG SNR that acts as a cutoff for poor signal quality, the values observed in Chapter 2 can be compared to those in literature. Constantinescu et al. (2017) reported sEMG SNR values in healthy and head and neck cancer participants with dysphagia during dry swallows. When comparing the values observed by Constantinescu et al. (2017) with those from Chapter 2, we find that the SNR observed in healthy individuals was consistent with their findings suggesting SNR values around 15 dB. However, the SNR values in the stroke group (approximately 8.1 dB) were much lower than those in head and neck cancer survivors with dysphagia, who demonstrated SNR values of approximately 17 dB (Constantinescu, Hodgetts, et al., 2017).

The lower SNR values observed in stroke participants likely played a large role in the relatively poor performance of the algorithm, even when a modified version was generated using stroke data. Low SNR, which may be attributed to small peak amplitudes of swallow signals or high levels of baseline noise, would disturb the segmentation stage of the algorithm. Post-hoc analysis supported both of these hypotheses. In this data set the baseline amplitude thresholds of stroke participants were significantly higher than in the healthy participants and the root mean square of swallow activity in stroke participants was smaller than those observed in healthy. A combination of these characteristics likely resulted in a higher number of signals that were not successfully segmented. This trend can be observed in the results from Chapter 3, where four of eleven trials evaluated had at least one swallow that failed to be segmented.

Another possible contributor to the lower recall values observed in the stroke population may be attributed to the poor test-retest reliability of normalized peak amplitude and duration values in the stroke group. These results suggest that these measures may not be reliable between trials of sEMG recording in stroke patients. This would be expected to impact algorithm performance because normalized peak amplitude and duration are two of the four parameters used in the classification stage of the algorithm. Poor repeatability of these parameters could result in a lack of consistency between the calculated values for the Training and Testing groups, inhibiting the success of the modified algorithm.

Despite these characteristics, the performance of the modified algorithm did fall within the acceptable range of performance and these results suggest that from a swallow-detection algorithm perspective it may be possible to facilitate independent swallowing therapy in stroke patients. However, there are many other things that would have to be considered first including: cognitive ability to follow along with software prompts, physical dexterity to correctly place the device for use, and a larger, more significant number of participants for algorithm validation. In closing, the findings from these studies suggest that further work is warranted to better understand how mobile health and sEMG biofeedback can improve swallowing therapy in stroke patients who experience dysphagia.

Limitations and Recommendations

In both of the presented studies, researchers were unaware of the location of lesion and also the severity and diagnosis of swallowing impairment. In order to successfully compare measures of signal characteristics with severity of stroke or affected versus unaffected side, more reliable and objective measures should be used to gather information about patient demographics. Ideally, researchers would collect the participant's medical history and the results of their videofluoroscopic swallowing study. Specifically, using the standard assessment tool developed by Martin-Harris et al. (2008) for quantifying swallowing impairment would allow researchers to have objective information about the severity and the specific cause of swallowing impairment. Additionally, this tool also could be used to identify if the individual is experiencing abnormal hyolaryngeal elevation, suggesting localized dysfunction in the submental muscles (Martin-Harris et al., 2008).

The small sample size of the studies presented in Chapters 2 and 3 limit their generalizability and results should be treated as preliminary. To further understand how the signals may differ between stroke survivors with dysphagia and healthy individuals, another comparison should be completed with more participants in each group. A more detailed understanding of how these signals differ may help to guide future work in the modification of the swallow detection algorithm tested in Chapter 3. Additionally, a validation study with a larger sample size would provide more evidence to support that this swallow-detection algorithm can provide accurate feedback to stroke survivors during sEMG biofeedback swallowing therapy.

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